Health Evidence Review Commission's Oral Health Advisory Panel

March 6, 2024

1:00 PM - 3:00 PM

Online Meeting

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Section 1.0

Call to Order

AGENDA
ORAL HEALTH ADVISORY PANEL (OHAP)
March 6, 2024
1:00 -3:00 pm
Online meeting
(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter
1	1:00	Call to Order, Review of Minutes	Ariel Smits
2	1:05	Straightforward items 1) Edits to the tongue tie guideline	Ariel Smits
3	2:00	New discussion items: 1) Dental telehealth 2) Fluoride varnish frequency 3) Frenectomy for tongue tie 4) Input from the OHA dental coding/rules workgroup	Ariel Smits
4	2:45	Other Business	Ariel Smits
5	2:55	Public Comment	
6	3:00	Adjournment	Ariel Smits

Note: Public testimony will be taken on each topic per HERC policy at the time at which that topic is discussed. Public testimony not related to a topic on the agenda will be taken at the end of the meeting.

Highlights

Health Evidence Review Commission's
Oral Health Advisory Panel (OHAP)

Virtual Meeting
October 11, 2023
1:00 PM – 3:00 PM

Members Present: Gary Allen, DMD; Karen Nolon; Laura McKeane; Dayna Steringer; Deborah Loy; Stacy Geisler, DMD, MD; Manu Chaudhry, DMD; Alison Noble.

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker; Daphne Peck.

Also Attending: Jessica Dusek**,** Janet Herb, and Amy Umphlett (OHA); Samantha Shepherd, Stephanie Asher, Mathew Sinnott, Pixie Needham, Jonathan Kim, sayj, Heather Simmons, Alyssa Franzen (CareOregon), Gita Yitta (AllCare CCO), Cathleen Olesitse, Jennie, Kimberley, Kathy, Laura Blanke, Vesna Hopkins, Yuberca Ward.

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 1:00 PM and roll was called. Highlights from 11/4/2022 meeting were reviewed and no changes were suggested.

- **Topic: 2024 CDT code placements**

• D0396: The staff suggestion was to place on line 469 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment ADVANCED RESTORATIVE (I.E., BASIC CROWNS). OHAP discussed that the 3D dental scan was similar to D0470 (diagnostic casts) which is currently on the Excluded file. Both D0396 and D0470 are used for crowns, dentures and orthodontic care. Current OHA dental rule states that these codes are not to be billed separately. OHAP members discussed that the code for the 3D scan which is used to make the 3D print (D0801-D0802 3d dental surface scan) are on line 256. Both D0396 and D0470 can be used for determination of the orthodontic benefit, which would make these types of procedures diagnostic. OHAP recommended after discussion that D0396 be placed on the Diagnostic Procedures File, and that D0470 and D0801-D0802 also be placed on the Diagnostic Procedure File. D0801-D0802 would be removed from line 256. OHA rulemaking will take place in the first quarter of 2024 and discussion could occur then about whether the rule should continue to require that these codes be bundled and not paid separately. HERC staff were directed to look at the ADA rulebook for all CDT codes that are considered diagnostic for consideration for placement on the Diagnostic Procedures File. HERC staff and OHA staff were directed to look at the dental rule (OAR 410-123-1200) for all codes that are listed as not separately billable and

see if this is still appropriate. The codes representing the services not separately billable in this rule will be brought to the next OHAP meeting for review. OHAP requested a meeting in the first quarter of 2024 to review the diagnostic CDT codes, the non-separately billable codes, and any CDT codes on the Excluded file.

• D1301: There was discussion about whether a dental office could bill separately for immunization counseling, or whether this was bundled into the actual vaccine administration fee. Smits noted that medical offices can bill separately for vaccine counseling, and be paid for this even if the patient elects to not receive the vaccine. The final decision was to place this code on the preventive services line.

• D0276: no discussion

• D2989: minimal discussion

• D2991: HERC staff literature review found several evidence-based reviews on hydroxyapatite which found that it can be beneficial in dental care products (toothpaste, mouthwash, etc.) but that its use in dentistry needs clinical trials. There was discussion that there are commercially available medicaments with hydroxyapatite which could be used in a dental office. There was discussion about making this code Excluded, but OHAP felt that it would be better placed on line 646 to make it clear that it was non-covered.

• D6089: This code is part of implant care. OHAP felt that this was outside the scope of general dentists, and should only be done by an implant trained oral health provider. The recommended placement was on the implant line

• D7284: There was discussion about whether this code was diagnostic or a surgical procedure. There is another CDT code for the pathology associated with the biopsy. Salivary glands can be excised for both diagnostic purposes, for example, to diagnose Sjogren's syndrome or evaluate an abnormal appearing gland. It can also be done as a therapeutic procedure, to remove a large or painful gland. OHAP determined that even when done as a therapeutic procedure, this procedure still had an element of being a diagnostic test and should be on the Diagnostic Procedures file.

•D7939: minimal discussion

•D9938 and D9939: no discussion

•D9954 and D9955: The Oregon Dental Board site was accessed, and it clearly states that the fabrication of an oral appliance is within the scope of a dentist, but only after a diagnosis of obstructive sleep apnea has been made by a physician. There was minimal discussion regarding the fabrication of an oral appliance. From the dental board site: "dentists legally are not in a position to diagnose sleep disordered breathing and sleep apnea; a physician must make the diagnosis and then prescribe oral appliance therapy before the dentist can treat it."

HERC staff noted that there were two HCPCS codes for oral appliances (K1027 and E0486) that are currently listed as "never reviewed." All of these codes should be added to the sleep apnea line. Use of oral appliances is governed by the sleep apnea treatment guideline. CDT D9947-D9951 which code for fabrication and adjustment of oral devices are on line 202.

•D9956: There was considerable debate about whether dentists could legally order a sleep study. The dental board site was accessed as noted above, and it was confirmed that diagnosing obstructive sleep apnea is outside the scope of practice for dentists in Oregon. This code was recommended for the Excluded file.

•D9957: This code had been suggested by staff to be placed on the sleep apnea line. However, due to the concern that diagnosis of OSA was outside of Oregon dental licensure, it was unclear if screening for OSA would be in scope. HERC staff was directed to ask the dental board about whether screening for OSA is in scope; if so, this code should be Diagnostic Procedures file. If not, D9957 should be Excluded.

- **Discussion on denture and implant coverage**

HERC staff have heard OHA member concern regarding lack of coverage for dentures and dental implants. Staff asked the OHAP what they would recommend for coverage expansion if funding for additional dental services was procured.

Members are aware of frustration around coverage of dentures. Allen noted that adult dentures are not a mandatory benefit under Medicaid by federal rule, and are only covered to the extent allowed by the Oregon Legislature. There are budgetary constraints to expanding benefits in these areas. Denture benefits are very expensive.

Suggestions for the most beneficial expansions of denture benefit would be to allow partial dentures for fewer numbers of missing teeth, when the front teeth are involved, or for missing premolars. There was discussion about allowing denture replacement sooner than currently allowed (10 years for full dentures) when the dentures are lost or stolen. Other members noted that current rule does allow denture replacement when stolen, lost in natural disaster, or other circumstances outside of the member's control. It was noted that earlier replacement may not be part of the rates for dental organizations. One member suggested focusing any additional funding on treatments to retain natural teeth, such as crowns after root canals. Currently, this benefit is very limited by age and type of teeth. Coverage of crowns was also cut years ago by rule/Legislative intent due to budget issues.

- **Additional topics discussed**

Allen requested that frenulectomy (lip tie) be limited to members under age 21 in the Prioritized List guideline. These services were limited to children in rule, but have been dropped from the current OHA dental rule for unclear reasons. OHAP requested that the

guideline regarding frenulectomy be modified to indicate that coverage is limited to patients under the age of 21.

- **Public Comment:** no additional public comment was received

- **Issues for next meeting:**

• Review of diagnostic CDT code placement
• Review of current excluded CDT codes in OHA rule

- **Next meeting:**
    - TBD

Section 2.0

Consent Agenda-

Straightforward Items

Frenectomy for Tongue Tie

Coverage Question: Should frenectomy be added as a treatment for tongue tie?

Question source: Holly Jo Hodges, CCO medical director

Background:

The lingual frenum is the small band of tissue connecting the tongue to the floor of the mouth. Ankyloglossia, also known as "tongue-tie," is a congenital condition in which a neonate is born with an abnormally short, thickened, or tight lingual frenulum that restricts mobility of the tongue. It variably causes reduced anterior tongue mobility and has been associated with functional limitations in breastfeeding, swallowing, articulation as well as orthodontic problems including malocclusion, open bite, and separation of lower incisors, mechanical problems related to oral clearance, and psychological stress This condition may be surgically corrected, often as an office procedure in neonates, by simple excision (i.e. frenectomy, frenotomy), or with a more extensive procedure (frenulotomy or frenuloplasty). The focus on this issue is for frenotomy and frenuloplasty, which are more extensive procedures used to address concerns about social function, speech and dental or orthodontic work. While the major focus of the AHRQ report was about breastfeeding outcomes, frenotomy (a simple clipping procedure which can be performed with a scissors) is already covered for breastfeeding issues and no change is proposed.

Currently, frenotomy (the incision into the frenum) is covered for treatment of tongue tie. Dr. Hodges has seen requests for frenectomy (a more invasive procedure involving the removal of the frenum) for this condition. Frenectomy is considered one possible treatment of this condition. Currently, frenectomy is only covered for cancer of the mouth.

Frenotomy (also known as frenulotomy) is the clipping or cutting of the frenum under the tongue, generally and using straight scissors to divide the frenulum, generally without sedation. The ensuing wound does not typically require repair. This is done mainly for breastfeeding latching issues. Laser frenotomy or frenulotomy has also been described. Frenotomy may be done by ENTs, dentists, or other professionals.

Frenectomy or frenuloplasty is more technically involved than frenotomy or frenulotomy. Frenectomy is the complete removal of the frenulum. It can be done surgically or using a laser device. Frenuloplasty generally refers to rearranging tissue or adding grafts after making incisions and closing the resultant wound in a specific pattern to lengthen the anterior tongue. Specific types of frenuloplasty include Z-frenuloplasty, which involves making a longitudinal incision along the length of the lingual frenulum combined with perpendicular incisions at tongue tip and floor of the mouth. These cuts create a Z-type incision. Submucosal flaps are then elevated, and transposed flaps are sutured closed, resulting in increased tongue length and mobility. A second type of frenuloplasty involves a horizontal division at the base of the frenulum where a harvested buccal mucosal graft is inserted and affixed to fill the defect created by the incision. Horizontal-to-vertical frenuloplasty is a third type in which a horizontal incision is created at mid-frenulum to release the tethering fibrotic band. The incision is then converted to a vertical orientation and closed with sutures to effectively elongate the anterior tongue. Frenuloplasty is most commonly performed under a general anesthetic and used in older infants and children or in more

complex frenulum repairs. This procedure is usually performed for patients with concerns of developing periodontal disease.

Previous HSC/HERC reviews:

No previous review of CPT 41115 was found.

The CDT code for frenectomy was reviewed in 2013, but the actual code reviewed at that time represented all of the following procedures: frenulectomy, frenectomy and frenotomy (previous CDT code D7960 FRENULECTOMY - ALSO KNOWN AS FRENECTOMY OR FRENOTOMY). This review created the current frenotomy guideline for tongue tie. CDT D7960 was replaced with two codes in 2020, which were reviewed as part of the new code review. During that review, D7962 (lingual frenectomy) was added to the dental caries line and the feeding problems in newborns line. In November 2022, D7962 was removed from the dental caries line and added to the lower tongue tie line (now line 590). The other daughter code of D7960 was D7961 (Buccal / labial frenectomy (frenulectomy)) which refers to lip tie release and was placed on the dental caries line and line 653 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY with a guideline.

Frenectomy for Tongue Tie

Current Prioritized List/Coverage status:

CPT/CDT code	Code description	Used for	Current placement
41010	Incision of tissue connecting tongue and floor of mouth	Frenotomy, simple tongue frenum clipping for "tongue-tie"	18 FEEDING PROBLEMS IN NEWBORNS 163 CARCINOMA IN SITU OF UPPER AIRWAY, INCLUDING ORAL CAVITY 590 TONGUE TIE AND OTHER ANOMALIES OF TONGUE
41115	Removal of tissue connecting tongue and floor of mouth	Frenectomy, frenuloplasty (more extensive surgery)	163 285 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX 590
D7961	Buccal / labial frenectomy (frenulectomy)	"Lip tie"	341 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) 653 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
D7962	Lingual frenectomy (frenulectomy)	also known as frenulotomy for frenotomy used for simple clipping of the frenum	18,590
D7963	Frenuloplasty	Frenectomy, frenuloplasty (more extensive surgery)	341

GUIDELINE NOTE 48, FRENULECTOMY/FRENULOTOMY

Lines 341,653

Labial frenulectomy/frenulotomy (D7961) is included on this line for patients under age 21 in the following situations:

A) When deemed to cause gingival recession
B) When deemed to cause movement of the gingival margin when frenum is placed under tension.
C) Maxillary labial frenulectomy not covered until age 12 and above.

Otherwise, D7961 is included on Line 653.

GUIDELINE NOTE 139, FRENOTOMY FOR TONGUE TIE IN NEWBORNS

Lines 18,590

Ankyloglossia (ICD-10-CM Q38.1) is included on Line 18 for pairing with frenotomy (CPT 41010, CDT D7962) only when it interferes with breastfeeding. Otherwise, Q38.1 and CPT 41010 and CDT D7962 are included on Line 590.

Frenectomy for Tongue Tie

Evidence:

1) **AHRQ 2015**, systematic review of treatments for ankyloglossia or ankyloglossia with concomitant lip-tie in neonates and infants with breastfeeding difficulties and in children aged 0-18 years
    a. Studies
        i. 1 poor quality RCT and 9 observational studies addressed speech and articulation concerns.
    b. Breastfeeding: All included studies used frenotomy
    c. Speech and articulation concerns (in older children):
        i. 2 poor quality retrospective cohort series on frenotomy
        ii. Relevant case series examined different treatment methods including simple division with scalpel, scissors, and CO2 laser, frenuloplasty, and the addition of genioglossus myotomy. All studies reported positive outcomes and none reported significant harms, but as noted, these studies provide no comparative effectiveness data.
        iii. One poor quality RCT randomized children presenting to a cleft lip and palate-craniofacial clinic between 1999 and 2003 with a tight frenulum (<15mm), an articulation or speech problem related to tongue tie, and/or age greater than 3 years to four-flap Z-frenuloplasty or horizontal-to-vertical frenuloplasty. The study included 16 children with articulation problems, of whom 11 underwent four-flap Z-frenuloplasty (7 male, 4 female) and the remainder (2 male, 3 females) horizontal-to-vertical frenuloplasty. Ages were similar between treatment groups (Z-frenuloplasty: mean 5.7 ± 2.14 vs. horizontal-to-vertical: mean 5.56 ± 1.52). Ten of eleven children in the Z-plasty arm had two orders of magnitude improvement (i.e., severe to mild) and seven had complete resolution of articulation problems. In contrast, no patients in the horizontal-to-vertical group had two order of magnitude improvement or complete resolution. Two had one level improvement in articulation and three had none.
    d. Social concerns related to tongue mobility
        i. One study identified on social concerns which studied frenotomy
    e. Conclusions
        i. Speech outcomes: Given the lack of good-quality studies and limitations in the measurement of outcomes, we considered the strength of the evidence for the effect of surgical interventions to improve speech and articulation to be insufficient.
        ii. Social concerns related to tongue mobility: With only one poor-quality comparative study, strength of evidence related to the ability of treatment for ankyloglossia to alleviate social concerns is currently insufficient. Also, with only three comparative studies with small sizes and limitations in the measurement of outcomes related to tongue mobility, we considered the strength of evidence for the effect of surgical interventions to improve the short-term outcome of mobility to be insufficient
        iii. Overall conclusions: A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain. However, with small, inconsistently conducted studies, strength of evidence is low to insufficient, preventing us from drawing firm conclusions at this time. Research is lacking on nonsurgical interventions, as

well as on outcomes other than breastfeeding, particularly speech and dental outcomes. In particular, there is a lack of evidence on significant long-term outcomes, such as exclusive breastfeeding at 6 months of age or at 1 year of age, growth, and other measures of health outcomes. Harms are minimal and rare; the most commonly reported harm is self-limited bleeding

Other payer policies:

1) Aetna 2023
    a. Aetna considers lingual or labial frenectomy, frenotomy, or frenuloplasty medically necessary for ankyloglossia when newborn feeding difficulties or childhood articulation problems exist.
    b. CPT 41010 and 41115 are both covered
2) UHC 2023
    a. Frenulectomy and Frenuloplasty are indicated for the following:
        i. When attachment of the Frenum is coronal to the mucogingival junction, within the free gingiva, or in the papilla causing a diastema, gingival recession, or stripping
        ii. When the position attachment of the Frenum is interfering with proper oral hygiene
        iii. Prior to the construction of a removable denture replacing teeth in the area of aberrant frenal attachment
        iv. When there is a functional disturbance, including, but not limited to mastication, swallowing, and speech
        v. For Ankyloglossia or papillary penetrating attachment of maxillary labial Frenum in newborns when there is interference with feeding
    b. Coverage includes both CPT 41010 and 41115
3) VA 2010
    a. Surgery for tongue-tie is not covered except in cases where total or complete ankyloglossia is documented.
    b. Includes both CPT 41010 and 41115

OHAP input:

Frenectomy for Tongue Tie

HERC staff summary: Frenectomy/frenuloplasty for speech issues was studied only in children with craniofacial anomalies and found to be helpful in one poor quality RCT and several observational studies. Coverage of frenectomy for children with craniofacial anomalies and speech difficulties can be done on an individual review basis. Frenectomy and frenuloplasty are more extensive procedures with more risks of harms.

In addition, the Prioritized List should be clarified regarding coverage of frenectomy/frenuloplasty only for periodontal issues or treatment of cancer.

A high quality systematic review from a highly trusted source (AHRQ) found evidence only for frenotomy for breast feeding outcomes. As previously reviewed by HERC, the evidence for breast feeding outcomes is mixed and the strength of evidence is low; however, given the low risk nature of the intervention, the HERC elected to cover this procedure for breast feeding difficulties. Staff recommend no changes in coverage of frenotomy for breastfeeding outcomes. Due to lack of evidence, frenectomy and frenuloplasty should not be covered for breastfeeding issues, and the guideline needs to be clarified to reflect noncoverage.

HERC staff recommendations:

1) Add CDT D7963 (Frenuloplasty) to line 590 TONGUE TIE AND OTHER ANOMALIES OF TONGUE
2) Modify GN139 as shown below
3) Add CPT 41115 (Removal of tissue connecting tongue and floor of mouth) and CDT D7963 to line 217 DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment BASIC PERIODONTICS and 254 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION
    a. Remove CPT 41115 and CDT D7963 from line 341 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) Treatment ORAL SURGERY
4) Modify GN 48 as shown below

GUIDELINE NOTE 139, FRENOTOMY FOR TONGUE TIE IN NEWBORNS

Lines 18,590

Ankyloglossia (ICD-10-CM Q38.1) is included on Line 18 for pairing with frenotomy (CPT 41010, CDT D7962) only when it interferes with breastfeeding. Otherwise, Q38.1 and CPT 41010 and CDT D7962 are included on Line 590. Frenectomy/frenuloplasty (CPT 41115, CDT D7963) when used for treatment of tongue tie is only included on line 590 due to lack of evidence. See Guideline Note 48 for other coverage of frenectomy/frenuloplasty.

GUIDELINE NOTE 48, FRENULECTOMY/FRENULOTOMY**/FRENECTOMY**

Lines 163,285,217,254,~~341,~~590,653

Labial frenulectomy/frenulotomy (D7961) and lingual frenectomy/frenuloplasty (CPT 41115, CDT D7963) are ~~is~~ included on ~~this~~ line 254 for patients under age 21 in the following situations:

A) When deemed to cause gingival recession
B) When deemed to cause movement of the gingival margin when frenum is placed under tension.
C) ~~Maxillary labial frenulectomy not covered until~~ The patient is age 12 and above.

Frenectomy for Tongue Tie

CPT 41115 and CDT D7961 and D7963 are included on line 254 when used as part of orthodontic treatment for severe malocclusion.

CPT 41115 is included on lines 163 and 285 when used as part of the treatment of cancer of the oral cavity.

Otherwise D7961 is included on Line 653; CDT D7963 and CPT code 41115 are on line 590.

Effective Health Care Program

Comparative Effectiveness Review
Number 149

Treatments for Ankyloglossia and Ankyloglossia With Concomitant Lip-Tie

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Comparative Effectiveness Review

Number 149

Treatments for Ankyloglossia and Ankyloglossia With Concomitant Lip-Tie

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U.S. Department of Health and Human Services
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This report is based on research conducted by the Vanderbilt Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2012-00009-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

Persons using assistive technology may not be able to fully access information in this report. For assistance contact EffectiveHealthCare@ahrq.hhs.gov.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of Key Informants who participated in developing this report follows:

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

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Treatments for Ankyloglossia and Ankyloglossia With Concomitant Lip-Tie

Structured Abstract

Objectives. We systematically reviewed the literature on surgical and nonsurgical treatments for infants and children with ankyloglossia and ankyloglossia with concomitant lip-tie.

Data sources. We searched MEDLINE® (PubMed®), PsycINFO®, Cumulative Index of Nursing and Allied Health Literature (CINAHL®) and Embase (Excerpta Medica Database), as well as the reference lists of included studies and recent systematic reviews. We conducted the searches between September 2013 and August 2014.

Review methods. We included studies of interventions for ankyloglossia published in English. Two investigators independently screened studies against predetermined inclusion criteria and independently rated the quality of included studies. We extracted data into evidence tables and summarized them qualitatively.

Results. We included 58 unique studies comprising 6 randomized controlled trials (RCTs) (3 good, 1 fair, 2 poor quality), 3 cohort studies (all poor quality), 33 case series, 15 case reports, and 1 unpublished thesis. Most studies assessed the effects of frenotomy (a procedure in which the lingual frenulum is divided) on breastfeeding-related outcomes. Four RCTs reported improvements in breastfeeding efficacy using either maternally reported or observer ratings, while two RCTs using observer ratings found no improvement. Mothers consistently reported improved breastfeeding effectiveness after frenotomy, but outcome measures were heterogeneous and short term. Future studies could provide additional data to confirm or change the measure of effectiveness; thus, we consider the strength of evidence (SOE; confidence in the estimate of effect) to be low at this time. Furthermore, this literature is characterized by (1) a lack of details about the surgical procedure, (2) cointerventions allowed variably in control groups, and (3) diversity of provider settings. Pain outcomes improved for mothers of frenotomized infants compared with control in one study of 6-day old infants but not in studies of infants a few weeks older. Given these inconsistencies and the small number of comparative studies and participants, the SOE is low for an immediate reduction in nipple pain. Three studies with significant limitations reported improvements in other feeding outcomes with frenotomy, and four poor-quality studies reported some improvements in speech articulation but mixed results related to overall speech sound production. Three poor-quality comparative studies noted some improvements in social concerns and gains in tongue mobility in treated participants. SOE for all of these outcomes is insufficient. SOE is moderate for minor and short-term bleeding following surgery and insufficient for other harms (reoperation, pain).

Conclusions. A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain, but with small short-term studies, inconsistently conducted, SOE is generally low to insufficient. Comparative studies reported improvements in some measures of speech, but assessment of outcomes was inconsistent. Few studies addressed tongue mobility and self-esteem issues.

Research is lacking on nonsurgical interventions, as well as on outcomes other than breastfeeding.

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Executive Summary

Introduction

Ankyloglossia is a congenital condition characterized by an abnormally short, thickened, or tight lingual frenulum, or an anterior attachment of the lingual frenulum, that restricts mobility of the tongue.[1] It variably causes reduced anterior tongue mobility and has been associated with functional limitations in breastfeeding; swallowing; articulation; orthodontic problems, including malocclusion, open bite, and separation of lower incisors; mechanical problems related to oral clearance; and psychological stress. One review including studies of infants, children, and adults reported rates of ankyloglossia ranging from 0.1 to 10.7 percent,[2] but definitive incidence and prevalence statistics are elusive due to an absence of a criterion standard or clinically practical diagnostic criteria.

Recognition of potential benefits of breastfeeding in recent years has resulted in a renewed interest in the functional sequelae of ankyloglossia. In infants with anterior or posterior ankyloglossia, there is a reported 25- to 80-percent incidence of breastfeeding difficulties, including failure to thrive, maternal nipple damage, maternal breast pain, poor milk supply, maternal breast engorgement, and refusing the breast.[2] Ineffective latch is hypothesized to underlie these problems. Mechanistically, infants with restrictive ankyloglossia cannot extend their tongues over the lower gumline to form a proper seal and therefore use their jaws to keep the breast in the mouth for breastfeeding. Adequate tongue mobility is required for breastfeeding, and infants with ankyloglossia often cannot overcome their deficiency with conservative measures such as positioning and latching techniques, thereby requiring surgical correction.[2]

Nonetheless, consensus on ankyloglossia's role in breastfeeding difficulties is lacking. A minority of surveyed pediatricians (10%) and otolaryngologists (30%) believe it commonly affects feeding, while 69 percent of lactation consultants feel that it frequently causes breastfeeding problems.[3] Therefore, depending on the audience, enthusiasm for its treatment varies. Currently, the U.K. National Health Service and the Canadian Paediatric Society recommend treatment only if it interferes with breastfeeding.[4,5] A standard definition of "interference" with breastfeeding is not provided, leaving room for interpretation and variation in treatment thresholds. The absence of data on the natural history of untreated ankyloglossia further promulgates uncertainty. Some propose that a short frenulum elongates spontaneously due to progressive stretching and thinning of the frenulum with age and use.[1] However, there are no prospective longitudinal data on the congenitally short lingual frenulum. Without this information it is difficult to inform parents fully about the long-term implications of ankyloglossia, thereby complicating the decision-making process.

Although most ankyloglossia research is focused on the infant and breastfeeding issues, concerns beyond infancy include speech-related issues, such as difficulty with articulation, and social concerns related to limited tongue mobility. Individuals with untreated ankyloglossia may experience difficulty with oral mechanism, particularly in relation to licking ice cream, kissing, drooling, playing wind instruments, and licking the lips. Self-esteem or psychological issues may also be a concern for affected older patients.

Treatment Strategies

Ankyloglossia may be treated with surgical or nonsurgical approaches. Surgical modalities include frenotomy, frenulectomy, and frenuloplasty. These interventions involve clipping or

cutting of the lingual frenulum, generally without sedation. Laser frenotomy or frenulotomy has also been described, and proponents argue that its use is more exact and provides better hemostasis than standard frenotomy or frenulotomy. Frenuloplasty, more technically involved than frenotomy or frenulotomy, generally refers to rearranging tissue or adding grafts after making incisions and closing the resultant wound in a specific pattern to lengthen the anterior tongue. Frenuloplasty is most commonly performed under a general anesthetic and used in older infants and children or in more complex frenulum repairs.

Nonsurgical approaches include speech therapy, lactation interventions, and observation to determine if intervention is warranted.

Scope and Key Questions

Scope of the Review

This systematic review provides a review of potential benefits of treatments (surgical and nonsurgical) as well as harms associated with those therapies in individuals with ankyloglossia and tight labial frenulum (lip-tie) concomitant with ankyloglossia. We sought information on outcomes related to breast- and bottle-feeding and related to tongue-tie in later life (e.g., orthodontic and dental issues, speech, self-esteem).

Key Questions

We synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ 1. What are the benefits of various treatments in breastfeeding newborns and infants with ankyloglossia intended to improve breastfeeding outcomes? Surgical treatments include frenotomy (anterior and/or posterior), frenuloplasty (transverse to vertical frenuloplasty), laser frenulectomy/frenulotomy, and Z-plasty repair. Nonsurgical treatments include complementary and alternative medicine therapies (e.g., craniosacral therapy), lactation intervention, physical/occupational therapy, oral motor therapy, and stretching exercises/therapy.

KQ 2a. What are the benefits of various treatments in newborns, infants, and children with ankyloglossia intended to prevent, mitigate, or remedy attributable medium- and long-term *feeding* sequelae, including trouble bottle-feeding, spilling and dribbling, difficulty moving food boluses in the mouth, and deglutition?

KQ 2b. What are the benefits of various treatments in infants and children with ankyloglossia intended to prevent, mitigate, or remedy attributable *other* medium- and long-term sequelae, including articulation disorders, poor oral hygiene, oral and oropharyngeal dysphagia, sleep disordered breathing, orthodontic issues including malocclusion, open bite due to reverse swallowing, lingual tipping of the lower central incisors, separation of upper central incisors, crowding, narrow palatal arch, and dental caries?

KQ 3. What are the benefits of various treatments for ankyloglossia in children through 18 years of age intended to prevent or address social concerns related to tongue mobility (i.e., speech, oral hygiene, excessive salivation, kissing, spitting while talking, and self-esteem)?

KQ 4. What are the benefits of simultaneously treating ankyloglossia and concomitant tight labial frenulum (lip-tie) in infants and children through age 18 intended to improve or remedy breastfeeding, articulation, orthodontic and dental, and other feeding outcomes? What are the relative benefits of treating only ankyloglossia when tight labial frenulum (lip-tie) is also diagnosed?

KQ 5. What are the harms of treatments for ankyloglossia or ankyloglossia with concomitant lip-tie in neonates, infants, and children through age 18?

Analytic Framework

Figure A depicts KQs 1, 4, and 5 within the context of the PICOTS (population, intervention, comparator, outcomes, timing, setting). The figure examines surgical and nonsurgical treatments in neonates and infants to improve breastfeeding outcomes. Intermediate outcomes include maternal nipple pain, ability to latch and maintain latch, tongue mobility, and aerophagia. Final outcomes include duration of breastfeeding, failure to thrive, infant weight gain, and oral and oropharyngeal dysphagia. Harms (KQ 5) may occur at any point after the intervention is received.

Figure A. Analytic framework for ankyloglossia in neonates and infants

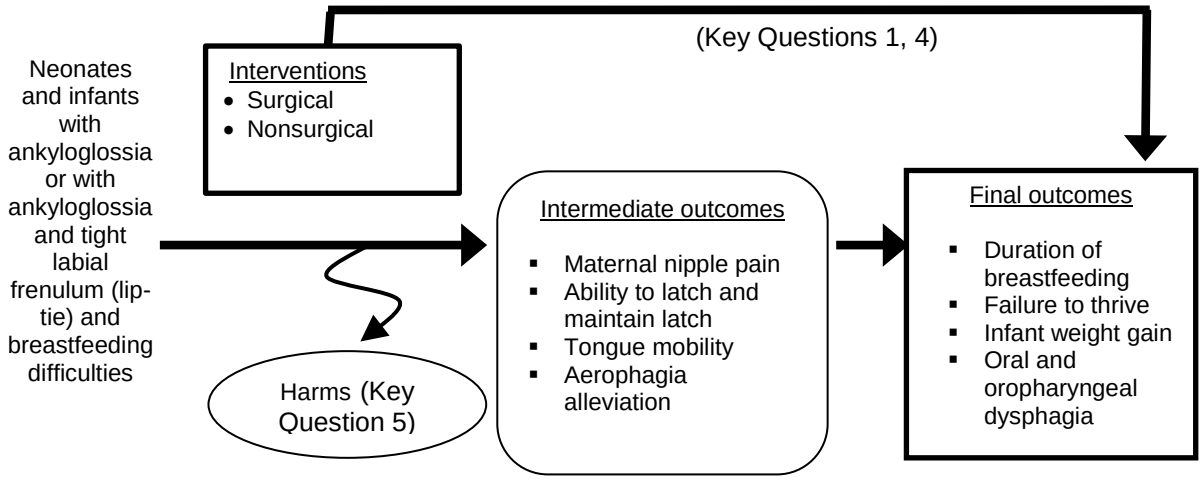
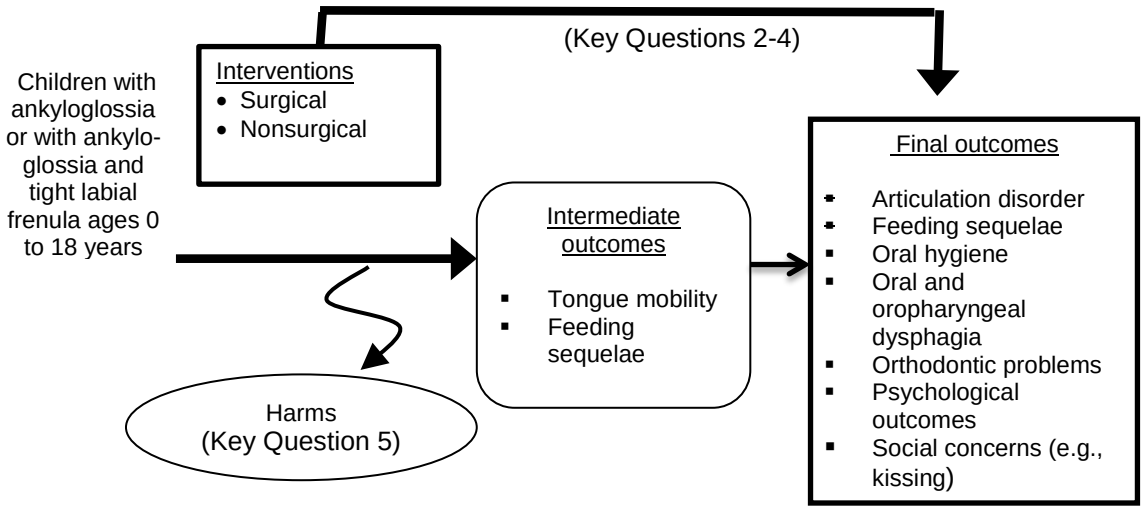


Figure B depicts KQs 2, 3, 4, and 5 within the context of the PICOTS. The figure examines surgical and nonsurgical treatments in infants and children with ankyloglossia (KQ 2, KQ 3) or ankyloglossia with concomitant lip-tie (KQ 4). The intermediate outcomes include maternal nipple pain and tongue mobility, and final health outcomes are articulation disorder, oral hygiene, oral and oropharyngeal dysphagia, orthodontic problems, psychological outcomes, and social concerns, including kissing. Harms (KQ 5) may occur at any point after the intervention is received.

Figure B. Analytic framework for ankyloglossia in infants and children through18 years of age



Methods

Literature Search Strategy

A librarian employed search strategies provided in Appendix A of the full report to retrieve research on interventions for children with ankyloglossia. We searched MEDLINE® via the PubMed® interface, PsycINFO® (psychology and psychiatry literature), the Cumulative Index of Nursing and Allied Health Literature (CINAHL®) and Embase (Excerpta Medica Database). We limited searches to the English language and imposed no publication date restrictions. Our last search was conducted in August 2014. We manually searched reference lists of included studies and of recent narrative and systematic reviews and meta-analyses.

Inclusion and Exclusion Criteria

We developed criteria for inclusion and exclusion in consultation with a Technical Expert Panel (Table A).

Table A. Inclusion criteria

Category	Criteria
Study population	Children ages 0–18 with ankyloglossia or ankyloglossia with concomitant tight labial frenulum (lip-tie); studies with participants with Van der Woude syndrome, Pierre Robin syndrome or sequence, Down syndrome, or craniofacial abnormalities were excluded ,as were studies of premature babies (<37 weeks of gestation[5])
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials, prospective and retrospective cohort studies, nonrandomized controlled trials, prospective and retrospective case series, and crossover studies Case reports to assess harms Other criteria Original research studies providing sufficient detail regarding methods and results to enable use and aggregation of the data and results Studies must address one or more of the following: • Surgical interventions (simple anterior frenotomy, frenulotomy, or frenectomy; laser frenotomy, , or frenulectomy; posterior frenulectomy; Z-plasty repair) • Nonsurgical treatments, including complementary and alternative medicine therapies (e.g., craniosacral therapy, myofascial release, and other chiropractic therapies), lactation intervention, speech therapy, physical therapy, oral motor therapy, and stretching exercises/therapy • Baseline and outcome data (including harms) related to interventions for ankyloglossia Relevant outcomes must be able to be extracted from data in the papers Data must be presented in the aggregate (vs. individual-participant data)

Study Selection

Two reviewers independently assessed each abstract. If one reviewer concluded that the article could be eligible based on the abstract, we retained it for full-text assessment. Two reviewers independently assessed the full text of each included study. Disagreements were resolved by a senior reviewer.

Data Extraction and Synthesis

We extracted data from included studies into an evidence table that reports study design, descriptions of the study populations (for applicability), description of the intervention, and baseline and outcome data on constructs of interest. Data were initially extracted by one team member and reviewed for accuracy by a second. The final evidence table is presented in Appendix D of the full report.

We extracted outcomes for all included studies, and data are presented in summary tables and analyzed qualitatively in the text.

Quality (Risk-of-Bias) Assessment of Individual Studies

We used four tools to assess the quality of individual studies: the Cochrane Risk of Bias Tool for Randomized Controlled Trials;[6] a cohort study assessment instrument based on questions and a tool for case series, both adapted from RTI Item Bank questions;[7] and a four-item harms

assessment instrument for cohort studies derived from the McMaster Quality Assessment Scale of Harms (McHarm) for Harms Outcomes[8] and the RTI Item Bank.[7] The tools are presented in Appendix E of the full report.

Quality assessment of each study was conducted by two team members independently. Discrepancies were adjudicated through discussion between the assessors to reach consensus or via a senior reviewer. The results of these tools were then translated to the Agency for Healthcare Research and Quality standard of "good," "fair," and "poor" quality designations, as described in the full report. Quality ratings for each study are in Appendix F of the full report.

Strength of the Body of Evidence

Two senior investigators graded the entire body of evidence using methods based on the "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[9] The team reviewed the final strength-of-evidence designation. Strength of evidence is assessed for a limited set of critical outcomes, typically those related to effectiveness of an intervention, and reported in comparative studies.

The possible grades were—

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

Applicability

Applicability describes issues related to how applicable (generalizable) the included studies are likely to be in practice. We assessed applicability by identifying potential population, intervention, comparator, outcome, and setting (PICOS) factors likely to affect the generalizability of results (i.e., applicability to the general population of children with ankyloglossia). For this particular review, the most likely factors that could affect applicability are the severity/degree of ankyloglossia, age range of participants, setting of intervention (e.g., newborn nursery, outpatient office), and provider (e.g., otolaryngologist, lactation consultant, dentist, pediatrician).

Results

Article Selection

We identified 1,626 nonduplicative titles or abstracts with potential relevance, with 244 proceeding to full-text review (Figure 3 of the full report). We excluded 187 studies at full-text review, which yielded 57 published studies included in the review. We also included one unpublished thesis in our results; thus, the report summarizes data from 58 unique publications.

KQ 1. Benefits of Interventions To Improve Breastfeeding Outcomes

Twenty-nine studies addressed the benefits of surgical treatments intended to improve breastfeeding outcomes; there were no studies of nonsurgical treatments. These studies included five randomized controlled trials (RCTs) conducted in the United Kingdom (n = 3),[10-12] United States (n = 1),[13] or Israel (n = 1)[14] and one poor-quality retrospective cohort study conducted in the United States.[15] We rated the RCTs as good,[10,11,13] fair,[12] and poor[14] quality for outcomes related to breastfeeding effectiveness and maternal pain related to breastfeeding. One poor-quality retrospective cohort study and 23 case series also addressed outcomes of surgical treatment. We focused on RCTs of higher quality in this summary but noted that the lower quality studies typically reported improvements in breastfeeding effectiveness.

Two RCTs compared frenotomy to sham surgery,[11, 13] one to usual care,[10] and one to intensive lactation consultation,[12] and one used a crossover design to compare frenotomy followed by sham surgery to sham surgery followed by frenotomy, with assessment of breastfeeding after each order of intervention (i.e., frenotomy and sham).[14] Similarly, the retrospective cohort study compared frenotomy to usual care.[15] For all studies, sham comparison involved taking infants to an intervention room for the same amount of time as the infants receiving the procedure and then returning them to the mothers.

The earliest reported RCT used nonblinded maternally assessed breastfeeding effectiveness and reported that 96 percent of frenotomized infants had improved feeding within 48 hours, compared with 3 percent in the control group, but this study had significant limitations.[12] In a later RCT, mothers again self-reported improved breastfeeding among infants immediately after frenotomy (78% in the treated group vs. 47% in the comparison group; $p < 0.02$).[11]

Three RCTs used an observer to assess breastfeeding effectiveness. In all three, the observer was blinded to the treatment. Among these,[10,11,13] one reported improvement in breastfeeding effectiveness based on the Infant Breastfeeding Assessment Tool (IBFAT; score range, 0 [poor feeding] to 12 [vigorous and effective feeding]) score immediately postfrenotomy compared with sham treatment (mean, 11.6 ± 0.81 vs. 8.07 ± 0.86; $p = 0.026$).[13] In contrast, in two of the three RCTs, the independent blinded observers did not detect a difference in breastfeeding improvement. Outcomes that failed to show a difference in these two RCTs included percent improvement (50% vs. 40%) immediately after intervention[11] and Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH) and IBFAT change 5 days postintervention: LATCH change score median 1 (interquartile range [IQR], 0 to 2) versus median 1 (IQR, 0 to 2); $p = 0.52$ and IBFAT change score 0 (IQR, -1.8 to 1.0) versus 0 (IQR 0 to 1); $p = 0.36$.[10]

One RCT reported significant and immediate improvement in maternally reported nipple pain among frenotomized infants compared with sham treatment.[13] Both remaining RCTs found nonsignificant reductions in maternally reported nipple pain between the frenotomy and sham groups at immediate[11] and 5-day[10] postprocedure assessments. However, in the one study that assessed pain at 5 days (the longest followup), a large number of infants in the control group had crossed over to receive frenotomy before outcomes were assessed.[10]

Harms were rare and nonsignificant, and are discussed in more detail in KQ 5.

KQ 2a. Benefits of Treatments To Mitigate Feeding Sequelae

Three studies examined medium- and long-term benefits related to feeding outcomes and sequelae of various interventions for infants and children with ankyloglossia.[12,16,17] One was an

RCT[12] (fair quality for feeding outcomes) and one was a poor-quality retrospective cohort study;[16] the remaining study was a case series, so it provided no data for comparison.[17]

In one RCT that included bottle-fed infants, 76 percent had major problems with dribbling and 71 percent had "excess wind" (gas). Mothers reported significant improvement in bottle-feeding in all eight infants who received the frenotomy and in none of the nine who did not. The interval to ascertainment of the outcomes was not specifically reported, but outcomes were obtained within the first 4 weeks of life.[12]

The retrospective cohort study compared parent-reported (typically maternal) outcomes at age 3 years for three groups of children born in 2010: children who received frenotomy for tongue-tie (n = 71; frenotomy group); those whose parents were offered frenotomy for tongue-tie for their children but declined it (n = 15; no-frenotomy group); and children without ankyloglossia (n = 18; control group).[16] The frenotomy group performed better than the no-frenotomy group at age 3 years on cleaning the teeth with the tongue, licking the outside of the lips, and eating ice cream, and did not differ significantly from the comparison group without ankyloglossia.

KQ 2b. Benefits of Treatments To Prevent Other Sequelae

Two cohort studies attempted to assess the effectiveness of frenotomy for preventing other sequelae,[16,18] and one RCT compared two surgical approaches to frenotomy.[19] A speech-language pathologist measured speech outcomes in two studies,[18,19] with the third study using parental assessment.[16] No studies included data related to sleep disordered breathing, occlusal issues, and dysphagia in nonbreastfeeding children.

Two poor-quality cohort studies[16,18] reported an improvement in articulation and intelligibility with ankyloglossia treatment, but benefits in word and sentence accuracy and intelligibility and fluent speech were unclear. The one poor-quality RCT comparing surgical methods reported improved articulation in patients treated with four-flap Z-frenuloplasty compared with horizontal-to-vertical frenuloplasty.[19] Numerous noncomparative studies[20-26] reported a speech benefit after treating ankyloglossia; however, these studies primarily discussed modalities, with safety, feasibility, or utility as the main outcome rather than speech itself, and they provided no comparative data.

KQ 3. Benefits of Treatments To Prevent Social Concerns Related to Tongue Mobility

Only one poor-quality retrospective cohort study assessed outcomes related to social concerns other than speech in 3-year-old children who had received frenotomy as infants.[16] The group that had received frenotomy had better parent-reported ability to clean teeth with tongue, lick outside of lips, and eat ice cream compared with untreated participants.

KQ 4. Benefits of Simultaneously Treating Ankyloglossia and Lip-Tie

We did not identify any studies addressing this question.

KQ 5. Harms of Treatments for Ankyloglossia or Ankyloglossia With Concomitant Lip-Tie in Neonates, Infants, and Children Through Age 18

In order to identify all possible harms, we sought harms from all comparative studies and case series that we identified as potentially providing effectiveness data, and we sought case reports of harms. With this approach, we examined harms information from 46 studies that reported that they had looked for harms, either reporting actual harms or specifically indicating that they found none. These included 6 RCTs, 1 cohort study, 25 case series, and 15 case reports. Most studies that reported harms information explicitly noted that no significant harms were observed (n = 17) or reported minimal harms. Among studies reporting harms, bleeding was most frequently reported. Bleeding was typically described as minor and limited. Reoperation was noted in seven studies. Few studies described the specific methods they used to collect harms data.

Discussion

Key Findings

Most of the studies included in this review addressed outcomes related to breastfeeding (Table B). Overall, three good-quality[10,11,13] and one fair-quality[12] RCT assessed whether surgical treatment of ankyloglossia improved breastfeeding effectiveness. Maternally reported breastfeeding effectiveness was significantly improved in the treated group compared with the untreated group in both RCTs that evaluated it either as a primary[12] or secondary[11] outcome. Only one of three RCTs that used blinded independent observers found significantly improved breastfeeding effectiveness among frenotomized infants immediately postprocedure.[13] A third RCT evaluated the mother's breastfeeding self-efficacy and found a significant improvement from baseline in the frenotomy group 5 days postprocedure.[10] In all, some evidence suggests that maternally reported breastfeeding outcomes improved, but data are unavailable to assess the durability of effects.

These same studies had disparate findings about whether frenotomy decreased maternal nipple pain during breastfeeding. Only the RCT performed on infants at 6 days of age showed a significant reduction in maternal pain.[13] Those performed on infants a few weeks older did not report either an immediate[11] or 5-day[10] reduction in pain. The difference between earlier frenotomy and later frenotomy on nipple pain may relate to cumulative trauma on the breast from several additional weeks with inefficient latch from tongue-tied infants.

We identified three studies examining feeding outcomes other than breastfeeding: one RCT,[12] one-poor quality retrospective cohort study,[16] and one case series.[17] Bottle-feeding and ability to use the tongue to eat ice cream and clean the mouth improved more in treatment groups in comparative studies. Bottle feedings to supplement breast feeding decreased over time in the case series.

Following breastfeeding outcomes, outcomes related to speech were most often reported in the ankyloglossia literature. Two poor-quality cohort studies[16,18] reported an improvement in articulation and intelligibility with ankyloglossia treatment, but benefits in word and sentence accuracy and intelligibility and fluent speech were unclear. One poor-quality RCT reported improved articulation in patients treated with Z-frenuloplasty compared with horizontal-to-vertical frenuloplasty.[19] Numerous noncomparative studies reported a speech benefit after

treating ankyloglossia; however, these studies primarily discussed modalities, with safety, feasibility, or utility as the main outcome, rather than speech itself.[23,26-28]

Few studies addressed social concerns. One retrospective cohort study noted improvements in using the tongue to clean the teeth and for licking in the treatment group compared with untreated participants.[16] In two comparative studies reporting on tongue mobility, mobility improved in treated patients.[18,19]

Harms of surgical interventions included minor bleeding, which was typically self-limiting, and need for reoperation, which was rare. Minor bleeding is not an unexpected occurrence in this type of surgical intervention. Eighteen studies reported that no significant harms were observed.

Strength of Evidence

Breastfeeding Outcomes

Very few higher quality comparative studies have addressed the effectiveness of surgical interventions to improve breastfeeding outcomes. In those few studies, mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and very short term. Future studies could provide additional data to confirm or change the measure of effectiveness; thus, we consider the strength of evidence to be low at this time. We considered the strength of evidence (confidence in the estimate of effect) to be low for an immediate reduction in nipple pain. Improvements were reported in the current studies, but additional studies are needed to confirm and support these results. Only one poor-quality cohort study addressed effects on the length of breastfeeding; thus, we considered the strength of evidence to be insufficient.

Other Feeding Outcomes

With only two comparative studies, both with significant study limitations, existing data are insufficient to draw conclusions about the benefits and harms of surgical interventions for infants and children with ankyloglossia on medium- and long-term feeding outcomes. The studies used different populations and measured different outcomes.

Speech Outcomes

Given the lack of good-quality studies and limitations in the measurement of outcomes, we considered the strength of the evidence for the effect of surgical interventions to improve speech and articulation to be insufficient.

Social Concerns Related to Tongue Mobility

With only one poor-quality comparative study, strength of evidence related to the ability of treatment for ankyloglossia to alleviate social concerns is currently insufficient. Also, with only three comparative studies with small sizes and limitations in the measurement of outcomes related to tongue mobility, we considered the strength of evidence for the effect of surgical interventions to improve the short-term outcome of mobility to be insufficient.

Harms

We considered the strength of evidence for minimal and short-lived bleeding as a minor harm of surgical interventions as moderate based on an expanded search for harms reports in addition to the comparative data. We considered the strength of evidence for reoperation and pain as

harms to be insufficient, given the small number of outcomes available for analysis. We acknowledge that harms are not systematically reported, and thus there may be substantial underreporting.

Table B. Strength of evidence for studies addressing surgical approaches for ankyloglossia

Outcome; Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of Evidence
Breastfeeding Outcomes						
Nipple pain RCT: 3 good,[10,11,13] 1 poor[14] (251) Retrospective cohort: 1 poor[15] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for an immediate reduction in nipple pain postprocedure due to inconsistent results across small studies.
Breastfeeding effectiveness RCTs: LATCH—2 good,[10,11] 1 poor[14] (193) IBFAT—1 good[13] (58) BSES-SF—1 fair[10] (107) Retrospective cohort: 1 poor[15] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for improved breastfeeding. Mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and very short term. Observer-rated measures did not show significant improvements. Future studies could provide additional data to confirm or change the measure of effectiveness.
Length of breastfeeding Retrospective cohort: 1 poor[15] (367)	High	NA	Direct	Imprecise	Undetected	Insufficient SOE due to the high risk of bias of the 1retrospective study
Other Feeding Outcomes						
Feeding outcomes RCT: 1 poor[12] (57) Retrospective cohort: 1 poor[16] (104)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE for all feeding outcomes, given small number of participants, lack of standard outcome measures, and poor quality of studies.

Table B. Strength of the evidence for studies addressing surgical approaches for ankyloglossia (continued)

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Speech Outcomes						
Speech and articulation Retrospective cohort: 1 poor[16] (104) Prospective cohort: 1 poor[18] (23)	High	Inconsistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor-quality cohort studies.
Oral motor skills Retrospective cohort: 1poor[16] (104) Prospective cohort: 1 poor[18] (23)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor-quality cohort studies.
Social Outcomes						
Social concerns Retrospective cohort: 1 poor[16] (104)	High	NA	Indirect	Imprecise	Undetected	Insufficient SOE based on 1 poor-quality cohort study.
Tongue mobility RCT: 1 poor[19] (16) Retrospective cohort: 1 poor[18] (15)	High	Consistent	Direct	Imprecise	Undetected	Insufficient SOE based on 2 small poor-quality studies.

Table B. Strength of the evidence for studies addressing surgical approaches for ankyloglossia (continued)

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Harms						
Bleeding RCT: 1 poor[11] (60) Case series: 14 poor[17,22,25,28-38], 2 good[27,39] (963)	High	Consistent	Direct	Imprecise	Suspected	Moderate SOE for minimal and short-lived bleeding based on an extensive search for harms reports in addition to the comparative data. Studies consistently reported minimal to no bleeding.
Reoperation RCT: 1 poor[10] (107) Retrospective cohort: 1 poor[15] (367) Case series:1 good,[39] 4 poor[23,24,40,41] (4,080)	High	Consistent	Direct	Imprecise	Suspected	Insufficient SOE due to very small numbers for the outcome.
Pain Case series: 2 good[27,42] (84)	High	Consistent	Indirect	Imprecise	Suspected	Insufficient SOE for minimal short-lived pain in infants. No studies reported excessive crying or an inability to feed soon after the intervention, but pain is arguably difficult to assess in infants, so outcomes were indirect and from poor-quality or noncomparative studies.

BSES –SF = Breastfeeding Self-Efficacy Scale-Short Form; IBFAT = Infant Breastfeeding Assessment Tool; LATCH = Latch, Audible swallowing, Type of nipple, Comfort, Hold; NA = not applicable; RCT = randomized controlled trial; SOE = strength of evidence.

Applicability

Newborns referred for treatment of ankyloglossia were born primarily at tertiary-care centers and recognized as having difficulty with breastfeeding concomitant with ankyloglossia. The frenotomy procedure itself is not technically difficult and is likely performed similarly across birthing sites; however, the criteria by which the decision is made to perform frenotomy are less clear. Moreover, newborns of mothers not choosing to breastfeed may not be recognized as having and/or diagnosed with ankyloglossia, as breastfeeding difficulties were used as an indicator to evaluate for ankyloglossia. At minimum, the studies in this report apply only to

infants with both ankyloglossia and feeding difficulties; data on ankyloglossia absent feeding difficulties were unavailable.

In these studies, various clinicians were involved in making the ankyloglossia diagnoses. However, assessment of breastfeeding difficulty and diagnostic criteria for ankyloglossia were not universally described. Lack of a consistent objective measure to define and classify this condition may limit the reproducibility of findings. Furthermore, the age of patients in these studies varied from a median of 6 days of age in one study[13] up to a mean of 33 days of age (range, 6 to 115) in another study.[11] Applicability of findings to older infants cannot be gleaned from these data, nor can durability of results.

Frenotomy was the only intervention employed in the good-quality RCTs.[10,11,13] However, the specifics of the procedure were variably reported. The degree of posterior extension of the frenulum incision was not clearly defined and appears to be at the discretion and clinical expertise of the clinician. Also, the severity of the ankyloglossia was inconsistently reported, making interstudy generalizations difficult and, more importantly, limiting the broader applicability of findings.

The comparators used were sham surgery[11,13] and no intervention.[10] Both "no intervention" and "sham surgery" are perhaps misnomers, however, since these infant-mother dyads underwent usual care, which could include, but is not limited to, lactation consultation, supportive care, and bottle-feeding advice.

The population studied in the question of benefit of ankyloglossia repair for social concerns included children and adults with wide variation in ages.

Research Gaps

A critical unknown at this point is a good description of the natural history of ankyloglossia by severity, including long-term risk of feeding, social, and speech production difficulties. Future studies should consider direct comparisons of alternative treatments, as currently available literature addressed only the comparison of frenotomy with sham. In order to conduct these studies, it would be helpful if the field could agree on a standardized approach to identifying and classifying ankyloglossia; this would also improve our ability to synthesize the data across studies.

Given variation in outcomes that may be associated with earlier versus later frenotomy, future studies should assess timing of frenotomy to determine whether more significant reduction in maternal pain is achievable by earlier treatment and whether mothers are more apt to breastfeed longer if the frenotomy is done earlier.

A significant gap in research is in understanding the durability of outcomes. Good-quality comparative studies evaluated breastfeeding effectiveness immediately[11,13] or within 5 days of frenotomy;[10] however, none adequately assessed whether effectiveness and other outcomes (e.g., changes in maternal nipple pain) were maintained months or, if appropriate, years later. Longer term followup of both treated infants and controls is needed. Because of the paucity of available data on other feeding outcomes, this entire research question represents a gap and a potential area for future research.

Similarly, substantially more research is needed to consider whether treatment of ankyloglossia in infancy prevents future speech production difficulties, as well as whether treatment later in life with frenotomy leads to improvement when speech problems arise. To conduct this research effectively, methods for evaluating risk and presence of speech production difficulties will need to be standardized, and outcomes agreed on. Understanding of the natural

history of speech concerns in children with ankyloglossia is lacking, as are comparative studies that use standardized measurement tools for speech outcomes.

No standard definitions of tongue mobility or established norms for mobility exist, and further research is needed to determine such parameters. Social concerns are difficult to measure objectively, so there will likely always be a subjective component to social outcomes. Larger studies that assess both treated and untreated individuals could provide useful data to minimize the potential bias found in the existing literature. Similarly, future research in objective measurement tools or validated self-report tools is needed.

Conclusions

A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain. However, with small, inconsistently conducted studies, strength of evidence is low to insufficient, preventing us from drawing firm conclusions at this time. Research is lacking on nonsurgical interventions, as well as on outcomes other than breastfeeding, particularly speech and dental outcomes. In particular, there is a lack of evidence on significant long-term outcomes, such as exclusive breastfeeding at 6 months of age or at 1 year of age, growth, and other measures of health outcomes. Harms are minimal and rare; the most commonly reported harm is self-limited bleeding. Future research is needed on a range of issues, including prevalence and incidence of ankyloglossia and problems with the condition. The field is currently challenged by a lack of standardized approaches to assessing and studying the problems of infants with ankyloglossia.

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Introduction

Background

Ankyloglossia

Ankyloglossia is a congenital condition in which a neonate is born with an abnormally short, thickened, or tight lingual frenulum that restricts mobility of the tongue. Ankyloglossia may be associated with other craniofacial abnormalities, but is also often an isolated anomaly.[1] It variably causes reduced anterior tongue mobility and has been associated with functional limitations in breastfeeding, swallowing, articulation, orthodontic problems including malocclusion, open bite, and separation of lower incisors, mechanical problems related to oral clearance, and psychological stress. Reported rates of ankyloglossia in one review including studies of infants, children, and adults ranged from 0.1 to 10.7 percent,[2] but definitive incidence and prevalence statistics are difficult to obtain because there criterion standard or clinically practical diagnostic criteria.

Anterior ankyloglossia is defined as tongue-tie with a prominent lingual frenulum and/or restricted tongue protrusion with tongue tip tethering. The diagnosis of posterior ankyloglossia is considered when the lingual frenulum is not very prominent on inspection but is thought to be tight on manual palpation or is found to be abnormally prominent, short, thick, or fibrous cord-like with the use of the grooved director. Although treatment is similar in anterior and posterior cases, posterior ankyloglossia is more subtle in presentation. Usually, clinicians recognize the anterior frenulum as the cause of ankyloglossia; however, an infant can have ankyloglossia even without obvious abnormalities of the anterior frenulum. Anterior ankyloglossia has been found more commonly in males and posterior ankyloglossia in females.[3] Posterior ankyloglossia is more likely to require revision surgery due to the relative difficulty of accurate diagnosis and treatment.

Estimates in the literature of the number of infants with ankyloglossia who have feeding difficulties are based on small case series without control groups. Mechanistically, infants with restrictive ankyloglossia cannot protrude their tongues over the gum line to contact their lips to form a proper latch and therefore use their jaws to keep the maternal nipple in the mouth for breastfeeding. Adequate tongue mobility is required, and infants with ankyloglossia often cannot overcome their deficiency with conservative measures such as positioning and latching techniques.[2] Ineffective latch associated with ankyloglossia is hypothesized to underlie breastfeeding problems in these infants including failure to thrive, maternal nipple damage, maternal breast pain, poor milk supply, maternal breast engorgement, and refusing the breast.[2]

Consensus on ankyloglossia's role in breastfeeding difficulties is lacking. A minority of surveyed pediatricians (10%) and otolaryngologists (30%) believe it commonly affects feeding, while 69 percent of lactation consultants feel that it frequently causes breastfeeding problems.[4] Therefore, depending on the audience, enthusiasm for its treatment varies. Currently, the U.K. National Health Service (NHS) and the Canadian Paediatric Society (CPS) recommend treatment only if it interferes with breastfeeding.[5] Unfortunately, a standard definition of "interference" with breastfeeding is not provided, leaving room for interpretation and variation in treatment thresholds. The absence of data on the natural history of untreated ankyloglossia creates even more uncertainty. Some propose that a short frenulum elongates spontaneously due to progressive stretching and thinning of the frenulum with age and use.[1] However, there are no

prospective longitudinal data on the fate of the congenitally short lingual frenulum. Without this information it is difficult to inform parents fully about the long-term implications of ankyloglossia, which complicates the decision making process.

Although most ankyloglossia research is focused on the infant and breastfeeding issues, concerns beyond infancy include speech-related issues, such as difficulty with articulation, and social concerns related to limited tongue mobility. Individuals with untreated ankyloglossia may experience difficulty with licking foods such as ice cream, kissing, drooling, playing wind instruments, and licking the lips. Self- esteem or psychological issues may also be a concern for affected older patients.

Treatment Strategies

Surgical Approaches

Surgical modalities include frenotomy, frenulectomy, and tongue tie release surgery. These interventions are often used interchangeably in the literature. In general, a lingual frenotomy involve clipping or cutting of the lingual frenulum using the proceduralist's fingers, a grooved tongue director, or other instrument to lift the tongue, which puts the tension on the frenulum and using straight scissors to divide the frenulum, generally without sedation. The ensuing wound does not typically require repair. Laser frenotomy or frenulotomy has also been described,[6] and proponents argue that its use is more exact and provides better hemostasis than standard frenotomy or frenulotomy.

Frenuloplasty is more technically involved than frenotomy or frenulotomy. It generally refers to rearranging tissue or adding grafts after making incisions and closing the resultant wound in a specific pattern to lengthen the anterior tongue. Specific types of frenuloplasty include Z-frenuloplasty, which involves making a longitudinal incision along the length of the lingual frenulum combined with perpendicular incisions at tongue tip and floor of the mouth. These cuts create a Z-type incision. Submucosal flaps are then elevated, and transposed flaps are sutured closed, resulting in increased tongue length and mobility. A second type of frenuloplasty involves a horizontal division at the base of the frenulum where a harvested buccal mucosal graft is inserted and affixed to fill the defect created by the incision. Horizontal-to-vertical frenuloplasty is a third type in which a horizontal incision is created at mid-frenulum to release the tethering fibrotic band. The incision is then converted to a vertical orientation and closed with sutures to effectively elongate the anterior tongue. Frenuloplasty is most commonly performed under a general anesthetic and used in older infants and children or in more complex frenulum repairs.

Nonsurgical Approaches

Nonsurgical approaches include speech therapy and lactation interventions and observation to determine if intervention is warranted (Table 1).

Table 1. Nonsurgical treatment approaches

Intervention	Description
Complementary and alternative procedures	Diverse group of therapies not conventionally practiced by physicians or allied health professionals (e.g., craniosacral therapy).
Lactation intervention	Counseling and recommendations from a lactation consultant for better, easier or more efficient breast-feeding. Focus on latching technique and infant and maternal positioning on breast.
Physical therapy/occupational therapy	Approaches to reduce tension in and stretch neck, back, and strap muscles to improve range of motion. This includes myofascial release and other manual techniques.
Speech therapy/oromotor therapy	Exercises and techniques intended to develop awareness, strength, coordination and mobility of the oral muscles including the tongue, lip, and palate. Evaluation and treatment of swallowing and speech disorders using specific exercises and procedures.
Observation	Supportive therapy for mother without any treatment approach and observation for improvement through natural history of the condition process.

Several measures have been developed to assess or describe ankyloglossia. Structured assessments can also be used to assess the effectiveness of breastfeeding. Table 2 outlines measures used in the studies reported in this review.

Table 2. Structured assessments and screening tools used in ankyloglossia literature

Measure	Description
Degree of Ankyloglossia	
Coryllos criteria	Scale for categorizing ankyloglossia based on proximity of frenulum attachment to tongue tip: Type 1=frenulum attached to tip of tongue. Type 2=frenulum attached 2-4 millimeters behind tongue tip on or behind alveolar ridge. Type 3=mid-tongue attachment. Type 4=attachment at base of tongue. Type 4 is associated with more difficulty with bolus swallowing and more significant symptoms.
Hazelbaker Assessment Tool for Lingual Frenulum Function (HATLFF)	Measure of ankyloglossia extent and severity that include items to assess the appearance and function of the tongue and frenulum. Lower scores indicate more severe ankyloglossia. HATLFF is scored: 0-14 with14=perfect; 11=acceptable if appearance item score is 10; <11=impaired function (frenotomy should be considered if management fails; frenotomy is necessary if appearance item score is <8). HATLFF score of 6-12=mild to moderate tongue-tie; <6=severe tongue-tie.[7, 8]
Breastfeeding Effectiveness	
Breastfeeding Self-Efficacy Scale (BSES)	Measure of maternal breastfeeding confidence that uses a 5-point (1=not at all confident to 5=always confident) Likert scale to assess agreement with statements such as "I can always position my baby correctly at my breast." BSES scores range from 33-165 on the 33-item instrument [9] and 14-70 on the 14-item BSES-Short Form.[10] Higher overall scores indicate higher levels of breastfeeding self-efficacy.
Infant Breastfeeding Assessment Tool (IBFAT)	Measure of clinician or maternally rated perception of 4 items related to effectiveness of and satisfaction with a feeding (readiness to feed, rooting, latching on, sucking) rated on a 3-point scale (e.g., 3=rooted effectively at once, 0=did not root). Higher scores indicate greater perceived effectiveness. IBFAT scores range from 0-12; 12=vigorous and effective feeding.[11]

Table 2. Structured assessments used in ankyloglossia literature (continued)

Measure	Description
Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH)	Measure of effectiveness of latch to the breast, feeding, comfort for mother, and maternal positioning rated on 3 levels with higher scores indicating greater effectiveness. LATCH score ≤8=breastfeeding difficulties.[12]

Scope and Key Questions

Scope of Review

This systematic review provides a comprehensive review of potential benefits of treatments (surgical and nonsurgical) as well as harms associated with those therapies in individuals with ankyloglossia and tight labial frenulum (lip-tie) concomitant with ankyloglossia. We assess outcomes related to breast and bottle-feeding and related to tongue tie in later life (e.g., orthodontic and dental issues, speech, self-esteem).

Key Questions

We have synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ1. What are the benefits of various treatments in breastfeeding newborns and infants with ankyloglossia intended to improve breastfeeding outcomes? Surgical treatments include frenotomy (anterior and/or posterior), frenuloplasty (transverse to vertical frenuloplasty), laser frenulectomy/frenulotomy, and Z-plasty repair. Nonsurgical treatments include complementary and alternative medicine therapies (e.g. craniosacral therapy), lactation intervention, physical/occupational therapy, oral motor therapy, and stretching exercises/therapy.

KQ2a. What are the benefits of various treatments in newborns, infants, and children with ankyloglossia intended to prevent, mitigate, or remedy attributable medium and long-term *feeding* sequelae including trouble bottle feeding, spilling and dribbling, difficulty moving food boluses in the mouth and deglutition?

KQ2b. What are the benefits of various treatments in infants and children with ankyloglossia intended to prevent, mitigate, or remedy attributable medium and long term *other* sequelae including articulation disorders, poor oral hygiene, oral and oropharyngeal dysphagia, sleep disordered breathing, orthodontic issues including malocclusion, open bite due to reverse swallowing, lingual tipping of the lower central incisors, separation of upper central incisors, crowding, narrow palatal arch, and dental caries?

KQ3. What are the benefits of various treatments for ankyloglossia in children through 18 years of age intended to prevent or address social concerns related to tongue mobility (i.e., speech, oral hygiene, excessive salivation, kissing, spitting while talking, and self-esteem)?

KQ4. What are the benefits of simultaneously treating ankyloglossia and concomitant tight labial frenulum (lip-tie) in infants and children through age 18 intended to improve or remedy breastfeeding, articulation, orthodontic and dental, and other feeding outcomes? What are the relative benefits of treating only ankyloglossia when tight labial frenulum (lip-tie) is also diagnosed?

KQ5. What are the harms of treatments for ankyloglossia or ankyloglossia with concomitant lip-tie in neonates, infants, and children through age 18?

Table 3 outlines the population, intervention, comparator, outcomes, timing, and setting characteristics for each KQ.

Table 3. PICOTS

PICOTS	Criteria
Population	• KQ1: Breastfeeding newborns with ankyloglossia • KQ2 and KQ3: Infants and children with ankyloglossia • KQ4: Infants and children (newborns through18 years of age) with ankyloglossia and concomitant tight labial frenulum (lip-tie) KQ5: Children through age 18 treated for ankyloglossia or ankyloglossia and concomitant lip-tie.
Intervention(s)	• Surgical interventions, including frenotomy (anterior or posterior), frenuloplasty, laser frenulectomy and Z-plasty repair • Nonsurgical treatments include complementary and alternative medicine (CAM) therapies (e.g., craniosacral therapy), lactation intervention, and speech therapy (for children ages 2 to 18 years), physical/occupational therapy, oral motor therapy, and stretching exercises/therapy
Comparator	• Other surgical approach • Non-surgical interventions including lactation intervention, speech therapy, physical/occupational therapy oral motor therapy, and stretching exercises/therapy • Observation • Complementary and alternative medicine (CAM) therapies (e.g. craniosacral therapy) • Placebo (sham therapy)
Outcomes	• Breastfeeding, including latch, nipple pain, nipple excoriations, nipple infections (mastitis), weight gain, aerophagia, swallowing function, failure to thrive, milk transfer, low milk supply, breastfeeding cessation/duration of breastfeeding • Other feeding issues, including difficulty bottle feeding, moving food boluses in the mouth, deglutition, spilling and dribbling, reflux, dysphagia • Articulation • Speech (e.g., speech fluency, effort with speech, speech intelligibility) • Sleep disordered breathing (sleep apnea) • Oral hygiene • Excessive salivation • Orthodontic problems, including malocclusion, open bite due to reverse swallowing, lingual tipping of lower central incisors, separation of upper central incisors, crowding, and narrow palatal arch, dental caries • Psychological (e.g., self-esteem) • Harms, including excessive bleeding, airway obstruction, pain, transient poor feeding secondary to discomfort, dysphagia, complications related to dysphagia such as aspiration pneumonia, surgical site infection, nerve damage, salivary gland damage, ranulae, scarring, soft tissue damage, oral aversion, readherence, and need for further surgery/revision
Timing	• Short-term (breastfeeding) • Long-term (feeding) speech, psychological, oral hygiene
Setting	• Inpatient or outpatient pediatric care, operating room, newborn nursery or NICU, ENT clinic, primary care outpatient, dental office, breastfeeding medicine clinic

CAM = Complementary and alternative medicine; ENT = ear, nose and throat; KQ = Key Question; NICU = neonatal intensive care unit; PICOTS = population, intervention, comparator, outcomes, timing, setting

Analytic Framework

Figure 1 depicts KQs 1, 4, and 5 within the context of the PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting) described in the document. The figure examines surgical and nonsurgical treatments in newborns and infants to improve breastfeeding outcomes. Intermediate outcomes include maternal nipple pain, ability to latch and maintain latch, tongue mobility, and aerophagia. Final outcomes include duration of breastfeeding, failure to thrive, infant weight gain and oral and oropharyngeal dysphagia. Harms (KQ5) may occur at any point after the intervention is received.

Figure 1. Analytic framework for ankyloglossia in neonates and infants

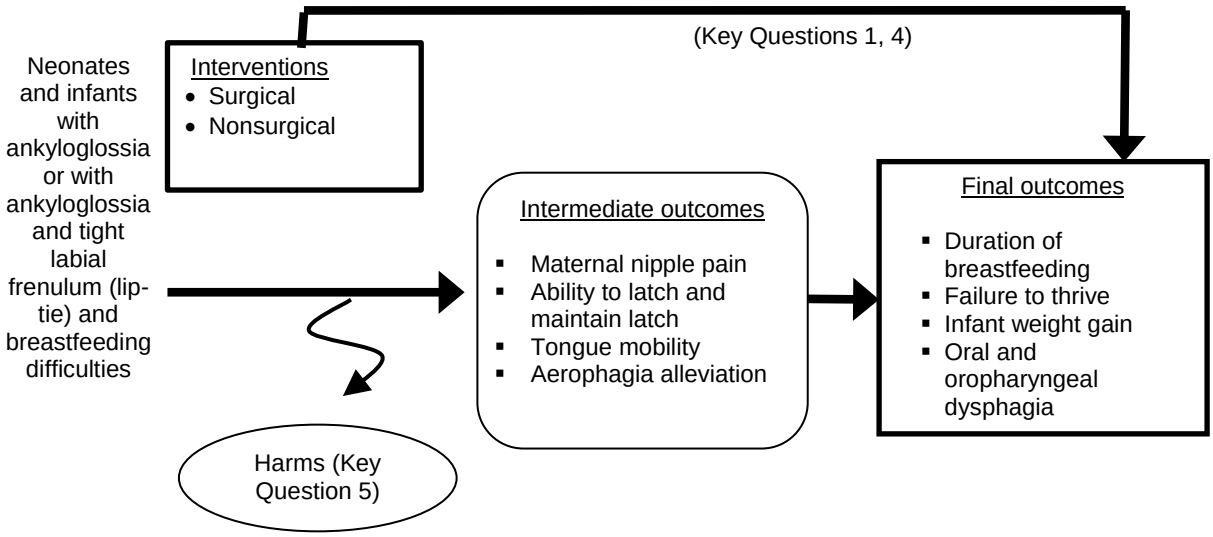
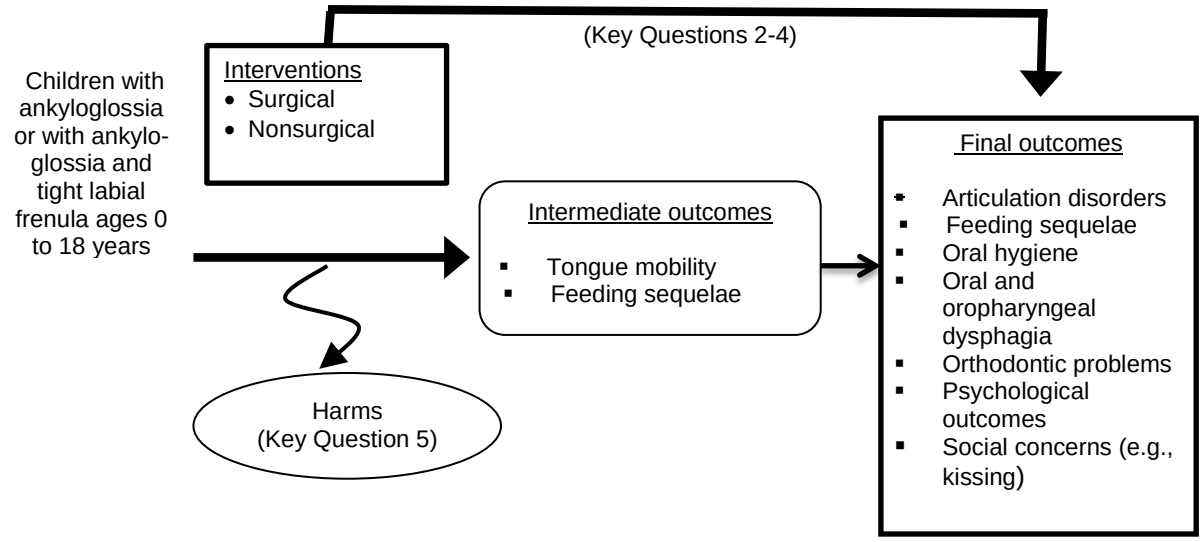


Figure 2 depicts KQs 2, 3, 4, and 5 within the context of the PICOTS described in the document. The figure examines surgical and nonsurgical treatments in infants and children with ankyloglossia (KQ2, KQ3) or ankyloglossia with concomitant tight labial frenulum (lip-tie) (KQ4). The intermediate outcome is tongue mobility and final health outcomes include articulation disorder, oral hygiene, oral and oropharyngeal dysphagia, orthodontic problems, psychological outcomes and social concerns including kissing. Harms (KQ5) may occur at any point after the intervention is received.

Figure 2. Analytic framework for ankyloglossia in infants and children through 18 years of age



Organization of This Report

The Methods section describes our processes including our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and methods for extraction of data into evidence tables, and compiling evidence. We also describe our approach to grading the quality of the literature and to describing the strength of the body of evidence.

The Results section presents the findings of the literature search and the review of the evidence by KQ, synthesizing the findings across strategies.

The Discussion section of the report discusses the results and expands on the methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research in the field.

The report includes a number of appendices to provide further detail on our methods and the studies assessed. The appendixes are as follows:

- Appendix A. Search Strategies
- Appendix B. Abstract and Full-Text Screening Forms
- Appendix C. Excluded Studies
- Appendix D. Evidence Tables
- Appendix E. Quality Assessment Forms
- Appendix F. Quality Scoring Results
- Appendix G. Case Reports Harms
- Appendix H. Conference Abstracts
- Appendix I. Applicability Tables

We also include a list of abbreviations and acronyms at the end of the report.

Uses of This Evidence Report

We anticipate this report will be of primary value to organizations that develop guidelines for clinical practitioners and to health care providers who take care of infants and children through 18 years of age with ankyloglossia. Interested organizations would include the American Academy of Pediatrics, the Pediatric Academic Societies (PAS), the Academy of Breastfeeding

Medicine(ABM), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), the American Speech-Language-Hearing Association (ASHA), the International Lactation Consultant Association (ILCA), Lactation Consultants of Australia and New Zealand (LCANZ), the College of Lactation Consultants of Western Australia (CLCWA), the American Orthodontic Society (AOS) and the American Association of Orthodontists (AAO), the NHS and other organizations and societies for pediatric care. Ankyloglossia is diagnosed and treated by an array of physicians and allied health professionals, but this most commonly includes pediatricians, otolaryngologists, dentists, and lactation consultants. This report supplies practitioners and researchers up-to-date information about the current state of evidence, and assesses the quality of studies that aim to determine the outcomes of treatments for ankyloglossia. It will be of interest to parents concerned about the health of their infants and facing treatment choices around care for their children with ankyloglossia.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to advance research methods, develop new treatment strategies, and optimize the effectiveness and safety of clinical care infants and children through 18 years of age with ankyloglossia.

Methods

In this chapter, we document the procedures that the Vanderbilt Evidence-based Practice Center used to produce a Comparative Effectiveness Review on the approaches to treatment for ankyloglossia. These procedures follow the methods suggested in the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[13]

Topic Refinement and Review Protocol

The topic for this report was nominated by the American Academy of Pediatrics in a public process using the Effective Health Care Web site. Working from the nomination, we drafted the initial Key Questions (KQs) and analytic framework and refined them with input from key informants representing the fields of pediatric care, pediatric otolaryngology, breastfeeding and lactation, dentistry, occupational therapy, and speech therapy. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team had any conflicts.

After review from AHRQ, the questions and framework were posted online for public comment. No changes to the questions or framework were recommended. We also developed population, interventions, outcomes, timing, and settings (PICOTS) criteria for intervention KQs.

We identified technical experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of pediatric care, pediatric otolaryngology, breastfeeding and lactation, dentistry, and speech-language pathology, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included nine members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to review and provide comments as our work progressed. TEP members participated in conference calls and discussions through e-mail to:

- Help to refine the analytic framework and KQs at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- Provide input on the information and domains included in evidence tables.

The final protocol was posted to the AHRQ Effective Health Care Web site.[14]

Literature Search Strategy

Search Strategy

To ensure comprehensive retrieval of relevant studies of therapies for children with ankyloglossia or ankyloglossia with concomitant tight labial frenulum (lip-tie), we used four key databases: the MEDLINE® medical literature database via the PubMed® interface, the PsycINFO® psychology and psychiatry database, the Cumulative Index of Nursing and Allied Health Literature (CINAHL®) and EMBASE (Excerpta Medica Database), an international biomedical and pharmacological literature database via the Ovid® interface. Search strategies applied a combination of controlled vocabulary (Medical Subject Headings (MeSH), PsycINFO headings, CINAHL medical headings, and Emtree headings, respectively) to focus specifically

on concepts related to ankyloglossia and its treatment as well as treatment harms. Literature searches were not restricted to a year range (i.e., searches were from inception of the database to the present) given the need to capture variations in practice patterns and trends in breastfeeding over time.

We included studies published in English only as a review of non-English citations retrieved by our MEDLINE search identified few studies of relevance. Appendix A lists our search terms and strategies and the yield from each database. Searches were executed between September 2013 and August 2014**.**

We carried out hand searches of the reference lists of recent systematic reviews or meta-analyses of therapies for ankyloglossia; the investigative team scanned the reference lists of articles included after the full-text review phase for studies that potentially could meet our inclusion criteria.

As we did not review medications or devices, we did not request Scientific Information Packets or regulatory information. We reviewed abstracts presented at annual meetings of key scientific societies including the American Association of Pediatrics (AAP), the Pediatric Academic Societies (PAS), the Academy of Breastfeeding Medicine (ABM), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), the American Speech-Language-Hearing Association (ASHA), the International Lactation Consultant Association (ILCA), Lactation Consultants of Australia and New Zealand (LCANZ), the College of Lactation Consultants of Western Australia (CLCWA), the American Orthodontic Society (AOS) and the American Association of Orthodontists (AAO). We identified relevant theses and dissertations through ProQuest Dissertations and Theses (PQDT).

Inclusion and Exclusion Criteria

Table 4 lists the inclusion/exclusion criteria we used based on our understanding of the literature, key informant and public comment during the topic-refinement phase, input from the TEP, and established principles of systematic review methods.

Table 4. Inclusion and exclusion criteria

Category	Criteria
Study population	Inclusion: Children ages 0-18 with ankyloglossia or ankyloglossia with concomitant tight labial frenulum (lip-tie); Exclusion: Studies with participants with Van der Woude syndrome, Pierre Robin syndrome, Down syndrome, or craniofacial abnormalities were excluded as were studies of premature babies (<37 weeks of gestation[15])
Publication languages	Inclusion: English Exclusion: Non-English
Admissible evidence (study design and other criteria)	Included study designs RCTs, prospective and retrospective cohort studies, nonrandomized controlled trials, prospective and retrospective case series, and cross over studies Case reports to assess harms Other criteria Original research studies providing sufficient detail regarding methods and results to enable use and aggregation of the data and results Studies must address one or more of the following: • Surgical interventions (simple anterior frenotomy, frenulotomy, or frenectomy, laser frenotomy, frenulotomy, or frenulectomy, posterior frenulectomy, Z-plasty repair) • Nonsurgical treatments include complementary and alternative medicine therapies (e.g. craniosacral therapy, myofascial release, and other chiropractic therapies), lactation intervention , speech therapy, physical therapy, oral motor therapy and stretching exercises/therapy • Baseline and outcome data (including harms) related to interventions for ankyloglossia Relevant outcomes must be able to be extracted from data in the papers Data must be presented in the aggregate (vs. individual participant data)

RCT = randomized controlled trial.

Study Selection

Once we identified articles through the electronic database searches and hand-searching, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion/exclusion criteria. Disagreements between reviewers were resolved by a senior reviewer. All abstract and full text reviews were conducted using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Excluded studies, and the reasons for exclusion, are presented in Appendix C. Reviewers included three clinicians with expertise in pediatrics and/or otolaryngology and two expert systematic reviewers.

Data Extraction

The staff members and clinical experts who conducted this review jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to

understand the studies and to determine their quality; we gave particular emphasis to essential information related to our key questions. Two evidence table templates were employed to facilitate the extraction of data based on study type; one form was designed for case series and one to accommodate all types of comparative studies. We based the format of our evidence tables on successful designs used for prior systematic reviews.

The team was trained to extract data by extracting several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. We repeated this process through several iterations until we decided that the tables included the appropriate categories for gathering the information contained in the articles. All team members shared the task of initially entering information into the evidence tables. A second team member also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The two data extractors reconciled disagreements concerning the information reported in the evidence tables. The full research team met regularly during the article extraction period and discussed global issues related to the data extraction process. In addition to outcomes related to intervention effectiveness, we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

The final evidence tables are presented in their entirety in Appendix D. Studies are presented in the evidence tables alphabetically by the last name of the first author. A list of abbreviations and acronyms used in the tables appears at the beginning of that appendix.

Data Synthesis

We considered the possibility of conducting a meta-analysis, but the small number of the studies, the study designs and the heterogeneity of interventions and outcomes made a meta-analysis inappropriate. We completed evidence tables for all included studies, and data are presented in summary tables and analyzed qualitatively in the text.

Quality (Risk of Bias) Assessment of Individual Studies

We used four tools to assess quality of individual studies: the Cochrane Risk of Bias Tool for Randomized Controlled Trials,[16] a cohort study assessment instrument and a tool for case series, both adapted from RTI Item Bank questions,[17] and a four-item harms assessment instrument for cohort studies derived from the McMaster Quality Assessment Scale of Harms (McHarm) for Harms Outcomes[18] and the RTI Item Bank.[17]

The Cochrane Risk of Bias tool is designed for the assessment of studies with experimental designs and randomized participants. Fundamental domains include sequence generation, allocation concealment, blinding, completeness of outcome data, and selective reporting bias. The RTI Item Bank-based cohort instrument was used to assess the quality of nonrandomized studies (e.g., cohort and case-control studies). Questions assess selection and follow up of study groups, the comparability of study groups, and the ascertainment of outcomes of interest for cohort studies. The case series tool assesses attrition, blinding, appropriateness of outcome measures, and reporting bias. The harms assessment tool documents whether harms were predefined and pre-specified and if standard scales were applied. We did not assess the quality of case reports, which we used solely for harms data. All four tools are presented in Appendix E.

Quality assessment of each study was conducted by two team members independently using the forms presented in Appendix E. Any discrepancies were adjudicated through discussion between the assessors to reach consensus or via a senior reviewer. Investigators did not rely on the study design as described by authors of individual papers; rather, the methods section of each

paper was reviewed to determine which rating tool to employ. The results of these tools were then translated to the AHRQ standard of "good," "fair," and "poor" quality designations as described below.

Determining Quality Ratings

- We required that randomized controlled trials (RCTs) receive a positive score (i.e., low risk of bias for RCTs) on all questions used to assess quality to receive a rating of good (equivalent to low risk of bias). RCTs had to receive at least five positive scores to receive a rating of fair (moderate risk of bias), and studies with less than or equal to four positive ratings were considered poor quality (high risk of bias). We designated an "unclear" rating on an individual question as a positive rating as long as the consensus of the investigators assessing quality was that study outcomes were not likely to be biased by the factor.
- We required that cohort studies receive positive scores on all elements to receive a rating of good, less than or equal to two negative ratings for fair, and greater than two negative scores for a rating of poor quality.
- Case series, or pre-post studies, have inherently high risk of bias. Nonetheless, prospective case series that enroll participants consecutively and control for potentially confounding factors may provide more evidence to support comparative studies. We assessed case series using questions identified in the AHRQ Effective Health Care program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[13] but did not assign a quality level for these studies as it would be inappropriate to assess them on the same scale as prospective cohort and RCT designs. Rather, the elements on which they were scored and the results are presented in Appendix F.
- For harms assessment we required that studies receive a positive score (i.e., an affirmative response) on all four questions to receive a rating of good. Studies had to receive three positive scores to receive a rating of fair, and studies with less than three positive scores received a rating of poor.

Strength of the Body of Evidence

We applied explicit criteria for rating the overall strength of the evidence for each key intervention-outcome pair for which the overall risk of bias is not overwhelmingly high. We established concepts of the quantity of evidence (e.g., numbers of studies, aggregate ending-sample sizes), the quality of evidence (from the quality ratings on individual articles), and the coherence or consistency of findings across similar and dissimilar studies and in comparison to known or theoretically sound ideas of clinical or behavioral knowledge.

The strength of evidence evaluation is that stipulated in the Effective Health Care Program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[13] and in the updated strength of evidence guide[19] which emphasizes the following five major domains: study limitations (low, medium, high level of limitation), consistency (inconsistency not present, inconsistency present, unknown or not applicable), directness (direct, indirect), and precision (precise, imprecise), and reporting bias. Study limitations are derived from the quality assessment of the individual studies that addressed the KQ and specific outcome under consideration. Each key outcome for each comparison of interest is given an overall evidence grade based on the ratings for the individual domains.

The overall strength of evidence was graded as outlined in Table 5. Two senior staff independently graded the body of evidence; disagreements were resolved as needed through discussion or third-party adjudication. We recorded strength of evidence assessments in tables, summarizing results for each outcome.

Table 5. Strength of evidence grades and definitions*

Grade	Definition
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	**We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome**. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

* Excerpted from Berkman et al., 2013.[19]

Applicability

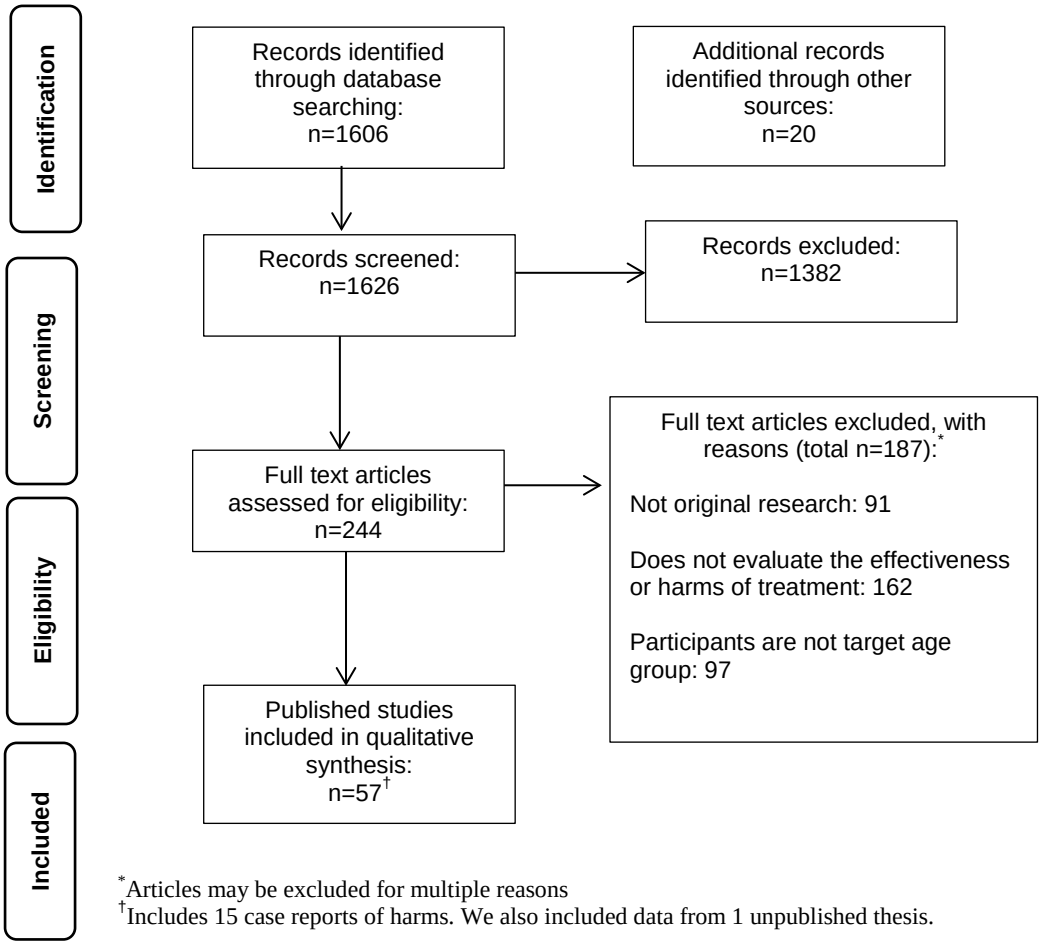
We assessed the applicability of findings reported in the included literature to the general population of children with ankyloglossia by determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include the severity of ankyloglossia in the study population, the age range of the participants, and the setting in which the intervention took place. We also attempted to capture information about the clinical provider including specialty and training. We describe any needs related to the setting, including anesthesia, surgical environment, materials for non-surgical interventions, etc.

Results

Results of Literature Searches

We identified 1,626 nonduplicative titles or abstracts with potential relevance, with 244 proceeding to full text review (Figure 3). We excluded 187 studies at full-text review, which yielded 57 published studies included in the review. We also included one unpublished thesis in our results, thus the report summarizes data from 58 unique publications.

Figure 3. Disposition of articles identified by the search strategy



*Articles may be excluded for multiple reasons
†Includes 15 case reports of harms. We also included data from 1 unpublished thesis.

Description of Included Studies

The 58 unique publications included in the review comprise six randomized controlled trials (RCTs), three assessed as good quality[7, 8, 20] for outcomes related to breastfeeding effectiveness and maternal pain related to breastfeeding. One RCT was rated as poor quality for breastfeeding effectiveness and pain outcomes.[21] One RCT was of poor quality for outcomes of tongue protrusion, frenulum length, and articulation/intelligibility,[22] and we rated one RCT as fair quality for measures of breast and bottle feeding.[23] The literature also includes three cohort studies (all poor quality[24-26]), 33 case series,[3, 6, 27-57] and 15 case reports (one of which reports

two cases and one of which reports five cases).[58-72] We also included one unpublished thesis (not quality rated). Table 6 outlines study characteristics.

Because case series do not include comparison groups, they do not provide comparative effectiveness data but were read to determine if they generally provided support for comparative data and as an additional source of harms. We used case reports to seek harms data only. We considered all comparative studies (RCTs and cohort studies) as poor quality for harms outcomes. We considered the quality for harms outcomes as good in four case series[49-52] and poor in 26.[3, 6, 27-48, 54, 56]

Table 6. Overview of comparative studies included

Characteristic	RCTs	Cohort Studies	Prospective Case Series	Retrospective Case Series	Total Literature
	(n=6)	(n=3)	(n=21)	(n=12)	(n=42)*
Intervention					
Frenotomy	3	3	3	5†	14†
Frenulotomy	0	0	6	1	7
Frenectomy	0	0	2	0	2
Frenuloplasty	0	0	3	2†	5†
Horizontal-to-vertical frenuloplasty	1††	0	1**	0	2††
Four-flap Z-frenuloplasty	1††	0	0	0	1††
Z-plasty with partial myotomy	0	0	0	1	1
Laser excision	0	0	2	0	2
Tongue-tie division (non-specified)	2	0	4	4	10
Length of last followup					
Immediately after intervention	1	1	2	1	5
≤1 month	0	0	7	1	8
>1 to ≤3 months	2	0	5	3	10
>3 to ≤6 months	1	0	1	2	4
>6 to ≤12 months	1	0	0	0	1
>12 months	1	2	2	1	6
Not reported/unclear	0	0	4	4	8
Provider					
Family practitioner	0	0	1	0	1
Pediatrician	0	0	1	1	2
Otolaryngologist	1	2	4‡	2	9
Otolaryngologist consultant or lactation consultant	0	0	1	0	1
Lactation consultant or pediatric surgeon	2	0	0	1	3
Neonatologist or pediatric dentist	1	1	1	0	3
General surgeon	0	0	4	2	6
Pediatric surgeon	0	0	3‡‡	1	4
Not reported/unclear	2	0	6	5	13

Table 6. Overview of comparative studies included (continued)

Characteristic	RCTs	Cohort Studies	Prospective Case Series	Retrospective Case Series	Total Literature
Study population					
United States/Canada	2	2	5	4	13
Europe	3	0	8	5	16
Asia	0	0	2	2	4
Other	1	1	6	1	9
Total N participants	324	473	1142	3846***	5785

N=number; RCT=randomized controlled trial.

* Literature also includes 15 case reports used for harms data and one unpublished thesis.

** Four children had horizontal to vertical frenuloplasty; one child had frenulotomy.

*** 2590 children in one study had tongue-tie division but the number responding to a follow-up survey was not clearly reported; therefore, these children are not included in the total participant count.

ǂ Providers included otolaryngologist in 54 cases and nurse in 51 cases.

ǂǂ Providers included pediatric surgeons, pediatricians, otolaryngologists, dentists, dermatologists, family practitioners, physician lactation consultants, and unspecified physicians

†One retrospective case series addressed frenotomy and frenuloplasty[48]

†† One RCT compared horizontal-to-vertical frenuloplasty to four-flap Z-frenuloplasty[22]

KQ (Key Question) 1. Benefits of Interventions To Improve Breastfeeding Outcomes

Key Points

- Results for reduction in nipple pain immediately after surgery were inconsistent, and potentially associated with how early after birth surgery occurred, with the one good quality study with positive results including the youngest infants.
- Frenotomy was associated with significantly improved maternally reported breastfeeding effectiveness immediately post-procedure compared with sham in two RCTs[7, 20], but inconsistent evidence that it improved infant's latch and breastfeeding effectiveness compared with no intervention. Results on whether frenotomy prolonged duration of breastfeeding were unclear and not consistent.
- No comparative study identified expressly evaluated the role of non-surgical interventions in improving breastfeeding effectiveness.

Overview of the Literature

Twenty-nine studies provided data on breastfeeding outcomes after surgical treatments for ankyloglossia. Only six included a comparison group and could provide information on comparative effectiveness. These studies included five randomized controlled trials conducted either in the United Kingdom (n=3),[8, 20, 23]United States (n=1),[7] or Israel (n=1)[21] and one retrospective cohort study conducted in the United States.[25] We rated three RCTs as good quality for outcomes related to breastfeeding effectiveness and pain related to breastfeeding.[7, 8, 20] One RCT was rated as fair[23] and one as poor quality for breastfeeding effectiveness and pain outcomes,[21] and we rated the cohort study as poor quality. The remainder of the studies were

case series and therefore used to identify harms (n=23). Case series were conducted in the United Kingdom (n=11),[28, 29, 32, 35, 36, 39, 41, 49, 50, 53, 57] United States (n=5),[3, 31, 44, 45, 56] Australia (n=3),[30, 38, 40] Finland (n=1),[48] Israel (n=2),[52, 55] and Canada (n=1).[27]

In the studies that provided breastfeeding outcomes, ankyloglossia was only identified in the presence of breastfeeding difficulties. It was diagnosed by clinician examination in all comparative studies but using different methods. In three studies, clinicians diagnosed it from exam without defining clear diagnostic criteria.[20, 23, 25] In others, ankyloglossia was defined as breastfeeding difficulties combined with either 1) Hazelbaker Assessment Tool of Lingual Frenulum Function (HATLFF) score between 6 and 12 and Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH) score ≤ 8[8], or 2) abnormal HATLFF (cut-off not defined).[7]

Two RCTs compared frenotomy to sham surgery,[7, 20] one to usual care,[8] one to intensive lactation consultation,[23] and one used a crossover design to compare frenotomy followed by sham surgery to sham surgery followed by frenotomy with assessment of breastfeeding after each order of intervention (i.e., frenotomy and sham).[21] Similarly, the retrospective cohort study compared frenotomy to usual care.[25] The frenotomy procedure was explicitly described by three of five RCTs and the cohort study. In all descriptions, the frenulum was divided with straight scissors: straight iris (1),[25] blunt tipped (2),[20, 23] unspecified (1).[7] Two RCTs mentioned frenotomy without specifying how it was technically performed.[8, 21] The cohort study was the only comparative study that described systematic use of anesthetic (i.e., viscous lidocaine) prior to ankyloglossia division;[25] however, when case series were considered, a total of four of 25 studies reported use of some anesthetic before surgery.[3, 25, 31, 49] In the sham procedure, infants were removed from their parents to a separate room for the same amount of time as those receiving the procedure.

Detailed Analysis

Overview by Study Design for All Breastfeeding Outcomes

Randomized Controlled Studies

Five RCTs addressed the benefits of treating ankyloglossia with frenotomy on breastfeeding outcomes among neonates and infants who had breastfeeding difficulties (Table 7). The first good quality RCT was single-blinded and randomly assigned infants causing maternally reported nipple pain or difficulty breastfeeding with concomitant and significant ankyloglossia diagnosed by lactation consultant based on HATLFF criteria to frenotomy (n=30) or a sham procedure (n=28).[7] Infants in this study were young (mean 6.0 ± 6.9 days), and had a gender distribution of approximately 2:1 male: female in both treatment groups. Primary outcomes were 1) nipple pain assessed using the Montreal Pain Questionnaire (MPQ-SF); 2) objective breastfeeding effectiveness using Infant Breastfeeding Assessment Tool (IBFAT); and 3) lingual frenulum function via the HATLFF appearance and function scores. Mothers assessed pain outcomes and were blinded to their infant's treatment group.

Mothers whose infants had frenotomy reported significantly less nipple pain immediately following the procedure (mean MQP-SF: 4.9 ± 1.46 vs. 13.5 ± 1.5, $p<0.001$), which remained significantly less than the sham group until the 4-week assessment. Moreover, the mean IBFAT score was higher among frenotomized infants than those undergoing the sham procedure (11.6 ± 0.81 vs. 8.07 ± 0.86, $p=0.026$) immediately post-procedure, but was no different from the sham group at 2-week postoperative evaluation.

A second good quality RCT randomized infants less than 4 months of age with breastfeeding problems and ankyloglossia to either frenotomy (n=30) or sham procedure (n=30). There was nearly identical distribution of males and females (~2:1) and mean ages between groups (33 vs. 28 days).[20] The primary outcome was objectively observed improvement in breastfeeding effectiveness using a score adapted from LATCH and IBFAT, and the secondary outcome was maternally reported improvement in breastfeeding immediately after intervention. Treatment allocation was blinded to both the parents and independent outcome assessor.

No difference in breastfeeding improvement was reported by trained objective observers immediately following intervention (50% [13/26] vs. 40% [12/30]). In contrast, mothers whose infants had frenotomy reported significantly improved breastfeeding compared with those in the sham group (78% [21/27] vs. 47% [14/30] $p<0.02$). There was no immediate difference in the reduction in maternal reported pain scores between the frenotomy and sham groups (mean -2.5 ± 1.9 and -1.3 ± 1.5, p=0.13). Although the study reports that they re-assessed outcomes at 3 months, the data are not provided by treatment group.

A third good quality RCT randomized term infants with breastfeeding difficulties and ankyloglossia (HATLFF score between 6 – 12 and LATCH score ≤ 8) to either frenotomy (n=55) or no intervention (n=52).[8] All dyads consulted with a lactation consultant prior to randomization. Infants with severe ankyloglossia (defined as HATLFF < 6) were excluded and offered immediate frenotomy. At randomization, the median age was 11 days (IQR 8 – 14) and 11 days (IQR 8 – 16) in the frenotomy and control groups, respectively (p=0.94). This study did not report on gender of enrolled infants, but matched infants on age and birth order. Primary outcomes assessed 5-days and 8 weeks post-procedure included 1) change in maternal pain using VAS and 2) LATCH score. Secondary outcomes were method of feeding (i.e., bottle vs. breast), percent breastfeeding, and Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) score. Independent researchers collecting outcomes, but not mothers, were blinded to infant group assignment and performed assessment at the 5-day follow-up visit. The 8-week assessment was limited since 35 of 52 in the comparison group requested frenotomy before that follow-up date due to continued breastfeeding problems. Therefore, the 8-week comparison was between 52 of 55 of the frenotomized infants, and 50 of 52 in the "no intervention" group of whom only eight of 50 (15%) had not had frenotomy at the time of this follow-up assessment.

Five days after the procedure, reductions in pain scores were not significantly greater among mothers whose infants had a frenotomy (median -2 [IQR -3 to 0.4] vs. -1 [-13.5 to 1]). Of note, 17 percent randomized to usual care did not wait 5 days before getting a frenotomy due to painful breastfeeding. Similarly, no significant improvement in median maternal pain was reported 8 weeks post-procedure (median -2 [IQR -3 to -1] vs. -2 [-3.5 to -0.6], p=0.83). Infant outcomes showed no differential median improvement between frenotomy and control group at 5-days for LATCH score (median 1 [IQR 0 – 2] vs. 1 [0 – 2], p=0.52) or IBFAT score (median 0 [IQR -1.8 to 1.0] vs. 0 [IQR 0 – 1]), p=0.36).

In contrast, compared with controls, there was improvement in both median BSES-SF score (median 9 [IQR 1.8 – 12.3] vs. 1 [-4 to 7.5] p=0.0002) and HATLFF score (4.5 [IQR 3.3 – 6] vs. 0 [0 – 2.3], $p<0.001$) 5-days post-intervention in the frenotomy group. Between 5-days and 8 weeks post-intervention, there was less improvement in the median BSES-SF score among frenotomy infants compared with those in the control group, but this difference was not statistically significant (3 [IQR 0 – 13] vs. 10 [2 – 18], p=0.082). The BSES-SF improvement occurred more rapidly after frenotomy in the surgery group than in the control group, but by 8-weeks both groups were nearly equivalent in overall improvement (5-day median + 8-week

median: frenotomy 9 + 3=12 vs. control 1 + 10=11). However, this comparison is difficult to interpret because so many control infants underwent frenotomy between the 5- and 8-week assessments. Crossover to frenotomy may also explain the equivalence of exclusive breastfeeding rates between groups at the 8-week assessment (intervention 82.7% vs. 80%, p=0.73).

A fair quality RCT randomized infants born with ankyloglossia diagnosed within the first 5 months with feeding problems to either frenotomy (n=28) or a control group who had intensive support, advice and help from lactation consultants (n=29).[23] The percentage of the tongue attached by the frenulum was gauged by clinician visualization to be between 0 percent (i.e., none) and 100 percent (i.e., to the tongue tip). This was judged to be 25 percent in six patients, 50 percent in 13, 75 percent in 15, and 100 percent in 23. Infants in both the frenotomy and control group had similar ages (20 vs. 18 days), but gender distribution was only recorded for the frenotomy group where there was a 1:1 ratio of males to females. The primary outcome was maternally reported improvement in breastfeeding. Most (96%) of frenotomized infants had improved feeding with 48 hours compared with 3 percent in the control group. The study was, however, entirely unblinded and all outcomes were by maternal report.

The final poor quality trial randomized full-term healthy for gestational age infants, ages 1 to 21 days, who were referred to a lactation clinic due to maternal nipple pain, and diagnosed with ankyloglossia by a neonatologist to either frenotomy followed by sham procedure (n=15) or vice versa (n=11) with assessment of breastfeeding after each intervention type in both arms.[21] Neither infant ages nor gender distribution was reported. The study's primary outcomes were maternal breastfeeding pain or nipple trauma measured by a standard Visual Analog Scale (VAS) and breastfeeding LATCH scores. Main outcome assessors were the mothers who were blinded to infant treatment group. Comparative group results were not reported, therefore preventing comparative analysis in this review.

Table 7. Breastfeeding effectiveness following surgical procedures

Outcome Measure	Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Days (IQR, Range, Mean, or Mean ± SD)	Baseline Measures	Outcomes at 5 Days	Outcomes at 8 Weeks
LATCH	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Good	Mean at 5 days followup (IQR) G1: 11 (8-14) G2: 11 (8-16)	G1+G2: ≤ 8	Median (IQR) G1: 9 (8-10) G2: 9 (8-10) G1 vs. G2: p= 1.0	Median (IQR) G1: 10 (10-10) G2: 10 (10-10) G1 vs. G2: p= 0.41
	Dollberg et al., 2006[21] RCT G1: Frenotomy, breastfeeding/ sham, breastfeeding, 15/14 G2: Sham, breastfeeding, frenotomy, breastfeeding, 11/11 Quality: Poor	Range of days G1+G2: 1-21	Mean ± SD G1+G2: 6.4±2.3	Mean ± SD G1+ G2: 6.8 ± 2.0 p=0.06 compared with baseline	NA
BSES-SF	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Fair	Mean at 5 days followup (IQR) G1: 11 (8-14) G2: 11 (8-16)	NR	Median (IQR) G1: 54 (43-62) G2: 53 (40.8-61) G1 vs. G2: p= 0.53	Median (IQR) G1: 63 (59-68) G2: 63 (57-69) G1 vs. G2: p= 0.62
IBFAT	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Good	Mean at 5 days follow=up (IQR) G1: 11 (8-14) G2: 11 (8-16)	NR	Median (IQR) G1: 12 (11-12) G2: 12 (11-12) G1 vs. G2: p= 0.76	Median (IQR) G1: 12 (12-12) G2: 12 (12-12) G1 vs. G2: p= 0.58
	Buryk et al. 2011[7] RCT/Newborn nursery or clinic, otolaryngology clinic G1: Frenotomy, 30 G2: Sham procedure, 28 Quality: Good	Mean days ± SD at enrollment G1: 6.2±6.9 G2: 6.0±7.0	IBFAT, mean ± SE G1: 9.3±0.69 G2: 8.5±0.73	Immediately after procedure, mean ± SE G1: 11.6±0.81 G2: 8.07±0.86 G1 vs. G2, p=0.029 Effect size: 0.31	NA

Note: Not all RCTs reported these measures. BSES-SF = Breastfeeding Self-Efficacy Scale-Short Form; G = group; IBFAT = Infant Breastfeeding Assessment Tool; IQR = interquartile range; LATCH = Latch, Audible swallowing, Type of nipple, Comfort, Hold; N = number; NA = not applicable; SD = standard deviation; SE = standard error.

Cohort Studies

A single poor quality retrospective cohort study compared frenotomy to no intervention.[25] It included 367 infants with feeding or latching difficulties that caused maternal pain when breastfeeding, 302 of whom underwent frenotomy. In this cohort, 58.6 percent of infants were male, mean age at ankyloglossia diagnosis was 18 days, and the majority of patients were either Caucasian (70.3%) or African American (15.5%). Ankyloglossia grade was recorded using Coryllos et al. system.[73] Overall, 17.4 percent had type I, 45.5 percent type II, 25.3 percent type III, 18 percent type IV, and 5.8 percent indeterminate. Outcomes were only assessed in the 91 mothers (24.9%) who agreed to participate in a follow-up survey (82 had frenotomy, 9 no intervention), thus limiting its generalizability. Nonetheless, 80.4 percent of interviewed mothers whose infant had undergone frenotomy felt it had benefited their child's ability to feed. Breastfeeding was continued in 82.9 percent of 82 frenotomized infants for a mean 7.09 months total compared with 66.7 percent of nine infants not treated who breastfed a mean 6.28 months total. In all, 17.1 percent and 33.3 percent in the frenotomy and no intervention group stopped breastfeeding due to difficulty or pain due to ankyloglossia. Having a frenotomy in the first week of life versus later did not affect the total months of breastfeeding (mean: ≤7 days 7.11 vs. >7 days 7.06 months; p<0.9).

Case Series

We identified 23 case series that addressed treatments for ankyloglossia on effectiveness of breastfeeding. All studies focused on surgical treatments, which included frenotomy, frenulotomy, or frenuloplasty. None explicitly evaluated non-surgical interventions. By design, none included a comparison group, thereby eliminating the ability to assess comparative effectiveness of surgical approaches, although the studies typically reported improvements in breastfeeding effectiveness after surgery. Harms reported in case series are included in KQ5.

Analysis of Breastfeeding Effectiveness

Immediate Outcomes

Breastfeeding effectiveness was evaluated in four of five RCTs (Table 8).[7, 8, 20, 23] We rated two RCTs as good quality for these outcomes[7, 20] and two as fair quality.[8, 23] Among the three RCTs that used a blinded independent reviewer to assess effectiveness,[7, 8, 20] one reported objective improvement in breastfeeding effectiveness based on IBFAT score immediately post-frenotomy compared with sham treatment (mean 11.6 ± 0.81 vs. 8.07 ± 0.86; p=0.026).[7] In contrast, in two of the three RCTs, the independent blinded observers did not detect a difference in breastfeeding improvement. Outcomes that failed to show a difference in these two RCTs included percent improvement (50% vs. 40%) immediately after intervention[20]and LATCH and IBFAT change 5-days post-intervention (LATCH change: median 1 [IQR 0 – 2] vs. median 1 [IQR 0 – 2], p=0.52 and IBFAT change: 0 [IQR -1.8 to 1.0] vs. 0 [IQR 0 – 1], p=0.36).[8]

Three of four RCTs with usable data used maternally reported improvement in breastfeeding as an outcome,[8, 20, 23] and in one, it was the primary outcome measure of effectiveness.[23] Maternally reported outcomes differed from objective independent assessment reported above. For example, in one RCT, mothers self-reported improved breastfeeding among infants

immediately after frenotomy (78% in the treated group vs. 47% in the comparison group, p<0.02).[20] Similarly, another trial using non-blinded maternally assessed breastfeeding effectiveness reported that 96 percent of frenotomized infants had improved feeding with 48 hours compared with 3 percent in a control group who had intensive lactation consultant support.[23] Finally, one RCT used the BSES-SF as a secondary outcome and found that mothers whose infants had had frenotomy had significantly improved scores 5 days after intervention (median BSES-SF =9 [IQR 1.8 – 12.3] vs. 1 [IQR -4 to 7.5], p=0.0002).[8]

Longer Term Outcomes

Three RCTs[7, 8, 20]and the retrospective cohort study[25] followed up dyads during the first postoperative year. One RCT contacted mothers 3 months after frenotomy, but did not stratify results by treatment group.[20] Overall, 92 percent (54/59) of all patients reported improved feeding, with 56 percent reporting full resolution of breastfeeding difficulties. Moreover, 65 percent (38/59) of infants were being breastfed at 3 months of age, whereas 51 percent (30/59) were continuing to breastfeed at second outcome assessment (4.5 months). The second RCT evaluated results 2-weeks post-operatively and found no difference between those who underwent frenotomy or sham treatment.[7] A third RCT found no difference in breastfeeding effectiveness between groups as measured by LATCH score at an 8-week follow-up survey, but mothers did report nonsignificantly improved BSES-SF scores among frenotomized infants.[8] Of note, 35 of 52 children assigned to the control arm had undergone frenotomy after 5 days. Seventeen of 35 had not had surgery, and two additional infants were lost to followup at 8 weeks.

The retrospective cohort reported that breastfeeding was continued in 82.9 percent of frenotomized infants for a mean 7.09 months total compared with 66.7 percent of infants not treated who breastfed a mean 6.28 months total. In all, 17.1 percent in the frenotomy and 33.3 percent in the no intervention group stopped breastfeeding due to difficulty or pain due to ankyloglossia. Having had frenotomy in the first week of life versus later did not affect the total months of breastfeeding (mean: ≤7 days 7.11 vs. >7 days 7.06 months; p<0.90).

Maternal Pain Outcomes

Among comparative studies, three RCTs, rated as good[7, 8, 20] for pain outcomes, reported on maternal nipple pain outcomes. Of these, one reported significant and immediate improvement in maternally reported nipple pain among mothers of frenotomized infants compared with sham treatment.[7] Both remaining RCTs found nonsignificant reductions in maternally reported nipple pain between the frenotomy and sham groups at immediate[20] and 5-day[8] post-procedure assessments. Of note, 17 percent of infants randomized to no intervention in the study that followed patients out five days[8] requested and received early frenotomy before the data were collected.

Table 8. Breastfeeding-associated pain scores after surgical procedures

Outcome Measure	Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Days	Baseline Measures, Mean ±SD	Followup Measures
Visual Analog Scale	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Good	Mean at 5 days followup (IQR) G1: 11 (8-14) G2: 11 (8-16)	NR	5 days, median (IQR) G1**:** 3 (1-4.3**)** G2**:** 3 (2-6) G1 vs. G2: p=0.13 8 weeks, median (IQR) G1: 0 (0) G2: 0 (0-1) G1 vs. G2: p=0.41
	Berry et al. 2012[20] RCT/Hospital (not specified) G1: tongue-tie division, 30/27 G2: sham procedure, 30/3 Quality: Good	Mean (range) G1: 33 (6-115) G2: 28 (5-111)	G1: 4.1± NR G2: 4.2± NR	Mean immediately after procedure G1: 1.6 G2: 2.9 Mean change ± SD: G1: -2.5 ± 1.9 G2: -1.3 ± 1.5, p=0.13 (95% CI: -0.3 to 2.4)
Short-Form McGill Pain Questionnaire	Buryk et al. 2011[7] RCT/Newborn nursery or clinic, otolaryngology clinic G1: Frenotomy, 30 G2: Sham procedure, 28 Quality: Good	Mean ± SD at enrollment G1: 6.2±6.9 G2: 6.0±7.0	G1: 16.8±10.6 G2: 19.2±9.9	Mean ± SD immediately after procedure G1: 4.9±1.46 G2: 13.5±1.5 G1 vs. G2: p<0.001 Effect size: 0.38

G=group; IQR=interquartile range; N=number; NR=not reported; RCT=randomized controlled trial; SD=standard deviation.

KQ2a. Benefits of Treatments To Mitigate Feeding Sequelae

Key Points

- Existing data are insufficient to draw conclusions about the benefits of surgical interventions for infants and children with ankyloglossia on medium- and long-term feeding outcomes other than breastfeeding. The studies used different populations and measured different outcomes.

Overview of the Literature

We identified three studies examining medium- and long-term benefits related to feeding outcomes and sequelae of various interventions for infants and children with ankyloglossia (Table 9).[23, 24, 35] One was an RCT[23] (fair quality for feeding outcomes) and one was a poor

quality retrospective cohort study[24]; the remaining study was a case series.[35] All studies were single center or single surgeon studies. Two studies were conducted in the United Kingdom[23, 35] and one study in the United States.[24]

Detailed Analysis

Comparative data were included in two studies.[23, 24] A detailed description of the included fair quality RCT study design and population are reported in the detailed analysis for KQ1. In summary, the study[23] randomized infants born with ankyloglossia and diagnosed within the first 5 months with feeding problems to either frenotomy (n=28) or a control group who had intensive support, advice and help from lactation consultants (n=29). Outcomes were based solely on maternal-report within 48-hours of randomization. However, in the RCT the control group was offered – and the majority elected to receive –frenotomy within 48 hours of randomization to the comparison group, so the outcomes do not reflect "medium to long term" feeding outcomes. This study was included herein, because it includes data on bottle-feeding efficiency. Outcomes related directly to breastfeeding are presented in KQ1.

Among pre-treatment bottle fed infants, 76 percent had major problems with dribbling, and 71 percent had "excess wind" (gas). Mothers reported significant improvement in feeding in all eight who received the frenotomy and in none who did not. The interval to ascertainment of outcomes was not specifically reported, but outcomes were obtained within the first 4 weeks of life.

The retrospective cohort study compared parent-reported (typically maternal) outcomes at age 3 years for children born in 2010 who 1) received frenotomy for tongue-tie (n=71; frenotomy group), 2) were offered but declined frenotomy for tongue-tie (n=15; no frenotomy group), and 3) children without ankyloglossia (n=18; control group).[24] Three questions rated on a 5-point Likert scale were used to assess a child's difficulty (a) cleaning his or her teeth with the tongue, (b) licking the outside of his or her lips, and (c) eating ice cream. With respect to answers on each of the questions, the frenotomy group performed better than the no frenotomy group at age 3 years and did not differ significantly from the comparison group without ankyloglossia. P-values were presented without reporting the central tendency (e.g., median, mean) or variance (IQR, SD) from which they were calculated. Therefore, further comparative description or analysis was not possible.

In the case series of 62 infants, 51 had complete outcome data (11 lost to follow-up).[35] Of these, infant ages ranged from 12 to 35 days at time of referral for frenulotomy by plastic surgeon, and outcomes were assessed prospectively over an 8-month period, on the day of frenulotomy, and at 2-weeks post-procedure at outpatient appointment. Over this period, the number of breastfeeding sessions decreased from 10 ± 0.7 pre-frenulotomy to 7 ± 0.5 post-frenulotomy ($p<0.0001$) and bottle feeding supplementary sessions per day were reduced from nine to two at 2-week follow-up ($p<0.0001$). The authors suggest that this reflects longer-term improvement in feeding efficiency.

Table 9. Feeding sequelae

Study Study Design/Setting Groups, N Enrollment/N Final Quality	Age, Mean Days	Outcomes
Hogan et al. 2005[23] RCT/Outpatient (not specified) G1: Tongue-tie division, 28/28 G2: Usual care and advice from lactation consultants, 29/29 Quality: Fair	G1: 20 G2: 18 Range G1+G2: 3-70	• 96% of G1 infants improved in overall (breast and bottle) feeding (as rated by mothers) compared with 3% in G2 (p<0.001) • Feeding improved in 100% (n=8) of bottle fed infants in G1 vs. 0 in G2 (p<0.001) • Most G2 participants also received frenotomy shortly after randomization
Walls et al. 2014[24] Retrospective Cohort/Outpatient clinic, postpartum ward G1: Frenotomy, 71/71 G2: No surgery, 15/15 G3: No ankyloglossia, 18/18 Quality: Poor	3 years	• More children in G1 vs. G2 improved in oral motor activities including difficulty cleaning teeth with tongue (p=0.0006), difficulty licking outside of lips (p<0.0001), and difficulty eating ice cream (p=0.0003) • Outcomes did not differ significantly between participants in G1 and G3

G=group; N=number; NR=not reported; RCT=randomized controlled trial.

KQ2b. Benefits of Treatments To Prevent Other Sequelae

Key Points

- Two studies reported better articulation among children who had received ankyloglossia treatment compared to those who had not, but results related to word, sentence, and fluent speech were inconsistent.
- Results in two studies comparing children with ankyloglossia who received treatment to children without a history of ankyloglossia were inconsistent.
- One small, poor quality RCT compared two surgical methods and reported that children in a four-flap Z-frenuloplasty group had greater articulation gains than those in the horizontal-to-vertical frenuloplasty group.
- Although a number of case series report positive outcomes related to speech after treating ankyloglossia, most discussed modalities, with safety, feasibility or utility as the main outcome, rather than speech itself.

Overview of the Literature

Ten studies addressed ankyloglossia treatment in children with speech and articulation concerns. One RCT[22] rated as poor quality comparing two different surgical techniques and one

poor quality cohort study[24] were conducted in the United States. An additional poor quality retrospective cohort study was conducted in Israel (Table 10).[26] Of seven case series addressing this question, two were conducted in the United States,[42, 43] one each from the United Kingdom,[51] China,[37] India,[47] Japan,[54] and Korea.[34] No study addressed the effect of ankyloglossia on sleep disordered breathing, dental/occlusal issues, or dysphagia.

Among the comparative studies identified, two of three had speech and articulation assessed by speech-language pathologists,[22, 26] while the third relied on parental report.[24] Professional assessment was performed by speech-language pathologists using the Articulation and Naming Test[26] in one of two studies in which they were the outcome assessors and with the other using consensus between speech-language pathologists.[22] The third study used a non-validated parental survey to determine parent perception of the severity of the child's speech misarticulations.[24]

Detailed Analysis

Cohort Studies

One poor quality retrospective cohort study[24] compared three treatment groups of children who were three years old in 2010 who had: (1) ankyloglossia and frenotomy within the first month of life (n=71), (2) ankyloglossia and whose parents declined frenotomy during the same period (n=21), and (3) a control group of randomly selected 3-year old patients with no history of ankyloglossia (n=18). Three-year old subjects were chosen because that is the age that speech and articulation abnormalities typically present. Pediatric otolaryngologists assessed ankyloglossia using Coryllos criteria in the postpartum ward or during outpatient clinical examination. Parents of all identified patients were then contacted for a telephone survey that consisted of nine questions related to the health care provider who identified restriction, recommendations for surgery, intelligibility of speech to parent(s), impaired speech sounds, deficiencies in oral motor activities, and perceived need for speech therapy. Speech intelligibility was graded on a 5-point Likert scale (1=poor to 5=well-developed).

Overall, 36 of 86 with treated or untreated ankyloglossia had parent-identified speech difficulties. Three-way comparison found statistically improved speech scores among treated versus untreated groups (mean 4.52 ± 0.61 vs. 3.60 ±0.63, $p<0.0001$) and between the control and untreated groups (mean 4.33 ± 0.77 vs. 3.60 ±0.63, $p=0.01$). No difference was found between the treatment and non-ankyloglossia control arms. The authors suggest that these results indicate that frenotomy can improve speech, and that speech outcomes for children after frenulum release are on par with those of children who never had ankyloglossia. However, little information is provided about why children in the untreated group did not receive frenotomy or why certain children were treated, nor were parents unaware of the treatment their child had received making recall bias a clear possibility.

A second poor quality retrospective cohort study recruited children who underwent frenotomy for ankyloglossia between ages of 2 days and 4 weeks and who were 4 to 8 years of age at the time of the study.[26] These children were age-matched to children with untreated ankyloglossia whose parents reported a history of breastfeeding difficulties (nipple pain and/or latching difficulties) and to children with no history of ankyloglossia. All patients were administered the Articulation and Naming Test[74] by two speech-language pathologists who were blinded to the group assignment. Each child's oral anatomy was systematically assessed from a standard oral motor evaluation test and scored.

In all, 23 children (17 males, 6 females) were divided into age-matched groups based on treatment status: treated (n=8; mean age 6.2 ± 1.8), untreated (n=7; mean age 6.2 ± 1.9), and controls (n=8; mean age 5.8 ± 1.9). All were found to have normal oral anatomy on examination. No significant differences were detected between treated and control patients in word, sentence, and fluent speech intelligibility. In contrast, children with untreated ankyloglossia had more articulatory errors than those who had been treated (14.5 ± 10 errors vs. 6.0 ± 4.2 errors).

Relevant case series examined different treatment methods including simple division with scalpel, scissors, and CO2 laser,[51] frenuloplasty,[42, 43, 54] and the addition of genioglossus myotomy.[34] All studies reported positive outcomes and none reported significant harms, but as noted, these studies provide no comparative effectiveness data.

Table 10. Comparative studies with speech outcomes

Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Years	Key Outcomes
Walls et al. 2014[24] Retrospective cohort/Outpatient clinic, postpartum ward G1: Frenotomy, 71/71 G2: Untreated, 15/15 G3: No ankyloglossia, 18/18 Quality: Poor	3 years	• 36 of 86 patients in G1 and G2 were reported by parents to have speech difficulties at age 3 • Using a Likert scale of 1 (poor outcome), 3 (intelligible), 5 (well developed), parents reported (mean ± SD): G1: 4.52 ± 0.61 G2:3.60 ± 0.63 G3: 4.33 ± 0.77 • Parental measures of speech were significantly higher in G1 compared with G2 (p<0.0001) and G2 compared with G3 (p=0.01), but not in G1 compared with G3 (p=0.38)

Table 10. Comparative studies with speech outcomes (continued)

Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Years	Key Outcomes
Dollberg et al. 2011[26] Retrospective cohort/NR G1: Frenotomy, 8/8 G2: Untreated tongue-tie, 7/7 G3: No ankyloglossia, 8/8 Quality: Poor	G1: 6.2 ± 1.8 G2: 6.2 ± 1.9 G3: 5.8 ± 1.9	• Investigators assessed consonant articulation errors, word production accuracy, word intelligibility, sentence intelligibility and fluent-speech intelligibility. • Although differences were observed, including with treated children consistently having fewer problems across measures than untreated children, none of the differences was statistically significant, possibly due to small sample size. There were minimal, nonsignificant differences in the mean number of errors between treated children and those without ankyloglossia: Consonant articulation errors mean ± SD (SEM): G1: 6.0 ± 7.5 (2.7) G2: 7.1 ± 6.9 (2.6) G3: 1.0 ± 2.9 (1.0) G1 vs. G2: p=0.76 (95% CI: -6.96 to 9.19) G1 vs. G3: p=0.11 (95% CI: -1.43 to 11.39) Word production accuracy mean ± SD (SEM): G1: 6.0 ± 4.2 (1.5) G2: 14.5 ± 10.0 (3.7) G1 vs. G2: p=0.076 (95% CI: -1.15 to 18.09) G3: 8.8 ± 11.6 (3.1) G1 v. G3: p=0.53 (95% CI: -12.54 to 7.28) Word intelligibility mean ± SD (SEM): G1: 1.3 ± 0.1 (0.1) G2: 1.7 ± 0.36 (0.1) G1 vs. G2: p=0.33 (95% CI: 0.04 to 0.714) G3: 1.4 ± 0.4 (0.1) G1 vs. G3: 0.50 (95% CI: -0.46 to 0.25) Sentence intelligibility mean ± SD (SEM): G1: 1.3 ± 0.2 (0.1) G2: 1.6 ± 0.46 (0.2) G1 vs. G2: p=0.16 (95% CI: -0.147 to 0.749) G3: 1.4 ± 0.4 (0.1) G1 vs. G3: p=0.46 (95% CI: -0.49 to 0.24) Fluent-speech intelligibility mean ± SD (SEM): G1: 1.5 ± 0.4 (0.1) G2: 1.6 ± 0.5 (0.2) G1 vs. G2: p=0.6 (95%CI: -0.416 to 0.689) G3: 1.2 ± 0.3 (0.1) G1 vs. G3: p=0.229 (95%CI: -0.18 to 0.68)

CI = confidence interval; G = group; N = number; NR = not reported; SD = standard deviation; SEM = standard error of the mean

Comparison of Surgical Approaches

One RCT randomized children presenting to a cleft lip and palate-craniofacial clinic between 1999 and 2003 with a tight frenulum (<15 mm), an articulation or speech problem related to tongue tie, and/or age greater than 3 years to four-flap Z-frenuloplasty or horizontal-to-vertical frenuloplasty.[22] Technical aspects of both surgical procedures were well described. Primary outcomes were changes from pre-operative to follow-up (>10 months) in frenulum length, tongue-protrusion measurements, and speech assessment. Both frenulum length and tongue protrusion were measured pre- and post-operatively by trained independent raters. Each patient had speech evaluations performed by two independent speech-language pathologists.

The study included 16 children with articulation problems, of whom 11 underwent four-flap Z-frenuloplasty (7 male, 4 female) and the remainder (2 male, 3 females) horizontal-to-vertical frenuloplasty. Ages were similar between treatment groups (Z-frenuloplasty: mean 5.7 ± 2.14 vs. horizontal-to-vertical: mean 5.56 ± 1.52). Pre-operatively, children in the Z-frenuloplasty arm had articulation difficulties rated as severe in six (55%) and moderate in five by the speech-language pathologists. Of the five patients in the horizontal-to-vertical frenuloplasty group, three (60%) were rated as severe and two (40%) as moderate. Ten of eleven children in the Z-plasty arm had two orders of magnitude improvement (i.e., severe to mild) and seven had complete resolution of articulation problems. In contrast, no patients in the horizontal-to-vertical group had two order of magnitude improvement or complete resolution. Two had one level improvement in articulation and three had none. Table 11 reports key outcomes in comparative studies.

Table 11. Comparison of surgical approaches

Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Years	Key Outcomes
Heller et al. 2005[22] RCT/Craniofacial clinic G1: Four flap Z-frenuloplasty, 11/11 G2: Horizontal-to-vertical frenuloplasty, 5/5 Quality: Poor	G1: 5.7 ± 2.14 G2: 5.56 ± 1.52	• In the four-flap Z-frenuloplasty group, 6 (55%) participants were rated by a speech-language pathologist as having severe articulation difficulties at baseline; 4 (45%) were rated as having moderate difficulties. • After treatment, 10/11 had 2 orders magnitude improvement; 7 had complete resolution. • In the horizontal-to-vertical group, 3 (60%) participants were rated by a speech-language pathologist as having severe articulation difficulties at baseline; 2 (40%) were rated as having moderate difficulties. • After treatment, 2/5 had 1 order magnitude of improvement; 0 had complete resolution; 3 had no improvement

G = group; N = number; RCT = randomized controlled trial

KQ3. Benefits of Treatments To Prevent Social Concerns Related to Tongue Mobility

Key Points

- Evidence is insufficient to assess the effects of intervention on social concerns related to tongue mobility.
- Studies assessed different surgical interventions and different patient populations with widely varying age ranges.

Overview of the Literature

We identified nine studies that addressed either social concerns[24, 33, 42, 51] and/or tongue mobility.[6, 22, 26, 42, 43, 46, 51] Studies related to the effect of ankyloglossia on social concerns included one poor quality retrospective cohort[24] and three case series[33, 42, 51] that included outcome data for social concerns (e.g., drooling, embarrassment, kissing). The retrospective cohort was conducted in the United States[24] and case series in the United Kingdom,[51]United States,[42] and Brazil.[33] None reported objective measurements of social concerns; instead each used parent- or patient-report to measure improvement. Subject age ranges varied significantly with the cohort study concentrating on 3 year old children[24]and case series including wider age ranges.[33, 42, 51] The studies employed different surgical techniques and used different terminology without technical explanation: laser excision,[6, 51] frenotomy,[24, 33, 34] frenectomy,[6, 33] and horizontal-to-vertical frenuloplasty.[42, 43] Two studies described novel approaches to ankyloglossia repair, frenuloplasty with buccal mucosal graft,[46] and four flap Z-frenuloplasty.[22]

Studies assessing the effect of ankyloglossia treatment on tongue mobility included a single RCT from the United States (rated as poor quality for outcomes related to tongue mobility),[22]a poor quality retrospective cohort study[26] from Israel, and five case series: three from the United States[42, 43, 46] and one each from the United Kingdom,[51] and Brazil.[6] One of two comparative studies objectively measured frenulum length and tongue protrusion,[22] while the other used speech-language pathologists to rate children's tongue movement.[26]

Detailed Analysis

Social Concerns

One comparative study addressed the effect of ankyloglossia treatment on social concerns unrelated to speech.[24] This retrospective cohort study enrolled 3-year old patients who received a frenotomy in infancy (n =71) and age- matched children with untreated ankyloglossia (n=15) and a control group of children without ankyloglossia (n=18). This study design and patient population is described in detail in KQ2 as it relates to feeding outcomes and in KQ2b with respect to speech outcomes. In short, parents were contacted in a telephone survey developed by a speech-language pathologist using a Likert scale to detect improvement in 1) difficult cleaning teeth with tongue, 2) difficulty licking outside of lips, and 3) difficulty eating ice cream.

Compared with individuals with non-treated ankyloglossia, those that were treated had significantly less difficulty cleaning the teeth with the tongue ($p = 0.0006$), licking the outside of their lips ($p < 0.0001$) and eating ice cream ($p = 0.0003$). Similarly, control patients had significantly less difficulties with these tasks compared with untreated children ($p<0.05$). Unfortunately, the central tendency and variance from which these p-values were derived were

not presented in the manuscript. Because this study was retrospective and included only parent report, both recall bias and confounding by indication are likely.

In one case series of older patients (mean age 29.8 ± 10.0 years), pre- and post-procedure patient survey was used to determine improvement.[42] Seven of 15 participants reported embarrassment due to their ankyloglossia. In the six patients who elected to undergo frenuloplasty (mean age 17.3 ± 3.2 years), all reported improvement in tongue function in at least three of six areas which included: licking ice cream, licking lips, cleaning teeth, kissing, and playing a wind instrument. Another case series reported subjective improvement in oral hygiene (n=18/21) after laser frenectomy.[51] Limiting these findings was the absence of pre-procedure status of these patients in these domains and how each was assessed. In addition to not including a comparison group of any type, case series are strongly affected by selection bias and are, by nature, not comparative studies.

Tongue Mobility

We identified two comparative studies that provided data on tongue mobility (Table 12).[22, 26] One RCT enrolled 16 children (mean age 5.7±2.14) randomized to either four-flap Z-frenuloplasty or horizontal-to-vertical frenuloplasty.[22] A thorough review of its study design is described in KQ2b in relation to speech outcomes. Authors measured frenulum length and tongue protrusion using a string to record the distance from the lower dentition to tongue tip during maximum protrusion of the tongue. The string was then transferred to a ruler for measurement in millimeters (mm). Three trained raters measured each patient's tongue protrusion.

The study reported improved tongue tip mobility in all 11 patients who underwent Z-frenuloplasty. The mean frenulum length in this group was 49.4 ± 16.6mm, which was significantly longer than pre-operatively (11.9 ± 6.1 mm, $p<0.001$). Thus, the mean gain in length was 37.5 ± 13.5 mm. In contrast, mean frenulum length for horizontal-to-vertical frenuloplasty was 22.6 ± 7.02 from 11.4 ± 3.36 mm, which was significantly longer, but less so than in the comparison group. Both groups were able to protrude the tongue past the inferior dentition. Mean gains in tongue protrusion for Z-frenuloplasty and horizontal-to-vertical frenoplasty were 36.2 ± 7.6 mm and 13.2 ± 2.6 mm, respectively. Measurements in both groups were significantly improved from baseline (p values <0.01).

The retrospective cohort study compared outcomes among children with ankyloglossia that was treated with frenotomy (n=8), untreated children with ankyloglossia (n=7) and a control group without a history of ankyloglossia (n=8). Design of this cohort is summarized as part of KQ2b in relation to speech outcomes. In terms of tongue mobility, speech-language pathologists examined each child's oral anatomy and tongue movements by performing 10 different exercises as part of a standardized oral motor evaluation test: protrusion, elevation, left and right movements, licking of lower and upper lips, clicking, touching hard palate, elevation of mid-tongue toward the hard palate). Each task was scored from 0 (normal) to 1 (for distorted movement or inability to perform task). Untreated individuals had more difficulties in tasks of tongue movement (11.4 ± 7.6 uncompleted tasks) compared with treated children (3.7 ± 4.2). Children with no history of tongue-tie had the lowest rate of uncompleted tasks (1.2 ± 1.6).

Five case series reported improvements in mobility and elevation.[6, 42, 43, 46, 51] Two case series assessing the safety of CO2 laser (total n=36) concluded that it was safe and effective alternative to conventional release.[6, 51] Both studies reported improvement in tongue mobility after repair but one[6] described greater improvement if the patient received speech therapy prior to release. A

third case series in participants (mean age 8 at surgery, 15 with ankyloglossia and two with short labial frenulums) reported improvements in tongue mobility in the 3-4 months following surgery in an unspecified number of participants.[46] For most of these studies there was minimal explanation of expectations for normal tongue mobility. For the few studies with objective measurements, the total sample size (n= 52) was too small and the ages too varied to establish normative data.

Table 12. Outcomes of interventions for social concerns related to tongue mobility

Author, Year Study Design/Setting Groups, N at Enrollment/Followup Quality	Age, Years, Mean ± SD	Key Outcomes
Social Concerns		
Walls et al. 2014[24] Retrospective cohort/Outpatient clinic, postpartum ward G1: Frenotomy, 71/71 G2: Untreated, 15/15 G3: No ankyloglossia, 18/18 Quality: Poor	3	• More parents in G1 vs. G2 reported improvements in difficulty in cleaning teeth with tongue (p=0.0006), difficulty licking outside of lips (p<0.0001), and difficulty eating ice cream (p=0.0003) • No significant differences between G1 and G3
Tongue Mobility		
Heller et al. 2005[22] RCT/Craniofacial clinic G1: Four flap Z-frenuloplasty, 11/11 G2: Horizontal –to-vertical frenuloplasty, 5/5 Quality: Poor	G1: 5.7 ± 2.14 G2: 5.56 ± 1.52	• Mean frenulum length increased from mean 11.9 ± 6.1 mm to 49.4 ± 16.6 mm (p<.0001) in G1 and from 11.4 ± 3.36 mm to 22.6 ± 7.02 (p=0.02) in G2 • Mean gain in tongue protrusion of 36.2 ± 7.6 mm (range 23-45 mm) in G1 (p<.0001); mean gain for G2 was 13.2 ± 2.6 (range 9-16) mm (p=0.0003) • Study did not define optimal ranges for tongue mobility
Dollberg et al. 2011[26] Retrospective cohort/NR G1: Frenotomy, 8/8 G2: Untreated tongue-tie, 7/7 G3: No ankyloglossia, 8/8 Quality: Poor	G1: 6.2 ± 1.8 G2: 6.2 ± 1.9 G3: 5.8 ± 1.9	• Children in G2 had more difficulties in tasks of tongue movement compared with G1 (11.4 ± 7.6 uncompleted tasks in G2 vs. 3.7 ± 4.3 in G1, p=0.12, 95% CI: -0.26 to 0.18) • Differences between G1 and G3 were not significant

G=group; mm=millimeters; N=number; RCT=randomized controlled trial; SD=standard deviation.

KQ4. Benefits of Simultaneously Treating Ankyloglossia and Concomitant Lip-Tie

We identified no studies that presented outcomes specifically for infants or children treated simultaneously for ankyloglossia and lip tie. One study reported that some of the participants also had lip-tie, but the outcomes were not presented separately for this subset.[31]

KQ5. Harms of Treatments for Ankyloglossia or Ankyloglossia With Concomitant Lip-Tie in Neonates, Infants, and Children Through Age 18

Key Points

- Most studies that reported harms information explicitly noted that no significant harms were observed (n=17) or reported minimal harms, most commonly self-limited bleeding, which would be expected with oral surgery.

Overview of the Literature

We identified 46 studies addressing harms (31 RCTs, cohort studies, or case series and 15 case reports). One RCT conducted in the United Kingdom reported minor harms of surgery and need for reoperation.[8] A single retrospective cohort study conducted in the United States reported harms (scarring).[25]. Twelve of 33 case series reported minor harms: four from the United States,[3, 31, 42, 46] four from the United Kingdom,[29, 49-51] one from Brazil,[6] one from Finland,[48] one from Israel,[52]and one from China[37] Seventeen studies (13 case series, four RCTs) specifically noted that no harms were observed. We included case reports specifically to address harms; details of the 15 case reports yielding harms data are in Appendix G.

Detailed Analysis

Data on harms were only available for studies of surgical interventions. Given the paucity of comparative data on this topic, we also sought case series and case reports to ensure that we captured possible evidence of harms associated with treatment. Of six RCTs, four reported that there were no harms, one was silent on the subject, and one study reported that 64 percent of participants had a small white patch at the base of the frenulum (likely healing slough) that took approximately 7 days to heal and four of 99 (4%) required a reoperation.[8] Among the three cohort studies, two did not address harms. In the one cohort study that reported harms, eight of 302 (2.6%) participants had a recurrence due to scarring or incomplete clipping that required reoperation.[25] Harms were described in 11 of 33 case series. Minor bleeding occurred in six and infant distress/pain was described as affecting 2 of 36 infants (5.6%) in another.[49] Rates of reoperation ranged from 0.1 percent[37] to 27 percent[31], with a need for reoperation occurring in a total of five case series. One case series reported mild wound cicatrization following frenuloplasty involving use of buccal mucosa grafts.[46] Another case series reported no complications after CO2 laser excision, but in patient surveys two of 21 disagreed with the statement "no pain" and one of 21 disagreed with the statement "no blood."[51]

To ensure that we did not miss potential harms of surgical intervention, we searched for case reports of harms and identified 15,[58-72] details of which are presented in Appendix G. Among 15 case reports (two of which reported multiple cases[58, 72]), there were two cases of surgical site infection, three cases of reoperation and four reports of swelling and pain. One case reported post-surgical mucocele in a 12-year-old patient.[59] Only two cases, in Nigeria, sustained harms to the degree that they were hospitalized for bleeding; in these cases, the authors indicated that the procedure was done by inexperienced clinicians and that this likely accounted for the excessive bleeding.[60]

Gray Literature

Conference Abstracts

We searched for conference paper and poster abstracts from recent national and international societies and associations related to pediatrics, nursing, breastfeeding medicine, lactation, otolaryngology, dentistry, orthodontics, speech and hearing. Conference abstracts predominantly addressed prevalence of ankyloglossia, investigation into incidence of anterior versus posterior rates of tongue-tie, rates of surgical treatment interventions, and case reports of successful surgical interventions to address breastfeeding issues. Results reported in abstracts generally aligned with our findings, with abstracts noting maternally reported improvements in breastfeeding effectiveness and nipple pain (Appendix H).

Dissertations and Theses

Although we did not identify any relevant dissertations in our search, one TEP member who recently completed a master's degree at the University of Liverpool allowed us to use findings from her unpublished thesis. She conducted a retrospective survey of parents in the United States of children who had had frenotomy for ankyloglossia either before or after age 12 weeks (Table 13).[75] The survey included questions related to breastfeeding effectiveness and pain, supplemental bottle feeding, feeding with solid food, knowing and pronouncing words, and oral hygiene and was sent to parents of children treated between 2006 and 2011 at a single institution. Findings supported the published literature in reporting improvements after frenotomy in maternally reported outcomes. This study adds to the published literature in assessing early versus late outcomes, finding improved outcomes associated with early treatment. Because it is not a published study, we did not include it in our strength of evidence assessment but provide the results here.

Findings included data from 125 children with ankyloglossia who received frenotomy, 51 of whom were treated before 12 weeks of age (early treatment) and 74 who were treated after (late treatment). All children in the early treatment group were diagnosed within 90 days of birth, while 43 of the late treatment arm were diagnosed by 90 days, eight by 180 to 365 days, and 15 at >365 days of age.

Breastfeeding Outcomes

Children in the early treatment group had a longer duration of breastfeeding compared with the later treatment group. Within the early treatment group, about a third either did not have a latch issue or it was resolved prior to frenotomy, while in 45 percent of the cases the issue was resolved with frenotomy. Nonetheless, in almost a quarter (23.5%), latch issues led to abandonment of breastfeeding. In the late treatment group, however, most (82%) either never had a latch issue or it resolved before the frenotomy, with only 1.4 percent having latch resolved via frenotomy. Pain was resolved after frenotomy in about a third (33.3%) of the early treatment group, whereas about half either did not have pain or it had resolved prior to frenotomy in this group. Among infants diagnosed and treated late, mothers reported that most (89%) did not have pain or that it resolved prior to frenotomy.

Other Feeding Outcomes

In terms of latching to a bottle, in the early treatment group, 75.5 percent either had no issue or had it resolve prior to treatment. Twenty-four percent had problems with latch to a bottle resolved with frenotomy.

Speech Outcomes

Speech issues were unique (as expected) to children with a later treatment. Among these children, pronunciation issues were resolved in in 43.1 percent (n=31/72) of the cases.

Other Outcomes

In this study, no children in the early frenotomy group had oral hygiene issues, compared to 15 in late treatment arm. Issues resolved with frenotomy in 18.1 percent (n=13/122) of children in this group.

Table 13. Outcomes reported in unpublished thesis*

Outcome	Issues With:	Not Breastfed or Not an Issue or Issue Resolved Without Frenotomy N (% of Group)	Issue Resolved With Frenotomy N (% of Group)	Issue Did Not Resolve With Frenotomy N (% of Group)	Issue Resulted in Abandoning Breastfeeding N (% of Group)
Breast-feeding	**Latch to mother's nipple**				
	Early group	16/51 (31.4)	23/51 (45.1)		12/51 (23.5)
	Late group	61/74 (82.4)	1/74 (1.4)		12/74 (16.2)
	All	77/125 (61.6)	24/125 (19.2)		24/125 (19.2)
	Issues with maternal pain				
	Early group	27/51 (52.9)	17/51 (33.3)		7/51 (13.7)
	Late group	65/73 (89.0)	1/73 (1.4)		7/73 (9.6)
	All	92/124 (74.2)	18/124 (14.5)		14/124 (11.3)
	Breastfeeding in reasonable amount of time				
	Early group	22/49 (44.9)	17/49 (34.7)		10/49 (20.4)
	Late group	60/73 (82.2)	0/73 (0)		13/73 (17.8)
	All	82/122 (67.2)	17/122 (13.9)		23/122 (18.9)
	Supplemental bottle feeds				
	Early group	46/51 (90.2)	4/51 (7.8)		1/51 (2.0)
	Late group	69/74 (93.2)	0/74 (0)		5/74 (6.8)
	All	115/125 (92)	4/125 (3.2)		6/125(4.8)

Table 13. Outcomes reported in unpublished thesis* (continued)

Outcome	Issues with:	Not Breastfed or not an Issue or Issue Resolved Without Frenotomy N (% of Group)	Issue Resolved With Frenotomy N (% of Group)	Issue Did Not Resolve With Frenotomy N (% of Group)	Issue Resulted in Abandoning Breastfeeding N (% of Group)
Other Feeding Outcomes	**Latch to bottle**				
	Early group	37/49 (75.5)	12/49 (24.4)	0/49 (0)	
	Late group	64/73 (87.7)	7/73 (9.6)	2/73 (2.7)	
	All	101/122 (82.8)	19/122 (15.6)	2/122 (1.6)	
	Spoon feeding				
	Early group	50/51 (98)	0/51 (0)	1/51 (2)	
	Late group	69/73 (94.5)	4/73 (5.5)	0/73 (0)	
	All	119/124 (96)	4/124 (3.2)	1/124 (0.8)	
	Solid feeding				
	Early group	49/50 (98)	0/50 (0)	1/50 (2)	
	Late group	68/74 (91.9)	6/74 (8.1)	0/74 (0)	
	All	117/124 (94.4)	6/124 (4.8)	1/124 (0.8)	
Speech and Other Outcomes	**Pronunciation**				
	Early group	48/48 (100)	0/48 (0)	0/48 (0)	
	Late group	32/72 (44.4)	31/72 (43.1)	9/72 (12.5)	
	All	80/120 (66.7)	31/120 (25.8)	9 /120 (7.5)	
	Oral hygiene				
	Early group	50/50 (100)	0/50 (0)	0/50 (0)	
	Late group	57/72 (79.2)	13/72 (18.1)	2/72 (2.8)	
	All	107/122 (87.7)	13/122 (10.7)	2/122 (1.6)	

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G = group; N = number.

Discussion

We identified 57 published studies for this review, six of which were randomized controlled trials (RCTs), three were cohort studies, and the remainder case series (n=33) and case reports (n=15). The analysis and discussion concentrate on comparative studies (RCTs and cohorts), as these studies were used for strength of evidence assessment. Case series were included in the results only to ensure that the full range of available literature is made available to the end users of this report. Harms were reported from all included studies as well as a specific search for case reports.

Three RCTs were assessed as good[7, 8, 20] and one as fair[23] quality for outcomes related to breastfeeding effectiveness and associated maternal pain. One RCT was rated as poor quality for breastfeeding effectiveness and pain outcomes.[21] One RCT addressing tongue protrusion, frenulum length, and speech outcomes was rated as poor quality for those outcomes,[22] and we rated one RCT as fair quality for measures of bottle feeding.[23] We rated all three cohort studies as poor quality.[24-26]

We assessed the quality of harms reporting in RCTs and cohort studies as poor and as good in four case series[49-52] and poor in 23.[3, 6, 27-29, 31, 32, 34, 35, 37-40, 42-45, 48-51, 54, 56] We also included data from one unpublished thesis (not quality scored).

Key Findings and Strength of Evidence

KQ (Key Question) 1. Benefits of Interventions Intended To Improve Breastfeeding Outcomes

Key Findings

Overall, three good[7, 8, 20] and one fair[23] quality RCTs assessed whether treatment of ankyloglossia improved breastfeeding effectiveness. While only one of three RCTs that used blinded independent observers found significantly improved breastfeeding effectiveness among frenotomized infants immediately post-procedure,[7] maternally reported breastfeeding effectiveness was significantly improved in the treated group compared with untreated in two of two RCTs that evaluated it either as a primary[23] or secondary[20] outcome. A third RCT evaluated the mother's breastfeeding self-efficacy and found a significant improvement from baseline in the frenotomy group 5-days post-procedure.[8] In all, there is some evidence that maternally reported breastfeeding outcomes improve. Comparative data are lacking to assess the durability of effects.

These same studies had disparate findings about whether frenotomy decreased maternal nipple pain during breastfeeding. Only the RCT performed on infants at 6 days of age showed a significant reduction in maternal pain.[7] Those performed on infants a few weeks older did not report either an immediate[20] or 5-day[8] reduction in pain. The difference between earlier frenotomy and later frenotomy on nipple pain may relate to cumulative trauma on the breast from several additional weeks with inefficient latch from tongue-tied infants.

Strength of the Evidence

Few comparative studies have addressed the effectiveness of surgical interventions to improve breastfeeding outcomes. Mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and most were short term. Future

studies could provide additional data to confirm or change the measure of effectiveness; thus we consider the strength of the evidence (confidence in the estimate of effect) to be low at this time.

We also considered the strength of the evidence to be low for an immediate reduction in nipple pain. Improvements were reported in the current studies, but additional studies are needed to confirm and support these results. Only one poor quality cohort study addressed effects on the length of breastfeeding; thus, we considered the strength of the evidence to be insufficient (Table 14).

Table 14. Strength of the evidence for studies addressing surgical approaches for ankyloglossia and breastfeeding outcomes

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Nipple pain RCT: 3 good, [7, 8, 20] 1 poor[21] (251) Retrospective cohort: 1 poor[25] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for an immediate reduction in nipple pain post-procedure due to inconsistent results across small studies.
Breastfeeding effectiveness RCTs-LATCH: 2 good,[8, 20] 1 poor [21] (193) IBFAT: 1 good[7] (58) BSES: 1 fair[8] (107) Retrospective cohort: 1 poor[25] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for improved breastfeeding. Mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and most were short term. Observer-rated measures did not show effectiveness. Future studies could provide additional data to confirm or change the measure of effectiveness.
Length of breastfeeding Retrospective cohort: 1 poor[25] (367)	High	NA	Direct	Imprecise	Undetected	Insufficient SOE due to the high risk of bias of the one retrospective study

BSES = Breastfeeding Self-Efficacy Score; IBFAT = Infant Breastfeeding Assessment Tool; LATCH = Latch, Audible swallowing, Type of nipple, Comfort, Hold; NA = not applicable; RCT = randomized controlled trial; SOE = strength of the evidence.

KQ2a. Benefits of Treatments To Mitigate Feeding Sequelae

Key Findings

We identified three studies examining feeding outcomes other than breastfeeding: one RCT,[23] one poor quality retrospective cohort study,[24] and one case series.[35] All three studies were single center or single surgeon studies. Bottle feeding and ability to use the tongue to eat ice cream and clean the mouth improved more in treatment groups in comparative studies. Supplementary bottle feedings decreased over time in the case series.

Strength of the Evidence

With only two comparative studies, both with significant study limitations, existing data are insufficient to draw conclusions about the benefits of surgical interventions for infants and children with ankyloglossia on medium- and long-term feeding outcomes. The studies used different populations and measured different outcomes (Table 15).

Table 15. Strength of the evidence for studies addressing surgical approaches and feeding outcomes

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Feeding outcomes RCT: 1 poor[23](57) Retrospective cohort: 1 poor [24](104)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE for all feeding outcomes given small number of participants, lack of standard outcome measures, and poor quality of studies.

RCT = randomized controlled trial; SOE = strength of the evidence.

KQ2b. Benefits of Treatments To Prevent Other Sequelae

Key Findings

Speech concerns were the second most prevalent topic in the ankyloglossia literature, after breastfeeding. A speech-language pathologist measured speech outcomes in two studies[22, 26] with the third using parent report.[24] No studies included data related to sleep disordered breathing, occlusal issues and dysphagia in the non-breastfeeding child. Two cohort studies attempted to assess the effectiveness of frenotomy, [24, 26] and one compared two surgical approaches to frenotomy. [22]

Two poor quality cohort studies[24, 26] reported an improvement in articulation and intelligibility with ankyloglossia treatment, but benefits in word, sentence and fluent speech were unclear. The one poor quality RCT reported improved articulation in patients treated with Z-frenuloplasty compared to horizontal-to-vertical frenuloplasty.[22] Numerous non-comparative studies reported a speech benefit after treating ankyloglossia; however these studies primarily discussed modalities, with safety, feasibility or utility as the main outcome, rather than speech itself.[33, 34, 37, 42, 43, 47, 48, 51]

Strength of the Evidence

Given the lack of good quality studies and limitations in the measurement of outcomes, we considered the strength of the evidence for the effect of surgical interventions to improve speech and articulation to be insufficient (Table 16).

Table 16. Strength of the evidence for studies addressing surgical approaches and other outcomes

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/SOE
Speech and articulation Retrospective cohort: 1 poor[24] (104) Prospective cohort: 1 poor[26] (23)	High	Inconsistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor quality cohort studies
Oral motor skills Retrospective cohort: 1 poor [24](104) Prospective cohort: 1 poor[26] (23)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor quality cohort studies

SOE = strength of the evidence.

KQ3. Benefits of Treatments To Prevent Social Concerns Related to Tongue Mobility

Key Findings

Only one poor quality comparative, retrospective cohort study assessed outcomes related to social concerns other than speech.[24] It reported significantly improved ability to clean teeth with tongue, licking outside of lips, and eating ice cream in the treatment group compared with untreated participants. The intermediate outcome of improved tongue movement or mobility after ankyloglossia repair was assessed in two comparative studies—one poor quality RCT[22] and one poor quality cohort study.[26] The RCT assessed tongue mobility using two different surgical techniques for treating ankyloglossia and found that both approaches significantly improved tongue mobility, but that Z-frenuloplasty was superior.[22] In the cohort study, individuals with untreated ankyloglossia had the worst tongue mobility followed in order by children with treated ankyloglossia, and those with no history of ankyloglossia.[26]

Strength of the Evidence

With only one poor quality comparative study, strength of the evidence related to the ability of treatment for ankyloglossia to alleviate social concerns is currently insufficient. Also, with only three comparative studies with small sizes and limitations in the measurement of outcomes related to tongue mobility, we considered the strength of the evidence for the effect of surgical interventions to improve the short-term outcome of mobility to be insufficient (Table 17).

Table 17. Strength of the evidence for studies addressing surgical approaches and social concerns related to tongue mobility

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/SOE
Social concerns Retrospective cohort: 1 poor[24] (104)	High	NA	Indirect	Imprecise	Undetected	Insufficient SOE based on 1 poor quality cohort study
Tongue mobility RCT: 1 poor[22] (16) Retrospective cohort: 1 poor[26] (15)	High	Consistent	Direct	Imprecise	Undetected	Insufficient SOE based on 2 small, poor quality studies

RCT = randomized controlled trial; NA = not applicable; SOE = strength of the evidence.

KQ4. Benefits of Simultaneously Treating Ankyloglossia and Lip-Tie

We did not identify any studies addressing this question.

KQ5. Harms of Treatments for Ankyloglossia or Ankyloglossia With Concomitant Lip-Tie in Neonates, Infants, and Children Through Age 18

Key Findings

We identified all possible harms reported within comparative studies and case series that potentially provided effectiveness data. We also sought case reports of harms. With this approach, we reported harms from 51 studies that reported that they had looked for harms, either reporting actual harms or specifically indicating that they found none. These included five RCTs, one cohort study, 28 case series, and 15 case reports. We considered all comparative studies (RCTs and cohort studies) as poor quality for harms outcomes. We considered the quality for harms outcomes as good in four case series[49-52] and poor in 24.[3, 6, 27-48]Most studies that reported harms information explicitly noted that no significant harms were observed (n=18) or reported minimal harms. Among studies reporting harms, bleeding and the need for reoperation were

most frequently reported. Bleeding was typically described as minor and limited. Few studies described what specific methods they used to collect harms data.

Strength of the Evidence

We considered the strength of the evidence for minimal and short-lived bleeding as a harm of surgical interventions as moderate based on an expanded search for harms reports in addition to the comparative data. We considered the strength of the evidence for reoperation and pain as harms to be insufficient given the small number of studies that included these outcomes (Table 18).

Table 18. Strength of the evidence for studies addressing harms of surgical approaches

Outcome ***Number of Studies and Quality (Total Participants)***	**Study Limitations**	**Consistency**	**Directness**	**Precision**	**Reporting Bias**	**Finding/SOE**
Bleeding RCT: 1 poor[20] (60) Case series: 14 poor[6, 27-29, 32, 34, 35, 38-40, 42-45], 2 good [50, 51] (963)	High	Consistent	Direct	Imprecise	Suspected	Moderate SOE for minimal and short-lived bleeding based on an extensive search for harms reports in addition to the comparative data. Studies consistently reported minimal to no bleeding.
Reoperation RCT: 1 poor[8] (107) Retrospective cohort: 1 poor[25] (367) Case series:1 good,[50] 4 poor[3, 31, 37, 48] (3577)	High	Consistent	Direct	Imprecise	Suspected	Insufficient SOE due to very small numbers of the outcome reported at all in studies.
Pain Case series: 2 good[49, 51] (84)	High	Consistent	Indirect	Imprecise	Suspected	Insufficient SOE for minimal, short-lived pain in infants. No studies reported excessive crying or an inability to feed soon after the intervention, but pain is arguably difficult to assess in infants, so outcomes were indirect and from poor quality or noncomparative studies.

RCT = randomized controlled trial; SOE = strength of the evidence.

Findings in Relationship to What Is Already Known

Few recent reviews assessed outcomes of ankyloglossia treatment,[2, 5, 76, 77] and our findings generally align with those prior reviews, concluding that current evidence is drawn from a small literature base with inconsistent findings related to the benefits of ankyloglossia treatments for increasing breastfeeding effectiveness or reducing maternally reported nipple pain. In a review focused solely on frenotomy and breastfeeding, the authors rated most of the seven studies evaluating frenotomy as poor quality (mean score of 24.4, range 9-40 on a 47-point scale).[76] Studies included one RCT, and all used different outcome-measures to assess effects of frenotomy. Outcomes (breastfeeding mechanics, nipple pain, rate of breastfeeding, sucking, weight gain) all improved post-procedure, and no studies reported significant adverse effects. Another review and meta-analysis addressing frenotomy and breastfeeding included four RCTs and 12 observational studies and concluded that moderate quality evidence supports the effectiveness of frenotomy for improving latching and nipple pain.[77] The risk ratio for overall improvement in latching was 2.88 (95% confidence interval [CI]: 1.82 to 4.57) in meta-analysis of four RCTs, and the mean difference in pain scores was -5.10 (95% CI: -5.60 to -4.59) in meta-analysis of three RCTs. The review noted that no major complications were reported in the studies analyzed.

In a review addressing diagnosis and treatment and including 10 studies assessing effects of treatment on breastfeeding outcomes, breastfeeding mechanics and related outcomes typically improved.[2] Four studies of tongue mobility and three of speech problems also reported improvement. The review notes insufficient evidence related to choice of procedure, timing of procedure, or surgical versus conservative management; however, the investigators did not include any quality metrics for included studies.

A fourth recent review assessed outcomes related to breastfeeding and speech.[5] The 20 studies included ranged from level 4 case series to randomized controlled trials, and concluded that there is both objective and subjective evidence that frenotomy benefits breastfeeding (facilitated breastfeeding, enhanced milk transfer to the infant, and contributed to protecting maternal nipple and breast health), but tempered this by recognizing that there were a limited number of studies available with high quality evidence. Outcomes in four studies addressing speech articulation reported few definitive improvements following treatment. This review did not evaluate non-surgical management or broader outcomes.

Applicability

We set inclusion criteria intended to identify studies with applicability to newborns, infants, and children with ankyloglossia. Studies differed in terms of study population and outcome measures. Most studies were non-comparative, and lack of direct comparisons of treatment options further hinders the ability to understand what findings will best extrapolate to a specific newborn or infant or decisions about care protocols. Overall the data on breastfeeding and maternal breast pain that are available may be applicable to newborns with ankyloglossia with concomitant feeding problems. There is no evidence to suggest that the data would be applicable to infants with ankyloglossia who do not present with feeding problems. Appendix I contains applicability tables for individual KQs.

Applicability of Studies With Breastfeeding Outcomes

Newborns referred for treatment of ankyloglossia were born primarily at tertiary care centers and recognized as having difficulty with breastfeeding concomitant with ankyloglossia. The frenotomy procedure itself is not technically difficult and is likely performed similarly across birthing sites; what is less clear is whether the diagnostic criteria by which the decision is made to perform the procedure are similar across practice settings. Moreover, newborns of mothers not choosing to breastfeed may not be recognized as having and/or diagnosed with ankyloglosssia as breastfeeding difficulties were used as an indicator to evaluate for ankyloglossia. Interestingly, two studies[7, 8] reported that all patients had lactation consultation prior to enrollment without significant improvement in feeding. Arguably, this limits the applicability of their results to newborns that had failed to improve adequately with such consultation.

In these studies, various clinicians were involved in making the ankyloglossia diagnoses; however, assessment of breastfeeding difficulty and diagnostic criteria for ankyloglossia were not universally described. Lack of a consistent objective measure to define and classify this condition may limit the reproducibility of findings. Furthermore, patients in these studies were between a median 6 days of age[7] and up to a mean 33 days of age (range 6 to 115) in another study.[20] Applicability to findings in older infants cannot be gleaned from these data; nor can durability of results.

Frenotomy was the only intervention employed in the good quality RCTs.[7, 8, 20] However, the specifics of the procedure were variably reported. As such the degree of posterior extension of the frenulum incision was not clearly defined and appears to be at the discretion and clinical expertise of the clinician. Also, the severity of the ankyloglossia was inconsistently reported, making inter-study generalizations difficult and, more importantly, limiting the broader applicability of findings.

The comparators used were sham surgery[7, 20] and usual care.[8] These outcomes are identical except in regards to blinding and outcome assessment. Both no intervention and sham surgery are perhaps misnomers, however, since these infant-mother dyads underwent usual care, which could include, but is not limited to, lactation consultation, supportive care, and bottle-feeding advice. Finally, there is insufficient evidence from available literature to assess the applicability of frenotomy on durability of breastfeeding.

Applicability of Studies With Other Feeding Outcomes

Only one study with comparative poor quality retrospective cohort data addressed other feeding outcomes.[24] The study's intervention group received frenotomy for ankyloglossia, which was identified within the first month of life, and was compared to dyads who were also offered, but declined, frenotomy for the same indication in the same time period. Although this is a common decisional dilemma for parents of infants with congenital ankyloglossia, in usual clinical care, surgical intervention is not considered unless congenital ankyloglossia co-occurs with breast- or other feeding problems. Furthermore, there are several biases inherent in this treatment decision. First, those with "worse" ankyloglossia are more likely to get treated. Second, mothers who more strongly want to breastfeed may opt for division. Mothers who would rather pump or bottle feed with formula would more likely chose observation. Third, practitioners' presentation of the evidence may sway the decision, thus perpetuating their personal bias about effectiveness of frenotomy on improving breastfeeding and reducing

maternal pain. Additionally, the study was conducted in an academic medical center in large, urban area with ankyloglossia severity graded by pediatric otolaryngologists. Therefore, applicability of its findings and observations may not translate to other care environments (i.e. community hospital, rural) and many usual clinical care settings may not include practitioners from this sub-specialty, instead relying more on pediatricians, lactation consultants, family practitioners, or dentists.

Applicability of Studies With Speech Outcomes

Comparative studies providing data on speech outcomes were all rated as poor quality and included a randomized controlled trial[22] and two retrospective cohort studies.[24, 26] The RCT compared two different frenuloplasty approaches for treatment of children of a mean age of approximately 6 years with a tight frenulum effecting articulation or intelligibility[22] and found that children treated with either four-flap Z-frenuloplasty and horizontal-to-vertical frenuloplasty had significant improvement in articulation as judged by trained speech-language pathologists. Applicability of these findings is limited due to the small sample size, inadequate characterization of candidate children, and that specialist pediatric craniofacial surgeons performed these surgeries at an urban tertiary care center. "Usual sites" where ankyloglossia is diagnosed and treated would have a difficult time extrapolating these findings considering the limitations.

Similarly, the cohort studies were performed solely in urban tertiary care centers. One assessed outcomes on 3-year old children treated for ankyloglossia as neonates compared to those who had untreated ankyloglossia, and a control group without a history of ankyloglossia.[24] Pediatric otolaryngologists made the diagnosis using standardized diagnostic criteria. The reason that infants presented for treatment of ankyloglossia was not identified. Further limiting the applicability is that these patients were all cared for at a tertiary care facility and outcomes were assessed using a non-validated parent reported telephone survey. Thus, there was no objective evaluation of speech. Parents of children with ankyloglossia would have a higher index of concern for speech issues than those whose children never had been diagnosed with tongue mobility restriction. The second poor quality retrospective cohort with a relatively small sample size (n=23) of children a mean of roughly 6 years of age that were similarly divided into those with treated ankyloglossia, untreated ankyloglossia, and a control group.[26] It was performed at a tertiary care facility in an Israeli urban center. Unfortunately, its applicability is limited similarly to that previously described except that speech-language pathologists objectively assessed speech using a standardized assessment tool. Both retrospective studies lacked explanations about the rationale for initial surgical intervention or reason parent chose not to intervene.

Applicability of Studies With Social Outcomes

The population studied in the question of benefit of ankyloglossia repair for social concerns included children and adults with wide variation in ages. Studies were rated as poor quality, were retrospective, and few in number. Outcomes in one were assessed by parental report and subject to recall bias[24] and social outcomes assessed were limited to licking lips, cleaning teeth with tongue and eating ice cream. Thus, the social concerns or implications of these issues are unclear. No other comparative study considered social concerns. In addition, at least two case series did consider the impact of ankyloglossia on kissing and playing a wind instrument[42] and drooling and oral hygiene.[33] Limiting these findings was the absence of preprocedure status of these patients in these domains and how each was assessed. In addition to not including a

comparison group of any type, case series are strongly affected by selection bias and are, by nature, not comparative studies. Moreover, patients were selected either by retrospective chart review or as they presented to otolaryngology clinics. Only surgical interventions were studied and no two studies measured the same outcomes. Typically, social concerns were measured as a secondary outcome. The setting was typically the outpatient setting, within academic medical centers.

Implications for Clinical and Policy Decision Making

A small body of evidence suggests that frenotomy may be associated with mother-reported improvements in breastfeeding and possibly reduction in nipple pain, when feeding difficulties are present. At this point, the evidence is fairly inconclusive on effectiveness for most outcomes. However, there does seem to be stronger evidence that harms are minimal to none, Thus, given the mixed evidence, clinicians and families will likely need to make individual decisions about pursuing intervention for ankyloglossia-related feeding and speech production difficulties. Importantly, no research evidence exists to assess any non-surgical interventions, so clinical and policy decision making will necessarily occur in the absence of evidence for nonsurgical interventions.

Limitations of the Comparative Effectiveness Review Process

This review included only studies published in English. However, our scan and review of non-English references revealed that high percentage of non-eligible items. Specifically, we determined that 502 of the 520 foreign language references identified in MEDLINE (search conducted in February 2014) would be excluded based on our criteria. Of the 18 potential includes, six appeared, from the information in the abstract and/or title to be eligible for inclusion; 12 did not include abstracts or sufficient information from the title to make an inclusion decision. Two of these appeared to be case reports and neither gave clear indications on whether harms of interventions were addressed. Given the high percentage of non-eligible items in this scan (97%), we feel that excluding non-English studies did not introduce significant bias into the review.

While we focused the review on comparative studies (studies including an intervention and a comparison group), we provide summaries of case series data to supplement the comparative findings given the small number of studies addressing ankyloglossia interventions. We further specifically sought case reports of any harms associated with ankyloglossia intervention. This approach may provide particularly useful information about harms as we found little evidence of serious harm of surgical interventions, though harms reporting was limited.

Limitations of the Evidence Base

The evidence base for the benefits of treatment in ankyloglossia is very limited. Overall, the evidence base consists of a few small studies that use varied outcomes and provide little information to adequately characterize participants. Infants vary in age at treatment from 6 to 33 days and in reasons for presentation. Studies are focused on neonates and infants who present because of breastfeeding difficulties, and while improving breastfeeding success is an important goal, by definition, this means data are unavailable on infants with ankyloglossia but without feeding difficulties in infancy. The degree to which these infants are likely to go on to develop

either feeding, speech or social impediments is inadequately understood. No study effectively assessed mid- and long-term comparative outcomes of frenotomy making it difficult to predict whether mother-reported improvements early in infancy led to longer term breastfeeding. In particular, there is a lack of evidence on significant long-term outcomes such as exclusive breast-feeding at six month of age or at one year of age, growth and other measures of health outcomes. Furthermore, studies are entirely lacking that compare surgical intervention to well-described skilled lactation consultation and other breastfeeding report. Although complementary and alternative methods of care are used in some practices, no studies are available. In addition, the literature base may be subject to publication bias. Most controlled studies reported only positive outcomes, and we identified no negative trials.

Finally, we found no comparative effectiveness data on nonsurgical interventions, although they are in use in clinical care, and in surgical studies, case series predominated, providing little comparative data.

Research Gaps

Breastfeeding Outcomes

Future studies should consider direct comparisons of alternative treatments as currently available literature only addressed the comparison of frenotomy to sham. In order to conduct these studies, it would be helpful if the field could agree upon on standardized approach to identifying and classifying ankyloglossia; this would also improve our ability to synthesize the data across studies.

A critical unknown at this point is a good description of the natural history of ankyloglossia by severity, including long term risk of feeding, social and speech production difficulties. Studies should also consistently report measures of severity.

Given variation in outcomes that may be associated with earlier versus later frenotomy, future studies should assess timing of frenotomy to determine whether more significant reduction in maternal pain is achievable by earlier treatment and whether mothers are more apt to breastfeed longer if done earlier.

A final gap in research is in understanding the durability of outcomes. Good quality comparative studies evaluated breastfeeding effectiveness immediately[7, 20] or within 5 days of frenotomy.[8] However, none adequately assessed whether effectiveness and other outcomes (e.g., changes in maternal nipple pain) were maintained months or, if appropriate, years later. Longer term follow up of both treated infants and controls is needed.

Other Feeding Outcomes

Because there is such a paucity of available data on other feeding outcomes, this entire research question represents a gap and a potential area for future research.

Speech and Other Outcomes

Similarly, substantially more research is needed to consider whether treatment of ankyloglossia in infancy prevents future speech production difficulties as well as whether treatment later in life with frenotomy leads to improvement when speech problems arise. To conduct this research effectively, methods for evaluating risk and presence of speech production difficulties will need to be standardized, and outcomes agreed upon. Understanding of the natural

history of speech concerns in children with ankyloglossia is lacking as are comparative studies that utilize standardized measurement tools for speech outcomes.

Social Concerns Related to Tongue Mobility

No standard definitions of tongue mobility or established norms for mobility exist, and further research is needed to determine such parameters. Social concerns are difficult to measure objectively so there will likely always be a subjective component to social outcomes. Larger studies that assess both treated and untreated individuals could provide useful data to minimize the potential bias found in the existing literature. Similarly, future research in objective measurement tools, or validated self-report tools, is needed.

Harms Reporting

Few studies prespecified harms or provided details of harms collection. Harms were not systematically reported, and therefore there may be substantial underreporting. Minor, limited bleeding and need for re-operation were reported in some studies, but methods for collecting harms in studies overall were poorly reported. Future studies would benefit from explicit description of methods for harms collection, including estimating blood loss, and assessment and explicit reporting.

Conclusions

A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain, but with small studies, inconsistently conducted, strength of the evidence is low to insufficient, preventing us from drawing firm conclusions at this time. Research is lacking on nonsurgical interventions as well as on outcomes other than breastfeeding, particularly speech and dental outcomes. In particular, there is a lack of evidence on significant long-term outcomes such as exclusive breast-feeding at six month of age or at one year of age, growth and other measures of health outcomes. Harms are minimal and rare; the most commonly reported harm is self-limited bleeding. Future research is needed on a range of issues, including prevalence and incidence of ankyloglossia and problems with the condition. The field is currently challenged by a lack of standardized approaches to assessing and studying the problems of infants with ankyloglossia.

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Abbreviations and Acronyms

AAP: American Academy of Pediatrics
AAPD: American Academy of Pediatric Dentistry
AAO: American Association of Orthodontists
AAO-HNS: American Academy of Otolaryngology – Head and Neck Surgery
ABM: Academy of Breastfeeding Medicine
AF: Analytic framework
AHRQ: Agency for Healthcare Research and Quality
AOS: American Orthodontic Society
ASHA: American Speech-Language-Hearing Association
BSES: Breastfeeding Self-Efficacy Scale
BSES-SF: Breastfeeding Self-Efficacy Scale Short Form
CAM: Complementary and alternative medicine
CER: Comparative Effectiveness Review
CINAHL: Cumulative Index of Nursing and Allied Health Literature
CLCWA: College of Lactation Consultants of Western Australia
CPS: Canadian Paediatric Society
ENT: Ear, Nose & Throat
EMBASE: Excerpta Medica Database
EPC: Evidence-based Practice Center
HATLFF: Hazelbaker Assessment Tool of Lingual Frenulum Function
IBFAT: Infant Breastfeeding Assessment Tool
ILCA: International Lactation Consultant Association
IQR: Interquartile range
KI: Key Informant
KQ: Key Question
LATCH: Latch, Audible swallowing, Type of nipple, Comfort, Hold
LCANZ: Lactation Consultants of Australia and New Zealand
MPQ-SF: Montreal Pain Questionnaire
NHS: National Health Service
MeSH: Medical Subject Headings
NICU: Neonatal intensive care unit
PAS: Pediatric Academic Societies
PICOTS: Population, Intervention, Comparator, Outcomes, Timing, Setting
PQDT: ProQuest Dissertations & Theses
RCT: Randomized controlled trial
SF-MQP: Short Form McGill Pain Questionnaire
SRDR: Systematic Review Data Repository
TEP: Technical Expert Panel
VAS: Visual Analog Scale for Pain

Appendix A. Search Strategies

Table A-1. PubMed search strategies

Search terms		Search results
#1	("Mouth Abnormalities"[Mesh:noexp] OR "Tongue Diseases/congenital"[Mesh:noexp] OR "Tongue/abnormalities"[Mesh] OR "Lingual Frenum"[Mesh] OR "Lip Diseases/congenital"[Mesh:noexp] OR "Lip/abnormalities"[Mesh] OR "Labial Frenum"[Mesh] OR "Ankyloglossia"[Supplementary Concept] OR "ankyloglossia"[tiab] OR (("tongue"[tiab] OR "lip"[tiab] OR "lingual"[tiab] OR "linguae"[tiab] OR "labial"[tiab] OR "maxillary"[tiab]) AND ("frenum"[tiab] OR "fraenum"[tiab] OR "frenulum"[tiab] OR "frena"[tiab] OR "frenula"[tiab])) OR (("tongue"[tiab] OR "lip"[tiab] OR "maxillary"[tiab]) AND ("tie"[tiab] OR "tied"[tiab])))	3501
#2	("Therapeutics"[Mesh] OR "therapy"[Subheading] OR "Treatment Outcome"[Mesh] OR "therapy"[tiab] OR "therapies"[tiab] OR "therapeutic"[tiab] OR "therapeutics"[tiab] OR "outcome"[tiab] OR "outcomes"[tiab] OR "Oral Surgical Procedures"[Mesh] OR “surgical”[tiab] OR “surgery”[Subheading] OR “surgery”[tiab] OR "frenulotomy"[tiab] OR "frenulectomy"[tiab] OR "frenotomy"[tiab] OR "frenectomy"[tiab] OR "frenuloplasty"[tiab] OR "z-plasty"[tiab] OR "h-plasty"[tiab] OR "laser"[tiab] OR "Rehabilitation of Speech and Language Disorders"[Mesh] OR "Speech Disorders "[Mesh] OR "Language Development Disorders "[Mesh] OR "speech therapy"[tiab] OR "speech therapies"[tiab] OR "language therapy"[tiab] OR "language therapies"[tiab] OR "oral motor therapy"[tiab] OR "oral motor therapies"[tiab] OR "Complementary Therapies"[Mesh] OR cam[sb] OR "complementary medicine"[tiab] OR "complementary therapy"[tiab] OR "complementary therapies"[tiab] OR "alternative medicine"[tiab] OR "alternative therapy"[tiab] OR "alternative therapies"[tiab] OR "cam"[tiab] OR "craniosacral therapy"[tiab] OR "cranial sacral therapy"[tiab] OR "myofascial release"[tiab] OR "myofascial therapy"[tiab] OR "rolfing"[tiab]) OR (“unsafe”[tiab] OR “safety”[tiab] OR “harm”[tiab] OR “harms”[tiab] OR “harmful”[tiab] OR “complication”[tiab] OR “complications”[tiab] OR “risk”[tiab] OR “risks”[tiab] OR “side-effect”[tiab] OR “side-effects” [tiab]OR ((undesirable OR adverse) AND (effect OR effects OR reaction OR reactions OR event OR events OR outcome OR outcomes))OR” sequelae” [tiab] OR “sequela” [tiab] OR ((postoperative OR surgical OR “post operative” OR “post surgical”) AND (complication OR complications)) OR “adverse effects”[Subheading] OR “complications”[Subheading] OR “contraindications”[Subheading])	10219702
#3	#1 AND #2	2065
#4	#3 AND eng[la]	1496
#5	#4 NOT (editorial[pt] OR letter[pt] OR comment[pt] OR review[pt] OR news[pt] OR historical article[pt] OR practice guideline[pt] OR meta-analysis[pt])	1252

Key: [Mesh: noexp] exact medical subject heading, not including the terms nested beneath it; [MeSH] medical subject heading; [Supplmentary Concept] indexing terms for chemicals, substances and rare diseases; [tiab] keyword in title or abstract; [sh] subheading; [la] language; [pt] publication type.

Table A-2. CINAHL search strategies

Search terms		Search results
S1	((MH "Mouth Abnormalities") OR (MH "Tongue Diseases") OR (MH "Tongue /AB") OR (MH "Lip Diseases") OR (MH "Lip/AB") OR (MH "Frenum (Oral)") OR (MH "Ankyloglossia") OR "ankyloglossia" OR (("tongue" OR "lip" OR "lingual" OR "linguae" OR "labial" OR "maxillary") AND ("frenum" OR "fraenum" OR "frenulum" OR "frena" OR "frenula")) OR (("tongue" OR "lip" OR "maxillary") AND ("tie" OR "tied")))	864
S2	((MH "Therapeutics+") OR (MH "Treatment Outcomes+") OR "therapy" OR "therapies" OR "therapeutic" OR "therapeutics" OR "outcome" OR "outcomes" OR (MH "Surgery, Oral+") OR "frenulotomy" OR "frenulectomy" OR "frenotomy" OR "frenectomy" OR "frenuloplasty" OR "z-plasty" OR "h-plasty" OR "laser" OR "surgery" OR "surgical" OR (MW "su") OR (MH "Speech Disorders+") OR (MH "Communicative Disorders+") OR (MH "Language Disorders+") OR (MH "Rehabilitation, Speech and Language+") OR "speech therapy" OR "speech therapies" OR "language therapy" OR "language therapies" OR "oral motor therapy" OR "oral motor therapies" OR (MH "Alternative Therapies+") OR "complementary medicine" OR "complementary therapy" OR "complementary therapies" OR "alternative medicine" OR "alternative therapy" OR "alternative therapies" OR "cam" OR "craniosacral therapy" OR "cranial sacral therapy" OR "myofascial release" OR "myofascial therapy" OR "rolfing")	1269326
S3	S1 AND S2	497
S4	S3 AND limiters: English language	495
S5	S4 AND limiters: Exclude MEDLINE records	96

Key: MH CINAHL medical subject heading; MW CINAHL subheading

Table A-3. PsycINFO search strategies

Search terms		Search results
#1	(SU.EXACT.EXPLODE("Mouth (Anatomy)") OR SU.EXACT.EXPLODE("Tongue") OR SU.EXACT.EXPLODE("Lips (Face)") OR IF("ankyloglossia" OR (("tongue" OR "lip" OR "lingual" OR "linguae" OR "labial" OR "maxillary") AND ("frenum" OR "frenum" OR "fraenum" OR "frenulum" OR "frena" OR "frenula")) OR (("tongue" OR "lip" OR "maxillary") AND ("tie" OR "tied"))))	2022
#2	(SU.EXACT.EXPLODE("Treatment") OR (IF("therapy" OR "therapies" OR "therapeutic" OR "therapeutics" OR "outcome" OR "outcomes" OR "frenulotomy" OR "frenulectomy" OR "frenotomy" OR "frenectomy" OR "frenuloplasty" OR "z-plasty" OR "h-plasty" OR "laser" OR "surgery" OR "surgical" OR "speech therapy" OR "speech therapies" OR "language therapy" OR "language therapies" OR "oral motor therapy" OR "oral motor therapies" OR "complementary medicine" OR "complementary therapy" OR "complementary therapies" OR "alternative medicine" OR "alternative therapy" OR "alternative therapies" OR "cam" OR "craniosacral therapy" OR "cranial sacral therapy" OR "myofascial release" OR "myofascial therapy" OR "rolfing")))	684785
#3	#1 AND #2	235

#4	#3 AND LA(English)	220
#5	#4 with peer reviewed and scholarly journals selected	207

Key: SU.EXACT.EXPLODE subject term

Table A-4. EMBASE search strategies

Search terms		**Search results**
#1	tongue disease/cn or tongue disease*.tw. or tongue abnormalit*.tw. or ankyloglossia/ or ankyloglossia.tw. or lip malformation/cn or lip malformation*.tw. or lip disease/cn or lip disease*.tw. or ((tongue/ or tongue.tw. or lip/ or lip*.tw. or labial.tw. or lingual.tw.) and (frenum.tw. or fraenum.tw. or frena.tw. or frenulum.tw. or frenula.tw.)) or ((tongue.tw. or lip/ or maxillary.tw.) and (tie.tw. or tied.tw. or ties.tw.))	1229
#2	th.fs. or therapy/ or therapy.tw. or therapies.tw. or therapeutic*.tw. or treatment outcome/ or treatment outcome*.tw. or outcome*.tw. or oral surgery/ or oral surger*.tw. or surgical.tw. or su.fs. or surgery.tw. or frenulotom*.tw. or frenulectom*.tw. or frenotom*.tw. or frenectom*.tw. or frenuloplast*.tw. or z plasty/ or z plasty.tw. or h plasty.tw. or laser surgery/ or speech rehabilitation/ or speech rehabilitation.tw. or speech disorder/ or speech disorder*.tw. or developmental language disorder/ or language development disorder*.tw. or speech therapy/ or speech therap*.tw. or language therap*.tw. or oral motor therap*.tw. or complementary therap*.tw. or cam.tw. or complementary medicine*.tw. or alternative medicine/ or alternative medicine*.tw. or alternative therap*.tw. or craniosacral therapy/ or craniosacral therap*.tw. or myofascial therap*.tw. or myofascial release.tw. or manipulative medicine/ or rolfing/ or rolfing.tw. or (Unsafe.tw. or safety/ or safety.tw. or harm.tw. or harms.tw. or harmful.tw. or complication/ or complication*.tw. or risk/ or risk*.tw. or side effect/ or side effect*.tw. or contraindication*.tw. or ((undesirable.tw. or adverse.tw.) and (effect.tw. or effects.tw. or reaction.tw. or reactions.tw. or event.tw. or events.tw. or outcome.tw. or outcomes.tw.)) or sequelae.tw. or sequela.tw. or ((postoperative.tw. or surgical.tw. or post operative.tw. or post surgical.tw.) and (event.tw. or events.tw. or outcome.tw. or outcomes.tw.)) or si.fs. or co.fs.)	8617400
#3	1 AND 2	730
#4	Limit 3 to English	585
#5	Limit 4 to human	541
#6	5 not (review.pt. or editorial.pt. or letter.pt. or note.pt. or short survey.pt. or conference paper.pt. or meta analysis/ or practice guideline/ or systematic review/)	431
#7	5 Exclude MEDLINE journals	25

Key: / Emtree heading; .tw. abstract, title and drug trade name; /cn congenital; .fs. subheading;
si.fs. side effects subheading; th.fs. therapy subheading; su.fs. surgery subheading; co.fs. complications subheading;
p.t. publication type

Appendix B. Abstract and Full-Text Screening Forms

Table B-1. Abstract screening questions

Ref ID	**Reviewer name**		
1. Does the study address the treatment of ankyloglossia and/or concomitant lip-tie or harms of treatment/no treatment (conservative management)? If "No" please skip to #4.	Yes	No	Cannot Determine
2. Is the study original research? (excludes reviews, commentary, editorials, letters; includes systematic reviews and meta analyses)	Yes	No	Cannot Determine
3. Does the study population include infants or children up to age 18?	Yes	No	Cannot Determine
4. If excluded, should the study be retained for any of the following reasons: Background/discussion Review of references Study population has congenital craniofacial malformation, Pierre Robin and/or cleft lip/palate Other _____	Yes	No	Cannot Determine
Comment			

Table B-2. Full-text screening questions

Ref ID	**Reviewer name**	
1. Is the study original research? (excludes narrative reviews, commentary, editorials, letters; includes systematic reviews and meta analyses)	Yes	No
2. Does the study evaluate the effectiveness of treatment for ankyloglossia and/or concomitant lip-tie OR is this a study or case report that provides data on harms of treatment?	Yes	No
3. Does the study population include infants or children up to age 18?	Yes	No
4. If excluded, should the study be retained for any of the following reasons: Background/discussion Review of references Study population has congenital craniofacial malformation, Pierre Robin and/or cleft lip/palate Other _____	Yes	No
Comment		

Appendix C. Excluded Studies

Abstract Review Exclusion Reasons

X-1 Does not address treatment of ankyloglossia and/or concomitant lip-tie or harms of treatment/no treatment

X-2 Not original research

X-3 Participants not in target age range

1. Oberndorf CP. Slips of the tongue and pen. J Abnorm Psychol. 1914;8(6):378-84. PMID: X-1
2. Special mental conditions. Psychol Bull. 1925;22(5):291-4. PMID: X-1
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4. Phillips JC. Rehabilitation in a case of manic depressive reaction with a speech defect. Case Reports in Clinical Psychology. 1951;2(4):50-2. PMID: X-3
5. Masters F, Georgiade N, Horton C, et al. The use of interlocking Z's in the repair of incomplete clefts of the lip and secondary lip deformities. Plast Reconstr Surg (1946). 1954 Oct;14(4):287-92. PMID: 13215109; X-1
6. Beers MD, Pruzansky S. The growth of the head of an infant with mandibular micrognathia, glossoptosis and cleft palate following the Beverly Douglas operation. Plast Reconstr Surg (1946). 1955 Sep;16(3):189-93. PMID: 13266547; X-1
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8. Watt OM. Lingual thyroid; complicating general anaesthesia. Anaesthesia. 1959 Apr;14(2):162-7. PMID: 13637370; X-1
9. Perzik SL. Early management in extensive cervical cystic hygroma and macroglossia. Arch Surg. 1960 Mar;80:460-3. PMID: 14432102; X-1
10. Kokic A, Gazabatt C. Dissection of labial frenum: a new technic. J Oral Surg Anesth Hosp Dent Serv. 1961 Jul;19:326-8. PMID: 13757671; X-1
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21. DesEnfants JA. The abnormal labial frenum. J Mo Dent Assoc. 1966 Oct;46(8):9-12. PMID: 5223623; X-1

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Full-Text Review Exclusion Reasons

X-4 Not original research
X-5 Does not evaluate effectiveness of treatment for ankyloglossia and/or concomitant lip-tie or is not a case series reporting on harms of treatments for ankyloglossia and/or concomitant lip-tie.
X-6 Participants are not target age group

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Appendix D. Evidence Table

Table D-1. Evidence table

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Amir et al., 2005[1] **Country:** Australia **Enrollment period:** Aug 2002 to July 2003 **Funding:** NR **Design:** Case series	**Intervention:** Frenotomy: Use index finger and thumb of non-dominant hand to stabilize and visualize lingual frenulum. Frenulum is divided by 2-3 mm with small sterile scissors, adjacent to tongue taking care to avoid vascular tissue. Encouraged to breast feed immediately after procedure. **Groups, n (%):** **G1:** intervention, 35/46 (76%) **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** None **Other non-surgical therapies:** NR **Setting of therapy:** hospital ward (n=4) or breastfeeding clinic (n=28) **Treatment duration:** Days / weeks **Last follow-up post-treatment:** phone interview 3 months post-treatment **N at enrollment:** **G1:** 66 at assessment **N at follow-up:** **G1:** 46 **Consultation with lactation consultant:** **G1:** Yes, referral	**Inclusion criteria:** • Infants presenting to breastfeeding service assessed with HATLFF • Impaired lingual function • Frenulum visualized to be thin membrane • Parents gave informed consent **Exclusion criteria:** • Score did not recommend release of frenulum (n=11) **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at assessment, mean (range):** **G1:** 18 (3-98) **Gender, n (%):** Male: **G1:** 29/46 (63) at assessment 22 males in frenotomy group Female: **G1:** 13 females in frenotomy group **Race/ethnicity:** NR **Indication for therapy, n (%):** Most important presenting problem Attachment to the breast **G1:** 12 (44) Nipple pain: **G1:** 6 (22) Prolonged feeding: **G1:** 5 (19) Poor weight gain: **G1:** 2 (7) Frequent feeding: **G1:** 1 (4) Nipple damage:	**Length of lingual frenulum when tongue is lifted:** **G1:** NR Mean HATLFF function score (n=35) **G1:** 10.9 ± 0.57 Mean appearance score **G1:** 5.9 ± 1.5 **Maternal:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:**NR **Maternal, n (%):** No difference in breastfeeding **G1:** 6/35 (17) Better attachment to breast: **G1:** 18/35 (51) Improved sucking: **G1:** 20/35 (57) Less pain: **G1:** 9/35 (26) Weight improved **G1:** 6/35 (17) Other difference: **G1:** 2/35 (44) No longer breastfeeding: n=3 **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No problems reported when mothers were queried. **Harms Detailed:** NA **Timing of harms:** NA

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G1: 1 (4) **Other characteristics:** Family history: Yes **G1:** 7 No **G1:** 36 Missing: **G1:** 3 **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR		

Comment: Maternal satisfaction also reported.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Argiris et al., 2011[2] **Country:** UK **Enrollment period:** Aug 2008 to Oct 2008 **Funding:** NR **Design:** Case series (prospective audit)	**Intervention:** Middle finger or index finger were used to lift infant tongue making tongue tie visible. Floor of mouth often compressed with gauze to prevent submandibular duct injury. Tongue tie was divided with blunt pair of scissors. Manual pressure with gauze administered to control blood loss. **Groups, n:** **G1:** intervention, 46 **Type of professional performing treatment:** otolaryngologist consultant or lactation consultant **Anesthesia used in surgical intervention:** No anesthetic or analgesic **Other non-surgical therapies:** NR **Setting of therapy:** Main OR then kept in peds ward for observation postop before discharge **Treatment duration:** NA **Last follow-up post-treatment:** 6 weeks post-treatment **N at enrollment:** **G1:** 46 **N at follow-up:** **G1:** 46 **Consultation with lactation consultant, n (%):** **G1:** 46 (100)	**Inclusion criteria:** •Presented with breastfeeding difficulties •Diagnosed with tongue-tie by lactation nurse consultant or ENT **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, weeks at intervention, mean:** **G1:** 4 (range 1 day to 12 weeks **Gender, n:** Male: **G1:** 33 Female: **G1:** 13 **Race/ethnicity:** NR **Indication for therapy:** breastfeeding difficulties **Other characteristics:** NR **Type of ankyloglossia, n (%):** Mild tongue tie (bound by thin mucous membrane **G1:** 20 (43) Severe tongue tie –tongue fused to floor of mouth **G1:** 23 (57) **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, %:** Sore nipples **G1:** 63 Damaged nipples: **G1:** 43 Coming on/off of breast, %: **G1:** 50 **Pain score, mean ± SD** **G1:** 6.63/10 ± 2.46 **Infant, %:** Poor latch **G1:** 67 Not satisfied after feeding **G1:** 30 Poor weight gain **G1:** 22 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, %:** Immediate improvement in breastfeeding **G1:** 70 Breastfeeding at follow-up, n (%) **G1:** 41/46 (89) Major improvement at followup, %: **G1:** 87% Reduced nipple pain, n (%): **G1:** 19 (40) **Pain score, mean ± SD** **G1:** 1.47/10 ± 1.34 **Change in pain score p-value:** p< 0.01 **Infant:** Improved latch, n (%) **G1:** 36 (78) More effective suck **G1:** 30 (64) **Child:** **G1:** NR **Need for reoperation:** **G1:** 3/46 **Harms:** Yes **Harms Details:** Blood loss, %: **G1:** 52 No correlation with degree of ankyloglossia **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Ballard et al., 2002[3] **Country:** USA **Enrollment period:** Jan 1998 to June 2001 **Funding:** Service grant from the March of Dimes, Ohio Chapter, Cincinnati Children's Hospital Medical Center, and University Hospital, Inc, members of the Health Alliance of Greater Cincinnati. **Design:** Prospective Case series	**Intervention:** The infant is placed supine with the elbows held flexed securely close to the face and the assistant's index finger on the chin for stabilization. The tongue is lifted gently with a sterile, grooved retractor so as to expose the frenulum. With sterile iris scissors, the frenulum is divided by approximately 2 to 3 mm at its thinnest portion, between the tongue and the alveolar ridge, into the sulcus just proximal to the genioglossus muscle. **Groups:** **G1:** Frenuloplasty **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Usually used if >4mo, type not specified **Other non-surgical therapies:** NR **Setting of therapy:** Hospital Inpatient & outpatient lactation center **Treatment duration:** NR **Last follow-up post-treatment:** post-operative day #3 phone call, some followed for 5 days **N at enrollment:** **G1:** 127 **N at follow-up:** **G1:** 123 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Breast feeding infants with short or tight lingual frenulum who might benefit from surgery based on clinical assessment and HATLFF score **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days or months at intervention:** **G1:** Median (25th, 75th percentile) age at presentation with poor latch was significantly lower than with maternal nipple pain: 1.2 days (0.7, 2.0) versus 2.0days (1.0, 12.0), respectively (p = 0.007). **Gender, ratio:** Boys:Girls: 1.5:1 **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding problems **Other characteristics:** Family history of tongue-tie: Positive: n= 26 **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Nipple pain levels based on an analog scale of 1 (extremely mild) to 10 (severe pain),: Mean ± SD: 6.9 ± 2.31 **Inpatients, n (%)** Nipple pain: **G1:** 32/88 (36.4) **Outpatients, n (%):** Nipple pain: **G1:** 21/35 (60) Moderate to severe nipple trauma with or without infection: 21 mothers Recurrent mastitis= 4 Suppressed lactation= 4 **Infant:** **G1:** Inpatients, n (%) Poor latch: 56 /88 (63.6) Outpatients, n (%): Poor latch: 14/35 (40) Failure to thrive: 6 (poor latch=4, nipple pain=2) **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Nipple pain levels based on an analog scale of 1 (extremely mild) to 10 (severe pain), Mean ± SD: 1.2 ± 1.52 (p < .0001) Comfortable breast feeding: 31/35 mothers Stopped breastfeeding: 3 **Infant: HATLFF** **G1:** Function score: 7.9 ± 1.86 Appearance score: 4.9 ± 1.81 There was significant correlation between function and appearance: r= 0.49, P<0.001. With ooor latch: Mean function score: 7.8 ± 1.88 Appearance score: 4.8 ± 1.87 With maternal nipple pain, Function score: 8.0 ± 1.85 Appearance score: 5.0 ± 1.76 The score differences not significant 5 failure to thrive (FTT) infants resumed breastfeeding and achieved a normal rate of growth within 3 to 5 days after the procedure. One severe failure to thrive patient

				advised by own pediatrician to start formula **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** None observed **Harms Details:** NA **Timing of harms:** Immediate & 3 days after Rx via phone call

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Berry et al., 2012[4] **Country:** UK **Enrollment period:** October 2003 to April 2004 **Funding:** NR (Authors report no competing financial interests) **Study Design:** RCT, blinded	**Intervention:** Tongue-tie division: The tongue-tie was put on a stretch with left index finger and holding lower lip clear with thumb. Tie was divided completely with sharp, blunt ended sterile scissors. And floor of mouth compressed with sterile gauze swabs. Baby immediately returned to mother. Feeding was reassessed. Infants who had been allocated to non-division were then taken to have procedure performed **Groups:** **G1:** Tongue-tie division **G2:** Sham tongue-tie division **Type of professional performing treatment:** Lactation consultant or pediatric surgeon **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NA **Setting of therapy:** Hospital (clinic not specified) **Treatment duration:** NA **Last followup post-treatment:** Three most post-treatment **N at enrollment:** **G1:** 30 **G2:** 30	**Inclusion criteria:** • Age < 4 months • Symptoms of breastfeeding problem • Tongue-tie present **Exclusion criteria:** • Bottle fed • Declined to participate • Infant failed to feed **Age, days or months at first diagnosis:** NR **Age at baseline, days, mean (range):** **G1:** 33 (6-115) **G2:** 28 (5-111) **Gender, n:** Male: **G1:** 21 **G2:** 19 **Race/ethnicity:** NR **Indication for therapy, n (%):** Difficulty with latch: **G1:** 23 (77) **G2:** 24 (80) Nipple pain/trauma: **G1:** 20 (67) **G2:** 19 (63) Inefficient feeding: **G1:** 19 (63) **G2:** 18 (60) All 3 indications: **G1:** 10 (33) **G2:** 9 (30) **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NA	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Breastfeeding pain score, mean: **G1:** 4.1 **G2:** 4.2 **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Breastfeeding pain score, mean: **G1:** 1.6 **G2:** 2.9 Change in pain score, mean ± SD: **G1:** -2.5 ± 1.9 **G2:** -1.3 ± 1.5 **G1 vs G2:** p=0.13 (95% CI: -0.3, 2.4) **Infant:** **Immediate** Improved breastfeeding maternal report, n (%) **G1:** 21 (78) **G2:** 14 (47) **G1 vs G2**: p< 0.02 95% CI (6-51%) Improved feeding objective observer, n (%): **G1:** 13/26 (50) **G2:** 12 (40) **G1 vs G2, p=ns** Mean age of babies whose mothers reported full resolution of feeding problem were 8 days younger than those reporting no improvement (26 vs. 34d) None reported worse feeding **3-month follow-up, n (%):** Improved feeding maternal report: **G1+ G2:** 54/59 (92) Full resolution of feeding problems: **G1+ G2:** 33/59 (56) No improvement in feeding:

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at followup: **G1:** 27 **G2:** 30 **Consultation with lactation consultant:** NR			**G1+ G2:** 5/59 (8) **Breastfeeding at 3 months:** **G1+ G2:** 38/59 (65) **Breastfeeding at second phone call (mean age 4.5 months), n (%):** **G1+ G2:** 30/59 (51) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details, n (%):** Small amount of bleeding following procedure: **G1+ G2:** 3 (5) "None of complications were significant" and all infants with complications were feeding better at 1 day after division **Timing of harms:** **G1:** Immediate

Comments: Parents and single observer who independently assessed outcomes were blinded to group.
All mothers contacted would choose to have the tongue tie divided again if they were in the same situation in the future.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Blekinsop, 2003[5] **Country:** UK **Enrollment period:** Retrospective audit: January 2002 to June 2002 Prospective audit: 2003 **Funding:** NR **Study Design:** Case series	**Intervention:** Frenulotomy: membrane stripped with sterile blunt edged scissors and baby immediately fed **Groups:** **G1:** Intervention **Type of professional performing treatment:** Pediatric surgeon or lactation consultant **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Hospital **Treatment duration:** NR **Last followup post-treatment:** 2 weeks **N at enrollment:** **G1:** 21 **N at followup:** **G1:** 20 **Consultation with lactation consultant, (%):** **G1:** Yes, (100)	**Inclusion criteria:** • Babies referred for frenotomy during time period **Exclusion criteria:** NR **Age, days or weeks at first diagnosis, range:** 1 day to 6 weeks **Age, days or months at intervention:** NR **Gender:** Male: **G1:** NR Female: **G1:** NR **Race/ethnicity:** **G1:** NR **Indication for therapy:** Breastfeeding issues **Other characteristics:** NA **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Stopped breastfeeding due to reduced milk supply: **G1:** 7 **Infant, n (%):** Feeding difficulty Fully resolved: **G1:** 10/20 (50) Significantly improved: **G1:** 8/20 (40) Slightly improved: **G1:** 2/20 (10) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No post treatment complications reported **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Buryk et al., 2011[6] **Country:** US **Enrollment period:** Dec 2007 to Dec 2008 **Funding:** U.S. gov't; authors report no financial disclosures **Design:** RCT Single blinded	**Intervention:** Frenotomy: tongue elevated and frenulum exposed with grooved director. Frenulum tissue was crushed with straight clamp to provide anesthesia and frenulum was incised with straight scissor. On occasion, direct pressure with fingertips needed to be applied for hemostasis **Groups:** **G1:** Frenotomy **G2:** sham procedure **Type of professional performing treatment:** otolaryngologist **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Newborn nursery, newborn care clinic, and otolaryngology clinic **Treatment duration:** 5 minutes **Last follow-up post-treatment:** 12 months **N at enrollment:** **G1:** 30 **G2:** 28 **N at follow-up:** At twelve months **G1 + G2:** 44 **Consultation with lactation consultant, n (%):** **G1:** 30 (100) **G2:** 28 (100)	**Inclusion criteria:** • Maternal report of nipple pain or difficulty breastfeeding combined with significant ankyloglossia diagnosed by lactation consultant (100% agreement with ENT assessment at time of procedure) using HATLFF **Exclusion criteria:** • Infant older than 30 days • Craniofacial abnormalities, including cleft lip or palate • Neurologically compromised infants • Any other contraindications to maternal breastfeeding **Age, days at enrollment, mean ± SD (range):** **G1+G2:** 6.0 ± 6.9 (1 – 35) **G1:** 6.2 ± 6.9 **G2:** 6.0 ± 7.0 **Age, days at intervention, mean ± SD:** **Mean age:** 6.7 days (one child at 2 weeks) **Gender, n (%):** Male: **G1:** 19 (63) **G2:** 19 (68) Female: **G1:** 11 (37) **G2:** 9 (32) **Indication for therapy:** Maternal report of nipple pain or difficult breastfeeding and HATFLL **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** **G1:** 0 **G2:** 0	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G1:** NR **Maternal:** Nipple pain assessed by SF-MQP (Short form McGill Pain Questionnaire), mean ± SD: **G1:** 16.8 ± 10.6 **G2:** 19.2 ± 9.9 Breastfeeding rates: NR **Infant:** IBFAT, mean ± SE **G1:** 9.3 ± 0.69 **G2:** 8.5 ± 0.73 **HATFLL appearance score, mean ± SD** **G1:** 6.0 ± 1.6 **G2:** 5.7 ± 2.2 **HATFLL function score, mean ± SD** **G1:** 9.4 ± 2.6 **G2:** 8.4 ± 2.0 **Child:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2**: NR **Maternal:** Nipple pain, immediately after procedure SF-MPQ: **G1:** 4.9 ± 1.46 **G2:** 13.5 ± 1.5 p value G1 vs G2: p<0.001 Effect size: 0.38 Breastfeeding rates, n (%): Two months: **G1+G2:** 36/58 (66) Six months: **G1+G2:** 23/58 (44) Twelve months **G1+G2:** 14/58 (28) **Infant:** IBAT, mean ± SE **G1:** 11.6 ± 0.81 **G2:** 8.07 ± 0.86 **G1 vs. G2:** p=0.029 effect size: 0.31 **Child:** NR **Need for reoperation:** NR **Harms:** No complications from the procedure in any infants **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Choi et al., 2011[7] **Country:** Korea **Enrollment period:** 2005 to 2010 **Funding:** NR **Study Design:** Case series	**Intervention:** Z-plasty combined with partial midline genioglottus myotomy Pull tongue tip in cephalic direction and release the lingual frenulum close to tongue base using a scalpel. Then mucosal layer of tongue is opened and contracted genioglossus muscle exposed. Pull tongue and cut only the predominantly tightened muscle portion horizontally using electrocautery and release. Dissect mucosal flap to prevent mucosal contracture, release mucosal layer 1 cm long at tongue base through z-plasty and close with 5-0 Vicryl suture **Groups:** **G1:** Intervention **Type of professional performing treatment:** Surgeon-not specified (Corresponding author in plastic and reconstructive surgery) **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NA **Last followup post-treatment:** Up to 6 months post-treatment overall range 3 months to 2 years	**Inclusion criteria:** NR **Exclusion criteria:** • Other congenital anomalies or with oral disease or anomaly **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, (range):** **G1:** 1-10 **Gender:** Male to female ratio: **G1:** 2.3:1 **Race/ethnicity:** NR **Indication for therapy:** Unclear Speech impediments Sucking and breastfeeding problems also mentioned in intro **Other characteristics** Family history: **G1:** 20% **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR (No patient had scar contracture during f/u) **Harms:** No **Harms Details:** No signs and symptoms that may typically result from a genioglossus myotomy procedure such as limited tongue movement or aggravated speech or articulation problems were seen. No aggravated scar contracture or speech problem post-therapy **Timing of harms:** NA

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at enrollment: **G1:** 106 **N at followup:** **G1:** 106 **Consultation with lactation consultant:** NR			

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dave et al., 2013 [8] **Country:** India **Enrollment period:** 6/2010 to 9/2012 **Funding:** None **Design:** Case series	**Intervention:** Surgery details not reported. Tongue tie release surgery **Groups:** **G1:** Tongue-tie release surgery **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** Speech therapy **Setting of therapy:** Outpatient & inpatient department of otorhinolaryngology **Treatment duration:** NR **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 7 **N at follow-up:** **G1:** 7 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Dysglossia with articulation disorder **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days or months at intervention, N :** **G1:** Up to 12 years: 5 13-19 years: 2 **Gender, n (%):** Male: **G1:** 5/7 (71.4) Female: **G1:** 2/7(28.6) **Race/ethnicity:** NR **Indication for therapy:** Dysglossia **Other characteristics:** All 7 patients were given speech therapy post-operatively **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** defects of linguadental and alveolar sounds as well as sibilants viz. ‘d’, ‘t’, ‘l’, ‘s’, ‘z’, (n=7)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** All improved (100%) satisfactorily **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dollberg et al., 2014[9] **Country:** Israel **Enrollment period:** 3/2010 to 10/2010 **Funding:** NR **Design:** Prospective case series	**Intervention:** Follow-up study after frenotomy. Procedure not described **Groups** **G1:** Frenotomy **Type of professional performing treatment:** Physician **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Hospital or office **Treatment duration:** NR **Last follow-up post-treatment:** 6 months (phone interview) **N at enrollment:** **G1:** 264 **N at follow-up:** **G1:** 244 **Consultation with lactation consultant, (%):** **G1:** yes (100)	**Inclusion criteria:** • All mothers of infants who had breastfeeding difficulties • Term infants with no congenital anomalies **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, median (range):** **G1:** 14 (1-135) **Gender, n (%):** Male: **G1:** 143 (59) Female: **G1:** 101 (41) **Race/ethnicity:** NR **Indication for therapy:** Maternal nipple soreness nipple pain with / without bruising Latching difficulties (repeated, frequent detachments of the infant from the breast) Inability to feed, falling asleep on the breast and other latching problems **Other characteristics:** Problems with breast feeding with previous offspring, 61.5% (64/104) First Born: 129 (53%) **Type of ankyloglossia:** **G1:** Coryllos type of tongue-tie, % I. 13 II. 31 III. 24 IV. 32 Coryllos type by gender, %, (M:F ratio): I. 79% M, 21% F (3.7:1) II. 57% M, 43% F (1.3:1) III. 62% M, 38% F (1.6:1)	**Length of lingual frenulum when tongue is lifted:** **G1:** Visual description of frenular thickness, n, (%): Thin: 105 (43) Thick: 96 (40) Graded (thin distally and thick proximally): 42 (17) Notched tongue tip: 78 (32) Tongue elevation above midmouth: 51 (21) **Maternal, n (%):** **G1:** Sore maternal nipples (VAS),: 203 (83) Nipple pain with bruising: 152 (62) Nipple pain without bruising: 92 (38) Latching difficulties 134 (55) **Infant:** Maternal perception of infant's pain, median (range) **G1:** 3 (0–10) **Child:** **G1:** NR	Length of lingual frenulum when tongue is lifted: **G1:** NR Maternal, n (%): Breast feeding difficulties: **G1:** Improvement: 180 (75) Significant improvement: 131 (54) No improvement: 48 (20) Worsening: 7 (3) Nipple wounds: **G1:** 50 /130 (38) reported wound disappearance Disappearance of nipple bruises (days), median (range) **G1:** 4 (1–15) Infant, n (%): **G1:** 217/244 (89) were still being breastfed at the 2-week follow-up Fully breastfed: 160 (74) Received more than half of their meals as breastmilk: 28 (13) Fed half or fewer of their meals as breastmilk: 29 (13) At 3-month follow-up: Still breastfeeding: 165 (68) Fully breastfed: 134/165 (81) At 6 months follow-up: Still breastfeeding:

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		IV. 49% M, 51% F (1:1) **Ankyloglossia with concomitant lip tie:** NR		137 of 244 (56) No statistically significant predictor in terms of history of breastfeeding of siblings, symptom (e.g., pain, bruising), or anatomy-- e.g.,Coryllos type and thickness of the frenulum) for improvement in breastfeeding **G1:** Mothers reported that fibrin deposition over the wound disappeared within a median of 9 days (range, 2–14 days). Infant's crying duration post-frenotomy in minutes, n (%): < 1 = 192 (79) 1–5 = 49 (20) > 5 = 3 (1) Child: **G1:** NR Need for reoperation: **G1:** NR Harms: Yes Harms Details: **G1:** Minimal discomfort & minimal **G1:** Bleeding Bleeding time, median(range): 1 (0-6) minutes Acetaminophen use, n (%): **G 1 :** 44 (18) Timing of harms: immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dollberg et al., 2011 [10] **Country:** Israel **Enrollment period:** NR **Funding:** NR **Design:** Prospective Cohort	**Intervention:** NR **Groups:** **G1:** Frenotomy **G2:** Untreated tongue-tie **G3:** No tongue-tie/controls **Type of professional performing treatment:** Neonatologist or pediatric dentist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NR **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 8 **G2:** 7 **G3:** 8 **N at follow-up:** **G1:** 8 **G2:** 7 **G3:** 8 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Children who underwent frenotomy of tongue-tie during infancy who were at time of study between 4 – 8 years old • Age-matched children with untreated tongue-tie whose parents reported a history of breastfeeding difficulties (e.g. nipple pain during nursing, difficulties in latching or both) • Children with no tongue-tie as controls **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, days or months at intervention, range:** **G1:** 2 days- 4 weeks **G2:** NA **G3:** NA **Current age, years: mean ± SD :** **G1:** 6.2 ± 1.8 **G2:** 6.2 ± 1.9 **G3:** 5.8 ± 1.9 **Gender, n:** Male: **G1+G2+G3:** 17 Female: **G1+G2+G3:** 6 **Race/ethnicity:** NR **Indication for therapy:** NR **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child:** Tongue movement (oromotor test) Mean ± SD (95% CI): **G1:** 3.7 ± 4.3 (1.5) **G2:** 11 ± 7.6 (2.9) p=0.122, (-0.025, 0.179) **G3:** 1.2 +/-1.6 (0.5) **G1 v. G3:** p=0.28 (-0.023 – 0.073) Consonant articulation errors: **G1:** 6.0 ± 7.5 (2.7) **G2:** 7.1 ± 6.9 (2.6) p=0.76 (-6.96, 9.19) **G3:** 1.0 +/- 2.9 (1.0)**G1 v. G3:** p=0.11 (-1.43 – 11.39) Word production accuracy: **G1:** 6.0 ± 4.2 (1.5) **G2:** 14.5 ± 10.0 (3.7) p=0.076 (-1.150, 18.09) **G3:** 8.8 +/- 11.6 (3.1) **G1 v. G3:** p=0.53 (-12.54 – 7.28) Word intelligibility: **G1:** 1.3 ± 0.1 (0.1) **G2:** 1.7 ± 0.36 (0.1) p=0.33 (0.04, 0.714) **G3**: 1.4 +/- 0.4 (0.1) **G1 v. G3:** 0.50 (-0.46 – 0.25) Sentence

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				intelligibility: **G1:** 1.3 ± 0.2 (0.1) **G2:** 1.6 ± 0.46 (0.2) p=0.16 (-0.147, 0.749) **G3:** 1.4 +/- 0.4 (0.1) **G1 v. G3:** p=0.46 (-0.49 – 0.24) Fluent-speech intelligibility: **G1:** 1.5 ± 0.4 (0.1) **G2:** 1.6 ± 0.5 (0.2) P=0.6 (-0.416, 0.689) **G3:** 1.2 +/- 0.3 (0.1) **G1 v. G3:** p=0.229 (-0.18 – 0.68) **Need for reoperation:** **G1:** NR **G2:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA **Gap between lower incisors at age 4 – 8 years:** NR **Frenotomy** N=1 **Non-frenotomy** N=1

Comment: See related paper Dollberg et al, 2006

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dollberg et al., 2006[11] **Country:** Israel **Enrollment period:** Dec 2001 to Sept. 2004 **Funding:** NR **Design:** RCT	**Intervention:** Frenotomy, followed by careful hemostasis (i.e. mild pressure for several seconds to several minutes) **Groups:** **G1:** frenotomy followed by breastfeeding, then sham followed by breastfeeding **G2:** sham followed by breastfeeding, then frenotomy followed by breastfeeding **Type of professional performing treatment:** neonatologist or pediatric dentist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Lactation clinic at maternity hospital **Treatment duration:** NA **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 15 **G2:** 11 **N at follow-up:** **G1:** 14 **G2:** 11 **Consultation with lactation consultant, (%):** Yes (100)	**Inclusion criteria:** • Full-term healthy appropriate for gestational age infants • Age 1 to 21 days • Referred for lactation clinic for nipple pain • Diagnosis of ankyloglossia by neonatologist (ankyloglossia defined as: inability of infant to protrude tip of tongue over lower gum line while tip was tied to floor of mouth by tight cord of frenulum and tongue became heart shaped) **Exclusion criteria:** • One exclusion due to failure of blinding **Gestational Age, weeks, mean ± SD:** **G1+ G2:** 39.8 ± 1.2 **Age, days at intervention, range:** **G1+ G2:** 1-21 **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Nipple pain **Other characteristics:** family history in first degree relatives, n: **G1+ G2:** 4/25 Gestational weight: 3205 g (SD +/- 830) **Type of ankyloglossia, n:** Tongue protusion beyond alveolar ridge **G1+ G2:** 3/25 No tongue protrusion beyond alveolar ridge **G1+ G2:** 22/25 Anterior crease of tongue **G1+ G2:** 15/25 **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** Breastfeeding pain or nipple trauma (standard visual analog pain scale up to 10 points) mean ± SD **G1+ G2:** 7.1 ± 1.9 **Infant:** Breastfeeding latch score (LATCH score), mean ± SD **G1+ G2:** 6.4 ± 2.3 **Child:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** Breastfeeding pain or nipple trauma, mean ± SD **G1+ G2: 5.3** ± 2.2 p=0.001 compared to baseline **Infant:** Breastfeeding latch score (LATCH score), mean ± SD **G1+ G2:** 6.8 ± 2.0 p=0.06 compared to baseline **Child:** NR **Need for reoperation:** NR **Harms:** Mentioned no unexpected bleeding **Harms Details:** Authors reported no significant side effects and bleeding (a few drops) was controlled within seconds in all cases. Infant crying lasted a few seconds. **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Edmunds, et al., 2013[12] **Country:** Australia **Enrollment period:** NR **Funding:** None and no conflicts of interest **Study Design:** Case series	**Intervention:** Phenomenological study of breastfeeding mothers; first interview at diagnosis and follow-up interview 2 weeks later 7/10 underwent frenotomy **Groups:** **G1:** Intervention **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Public health service breastfeeding clinic **Treatment duration:** NA **Last followup post-treatment:** 2 weeks **N at enrollment:** **G1:** 10 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Infants initially diagnosed with tongue-tie **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** G1: 3 days-3 weeks **Age, days or months at intervention, mean ± SD:** NR **Gender, n (%):** NR **Race/ethnicity:** NR **Indication for therapy, n (%):** **G1:** NR **Other characteristics:** Family history: **G1:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** Breastfeeding concerns/difficulty **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Emond, et al., 2013[13] **Country:** UK **Enrollment period:** October 2011 to June 2013 **Funding:** NIHR (part of NHS) **Study Design:** RCT	**Intervention:** Frenotomy **Note:** Control group were offered frenotomy after 5 days **Groups:** **G1:** Intervention **G2:** Usual care control **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies, n (%):** NR **Setting of therapy:** Hospital clinic **Treatment duration:** NR **Last followup post-treatment:** Followup at 5 days, and then 8 weeks post-treatment **N at enrollment:** **G1:** 55 **G2:** 52 **Consultation with lactation consultant, (%):** **G1:** Yes (100) **G2:** Yes (100)	**Inclusion criteria:** • Term babies with a tongue-tie experiencing breast feeding problems • HATLFF score between 6-12 and LATCH score ≤ 8 **Exclusion criteria:** • Infant age ≥ 2 weeks old • Prematurity < 37 weeks • Congenital orofacial malformations • Infant weight loss (> 10% of birth weight) • Severe tongue-tie (HATLFF < 6) offered immediate frenotomy **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at 5 day followup, median (IQR):** **G1:** 11 (8-14) **G2:** 11 (8-16) **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding difficulties **Other characteristics:** Family history: NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal:** Breastfeeding pain, nipple excoriations, low milk supply, breast feeding cessation, etc (specify method and results, mean, median, %) **G1:** NR **G2:** NR **Infant:** Feeding method at assessment, n (%) Bottle **G1:** 1 (1.8) **G2:** 0 Bottle and breast **G1:** 10 (18.2) **G2:** 5 (9.6) Breast only **G1:** 44 (80) **G2:** 47 (90.4) OR 2.35 (0.76 to 7.31) p= 0.13 **Child:** **G1:** NR **G2:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal, median (IQR):** At 5 days followup Pain VAS score: **G1:** 3 (1-4.3) **G2:** 3 (2-6) **G1 vs G2:** p= 0.13 Change between baseline and 5 days Pain VAS score: **G1:** -2 (-3 to 0.4) **G2:** -1 (-13.5 to 1) **G1 vs G2:** p< 0.09 At 8 week follow-up Pain Visual Analogue Scale score (VAS): **G1:** 0 (0) **G2:** 0 (0-1) **G1 vs G2:** p= 0.41 Change between 5 days and 8 weeks Pain VAS score: **G1:** -2 (-3 to -1) **G2:** -1 (-3.5 to -0.61) **G1 vs G2:** p< 0.83 **G1:** NR **G2:** NR **G3:** NR **Infant, median (IQR):** At 5 days follow-up LATCH score: **G1:** 9 (8-10**)** **G2:** 9 (8-10) **G1 vs G2:** p= 1.0 IBAT score: **G1:** 12 (11-12**)** **G2:** 12 (11-12) **G1 vs G2:** p= 0.76 Self-efficacy score: **G1:** 54 (43-62**)** **G2:** 53 (40.8-61) **G1 vs G2:** p= 0.53 HATLFF score: **G1:** 13.5 (11-16) **G2:** 8 (7-11)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				G1 vs G2: p< 0.0001 **Change in scores between baseline and 5 days** **From 0-5 days:** HATLFF score **G1:** 4.5 (3.3 to 6) **G2:** 0 (0 to2.3) **G1 vs G2:** p< 0.0001 LATCH score: **G1:** 1 (0 to2**)** **G2:** 1 (0 to 2) **G1 vs G2:** p= 0.52 IBAT score: **G1:** 0 (-1.8 to1.0) **G2: 0** (0-1) **G1 vs G2:** p= 0.36 Self-efficacy score (BSES-SF): **G1:** 9 (1.8 to 12.3) **G2:** 1 (-4 to 7.5) **G1 vs G2:** p= 0.0002 **Feeding method, n (%):** Bottle: **G1:** 5 (9.4) **G2:** 8 (15.5) Bottle and breast: **G1:** 13 (24.5**)** **G2:** 6 (11.5) Breast only: **G1:** 35 (66**)** **G2:** 38 (73) OR 1.40 (0.60 to 3.22) p= 0.43 At 8 week follow-up LATCH score: **G1:** 10 (10-10) **G2:** 10 (10-10) **G1 vs G2:** p= 0.41 IBAT score: **G1:** 12 (12-12) **G2:** 12 (12-12) **G1 vs G2:** p= 0.58 Self-efficacy score (BSES-SF): **G1:** 63 (59-68) **G2:** 63 (57-69) **G1 vs G2:** p= 0.62

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				Infant weight, kg: **G1:** 5 (5-6) **G2:** 5 (5-6) **G1 vs G2:** p= 0.54 **Change in scores between 5 days and 8 weeks:** Self-efficacy score (BSES-SF): **G1:** 3 (0 to 13) **G2:** 10 (2 to 18) **G1 vs G2:** p= 0.082 **Feeding method, n (%):** Bottle: **G1:** 9 (17.3) **G2:** 10 (20) Bottle and breast: **G1:** 13 (25) **G2:** 8 (116) Breast only: **G1:** 30 (57.7) **G2:** 32 (64) OR 1.30 (0.59 to 2.89) p= 0.51 **Child:** **G1:** NR **G2:** NR **Need for reoperation, n (%):** **G1+G2:** 4/99 (4) **Harms:** No adverse events reported **Harms Details:** Small white patch at base of frenulum reported at 5 days, took median 7 days to heal (range 1-30) **G1+ G2:** 63 (64) **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Finigan, 2014 [14] **Country:** UK **Enrollment period:** Oct 2007 to Sept 2012 **Funding:** NR **Design:** Case series (retrospective audit)	**Intervention (description):** Ffrenulotomy: No description **Groups, n (%)** **G1:** intervention **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies, n (%):** NR **Setting of therapy:** Hospital clinic **Treatment duration:** NR **Last follow-up post-treatment:** varied **N at enrollment:** **G1:** 2590 **N at 3 month follow-up:** **G1:** 21% **Consultation with lactation consultant, n (%):** **G1:** NR	**Inclusion criteria:** Parents who chose frenulum division surgery **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1:** NR **Age, days or months at intervention, mean ± SD:** **G1:** NR **Gender, n (%):** NR **Race/ethnicity:** **G1:** NR **Indication for therapy:** NR **Other characteristics:** NR **Type of ankyloglossia:** Anterior, n (%): **G1:** NR Posterior, n (%): **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Breastfeeding pain, nipple excoriations, low milk supply, breast feeding cessation, etc **G1:** NR **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Reported immediate improvement in feeding (likert 1-10 scale) **G1:** 96% No improvement (included babies who were asleep, mothers with low milk supply and mothers with very sore nipples) **G1:** 4% 24-48 hour telephone follow-up Reported improvement in feeding **G1:** 71% No improvement (majority in this category did not respond to call) **G1:** 29% 3 month follow-up Continued to breastfeed **G1:** 43% (of the 21% who responded) Moved to bottle feeding, n=5 Mixed feed, n=12 **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. **G1:** NR **Need for reoperation:** **G1:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				Harms: NR **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Fiorotti et al., 2004[15] **Country:** Brazil **Enrollment period:** NR **Funding:** FAEP/FCM-UNICAMP, CAPES **Design:** Case series	**Intervention:** Stretched tongue upward during the application of the CO2 laser so that depth of incision could be controlled. CO2 laser applied (with 2mm spot size applied continuously at 6W and with an intensity of 191W/cm2) perpendicular to the lingual frenulum and the fibrous cord was vaporized. **Groups:** **G1:** Frenectomy using carbon-dioxide laser **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** Yes: 1) 10% lidocaine spray, 2) 1.8 ml of 2% lidocaine without vasoconstrictor into mobile portion of frenulum near tip of tongue and into fixed portion in the lingual region of inferior incisors **Other non-surgical therapies:** **G1:** speech therapy (some had speech therapy before surgery, n not reported) **Setting of therapy:** Outpatient ENT clinic **Treatment duration minutes, mean ± SD (range):** **G1:** 16 ± 2.80 (15-25) **Last follow-up post-treatment:** 15 days after surgery **N at enrollment:** **G1:** 15 **N at follow-up:** **G1:** 15 **Consultation with lactation consultant:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age (years) at intervention, mean ± SD (range):** **G1:** 6.89 ± 3.38; (2-15) **Gender, n:** Male: **G1:** 10 Female: **G1:** 5 **Race/ethnicity:** NR **Indication for therapy:** Respiration abnormality; difficulties in speech sounds; damaging oromyofunctional habits (thumb sucking, pacifier sucking), inadequate postural habits or discomfort during feeding **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** Speech-articular alterations: yes=10; no=5 Breathing: G1: Nasal: 9 Buccal:5 Mixed: 1	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** greater control and motor capacity of tongue reported by those with prior speech therapy (NOT QUANTIFIED) Speech therapy improved tongue mobility **Recovery of normal habits with (days) mean ± SD (range):** **G1:** 4.2 ± 0.77 (4–7) **Need for reoperation:** **G1:** NR **Harms:** None **Harms Details:** NA **Timing of harms:** Immediate & 15 days after

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Geddes et al., 2008 [16] **Country:** Australia **Enrollment period:** NR **Funding:** Medela AG **Design:** Case series	**Intervention:** Frenulotomy: lifted tongue with fingers to examine frenulum and ensure it was thin and devoid of blood vessels. Using sterile iris scissors, small cut made at anterior portion of frenulum extending just past the genioglossus muscle. Infant encouraged to breastfeed after procedure **Groups:** **G1:** intervention **Type of professional performing treatment:** Pediatric surgeon **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Breastfeeding clinic **Treatment duration:** NA **Last follow-up post-treatment, days mean ± SD (range):** **G1:** 13 ± 6 (7-29) **N at enrollment:** **G1:** 24 **N at follow-up:** **G1:** 24 **Consultation with lactation consultant, (%):** **G1:** Yes (100)	**Inclusion criteria:** • Mothers with healthy full term infants experiencing breastfeeding difficulties • Received breastfeeding advice and follow-up but not resolved **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD:** **G1:** 33 ± 28 **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding difficulties **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR 2 of the mothers not in lactation	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal mean ± SD:** LATCH score **G1:** 7.9 ± 1.4 Pain score **G1:** 3.6 ± 3.0 Nipple shield, n **G1:** 4/24 **Twenty-four hour milk production, measured by test-weigh method, mean** **G1:** 409 (n=8) **Infant mean ± SD:** Milk intake **G1:** 50.5 ± 29.1 g Milk transfer, mL/min **G1:** 5.6 ± 3.0 g **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal mean ± SD:** LATCH score **G1:** 9.4 ± 0.8 p<0.05 Pain score **G1:** 0.5 ± 1.2 p<0.05 Nipple shield, N **G1:** 1/24 **Twenty-four hour milk production, measured by test-weigh method, mean** **G1:** 615 (n=8) **Duration of breastfeeding, months mean ± SD** **G1:** 11.3 ± 5.2 (n=16) **Infant:** Milk intake **G1:** 69.1 ± 31.9 g p<0.01 Milk transfer, mL/min **G1:** 10.5 ± 5.5 g p<0.01 **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No complications reported **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Godley et al., 1994[17] **Country:** USA **Enrollment period:** 10/1988 to 2/1992 **Design:** Case series	**Intervention:** Frenulum divided horizontally below the undersurface of the tongue, a buccal mucosal graft harvested and the graft sutured into the sublingual wound **Groups:** **G1:** Frenuloplasty with Full thickness Buccal Mucosal Graft **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** Yes (General) **Other non-surgical therapies:** NR **Setting of therapy:** Hospital **Treatment duration:** 1 hour **Last follow-up post-treatment:** 3-4 months after surgery **N at enrollment:** **G1:** 15/17 with ankyloglossia **N at follow-up:** **G1:** 15 with ankyloglossia **Consultation with lactation consultant:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, mean (range):** **G1:** 8 (1-35) **Gender, n (%):** Male: **G1:** 10 (58.8) Female: **G1:** 7 (41.2) **Race/ethnicity:** NR **Indication for therapy:** Diagnosis of ankyloglossia **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR*	**Length of lingual frenulum when tongue is lifted (mm), mean:** **G1:** 3.7 mm **Maternal:** **G1:** NR **Infant:** **G1:** Restricted tongue mobility **Child:** **G1:** Restricted tongue mobility	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** Mobility of the tongue improved **Child:** **G1:** Mobility of the tongue improved **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details:** **G1:** 3 minor post- operative complications Graft loss=1 Swollen delayed graft take=1 Wound dehiscence=1 Wound cicatrization=3 **Timing of harms:** Immediate & 3-4 months After surgery

Comment: * 2/17 with short maxillary labial frenulum

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Griffiths et al., 2004[18] **Country:** UK **Enrollment period:** 12/1999 to 12/2001 **Funding:** NR **Design:** Prospective case series	**Intervention:** Tongue tie put on the stretch with left index finger while holding the lower lip clear with left thumb. The tie was divided completely with sharp, blunt-ended, sterile scissors, and the floor of the mouth was compressed with a paper towel or gauze. **Groups:** **G1:** Simple division of tongue-tie **Type of professional performing treatment:** Neonatal, pediatric surgeon **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient **Treatment duration:** Days / weeks **Last follow-up post-treatment:** 3 months after Rx **N at enrollment:** **G1:** 215 **N at follow-up:** **G1:** 215 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Infants younger than 3 months with a tongue tie and mother wanting to breastfeed but experiencing difficulty despite professional support. **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, days or months at intervention:** **G1:** 19 days **Gender:** Male/ Female ratio: 2:1 **Race/ethnicity:** NR **Indication for therapy:** 192/215 (88%) of infants had difficulty latching 167 (77%) mothers had painful, sore, or bleeding nipples 156 (72%) had “continuous” feeding cycle 112 (52%) had all three **Other characteristics:** Family history of tongue-tie: 44% 111 had tried bottle-feeding—either expressed breast milk (n = 104) or formula (n = 7)—of whom 85 (76%) had found it easy. Tongue-tie parameters, n (%): **G1:** Thickness Diaphanous 138 (64) Medium 59 (27) Thick 20 (9) Shape, n (%): Dimple 112 (52) Heart 88 (41) Pointed 17 (7) Percentage of tongue	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** Painful, sore, or bleeding nipples: 167 (77%) Mother-infant pairs with all 3 symptoms: 112 (52) Expressing and cup- or bottlefeeding: 104 (48) Use of nipple shield with professional guidance: 95 (44%) **Infant:** **G1:** Difficulty in latching on to the breast: 192/215 (88%) Those with a “continuous” feeding cycle: 156 (72) **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** Feeding postdivision, mean (%): 83 (70) breastfed for 3 months 92 (43) felt no immediate difference 32/53 mothers of awake infants (60) breastfed for 3 months. 173 (80%) feeding better by maternal assessment at 24 hours. 40 (19) Unchanged feeds 2 Increased difficulty feeding **At 3 months post division, n (%):** **G1:** Breastfed for at least 3 months: 138 (64) Breastfed for 6 to 12 weeks after division: 11 (5) Fed for less than 6 weeks: 68 (32) 72 (37%) had not started solids “Awful feeders” on breast, bottle, and with solids: 2(1) **Tongue extension:** **G1:** Yes: 204 (95) No: 4 (2 breastfed for 3 months)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		anchored by tissue, n (%) 100 124 (57) 75 54 (25) 50 26 (12) 25 11 (5) Overall 215 (100) **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR		**Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details:** **G1:** No serious complication. An increased cry after division: 128 (60) Duration of cry, n (%): 5 seconds or less: 56 (44) 20 seconds or less: 183 (85) More than 1 minute: 2 (1) Mean duration of cry: 15 seconds, median: 10 seconds Bleeding: Few drops of blood: 113 (52) Any bleeding: 131 (61) Small amount: 18 (9) Ulcer under the tongue > 48 hours: n=4 Mild complication: 6 (3) **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Heller et al., 2005[19] **Country:** USA **Enrollment period:** 1999 to 2003 **Funding:** NR **Design:** RCT	**Intervention:** 4-Flap Z-Frenuloplasty: 2 flaps were marked on one side at the tip of the tongue, and 2 more on the other side at the tongue base. After incisions made, flaps were transposed and then sutured. Horizontal- to-vertical frenuloplasty: Scissors were used to separate the deep tissue to release the tight muscular layers, and hemostasis was achieved with a Bovie cauterizer. With retraction of the single hook, the horizontal wound was converted to a vertical wound that was closed with interrupted 4–0 chromic sutures. **Groups:** **G1:** 4-Flap Z-Frenuloplasty **G2:** Horizontal- to-vertical frenuloplasty **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Yes **Other non-surgical therapies:** Discussion section also notes “exercises” were prescribed **Setting of therapy:** Multidisciplinary team at the Cleft Lip and Palate–Craniofacial Clinic **Treatment duration:** NR **Last follow-up post-treatment:** **G1:** 1.3 years (10-35 months) **G2:** 1.5 years (10-41 months) **N at enrollment:** **G1:** 11 **G2:** 5	**Inclusion criteria:** had a tight frenulum <15 mm Had articulation and speech problems related to the tongue-tie Older than 3 years of age **Exclusion criteria:** developmental delay were syndromic, or had significant oral pathology **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD :** **G1:** 5.7 ± 2.14 **G2:** 5.56 ± 1.52 **Gender, n (%):** Male: **G1:** 7 (77.8) **G2:** 2 (22.2) Female: **G1:** 4 (57.1) **G2:** 3 (42.9) **Race/ethnicity:** NR **Indication for therapy:** Articulation & Speech problems **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean ± SD:** **G1:** 11.9 ± 6.1 mm **G2:** 11.4 ± 3.36 mm **Maternal:** **G1:** NR **G2:** NR **Infant:** **G1:** NA **G2:** NA **Child:** Tongue protrusion: **G1:** -0.64 ± 1.91 mm **G2:** -0.6 ± 1.14 mm Articulation difficulties, n (%): Severe: **G1:** 6 (55) **G2:** 3 (60) Moderate articulation difficulties: **G1:** 5 (45) **G2:** 2 (40)	**Length of lingual frenulum when tongue is lifted (cm), mean ± SD:** **G1:** 49.4 ± 16.6 mm **G2:** 22.6 ± 7.02 mm **Maternal:** **G1:** NR **G2:** NR **Infant:** **G1:** NA **G2:** NA **Child:** Mean Frenulum length Gain: **G1:** 37.5 **±** 13.5 mm, (increase of 315% from the baseline mean), p<0.0001 **G2:** 11.2 ± 4.5 (increase of 98% from baseline mean), p<0.02 Tongue protrusion: **G1:** 35.54 ± 9.03 mm **G2:** 12.6 ± 1.7 Mean tongue protrusion Gain: **G1:** 36.2 ± 7.2 mm (p<0.0001) **G2:** 13.2 ± 2.6 mm (p=0.0003) **Speech/articulation, n (%):** Significant improvement in articulation errors of at least 2 orders: **G1:** 10 (91) **G2:** 0 One order of improvement: **G1:** 0 **G2:** 2 (40) Complete resolution of

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at follow-up: **G1:** 11 **G2:** 5 **Consultation with lactation consultant:** NR			speech problems: **G1:** 7 (64) **G2:** 0 No improvement in speech: **G1:** 1 (9) **G2:** 3 (60) **Need for reoperation:** **G1:** NR **G2:** NR **Harms:** None **Harms Details:** NA **Timing of harms:** Surgical or post-operative

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Hogan et al., 2005[20] **Country:** UK **Enrollment period:** March 2002 to July 2002 **Funding:** NR **Design:** RCT	**Intervention:** Tongue-tie division: tongue-tie put on a stretch with left index finger while holding lower lip clear with left thumb. Tie divided completely with sharp blunt end sterile scissors and floor of mouth compressed with gauze. Returned to mother for feeding after the procedure. Control group received intensive support, advice and help from lactation consultants. If no improvement after 48 hours they were offered division. **Groups:** **G1:** tongue-tie division **G2:** breastfeeding control group **Type of professional performing treatment:** lactation consultants, pediatric surgeon **Anesthesia used in surgical intervention:** None used **Other non-surgical therapies:** List reported by group **Setting of therapy:** Outpatient **Treatment duration:** NA **Last follow-up post-treatment:** Telephone follow-up at 24 hours, weekly for 4 weeks and after 4 months **N at enrollment:** **G1:** 28 **G2:** 29 **N at follow-up:** **G1:** 28 **G2:** 29 **Consultation with lactation consultant, n (%):** **G1:** 28 (100) **G2:** 29 (100)	**Inclusion criteria:** • Infants born with tongue-tie during 5 month period • Feeding problems **Exclusion criteria:** • Wanted immediate division • Feeding problems resolved **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at randomization, mean (range):** **G1:** 20 **G2:** 18 **G1+ G2:** (3-70) **Gender, n (%):** Male: **G1:** 14 **G2:** NR Female: **G1:** 14 **G2:** NR **Race/ethnicity:** NR **Indication for therapy, n (%):** Breastfed babies Latching problems **G1:** 17 (85) **G2:** 16 (80) Sore nipples **G1:** 16 (80) **G2:** 16 (80) Continuous feeds **G1:** 9 (45) **G2:** 12 (60) Top-up feeds **G1:** 6 (30) **G2:** 8 (40) Bottle-fed Slow bottle feeds **G1:** 5 (62) **G2:** 8 (88) Dribbling **G1:** 5 (62)	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** Length of tongue tie, n: **25%:** 5 breast fed and 1 bottlefed **50%:** 11 breast fed and 2 bottlefed **75%:** 9 breast fed and 6 bottlefed **100%:** 15 breast fed and 8 bottlefed **Maternal:** Painful, damaged nipples, n (%) **G1+ G2:** 32/40 (80) Mastitis **G1+ G2:** 6/40 (15) **Infant:** Breastfeeding latch problems, n (%) **G1+ G2:** 33/40 (82) **Child:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** **G1:** NR **G2:** NR **Infant:** Improvement in feeding, n (%) **G1:** 27/28 (96) **G2:** 1/29 (3) The remaining 28 mothers in G2 all requested tongue-tie division. Following this 27/28 improved. **Child:** NR **Need for reoperation:** NR **Harms:** Yes **Harms Details:** No problems with infection or bleeding, either primary or secondary **Timing of harms:** immediate

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G2: 7 (77) Excess wind **G1:** 2 (25) **G2:** 2 (25) **Other characteristics:** Breastfeeding **G1:** 20 **G2:** 20 Bottle feeding **G1:** 8 **G2:** 9 **Type of ankyloglossia:** See length of tongue tie **Ankyloglossia with concomitant lip tie:** NR		

Comment: Authors noted most babies cried for only a few seconds until they were given a feed.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Hong et al., 2010 [21] **Country:** US **Enrollment period:** July 2007 to July 2009 **Funding:** NR **Design:** Case series, retrospective	**Intervention:** Frenotomy **Groups:** **G1:** intervention **Type of professional performing treatment:** Pediatric ENT **Anesthesia used in surgical intervention:** Yes (20% Benzocaine topical) **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient pediatric ENT clinic **Treatment duration:** Days / weeks **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 341 **G1a:** 322 anterior **G1b:** 19 posterior **N at follow-up:** **G1:** 341 **Consultation with lactation consultant, (%):** **G1:** Yes (80)	**Inclusion criteria:** • Patients seen in pediatric ENT clinic for ankyloglossia (identified using ICD.9 code for ankyloglossia and CPT code for outpatient frenotomy **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, weeks at presentation, median (range):** **G1:** 2.7 (1 day to 24 weeks) **Gender, n (%):** **G1a:** Male: 221 (68.6) Female: 101 (31.4) **G1b:** Male: 7 (36.8) Female: 12 (63.2) **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding **G1b:** 89% nipple pain **G1b:** 84% latching on difficulties **G1b:** 80% prolonged feeds **G1b:** 16% (n=3) poor weight gain **Other characteristics:** NR **Type of ankyloglossia:** Anterior, n: **G1a:** 322 Posterior, n: **G1b:** 19 **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR Improved breastfeeding noted. **Child:** **G1:** NR **Need for reoperation:** Revision procedure, n (%) **G1a:** 12 (3.7) **G1b:** 4 (21.1) **G1a vs G1b:** p=0.008 **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Khoo et al., 2009 [22] **Country:** UK **Enrollment period:** June 2007 to July 2008 **Funding:** NR **Design:** Case series	**Intervention:** Frenulotomy: tongue tie put on a stretch using sterile notched tongue elevator and divided using curved blunt strabismus scissors **Groups:** **G1:** intervention **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** None Required **Other non-surgical therapies:** Reviewed in the clinic after appropriate intervention from qualified lactation consultants had failed to improve feeding difficulties **Setting of therapy:** TBD clinic in hospital **Treatment duration:** Days / weeks **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 62 **N at follow-up:** **G1:** 62 **Consultation with lactation consultant, (%):** **G1:** Yes (100)	**Inclusion criteria:** • Intervention from qualified lactation consultant failed to improve feeding difficulties • Symptomatic tongue-tie confirmed on examination **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD (%):** **G1:** < 90 days (100) **G1:** 23.5 ± 17.1 **Gender, n (%):** Male: **G1:** 42 (68) Female: **G1:** 20 (32) **Race/ethnicity:** NR **Indication for therapy, n (%):** Poor latch **G1:** 52 (84) Prolonged jaundice **G1:** 6 (11) Noisy feeding **G1:** 39 (63) Infant frustration **G1:** 50 (81) Infant not satisfied after feed **G1:** 27 (44) (e.g., breastfeeding, other feeding issues, speech, psychosocial) **Other characteristics, n (%):** Family history: **G1:** 19 (33) **Type of ankyloglossia, n (%):**	**Length of lingual frenulum when tongue is lifted:** 25% of tongue, n (%): **G1:** 7 (22) 50% of tongue, n (%): **G1:** 19 (30) 75% of tongue, n (%): **G1:** 15 (24) To tip of tongue, n (%): **G1:** 21 (34) **Maternal, n (%):** Nipple pain **G1:** 52 (84) Nipple trauma **G1:** 32 (52) **Infant mean ± SD:** Number feeds per day **G1:** 7.4 ± 2.4 Length of feed (minutes) **G1:** 41.6 ± 27.5 Time between feeds/min **G1:** 161.1 ± 44.3 Overall difficulty (0 to 10 scale) **G1:** 6.1 ± 2.7 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** NR **Infant:** Number feeds per day **G1:** 6.4 ± 1.5 p< 0.005 Length of feed (minutes) **G1:** 24.1 ± 17.4 p< 0.001 Time between feeds/min **G1:** 197.0 ± 45.3 p< 0.001 Overall difficulty (0 to 10 scale) **G1:** 1.9 ± 2.6 p< 0.001 **Child:** **G1:** NR **Need for reoperation:** NR **Harms:** Minor bleeding **Harms Details:** NA **Timing of harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		Movement Able to protrude tongue beyond lower gum line **G1:** 18 (31) Able to elevate tongue **G1:** 15 (24) **Ankyloglossia with concomitant lip tie:** NR		

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Klockars et al., 2009[23] **Country:** Finland **Enrollment period:** 1996 to 2006 **Funding:** No financial conflict of interest **Design:** Case series	**Intervention:** Frenotomy / Frenuloplasty procedure not described **Groups:** **G1:** intervention **G1a:** 1-23 months **G1b:** 2-5 years **G1c:** 6-12 years **G1d:** 13-18 years Frenotomy (no or local anesthesia), n (%) **G1:** 100/296 (34) **G1a:** 32/67 (48) **G1b:** 43/143 (30) **G1c:** 22/74 (30) **G1d:** 3/12 (25) Frenotomy (general anesthesia) **G1:** 46/296 (16) **G1a:** 14/67 (21) **G1b:** 21/143 (15) **G1c:** 9/74 (12) **G1d:** 2/12 (17) Frenuloplasty (no or local anesthesia) **G1:** 15/296 (5) **G1a:** 1/67 (1) **G1b:** 1/143 (1) **G1c:** 6/74 (8) **G1d:** 7/12 (58) Frenuloplasty (general anesthesia) **G1:** 135/296 (46) **G1a:** 20/67 (30) **G1b:** 78/143 (55 **G1c:** 37/74 (50) **G1d:** 0/12 (0) **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Varied **Other non-surgical therapies:** List reported by group **Setting of therapy:** NR **Treatment duration:** NR **Last follow-up post-treatment:** Varied. See age at query	**Inclusion criteria:** • Children who received frenotomy or frenuloplasty because of tongue-tie identified from hospital records based on WHO ICD code Q38.1 and NOMESCO classification (surgical procedure EJC20) **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, median (range):** **G1:** 4 (newborn to 18) **Age, years at query, median (range):** **G1:** 11 (9 months to 27) **Gender, n (%):** Male: **G1:** 216 (68) Female: **G1:** 101 (32) **Race/ethnicity:** NR **Indication for therapy, n (%):** Speech/articulation problems **G1:** 101/159 (64) Restricted movement **G1:** 28/159 (18) Lactation/nutrition problems **G1:** 13/159 (8) Different combinations of speech and nutrition problems **G1:** 8/159 (5) **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** Benefit (from operation) type not specified **Infant:** **G1:** Benefit (from operation) type not specified **Child:** Benefit from operation: (Type not specified) **Maternal/Infant/child, n (%):** Benefit from surgery: **G1:** 133/159 (84 %) probable or partial benefit: 9 No benefit from operation: **G1:** 7/159 (4%) Could not estimate possible benefit: **G1:** 19/159 (12%) **Need for reoperation, n:** **G1:** 48/317 including 4 who had 3 surgeries and 1 who had 4 By type of initial procedure and age group, n (%) Total, n (%) **G1:** 31/296 (10) **G1a:** 4/67 (6) **G1b:** 14/143 (10) **G1c:** 12/74 (16) **G1d:** 1/12 (8) Frenotomy (no or local anesthesia), n (%) **G1:** 29/100 (29)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at enrollment: **G1:** 317 **N at follow-up:** **G1:** 296 (information available for initial operation technique and anesthesia use) **Consultation with lactation consultant:** NR			**G1a:** 4/32 (13) **G1b:** 13/43 (30) **G1c:** 12/22 (55) **G1d:** 0 (0) Frenotomy (general anesthesia) **G1:** 1/46 (2) **G1a:** 0/14 (0) **G1b:** 0/21 (0) **G1c:** 0/9 (0) **G1d:** 1/2 (50) Frenuloplasty (no or local anesthesia) **G1:** 1/15 (1) **G1a:** 0/1 (0) **G1b:** 1/1 (100) **G1c:** 0/6 (0) **G1d:** 0/7 (0) Frenuloplasty (general anesthesia) **G1:** 0/135 (0) **G1a:** 0/20 (0) **G1b:** 0/78 (0) **G1c:** 0/0 (0) **G1d:** 0 (0) **Harms:** No immediate or long term postoperative effects Nearly 1/3 of patient operated on under local/no anesthesia needed reoperation **Harms Details:** N/A **Timing of harms:** N/A

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Lalakea et al., 2003[24] **Country:** USA **Enrollment period:** 3/1997 to 7/2000 **Funding:** NR **Design:** Prospective case series (Part II of study)	**Intervention:** Horizontal to vertical frenuloplasty with acetaminophen 650mg for analgesia as needed followed with a series of tongue mobility exercises for 1 month after surgery **Groups:** **G1:** Frenuloplasty **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Yes (Local anesthesia) **Other non-surgical therapies:** NR **Setting of therapy: Hospital** (Head and Neck surgery clinic or county hospital) **Treatment duration:** NR **Last follow-up post-treatment:** 3 months post-treatment **N at enrollment:** **G1:** 6/15 (for part II) **N at follow-up:** **G1:** 6 **Consultation with lactation consultant:** **G1:** NR	**Inclusion criteria:** Primary complaint of ankyloglossia Ankyloglossia as an incidental finding (as manifested by restricted tongue mobility and tight frenulum with or without notching of the tongue tip), History of ankyloglossia in adolescence or adulthood **Exclusion criteria:** Coexisting oral pathology that might affect oral mechanics or speech articulation (eg., cleft palate) **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, mean ± SD (range):** **G1:** 17.3 ± 3.2 years (14-23) **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Uncorrected ankyloglossia with speech problems & mechanical limitation such as difficulty licking the lips **Other characteristics:** family history: 8/15 (53%) **Type of ankyloglossia:** Anterior: **G1:** NR Posterior: **G1:** NR Mild: 4/14 Moderate: 9/14 Severe:1/14 **G1:** Frenulum Thin: 8/14 Thick: 6/14 Rolling or curling of tongue: 3/14 **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child:** Tongue protrusion: **G1:** 14.8 mm Tongue elevation: **G1:** 13.7 mm **G1:** Limited tongue motion: 2/6 Notched or heart-shaped tongue: 3/6 (50%) Limitation in Eating ice cream: 2 Licking lips;1 Cleaning teeth:1	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child:**1 month after surgery: Tongue protrusion: **G1:** 24 mm Tongue elevation: **G1:** 26.7 mm **G1:** Tongue protrusion: mean gain : 9.2 ± 8.3 mm ($p<0.05$) Tongue elevation: mean gain of 13 ± 4mm ($p<0.001$) Side-to side motion of tongue: normal (100%) Persistence of notching of tongue tip: 3 (100%) Gains in, n (%): Eating ice cream: 4 (67) Licking lips: 6 (100) Cleaning teeth:4 (67) Kissing: 3/3 (100) Play wind instrument: 1/2 (50) Speech: 2 (33.3) **Need for reoperation:** **G1:** NR **Harms:** No surgical complications Minor pain requiring no or minimal analgesia

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				Harms Details: NA **Timing of harms:** immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Marchesan et al., 2012[25] **Country:** Brazil **Enrollment period:** 2010 **Funding:** NR **Study Design:** Case series	**Intervention:** Frenectomy **Groups:** **G1:** Intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NA **Last followup post-treatment:** 30 days post-treatment **N at enrollment:** **G1:** 10 **N at followup:** **G1:** 10 **Consultation with lactation consultant:** **G1:** NR	**Inclusion criteria:** • Subjects who had never undergone speech therapy or lingual frenulum surgery evaluated by speech-language pathologists • Suspected frenulum alteration • No hearing impairment, mental retardation and/or motor or genetic syndromes • Both lingual frenulum and oral functions altered **Exclusion criteria:** • See above **Age, days or months at first diagnosis:** NR **Age, years at intervention, range:** **G1:** 2-33 **Gender, n (%):** Male: **G1:** 8 (80) Female: **G1:** 2 (20) **Race/ethnicity:** NR **Indication for therapy:** Both lingual frenulum and oral functions altered **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child, n (%):** Shape of tongue altered: **G1:** 6 (60) Speech alteration: **G1:** 8/10 (80)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child, n (%):** Shape of tip of tongue improved **G1:** 6/6 (100) Mouth opening improved during speech **G1**: 6/8 (75) Speech alteration improved **G1:** 4/8 (50) Difficulties in tongue protrusion and cleaning of oral cavity as well as drooling and open mouth were solved after surgery **Need for reoperation:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Comment: Results presented by patient in Table 1. Note two subjects are > age 18.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Masaitis et al., 1996 [26] **Country:** USA **Enrollment period:** 18 months **Funding:** NR **Design:** Prospective case series	**Intervention:** First the lingual frenulum was isolated and then using straight iris scissors, the membranous frenulum was clipped about 1cm. **Groups:** **G1:** Frenotomy **Type of professional performing treatment:** Pediatrician **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Medical center **Treatment duration:** NR **Last follow-up post-treatment:** Within 1st week after procedure and at 3 months **N at enrollment:** **G1:** 36 **N at follow-up:** **G1:** 36 **Consultation with lactation consultant, n (%):** G1: 36 (100)	**Inclusion criteria:** • All Primiparous and multiparous women from Mother-Baby Program with breastfeeding problems (through intraoral exam, maternal breast exam, breastfeeding assessment and verbal history) **Exclusion criteria:** NR **Age, days at first diagnosis:** **G1:** 1- 24 days **Age, days or months at intervention, mean ± SD:** **G1:** 5.7 days (range: 1-24 days); median 3 days **Gender, n (%):** Male: **G1:** 20 (55.6) Female: **G1:** 16 (44.4) **Race/ethnicity:** NR **Indication for therapy, n:** Incidence of indications: 1. Tongue does not cross alveolar ridge (29/36) 2. Heart shaped tongue (29/36) 3. Poor attachment at breast (27/36) 4. Injured nipples (maternal) (27/36) 5. Frenulum attached to tip of tongue (24/36) 6. Previous breastfeeding failure (maternal) 9/36) 7. Inadequate weight gain (7/36) 8. Clicking sound with nursing (4/36) 9. Breast abscess (1/36) 24/36 had same cluster of most frequent occurring items: heart shaped tongue, not able to extend past lower gum line, and injured nipples **Other characteristics:**	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Current feeding method, n (%): Breastfeeding, 1st week: **G1:** 32 (89) 3 months: **G1:** 19 (53) Only 2 mothers who weaned early (2/13) did so owing to continuous difficulty with breastfeeding. Other reasons included: maternal work (n=7), bottle easier (n=3), did not nurse 1st baby (n=3), physician recommendation to supplement with bottle weight gain mother switched (n=1), insufficient milk supply (n=1), frenotomy procedure at 12 days "too late" to reestablish breastfeeding (n=1) Bottle feeding: 1st week: **G1:** 4 (11) 3 months: **G1:** 17 (47) **Infant: G1:** Range of motion of the tongue improved in all 36 infants Range of motion of tongue: Normal: 1st week: **G1:** 33 (92) 3 months: **G1:** 36 (100)

		Family history: 21/36 (58%) had relatives with ankyloglossia Parity: First time mothers: 22/36 Of bottle fed infants at 3 months, 14/17 had frenotomies after 4 days (5 – 24). Of breastfeeding group at 3 months, 16/19 had their frenotomies under age of 4 days **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR		Better than previously: 1 week: 3 (8) 3 months: 0 Problems resolved: Yes, completely: 1 week: **G1:** 27 (75) 3 months: **G1:** 36 (100) Partially: **G1:** 1 week: 7 (19) 3 months: 0 No: **G1:** 1 week: 2 (6) 3 months: 0 Rate of infant growth: appropriate: 1 week: **G1:** 34 (94%) 3 months: **G1:** 36 (100) Slow: 1 week: G1: 2 (6) 3 months: 0 Choosing procedure again if needed at: 1 week: 100% (36/36) 3 months: 100% (36/36) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No complications nor any excessive bleeding **Harms Details:** NA **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Messner et al., 2002[27] **Country:** USA **Enrollment period:** 6/1997 to 6/2001 **Funding:** NR **Design:** Case series	**Intervention:** NR **Groups, n** **G1**: Frenuloplasty (horizontal to vertical) (n=29) OR Frenotomy (n=1) **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** **G1:** Yes General (n=26) Local (n=4) 11/26 had frenuloplasty in conjunction with another procedure **Other non-surgical therapies, n (%):** Tongue exercises for 1 month after surgery **G1:** 20 /24 (83.3) **Setting of therapy:** Otolaryngology clinics **Treatment duration:** NR **Last follow-up post-treatment:** 3.1 months (7 days to 8.5 months) **N at enrollment:** **G1:** 30 **N at follow-up:** **G1:** 28 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • primary complaint of ankyloglossia or if the ankyloglossia was an incidental finding • Tight lingual frenulum with associated feeding, speech or social difficulties or if they were anticipated to develop • aged 1 to 12 years **Exclusion criteria:** • cleft palate, generalized developmental delay **Age, days or months at first diagnosis, mean:** **G1:** 1.9 years (11 diagnosed at < 1 year of age) **Age, days or months at intervention, mean:** **G1:** 4.1 yrs. **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Tight lingual frenulum with associated feeding, speech, or social difficulties **Other characteristics:** Family history: 3/30 (10%) Attempted breastfeed: 25 Unable to breastfeed: 4/25 (3 with Latching problem: 1 with nipple pain) 20/26 parents (child's age 2 or older) reported child's speech adversely affected Difficulty with Ice cream: 7 Difficulty with wind instrument: 1 Difficulty licking lips: 8 Difficulty cleaning teeth: 2 Cuts under tongue: 1 Difficulty with speech: 20 **Type of ankyloglossia:**	**Length of lingual frenulum when tongue is lifted (cm), mean, median** Tongue elevation (measured interincisal distance with mouth maximally open, while maintaining contact of tongue tip with upper dentition): **G1:** 5.2 ± 5.6 mm Tongue Protrusion (maximum protrusion of tongue past lower teeth): **G1:** 14.2 ± 5.5 mm Tongue Mobility: **G1:** 2.3 (on a scale of 1 to 5) **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** Abnormal articulation: **G1:** 11 /15 (73.3%) Speech intelligibility (parent assessment): **G1:** 3.4 (on a scale of 1 to 5)	**Length of lingual frenulum when tongue is lifted (cm), mean, median** Tongue elevation: **G1:** 22 ± 8.7 mm ($p < 0.01$) Tongue Protrusion: **G1:** 25.8 ± 7.8 mm ($p < 0.01$) Tongue Mobility: **G1:** 4.6 (on a scale of 1 to 5), ($p < 0.01$) Mean gain in tongue elevation: **G1:** 17.1 ± 8.5 mm Mean Gain Tongue protrusion: **G1:** 11.3 ± 9.1 mm **Maternal, n (%):** Satisfaction with frenotomy/frenuloplasty: Less than completely satisfied : **G1:** 2/29 (6.9) Very or extremely satisfied: **G1:** 27/29 (93.1) **Infant:** **G1:** NR **Child, n (%):** Improved articulation: **G1:** 9 /11 (82) Persistent articulation difficulties: **G1:** 2 (18) Speech

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		NR **Ankyloglossia with concomitant lip tie:** NR		intelligibility: **G1:** 4.2 (on a scale of 1 to 5), p <0.01 **Need for reoperation:** **G1:** NR **Harms:** No complications observed **Harms Details:** NA **Timing of harms:** Immediate (surgical & postoperative)

Comment: 21/26 children aged 2+ underwent formal speech evaluation 15/21 had documented articulation errors believed to be d/t decreased tongue mobility 6/21 had age appropriate speech. All with abnormal speech were able to protrude tongue past lower incisionrs, with protrusion measurements ranging from 3 – 25 mm (mean 14.9mm). No stat difference between patients with abnormal and normal speech measurements for tongue protrusion or interincisal distance).

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Mettias et al., 2013[28] **Country:** UK **Enrollment period:** May 2010 to June 2011 **Funding:** NR **Study Design:** Case series	**Intervention:** Tongue tie division: Chin depressed with thumb of right hand to open mouth. Frenulum lubricated and numbed with lidocaine gel. Tongue-tie put on a stretch using index and middle fingers and divided using curved blunt scissors. Division completed by blunt fingertip dissection. Baby returned to mother for immediate breast feeding **Groups:** **G1:** Intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** Lignocaine gel 2% **Other non-surgical therapies:** List reported by group **Setting of therapy:** Outpatient clinic **Treatment duration:** NA **Last followup post-treatment:** Telephone questionnaire **N at enrollment:** **G1:** 63 **N at followup:** **G1:** 36 **Consultation with lactation consultant:** **G1:** referred by lactation Average referral time was 7.8 days from delivery	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, weeks at intervention, mean ± SD:** **G1:** 4.1 ± 3.2 **Gender, %:** Male: **G1:** 49.2 Female: **G1:** 50.8 **Race/ethnicity:** NR **Indication for therapy (%):** Difficulty breastfeeding: **G1:** 66.7 Poor growth: **G1:** 11.1 Limitation in tongue movement: **G1:** 22.2 Breast problems including cracking and sore nipples: **G1:** 27.7 Asymptomatic: **G1:** 13.9 **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** See indications for therapy **Infant:** **G1:** See indications for therapy **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Outcomes, n (%):** Preoperative problems were resolved: 36 (96.8) Reported delayed diagnosis and referral time: 9 (25) **Harms:** Yes (for n=36) **Harms Details, n (%):** Infant distress or discomfort (pain form procedure) **G1:** 2 (5.6) Mild bleeding on day of surgery stopped spontaneously: **G1:** 1 (2.8) Ulceration **G1:** 1 (2.8) n=2 mothers couldn't resume breastfeeding. No complications: **G1:** 32 (88.9) **Timing of harms:** NR

Comment: Some results presented in figures only. It is not clear when the follow-up questionnaire was administered.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Miranda et al., 2010 [29] **Country:** UK **Enrollment period:** 8 months **Funding:** NR **Design:** Case series, prospective data collection	**Intervention:** Frenulotomy: surgeon places two fingers on either side of frenulum to open mouth and lift tongue. Sharp sterile scissors used to release the frenulum. Piece of gauze used to absorb any mild sanguinous exudates **Groups:** **G1:** intervention **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** None **Other non-surgical therapies:** NR **Setting of therapy:** outpatient (only for neonates) **Treatment duration:** 30 seconds **Last follow-up post-treatment:** 2 weeks post-procedure **N at enrollment:** **G1:** 62 **N at follow-up:** **G1:** 51 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Diagnosis of ankyloglossia • Breastfeeding difficulty resistant to initial lactation consultant management **Exclusion criteria:** • Non-plastic surgery pediatric patients **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD :** **G1:** 12-36 days **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted::** **G1:** NR **Maternal, n (%):** Nipple pain **G1:** 27/51 (53) Nipple cracking: **G1:** 19/51 (37) Nipple bleeding **G1:** 11/51 (22) **Infant, n (%):** Poor latch: **G1:** 28/51 (55) Breastfeeding sessions/24 hours, mean ± SD: **G1:** 10 ± 0.7 Bottle feeding supplementary sessions/24 hours, mean ± SD **G1:** 9 ± 0.6 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n (%):** Breastfeeding improvements **G1:** (63) Reporting improvements Nipple pain: **G1:** 27/51 (100) Nipple cracking: **G1:** 19/51 (100) Nipple bleeding: **G1:** 11/51 (100) Pain score improvement: **G1:** 83% **Infant:** Weight gain n, (%) **G1:** 51/51 (100) Poor latch improvement **G1:** 28/51 (89) Two weeks post Breastfeeding sessions/24 hours, mean ± SD **G1:** 7 ± 0.5 p< 0.0001 Bottle feeding supplementary sessions/24 hours, mean ± SD **G1:** 2 ± 0.7 p< 0.0001 **Child:** **G1:** Weight gain occurred in 100% (51/51) of neonates at 2 weeks post-frenulotomy, of which 90% (46/51) gained in centile, 6%(3/51) remained at the same centile

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				and 4%(2/51) dropped 7.5 centiles. Neonates therefore gained 15 1.2 centiles (41st-56th) 1.4 males and 18 2.0 for females. **Need for reoperation:** NR **Harms:** No complications **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: O'Callahan et al., 2013[30] **Country:** US **Enrollment period:** December 2006 to March 2011 **Funding:** Middlesex hospital **Study Design:** Case Series	**Intervention:** Frenotomy; Infants swaddled and immobilized. Use of metal grooved elevator held with thumb and index fingers while middle finger maintained pressure on lower gum to keep jaw open (reverse "chop-stick" maneuver). Blunt-tipped curved scissors used to clip thin diaphanous membrane if present, mucosa at thinnest part of frenular protrusion near underside of tongue, and shiny white submucosal band if present. Maxillary frenotomy consisted of lifting infant lip with gauze and clipping parallel to gum with wide clamp and then cutting through crushed tissue. Hemostasis achieved by applying direct pressure using gauze for 2-4 minutes **Groups:** **G1:** Intervention **Type of professional performing treatment:** Pediatrician **Anesthesia used in surgical intervention:** Yes topical 20% benzocaine and three drops of 22% sucrose; NOTE: use of benzocaine no longer recommended in children under 2 as of April 2, 2011 **Other non-surgical therapies:** NA **Setting of therapy:** Pediatric clinic	**Inclusion criteria:** • Women whose infants underwent frenotomy asked to complete web-based questionnaire between December 2010 and May 2011 **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean (range):** **G1:** 35 (2-332) Age 2-30 days, n (%) **G1:** 131 (44) **G1a:** 60 (38) **G1b:** 71 (50) 31-60 days **G1:** 89 (30) **G1a:** 54 (35) **G1b:** 35 (25) 61-90 days **G1:** 36 (12) **G1a:** 24 (15) **G1b:** 12 (9) 91 to 323 days **G1:** 43 (14) **G1a:** 19 (12) **G1b:** 24 (17) **Gender, n (%):** Male: **G1:** 162 (51) **G1a:** 80 (51) **G1b:** 82 (58) Female: **G1:** 137 (49) **G1a:** 77 (49) **G1b:** 60 (43) **Race/ethnicity:** NR **Indication for therapy:** NR **Other characteristics:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal , n (%):** Mother sought breastfeeding consultation prior to frenotomy evaluation **G1a:** 153 (98) Maternal breastfeeding difficulties prior to frenotomy (i.e.nipple skin damage and/or bleeding, misshapen nipple, compression/stripe mark on nipple after breastfeeding, low milk supply, plugged ducts, and/or mastitis): **G1a:** 146 (93) **Infant, n (%):** Breastfeeding difficulties prior to frenotomy evaluation (i.e.latching issues, poor weight gain, weight loss, prolonged feedings, use of a bottle, chewing or lipsticking, and/or clicking sounds while nursing): **G1a:** 156 (99) Nipple pain **G1a:** 118 (75) Latching problems **G1a:** NR **Child:** Speech difficulty: **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal :** Exclusive breastfeeding post intervention, % **G1a:** 92 Duration months mean ± SD, (range) **G1a:** 14 ± 10.2 (0.5-54) Note n=46 did not provide duration data **Infant , n (%):** No nipple pain:: **G1a:** 64% P< 0.001 compared to baseline **Child:** **G1:** NR **Need for reoperation, n (%):** Multiple frenotomies **G1a:** 43 (27) **Harms, %:** 3 infants required cauterization with silver nitrate for persistent oozing No complications or negative side effects **G1a:** 94 Undergoing frenotomy was worth the emotional and physical discomfort to mother and infant **G1a:** 93 **Harms Details:** NA **Timing of harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	Treatment duration: **G1:** NA **Last followup post-treatment:** Varied **N at enrollment:** **G1:** 299 Survey respondents, n: **G1a:** Yes, 157 **G1b:** No, 142 **Consultation with lactation consultant:** NR	**Type of ankyloglossia:** Anterior, (Type 1 and Type 2), n (%): **G1:** 47 (16) **G1a:** 18 (12) **G1b:** 29 (20) Type III, n (%): **G1:** 107 (36) **G1a:** 52 (33) **G1b:** 55 (39) Type IV, n (%) **G1:** 145 (49) **G1a:** 87 (55) **G1b:** 58 (41) **Ankyloglossia with concomitant lip tie, n (%):** **G1:** 72 (37) **G1a:** 44 (44) **G1b:** 28 (29)		

Comment: Authors reported that half of the infants with latch issues as the presenting problem reported no issues after the intervention (N's were not reported). No new latching issues emerged.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Puthussery et al., 2011 [31] **Country:** UK **Enrollment period:** NR **Funding:** NR **Design:** Case series	**Intervention:** Laser excision: carbon dioxide laser with 10.6 µ.m wavelength and power of 4 W at 25J/cm^2 in continuous mode. Vertical incision made to release frenulum. **Groups, n:** **G1:** intervention, 21 **Type of professional performing treatment:** A single surgeon **Anesthesia used in surgical intervention:** Yes (general or local) for surgery. Also local with 2% lidocaine and 1:80,000 adrenaline infiltrated at the end of surgery for postoperative pain control and patients were discharged with analgesics PRN. **Other non-surgical therapies:** NR **Setting of therapy:** Day stay unit of hospital **Treatment duration:** NR **Last follow-up post-treatment:** Day 1, 7 and one month post-treatment **N at enrollment:** **G1:** 21 **N at follow-up:** **G1:** 21 **Consultation with lactation consultant:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, years at intervention, range:** **G1:** 3-30 **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Speech problems (n=10) Feeding problems (n=3) Oral hygiene issues (n=8) **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted :** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child: (parents and child filled out survey together)** Improved speech Strongly agree or agree: **G1:** 14/21 Improved tongue movement Strongly agree or agree: **G1:** 18/21 Improved oral hygiene Strongly agree or agree **G1:** 16/21 **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details:** Authors report no complications and no patients had bleeding or swelling that caused problems with airway or feeding. No pain: **G1:** 2/21 disagree, 2/21 neutral No bleeding: **G1:** 1/21 disagree, 1/21 neutral No swelling: **G1:** 0/21 disagree, 1/21 neutral **Timing of harms:** Unclear at which time-point the survey was administered.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Ridgers, et al., 2009[32] **Country:** UK **Enrollment period:** NR (16 month period listed in abstract; 24 month period listed in text) **Funding:** NR **Study Design:** Case series	**Intervention:** Division of tongue tie: mother holds baby, surgeon inserts left middle finger into baby's mouth between alveolar ridges, retracts the upper and lower lips with index finger and thumb of same hand. Wait until baby cries, as tongue is raised surgeon snips the excess fibrous tissue if tongue-tie assessed as significant. **Groups:** **G1:** Intervention **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** None **Other non-surgical therapies:** NR **Setting of therapy:** Inpatient lactation and breastfeeding clinic **Treatment duration:** NA **Last followup post-treatment:** Immediately post-treatment and 4 weeks after **N at enrollment:** **G1:** 220 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Infants with feeding difficulties and tongue ties **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, median (range):** **G1:** 10 (3-70) **Gender, n (%):** Male: **G1:** 141 (64) Female: **G1:** 79 (36) **Race/ethnicity:** NR **Indication for therapy, n (%):** Difficult attachment: **G1:** 95 (43) Nipple soreness: **G1:** 86 (39) Frequent feeds: **G1:** 57 (26) Infant not attaching: **G1:** 40 (18) Protracted feeds: **G1:** 40 (18) Dribbles on bottle: **G1:** 18 (8) Poor milk supply: **G1:** 17 (8) Infant never attached: **G1:** 9 (4) Mastitis: **G1:** 9 (4) **Other characteristics, n (%):** Family history: **G1:** 90 (41)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant, n (%):** Feeding problems full resolved: **G1:** 168 (67) Improved **G1:** 47 (21) No change **G1:** 5 (2) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** **G1:** Yes **Harms Details:** Minor bleeding, n (%) **G1:** 4 (2) Infant distress (crying) **Timing of harms:** Immediate or within 10-20 seconds for crying- stopped completely within maximum of two minutes for bleeding

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		Feeding Breast only: **G1:** 130 (59) Bottle only: **G1:** 35 (16) Combination: **G1:** 55 (25) **Type of ankyloglossia:** Anterior, n (%): Unable to protrude tongue beyond alveolar ridge or bottom lip; thick fibrous band and notching of tip on attempted protrusion: **G1:** 150 (68) Partial extrusion with significant feeding difficulties: **G1:** 44 (20) Unrestricted tongue movement but definite band visible: **G1:** 26 (12) **Ankyloglossia with concomitant lip tie:** NR		

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Riskin et al., 2014 [33] **Country:** Israel **Enrollment period:** Jan 2005 to Dec 2010 **Funding:** NR **Design:** Retrospective cohort	**Intervention (description)** Frenotomy **Groups, n (%)** **G1a:** intervention **G1b:** No intervention **Type of professional performing treatment:** Pediatric surgeons (38.5%), pediatricians (10.8%), otolaryngologists (7.7%), dentists (7.7), dermatologists (6.1%), family practitioners (3.1%) **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies, n (%):** NR **Setting of therapy:** NR **Treatment duration:** NR **Last follow-up post-treatment:** Varied **N at enrollment:** **G1:** 239 **N at follow-up:** **G1:** 183 Received frenotomy **G1a:** 65 (35.5) No frenotomy **G1b:** 118 (64.5) **Consultation with lactation consultant, n (%):** **G1:** 110 (60.1) Lactation support in hospital **G1a:** 41/65 (63.1) **G1b:** 69/118 (58.59)	**Inclusion criteria:** Newborns delivered at Bnai Zion medical center at gestational age ≥ 37 weeks diagnosed with tongue tie Diagnosis made by physicians, nurses or lactation consultants and confirmed by senior neonatologist at discharge **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1:** NR **Age, days or months at intervention, mean ± SD:** **G1:** NR **Age, years at interview, mean ± SD :** **G1:** 3.2 ± 1.3 **Gender, n (%):** Male: **G1:** (62.8) Female: **G1:** (37.2) **Race/ethnicity:** Jewish **G1:** 81.5% Arab **G1:** 18.5% **Indication for therapy:** Purpose of frenotomy Alleviate breastfeeding problems **G1a:** 40/65 (61.5) Alleviate breastfeeding problems only **G1a:** 19/65 (29.2) Alleviate breastfeeding + future speech problems **G1a:** 21/65 (32.3) Speech problems **G1a:** 20/65 (30.8) Other purposes	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Breastfeeding problems in first month of life Pain or sore nipples **G1:** 51 (29.5) Latch **G1:** 51 (27.9) Congestion (breast engorgement) **G1:** 39 (21.3) Insufficient milk supply **G1:** 30 (16.4) Inflammation or mastitis **G1:** 13 (7.1) Other unspecified problems **G1:** 13 (7.1) Spontaneous report of problems **G1a:** 38/65 (58.5) **G1b:** 40/118 (33.9) G1a vs G1b: p=0.002 Reported problems on specific questions Congestion **G1a:** 19 (29.2) **G1b:** 20 (16.9) G1a vs G1b: p=0.08 **Latch** **G1a:** 25 (38.5) **G1b:** 26 (22.0) G1a vs G1b: p=0.03 Lengthy breastfeedings **G1a:** 13 (20.0) **G1b:** 12 (10.2) G1a vs G1b: p=0.10 Infant exhaustion **G1a:** 12 (18.5) **G1b:** 7 (5.9) G1a vs G1b: p=0.02 Pain or sore nipples **G1a:** 24 (36.9) **G1b:** 27 (22.9) G1a vs G1b: p=0.06	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Reported improvement after frenotomy Alleviate breastfeeding problems **G1a:** 23/26 (88.5) Alleviate breastfeeding problems only **G1a:** 12/23 Alleviate breastfeeding + future speech problems **G1a:** 11/23 Speech problems **G1a:** 2/26 (7.7) Other purposes **G1a:** 1/26 (3.8) No improvement **G1a:** 10/65 (15.4) Could not tell **G1a:** 29/65 (44.6) **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. (specify method and results, mean, median, %) **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. (specify assessment method and results, mean, median, %) **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G1a: 4/65 (6.2) No reason given **G1a:** 1/65 (1.5) **Other characteristics n (%):** First degree relative with anklyoglossia **G1:** 64 (35) **Type of ankyloglossia:** Anterior, n (%): **G1:** NR Posterior, n (%): **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	Inflammation or mastitis **G1a:** 8 (12.3) **G1b:** 5 (4.2) G1a vs G1b: p=0.08 **Insufficient milk supply** **G1a:** 11 (16.9) **G1b:** 19 (16.1) G1a vs G1b: p=0.95 **Poor weight gain** **G1a:** 8 (12.3) **G1b:** 7 (7.9) G1a vs G1b: p=0.22 Other unspecified problems **G1a:** 6 (9.2) **G1b:** 7 (5.9) G1a vs G1b: p=0.60 **Infant:** Infant's exhaustion **G1:** 25 (14.4) Lengthy breastfeedings **G1:** 25 (14.4) Poor weight gain **G1:** 15 (8.2) **Child:** Reported speech problem **G1:** 19/183 (10.3) True rate speech problem (age > 2 years old at time of interview **G1:** 19/159 (11.9)	**Timing of harms:** NA

LATCH = Latch, Audible swallowing, Type of Nipple, Comfort, Hold; HATLFF = Hazelbaker Assessment Tool for Lingual Frenulum Function; BSES= Breastfeeding Self-Efficacy Scale; IBAT = Infant Breastfeeding Assessment Tool; VAS = Visual Analog Scale for Pain; MPQ = McGill Pain Questionnaire

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Rose et al., 2014[34] **Country:** UK **Enrollment period:** 1 year period **Funding:** NR **Design:** Case series	**Intervention (description):** Frenulotomy **Groups, n (%)** **G1:** intervention **Type of professional performing treatment:** (e.g., **G1a:** ENT physician **G1b:** ENT nurse **Anesthesia used in surgical intervention:** No **Other non-surgical therapies, n (%):** NR **Setting of therapy:** outpatient tongue-tie clinic **Treatment duration:** 20 minutues **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 162 **N at follow-up:** **G1:** 105 **G1a:** 54 **G1b:** 51 **Consultation with lactation consultant, n (%):** **G1:** NR	**Inclusion criteria:** Parents of patients treated for tongue-tie in < 6 month old at either ENT or nurse led outpatient clinic regardless of breast feeding problems **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1:** NR **Age, days or months at intervention, range :** **G1:** 7 days to 5 months (77% < 1 month) **Gender, n (%):** Male: **G1a:** 28 **G1b:** 29 Female: **G1a:** 26 **G1b:** 22 **Race/ethnicity:** **G1:** NR **Indication for therapy:** Varied **Other characteristics:** NR **Type of ankyloglossia: Anterior, n (%):** **G1:** NR **Posterior, n (%):** **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	**Length of lingual frenulum when tongue is lifted** **G1:** NR **Maternal:** Breastfeeding, n (%) **G1a:** 38 (70) **G1b:** 26 (51) Difficulty breastfeeding, n (%) **G1a:** 34/38 (89) **G1b:** 23/26 (88) **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. (specify method and results, mean, median, %) **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. (specify assessment method and results, mean, median, %) **G1:** NR	**Length of lingual frenulum when tongue is lifted** **G1:** NR **Maternal:** Immediate improvement in breastfeeding, n (%) **G1a:** 21/34 (62) **G1b:** 16/23 (70) No improvement in breastfeeding, n (%) **G1a:** 2/34 (6) **G1b:** 1/23 (4) Too early to tell if improvement in breastfeeding, n (%) **G1a:** 11/34 (32) **G1b:** 6/23 (26) Satisfaction scores: Overall experience (median scores): **G1a, G1b:** 10 **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. (specify method and results, mean, median, %) **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. (specify assessment method and results, mean, median, %) **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Sethi et al., 2013[35] **Country:** UK **Enrollment period:** February 2008 to February 2011 **Funding:** NR **Study Design:** Prospective case series	**Intervention:** Frenulotomy: Sterile iris scissors with blunt tips used to divide the frenulum and parent was able to attempt breastfeeding almost immediately after **Groups:** **G1:** Intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient ENT **Treatment duration:** NA **Last followup post-treatment:** At least 5 months after procedure by telephone **N at enrollment:** **G1:** 85 **N at followup:** **G1:** 52 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Presence of tongue-tie assessed by senior authors based on tongue protrusion, ability to suckle finger, length, elasticity and tongue shape **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean (range):** **G1:** 19 (3-120) **Gender, n:** Male: **G1:** 35 Female: **G1:** 17 **Race/ethnicity:** NR **Indication for therapy:** Referrals from midwives (n=25) lactation consultants (n=20) pediatricians (n=4) and GPs (n=3) All mothers had experienced problems breastfeeding **Other characteristics :**NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Sore nipples **G1:** 6/52 **Infant, n:** Poor latch **G1:** 49/52 Continual feeding **G1:** 18/52 Poor weight gain **G1:** 10/52 Excess wind **G1:** 2/52 **Feeding at baseline** Exclusively breastfeeding **G1:** 28/52 Supplementing with expressed breast milk **G1:** 22/52 Exclusively formula fed **G1:** 2/52 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Immediate improvement in breastfeeding: **G1:** 16/52 Improvement within 24 hours: **G1:** 8/52 Improvement within 1 week: **G1:** 13/52 Improvement within 2 weeks: **G1:** 3/52 No Improvement : **G1:** 12/52 **Infant, n:** Feeding after frenotomy Exclusively breastfeeding **G1:** 20/52 Supplementing with expressed breast milk: **G1:** 19/52 Exclusively formula fed: **G1:** 13/52 **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Srinivasan et al., 2006[36] **Country:** Canada **Enrollment period:** August 2004 to February 2005 **Funding:** No financial support and authors report no conflicts of interest **Study Design:** Case series	**Intervention:** Frenotomy: index and middle fingers of one hand used to isolate the frenulum, while other hand performed frenotomy under direct vision. An incision of 2 to 5 mm made using sterile scissors, severing the entire fibrous part of the frenulum. Sterile swabs used to compress any bleeding. Baby returned to mother for immediate breast feeding. **Groups:** **G1:** Frenotomy + counseling **Type of professional performing treatment:** Family practitioners **Anesthesia used in surgical intervention**: NR **Other non-surgical therapies:** List reported by group **Setting of therapy:** Breastfeeding clinic **Treatment duration:** NA **Last followup post-treatment:** Questionnaire after three months **N at enrollment:** **G1:** 27 **N at followup:** **G1:** 25 **Consultation with lactation consultant, (%):** **G1:** 100	**Inclusion criteria:** • Mothers with infants < 12 weeks • Intend to begin or continue breastfeeding • Frenotomy decision rule for breast feeding infant (see comment below) • Understand either English or French **Exclusion criteria:** • Babies with congenital anomalies or other developmental delay • Mothers unwilling to participate **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD (range):** **G1:** 19 ± 19 (2-71) **Gender, n (%):** Male: **G1:** 18 (66.7) Female: **G1:** 9 (29.6) **Race/ethnicity:** NR (“various”) **Indication for therapy:** Patients were referred to clinic for symptoms such as maternal nipple pain, latching difficulties, and/or poor infant weight gain. One subject had vasospasm of the nipple. Two subjects diagnosed with decreased milk supply. **Other characteristics:** NA **Type of ankyloglossia:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal, mean ± SD (range):** Short Form McGill Pain Questionnaire (includes both PRI and PPI): Nipple pain: Pain Rating Index (PRI) score: **G1:** 13.7 ± 10.9 (0-37 Present Pain Index (PPI) score: **G1:** 2.2 ± 1.3 (0-5) **Infant:** Breastfeeding latch, mean ± SD: **G1:** 6.7 ± 1.2 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal, mean ± SD (range):** Nipple pain: Pain Rating Index score: **G1:** 2.2 ± 3.1 (0-11) **Decrease in mean score:** 11.4 (p<0.0001, 95% CI: -15.544, -7.345) **Pain scores based on quality of latch postfrenotomy (compared subjects who had optimal latches postfrenotomy vs. those that did not):** Mean improvement in PRI (Optimal latch): 13.2 (95% CI -18.069 - -8.385) Mean improvement in PRI (Suboptimal latch): 7.9 (95% CI -16.512 - -0.735) Mean difference in PRI between subjects with optimal and suboptimal latches: 5.3 (p=0.21; 95% CI -3.277 – 13.944) Mean improvement in PPI (Optimal latch): 1.8 (95% CI – 2.379 - -1.287) Mean improvement in PPI (Suboptimal latch): 0.8 (95% CI -1.618 – 0.062) Mean difference in PPI between subjects with optimal and suboptimal latches: 1.1 (p=0.03, 95% CI 0.134 – 1.977)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		Ankyloglossia with concomitant lip tie: NR		**Infant:** Breastfeeding latch, Mean ± SD **G1:** 9.2 ± 0.9 Improvement in mean score, 2.5 (p< 0.0001, 95% CI, 2.038, 2.925) Breastfeeding after three months, n (%): **G1:** 21/27 (77.8) (reasons for stopping: persistent nipple pain, breast infection, personal reasons) Pain free after three months, n (%) **G1:** 23/25 (92) % felt frenotomy had helped: 22/25 (88%) **Child:** NR **Need for reoperation:** NR **Harms:** No complications noted during or after frenotomy. No extended incidents of bleeding requiring active management, no infant fever, and no hospital admission. **Harms Details:** NA **Timing of harms:** 3 months

Comment: Frenotomy Decision Rule: Mother with nipple pain/trauma while breastfeeding AND/OR inability to maintain latch AND/OR poor weight gain in the infant (<15 g/d), AND A visible membrane anterior to the base of the tongue, which restricts tongue movement, leading to: An inability to touch the roof of the mouth, OR An inability to cup an examining finger, OR An inability to protrude the tongue past the gum line
Note: Authors also report improvement in pain based on quality of latch.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Steehler et al., 2012[37] **Country:** USA **Enrollment period:** April 2006 to February 2011 **Funding:** NR **Study Design:** Retrospective cohort	**Intervention:** Infant swaddled and held upright. Topical viscous lidocaine applied to lingual frenulum exposed with cotton applicators or Tongue Tie groove director. Scissors used to release the frenulum. Posterior limit is anterior genioglossus muscle. Infant immediately breastfed following procedure **Groups:** **G1:** Frenotomy **G2:** No intervention **Type of professional performing treatment:** NR (Pediatric otolaryngologist reviewed the diagnosis) **Anesthesia used in surgical intervention:** Yes (topical viscous Lidocaine) **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NR **Last followup post-treatment:** 3 months to 5 years after treatment **N at enrollment:** From chart review **G1:** 302 **G2:** 62 **N at followup:** Mothers who then	**Inclusion criteria:** • Medical records of neonates and infants seen for feeding and latching difficulties along with pain when breastfeeding due to suspected ankyloglossia. Dx confirmed by peds ORL **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1+G2:** 18 days **Age, days or months at intervention, mean ± SD:** NR **Gender, n (%):** Male: **G1+G2:** 216 (58.9) Female: **G1+G2:** 151 (14.1) **Indication for therapy:** Feeding difficulties, latch problems, pain with breast feeding **Other characteristics:** Family history, n (%): **G1+G2:** Yes 127 (34.6) No 194 (52.9) Unknown 46 (12.5) Race Caucasian: **G1+G2:** 258 (70.3) African-American: **G1+G2:** 57 (15.5) Hispanic: **G1+G2:** 16 (4.4) Multiethnic: **G1+G2:** 12 (3.3) Indian: **G1+G2:** 10 (2.7) Asian: **G1+G2:** 6 (1.6)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal:** **G1:** NR **Infant:** Delayed speech articulation **G1:** NR **G2:** NR **Child:** Shape of tongue altered **G1:** NR **G2:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal, n (%):** Only includes participants in phone survey: Continued to breastfeed after diagnosis of ‘‘tongue tie,” n (%) : **G1:** NA **G2:** 6 (66.7) Total months breastfeeding after diagnosis of ‘‘tongue tie’’: **G1:** NA **G2:** 6.28 Breastfeeding discontinued due to difficulty or pain from ‘‘tongue tie,” n (%) **G1:** 14 (17.1) **G2:** 3 (33.3) Continued to breastfeed after frenotomy, n (%): **G1:** 68 (82.9) **G2:** NA Total months breastfeeding after frenotomy: **G1:** 7.09 **G2:** NA Within 1st week of life: **G1:** 7.11 months After 1st week of life: **G1:** 7.06 months p=not significant **Infant, n (%):** Child’s ability to feed (maternal survey report): **G1:** 66 (80.4) **G2:** NA

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	agreed to participate in f/u phone survey: **G1:** 82 **G2:** 9 **Consultation with lactation consultant:** NR	Arabic: **G1+G2:** 4 (1.1) Persian: **G1+G2:** 2 (0.5) Filipino: **G1+G2:** 1 (0.3) Unknown: **G1+G2:** 1 (0.3) **Type of ankyloglossia:** Anterior, n (%): **G1+G2:** 64 (17.4) Posterior, n (%): **G1+G2:** 18 (4.9) Type 1 **G1+G2:** 64 (17.4) Type 2 **G1+G2:** 167 (45.5) Type 3 **G1+G2:** 93 (25.3) Type 4 **G1+G2:** 18 (4.9) Insufficient data **G1+G2:** 25 (6.8) **Ankyloglossia with concomitant lip tie:** NR		Within 1st week of life; **G1:** 37/43 (86) After 1st week of life: **G1:** 29/39 (74.3) P<0.003 Based on type of ankyloglossia: 1: 13/16 (81.3) 2: 31/38 (83.8) 3: 18/21 (85.7) 4: 1/3 (33.3) **Child:** Age (in months) when beginning solid foods **G1:** 5.8 **G2:** 6 **Need for reoperation:** **G1:** 8 **Harms:** Yes **Harms Details, n (%):** Recurrent ankyloglossia secondary to scarring; 8 (2.6%) **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Toner et al., 2014 [38] **Country:** U.S. **Enrollment period:** 2003-2008 **Funding:** NR **Design:** Retrospective Case series	**Intervention (description)** Frenotomy. Oral cavity exposed with downward pressure on mandible. Tongue elevated with grooved director or cotton-tipped applicator and attachment of frenulum to undersurface of tongue is cut. Mild digital pressure sometimes applied to stop bleeding. **Groups, n (%)** **G1:** intervention **Type of professional performing treatment:** otolaryngologist **Anesthesia used in surgical intervention:** Yes, (52%) Topical lidocaine applied to frenulum and undersurface of tongue **Other non-surgical therapies, n (%):** NR **Setting of therapy:** Outpatient clinic **Treatment duration:** DNR **Last follow-up post-treatment:** Varied from a few months up to 6 years after procedure **N at enrollment:** **G1:** 55 **N at follow-up:** **G1:** 25 **Consultation with lactation consultant, n (%):** **G1:** NR	**Inclusion criteria:** Infants who had frenotomy in ORL office between 2003-2008 **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD :** **G1:** NR **Age, days or months at intervention, mean ± SD :** **G1:** NR **Gender, n (%):** NR **Race/ethnicity:** **G1:** NR **Indication for therapy:** Difficulty nursing in the first week of life **Other characteristics:** NR **Type of ankyloglossia: Anterior, n (%):** **G1:** NR **Posterior, n (%):** **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** **G1:** NR **Infant:** Difficulty latching for breastfeeeding **G1:** 76% Breastfeeding **G1:** 19 (76) Bottle feeding **G1:** 4 (16) Both breast and bottle fed **G1:** 2 (8) **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal, n (%):** Post-procedure improvement: Immediate: **G1:** 21 (84) 3-4 months after: G1: 1 (4) Time unknown: G1: 1(4) Family satisfaction with office procedure, 5 point scale Very satisfied **G1:** 23 (92) Somewhat satisfied **G1:** 2 (8) **Infant, n (%):** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No reported complications **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Wallace et al., 2006[39] **Country:** UK **Enrollment period:** Aug 2003 to Feb 2005 **Funding:** NR **Design:** Case series	**Intervention:** Tongue tie division: Index and middle finger placed under tongue in infant's mouth on either side of lingual frenulum to stretch it and divided with sterile iris scissors, being careful not to damage submandibular ducts. Infant promptly returned to mother for breastfeeding. **Groups:** **G1:** intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient clinic **Treatment duration:** NR **Last follow-up post-treatment:** Varied **N at enrollment:** **G1:** 11 **N at follow-up:** **G1:** 10 **Consultation with lactation consultant, (%):** **G1:** Yes (100)	**Inclusion criteria:** • Infants with breast feeding difficulties associated with tongue tie identified by lactation consultants **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, median (range):** **G1:** 10 (2-31) **Age, months at follow-up, median (range):** **G1:** 10 (3-20) **Gender, n (%):** Male: **G1:** 9/11 Female: **G1:** 2/11 **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Sore nipples, n **G1**: 6/10 **Infant:** Poor latch, n **G1:** 9/10 Continual feeding cycle **G1:** 5/10 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Breastfed for at least 4 months **G1:** 6/10 Failed to establish breastfeeding after division **G1:** 2/10 **Infant:** Improvements in breastfeeding immediately **G1:** 4/10 Improvements in breastfeeding 1-14 days **G1:** 3/10 No improvements **G1:** 3/10 **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Walls et al., 2014[40] **Country:** USA **Enrollment period:** January 2010 to December 2010 **Funding:** NR **Study Design:** Retrospective Cohort	**Intervention:** Frenotomy completed within the first month of life in 102 three year old children. No details of procedure reported **Groups:** **G1:** Frenetomy **G2:** No surgery **G3:** Control **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient clinic or postpartum ward **Treatment duration:** NR **Last followup post-treatment:** 3 years **N at enrollment:** **G1:** 71 **G2:** 15 **G3:** 18 **Consultation with lactation consultant, %:** **G1:** 64% had been referred to ORL from lactation consultants **G2:** 64% had been referred to ORL from lactation consultants **G3:** 64% had been referred to ORL from lactation consultants	**Inclusion criteria:** • Medical records of 3 year old patients with a past history of ankyloglossia who had received frenotomy within the first month of life • Three-year old patients with a past history of ankyloglossia but declined the frenetomy procedure during the same time period • Control Group compiled from the medical records of randomly assigned three-year old patients without a past history of ankyloglossia during the same time period **Exclusion criteria:** • Did not discuss why they excluded the charts of 31 frenotomy and 6 no intervention patients from the study **Age, days at first diagnosis:** **G1:** 9 days **G2:** 9 days **G3**: NA **Age, days or months at intervention:** **G1:** first month of life **G2:** NA **G3:** NA **Gender, n (%):** Male: **G1/G2/G3:** 62 (59) Female: **G1/G2/G3:** 42 (41) **Race/ethnicity:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child, n:** Speech difficulty: **G1+G2:** 36	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child:** Speech outcome (Likert scale): Mean ± SD : **G1:** 4.52 ± 0.61 **G2:** 3.60 ± 0.63 **G3:** 4.33 ± 0.77 Group differences-speech outcomes (Wilcoxon rank sum): **G1 vs. G2:** p<0.0001 **G1 vs. G3:** p=0.38 **G2 vs. G3:** p=0.01 Improved Oral motor activities (Fischer Exact): Difficulty cleaning teeth with tongue: **G1/G2:** p=0.0006 **G1/G3:** p=1.0000 **G2/G3**: p=0.0120 Difficulty licking outside of lips: **G1/G2:** p<0.0001 **G1/G3**: p=0.1120 **G2/G3**: p=0.0053 Difficulty eating ice cream: **G1/G2**: p=0.0003 **G1/G3**: p=0.58 **G2/G3**: p=0.0015 **Need for reoperation:** **G1:** NR **Harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G2: NR **G3:** NR **Indication for therapy:** Diagnosis of ankyloglossia **Other characteristics:** Family history: **G1+G2+G3:** 27 (32) **Type of ankyloglossia:** Coryllos criteria, n (%): **G1:** 20 (23) **G2:** 44 (51) **G3:** 22 (26) **Anklyoglossia with concomitant lip tie:** NR		**Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Yeh, 2008 [41] **Country:** Taiwan **Enrollment period:** 1980 to 2006 **Funding:** NR **Design:** Case series	**Intervention:** Tongue tie division: for infants, tongue is lifted superiorly by doctor's middle finger or middle and index fingers. With other hand, divides tongue tie using blunt tipped scissors. Cut is made incomplete to avoid injury to tongue, leaving small portion of frenulum intact. This portion then released by gentle push with a gauze sponge. Post division with compression with gauze sponge for 5 minutes routinely used to control bleeding was used early in doctors experience but later considered unnecessary. For patients with more teeth: tongue elevated upward with tongue depressor and doctor places scissors alongside lingual frenulum. If not too thick and vascular, about 2/3s of frenulum released by a quick cut. **Groups:** **G1:** intervention **Type of professional performing treatment:** pediatric surgeon **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** List reported by group **Setting of therapy:** Outpatient clinic **Treatment duration:** NA **Last follow-up post-treatment:** 3 months post-treatment **N at enrollment:** **G1:** 2620 infants and 158 children **N at follow-up:** **G1:** 2620 infants and 158 children **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Treated for tongue tie by author • No family history bleeding disorders **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days or months at intervention, mean ± SD:** NR **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** NR **Other characteristics:** No family history of bleeding disorders **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** 3 **Harms:** Yes **Harms Details:** Post division bleeding occurred in most cases, it was usually very mild and would stop spontaneously within a couple of minutes. None required hemostasis by prolonged compression or electrocautery. Indentation of tongue tip and recurrence of tongue-tie- repeat surgery in operating room under general anesthesia **Timing of harms:** Immediate and 3 month followup

Table D-2. Abbreviations in evidence table

µm	Micrometers
BSES-SF	Breastfeeding Self-Efficacy Scale – Short Form
CI	Confidence Interval
CM	Centimeters
CPT	Current Procedural Terminology
ENT	Otolaryngologist
g/d	Weight Velocity
HATLFF	Hazelbaker Assessment Tool for Lingual Frenulum Function
IBAT	Infant Breastfeeding Assessment Tool
ICD	International Classification of Diseases
IQR	Interquartile Range
J/cm^2	Joules per Area
LATCH	Latch, Audible swallowing, Type of Nipple, Comfort, Hold;
mL/min	Milliliters per Minute
MM	Millimeters
MPQ	McGill Pain Questionnaire
NA	Not Applicable
NOMESCO	Nordic Medico-Statistical Committee
NR	Not Reported
NS	Not Statistically Significant
ORL	Otorhinolaryngology
PRI	Pain Rating Index
PPI	Present Pain Intensity
RCT	Randomized, Controlled Trials
SD	Standard Deviation
SE	Standard error
SF-MQP	Short Form McGill Pain Scale
VAS	Visual Analog Scale for Pain
W/cm^2	Power per Area
WHO	World Health Organization

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Appendix E. Quality Assessment Forms

Table E-1. Cochrane Collaboration modified tool for assessing risk of bias, Part I

REF ID:				**Reviewer:**	
Domain	***Description***	***High risk of bias***	***Low risk of bias***	***Unclear risk of bias***	***Reviewer Assessment***
Selection bias ***Random sequence generation***	Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. **Reviewer Comments:**	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.	Random sequence generation method should produce comparable groups	Not described in sufficient detail	**Judgment: Random Sequence generation** □ **High** □ **Low** □ **Unclear**
Selection bias ***Allocation concealment***	Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment. **Reviewer Comments:**	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	Intervention allocations likely could not have been foreseen in advance of, or during, enrollment	Not described in sufficient detail	**Judgment: Allocation concealment** □ **High** □ **Low** □ **Unclear**
Reporting Bias ***Selective reporting***	State how the possibility of selective outcome reporting was examined by the authors and what was found. **Reviewer Comments:**	Reporting bias due to selective outcome reporting.	Selective outcome reporting bias not detected	Insufficient information to permit judgment of 'Low risk' or 'High risk'. (*It is likely that the majority of studies will fall into this category.)*	**Judgment: Selective reporting** □ **High** □ **Low** □ **Unclear**
Other bias ***Other sources of bias***	Any important concerns about bias not addressed above. If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry. **Reviewer Comments:**	Bias due to problems not covered elsewhere in the table.	No other bias detected	There may be a risk of bias, but there is either: Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias.	**Judgment: Other sources of bias** □ **High** □ **Low** □ **Unclear**

Table E-2. Cochrane Collaboration modified tool for assessing risk of bias for RCTs, Part II

REF ID:

Outcome(s):

Domain	***Description***	***High risk of bias***	***Low risk of bias***	***Unclear risk of bias***	***Reviewer Assessment***
Performance bias ***Blinding (participants and personnel)***	Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective. **Reviewer Comments:**	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Blinding was likely effective.	Not described in sufficient detail	**Judgment: Blinding (participants and personnel)** □ **High** □ **Low** □ **Unclear**
Detection bias ***Blinding (outcome assessment)***	Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective. **Reviewer Comments:**	Detection bias due to knowledge of the allocated interventions by outcome assessors.	Blinding was likely effective.	Not described in sufficient detail	**Judgment: Blinding (outcome assessment)** □ **High** □ **Low** □ **Unclear**
Attrition bias ***Incomplete outcome data***	Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported. **Reviewer Comments:**	Attrition bias due to amount, nature or handling of incomplete outcome data.	Handling of incomplete outcome data was complete and unlikely to have produced bias	Insufficient reporting of attrition/exclusions to permit judgment of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided)	**Judgment: Incomplete outcome data** □ **High** □ **Low** □ **Unclear**

Table E-3. Cohort study assessment

Questions to Assess the Risk of Bias			
1. Do the inclusion/exclusion criteria vary across the comparison groups of the study?	No	Yes	Comments
2. Does the strategy for recruiting participants into the study differ across groups?	No	Yes	Comments
3. Is the selection of the comparison group inappropriate, after taking into account feasibility and ethical considerations?	No	Yes	Comments
4. Was the outcome assessor not blinded to the intervention or exposure status of participants?	No	Yes	Comments
5. Were valid and reliable measures, implemented consistently across all study participants used to assess inclusion/exclusion criteria, intervention/exposure outcomes, participant health benefits and harms, and confounding?	No	Yes	Comments
6. Was the length of followup different across study groups?	No	Yes	Comments
7. In cases of high loss to followup (or differential loss to followup), was the impact assessed (e.g., through sensitivity analysis or other adjustment method)?	No	Yes	Comments
Questions to Assess Confounding			
8. Any attempt to balance the allocation between the groups or match groups (e.g., through stratification, matching, propensity scores)?	No	Yes	Comments
9. Were the important confounding variables taken into account in the design and/or analysis (e.g., through matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment such as instrumental variables)?	No	Yes	Comments
Questions to Assess Precision			
10. Are the statistical methods used to assess the primary benefit outcomes inadequate?	No	Yes	Comments
11. Are the statistical methods used to assess the main harm or adverse event outcomes inadequate?	No	Yes	Comments

Based on cohort questions from: Viswanathan M, Berkman ND, Dryden DM, et al. Assessing Risk of Bias and Confounding in Observational Studies of Interventions or Exposures: Further Development of the RTI Item Bank [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Aug. Available from: http://www.ncbi.nlm.nih.gov/books/NBK154461/

Table E-4. Minimum criteria to assess risk of bias in case series

Selection bias and confounding					
1. Were the important confounding and modifying variables taken into account in the design and analysis?	Yes	No	NA	NR	Comments
Performance bias					
2. Was any impact from a concurrent intervention or an unintended exposure that might bias results ruled out by the researchers?	Yes	No	NA	NR	Comments
3. Was the study free from variations from the study protocol that could compromise the conclusions of the study?	Yes	No	NA	NR	Comments
Attrition bias					
4. Was there a low rate of differential or overall attrition? (note: low≤20%)	Yes	No	NA	NR	Comments
5. Attrition did not result in a difference in group characteristics between baseline and follow-up	Yes	No	NA	NR	Comments
Detection bias					
6. Were the outcome assessors blinded to the intervention or exposure status of participants?	Yes	No	NA	NR	Comments
7a. Are the inclusion/exclusion criteria clearly stated? (note: consider whether level of detail would allow for replication)	Yes	No	NA	NR	Comments
7b. Were the measures implemented consistently across all study participants?	Yes	No	NA	NR	Comments
8a. Are interventions/exposures assessed using appropriate measures?	Yes	No	NA	NR	Comments
8b. Were the interventions implemented consistently across all study participants?	Yes	No	NA	NR	Comments
9a. Are primary outcome measurement approaches clearly described? List outcome. Outcome 1:	Yes	No	NA	NR	Comments
Outcome 2:					
Outcome 3:					
Outcome 4:					
Outcome 5:					
Outcome 6:					
9b. Are primary outcomes assessed using appropriate measures? List outcome. Outcome 1:	Yes	No	NA	NR	Comments
Outcome 2:	Yes	No	NA	NR	Comments
Outcome 3:	Yes	No	NA	NR	Comments

Outcome 4:	Yes	No	NA	NR	Comments
Outcome 5:	Yes	No	NA	NR	Comments
Outcome 6:	Yes	No	NA	NR	Comments
9b. Was outcome assessment implemented consistently across all study participants?	Yes	No	NA	NR	Comments
10a.Are confounding variables assessed using appropriate measures?	Yes	No	NA	NR	Comments
10b. Was assessment of confounding variables implemented consistently across all study participants?	Yes	No	NA	NR	Comments
11. Did the study account for secular trends and regression to the mean?	Yes	No	NA	NR	Comments
Reporting bias					
12a.Are the potential outcomes pre-specified by the researchers?	Yes	No	NA	NR	Comments
12b. Are harms pre-specified by the researchers?	Yes	No	NA	NR	Comments
13. Are all pre-specified outcomes reported?	Yes	No	NA	NR	Comments
13a. Are all pre-specified harms reported?	Yes	No	NA	NR	Comments

Table E-5. Harms risk-of-bias assessment

RefID: _____ Reviewer:_____

Question	Yes	No	Comments
Were the harms predefined using standardized or precise definitions?	Yes	No	Comments
Are all pre-specified harms reported?	Yes	No	Comments
Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Yes	No	Comments
Are the statistical methods used to assess the main harm or adverse event outcomes adequate?	Yes	No	Comments

Based on questions from: Viswanathan M, Berkman ND, Dryden DM, et al. Assessing Risk of Bias and Confounding in Observational Studies of Interventions or Exposures: Further Development of the RTI Item Bank [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Aug. Available from: http://www.ncbi.nlm.nih.gov/books/NBK154461/ and Santaguida P., Raina P. McMaster Quality Scale of Harms (McHarm) for primary studies: Manual for use of the McHarm. [Hamilton, ON: McMaster University, n.d.].

Appendix F. Quality Scoring Results

Table F-1. RCT quality score results

Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
Studies assessing HATLFF*								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Buryk et al. 2011[2]	Low	Low	Low	Low	Low	Low	Low	Good
Studies assessing LATCH†								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Berry et al. 2012[3]	Low	Low	Low	Low	Low	Low	Low	Good
Dollberg et al. 2006[4]	Low	Low	High	Unclear	High	Low	Low	Poor
Studies assessing IBFAT††								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Berry et al. 2012[3]	Low	Low	Low	Low	Low	Low	Low	Good
Buryk et al. 2011[2]	Low	Low	Low	Low	Low	Low	Low	Good
Studies assessing BSES§								
Emond et al. 2013[1]	Low	Low	Low	Low	High	Low	Low	Fair
Studies assessing								

Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
pain scores								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Berry et al. 2012[3]	Low	Low	Low	Low	Low	Low	Low	Good
Buryk et al. 2011[2]	Low	Low	Low	Low	Low	Low	Low	Good
Dollberg et al. 2006[4]	Low	Low	High	Unclear	High	Low	Low	Poor
Studies assessing infant weight gain								
Emond et al. 2013[1]	Low	Low	Low	Low	Unclear	Low	Low	Fair
Studies assessing frenulum length								
Heller et al. 2005[5]	Unclear	Unclear	Low	Unclear	Low	Unclear	Low	Poor

Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
Studies assessing tongue protrusion								
Heller et al. 2005[5]	Unclear	Unclear	Low	Unclear	Low	Unclear	Low	Poor
Studies assessing speech								
Heller et al. 2005[5]	Unclear	Unclear	Low	Unclear	Unclear	Unclear	Low	Poor
Studies assessing feeding (breast and bottle) measured by observers								
Hogan et al. 2005[6]	Unclear	Low	Low	Low	High	Low	Low	Fair

*HATLFF=Hazelbaker Assessment Tool for Lingual Frenulum Function
‡LATCH=Latch, Audible swallowing, Type of Nipple, Comfort, Hold
††IBFAT=Infant Breastfeeding Assessment Tool
§BSES= Breastfeeding Self-Efficacy Scale

Table F-2. Cohort quality score results

Author, Year	Inclusion/exclusion criteria across groups	Recruitment strategy across groups	Selection of the comparison group	Outcome assessor blinding	Valid & reliable measures across study participants	Length of followup different across groups	Assessment of impact of high loss to followup	Balancing allocation between groups/matching groups	Accounting for confounding factors	Adequacy of statistical methods to assess primary outcomes	Adequacy of statistical methods to assess harms or adverse events	Rating
Walls et al. 2014[7]	-	+	+	-	-	+	NA	-	-	+	+	Poor
Steehler et al. 2012[8]	+	+	+	-	-	-	-	-	-	+	+	Poor
Dollberg et al. 2011[9]	-	+	+	-	-	+	NA	+	-	-	-	Poor

NA=not applicable

Table F-3. Case series quality score results

Author, Year	Confounding and modifying variables accounted	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20%) attrition	Attrition did not result in difference in groups baseline & followup	Outcome assessors blinded	Clearly stated inclusion/exclusion criteria	Measures implemented consistently	Appropriate measures for assessing interventions/exposures	Interventions implemented consistently	Outcome: Latch	Appropriate measures for outcome assessment	Outcome: Nipple Pain	Appropriate measures for outcome assessment	Outcome: breastfeeding	Appropriate measures for outcome assessment	Outcome: feeding outcomes	Appropriate measures for outcome assessment	Outcome: infant growth	Appropriate measures for outcome assessment	Outcome: speech	Appropriate measures for outcome assessment	Outcome: Tongue mobility, protrusion	Appropriate measure for outcome assessment	Outcome: Oral hygiene	Appropriate measure for outcome assessment	Outcome: reoperation	Appropriate measure for outcome assessment	Outcome: Beneficial	Appropriate measure for outcome assessment	Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Pre-specified harms	Reporting of all pre-specified outcomes	Reporting of all pre-specified harms
Dollberg et al. 2014[10]	-	NA	+	+	NA	-	+	+	+	+					+	+															+	NR	NR	-	+	+	+	+
Finigan et al. 2014[11]	-	-	NR	-	NR	-	-	NR	+	NR							+	+													+	-	NA	NA	+	-	+	NA
Ito et al. 2014[12]	-	+	NR	+	NA	-	+	+	+	-											+	+									+	-	NA	NA	+	-	+	NA
Riskin et al. 2014[13]	-	-	NR	-	NR	NA	+	+	+	NA	+	+	+	+	+	+			+	+											+	-	-	-	+		+	

Author, Year	Rose et al. 2014[14]	Toner et al. 2014[15]	Dave et al. 2013[16]	Edmunds et al. 2013[17*]	O'Callahan et al. 2013[18]
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	-	-	-	-	-
Study free from variations from protocol	R N	R N	R N	+	+
Low rate (≤20%) attrition	-	-	+	+	-
Attrition did not result in difference in groups baseline & followup	R N	R N	A N	A N	-
Outcome assessors blinded	-	-	R N	-	-
Clearly stated inclusion/exclusion criteria	+	-	-	-	+
Measures implemented consistently	+	R N	R N	+	+
Appropriate measures for assessing interventions/exposures	+	+	R N	-	+
Interventions implemented consistently	R N	R N	+	A N	+
Outcome: Latch					
Appropriate measures for outcome assessment					
Outcome: Nipple Pain					
Appropriate measures for outcome assessment					
Outcome: breastfeeding					+
Appropriate measures for outcome assessment					+
Outcome: feeding outcomes	+				
Appropriate measures for outcome assessment	+				
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech			-		
Appropriate measures for outcome assessment			R N		
Outcome: Tongue mobility, protrusion					
Appropriate measure for outcome assessment					
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation					
Appropriate measure for outcome assessment					
Outcome: Beneficial	+	+			
Appropriate measure for outcome assessment	+	+			
Consistent implementation of outcome assessment	+	+	R N	R N	+
Appropriate measures for confounding variables assessment	-	-	-	-	-
Consistent assessment of confounding variables	A N	A N	A N	-	-
Secular trends and regression to the mean accounted for	A N	A N	A N	A N	A N
Pre-specified potential outcomes	+	+	-	-	+
Pre-specified harms	-	-	-	-	-
Reporting of all pre-specified outcomes	+	+	A N	+	+
Reporting of all pre-specified harms	A N	A N	A N	+	R N

Author, Year	Mettias et al. 2013[19]	Sethi et al. 2013[20]	Marchesan et al. 2012[21]	Argiris et al. 2011[22]	Cho et al. 2011[23]
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	-	-	-	NR	-
Study free from variations from protocol	-	+	+	+	-
Low rate (≤20%) attrition	-	-	+	NA	+
Attrition did not result in difference in groups baseline & followup	NR	NR	NA	NA	NA
Outcome assessors blinded	-	-	-	-	-
Clearly stated inclusion/exclusion criteria	-	-	+	+	-
Measures implemented consistently	+	+	+	+	+
Appropriate measures for assessing interventions/exposures	+	+	+	+	-
Interventions implemented consistently	+	+	+	+	+
Outcome: Latch				+	
Appropriate measures for outcome assessment				+	
Outcome: Nipple Pain				+	
Appropriate measures for outcome assessment				+	
Outcome: breastfeeding	+	-		+	
Appropriate measures for outcome assessment	+	+		+	
Outcome: feeding outcomes					
Appropriate measures for outcome assessment					
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech					-
Appropriate measures for outcome assessment					-
Outcome: Tongue mobility, protrusion			-		
Appropriate measure for outcome assessment			-		
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation					
Appropriate measure for outcome assessment					
Outcome: Beneficial					
Appropriate measure for outcome assessment					
Consistent implementation of outcome assessment	+	-	NR	+	NR
Appropriate measures for confounding variables assessment	-	NA	-	NR	-
Consistent assessment of confounding variables	-	NA	-	NA	-
Secular trends and regression to the mean accounted for	-	-	NA	NA	-
Pre-specified potential outcomes	+	+	-	+	-
Pre-specified harms	+	-	-	-	-
Reporting of all pre-specified outcomes	+	+	NA	+	NA
Reporting of all pre-specified harms	+	NA	NA	NA	NA

Author, Year	Puthussery et al. 2011[24]	Hong et al. 2010[25]	Miranda et al. 2010[26]	Khoo et al. 2009[27]	Klockars et al.
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	-	-	+	-	-
Study free from variations from protocol	+	+	+	NA	+
Low rate (≤20%) attrition	+	+	+	NA	-
Attrition did not result in difference in groups baseline & followup	NA	NA	NR	NA	NR
Outcome assessors blinded	-	-	-	-	-
Clearly stated inclusion/exclusion criteria	-	+	+	-	+
Measures implemented consistently	+	+	+	+	+
Appropriate measures for assessing interventions/exposures	+	+	+	+	+
Interventions implemented consistently	+	+	+	+	NR
Outcome: Latch			-		
Appropriate measures for outcome assessment			NA		
Outcome: Nipple Pain			-		
Appropriate measures for outcome assessment			NA		
Outcome: breastfeeding		-	-	+	
Appropriate measures for outcome assessment		NR	NA	+	
Outcome: feeding outcomes					
Appropriate measures for outcome assessment					
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech	+				
Appropriate measures for outcome assessment	+				
Outcome: Tongue mobility, protrusion	+				
Appropriate measure for outcome assessment	+				
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation		+			+
Appropriate measure for outcome assessment		+			+
Outcome: Beneficial					-
Appropriate measure for outcome assessment					-
Consistent implementation of outcome assessment	+	+	+	+	+
Appropriate measures for confounding variables assessment	-	NA	NA	NR	-
Consistent assessment of confounding variables	-	-	NA	NR	-
Secular trends and regression to the mean accounted for	NA	-	NA	NA	-
Pre-specified potential outcomes	+	+	+	+	+
Pre-specified harms	+	+-	-	-	-
Reporting of all pre-specified outcomes	+	+	+	+	+
Reporting of all pre-specified harms	+	NA	NA	NA	NA

Author, Year	2009[28]	Ridgers et al. 2009[29]	Geddes et al. 2008[30]	Yeh. 2008[31]	Srinivasan et al. 2006[32]
Confounding and modifying variables accounted		-	NR	-	-
Concurrent intervention/unintended exposure ruled out		-	NR	-	+
Study free from variations from protocol		+	+	NR	+
Low rate (≤20%) attrition		+	+	+	+
Attrition did not result in difference in groups baseline & followup		NA	NA	NA	NA
Outcome assessors blinded		-	-	-	-
Clearly stated inclusion/exclusion criteria		-	+	-	+
Measures implemented consistently		+	+	+	+
Appropriate measures for assessing interventions/exposures		+	+	NR	+
Interventions implemented consistently		+	+	+	+
Outcome: Latch			+		+
Appropriate measures for outcome assessment			+		+
Outcome: Nipple Pain			+		+
Appropriate measures for outcome assessment			+		+
Outcome: breastfeeding			+		+
Appropriate measures for outcome assessment			+		+
Outcome: feeding outcomes		+			
Appropriate measures for outcome assessment		+			
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech					
Appropriate measures for outcome assessment					
Outcome: Tongue mobility, protrusion					
Appropriate measure for outcome assessment					
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation				+	
Appropriate measure for outcome assessment				+	
Outcome: Beneficial					
Appropriate measure for outcome assessment					
Consistent implementation of outcome assessment		-	+	+	+
Appropriate measures for confounding variables assessment		-	NA	-	NA
Consistent assessment of confounding variables		NA	NA	-	NA
Secular trends and regression to the mean accounted for		-	NA	-	-
Pre-specified potential outcomes		-	+	-	+
Pre-specified harms		-	-	-	-
Reporting of all pre-specified outcomes		NA	+	NA	+
Reporting of all pre-specified harms		NA	NA	NA	-

Author, Year	Blenkinsop. 2003[33]	Wallace et al. 2006[34]	Amir et al. 2005[35]	Heller et al. 2005[5]	Griffiths. 2004[36]
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	NR	-	-	-	+
Study free from variations from protocol	+	-	-	-	+
Low rate (≤20%) attrition	+	+	-	+	+
Attrition did not result in difference in groups baseline & followup	NA	NA	NR	NA	+
Outcome assessors blinded	-	-	-	-	-
Clearly stated inclusion/exclusion criteria	-	-	+	-	+
Measures implemented consistently	+	+	+	NR	+
Appropriate measures for assessing interventions/exposures	+	+	+	NR	+
Interventions implemented consistently	+	+	+	+	+
Outcome: Latch					
Appropriate measures for outcome assessment					
Outcome: Nipple Pain					
Appropriate measures for outcome assessment					
Outcome: breastfeeding	-	+	+		+
Appropriate measures for outcome assessment	-	+	+		+
Outcome: feeding outcomes					
Appropriate measures for outcome assessment					
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech				-	
Appropriate measures for outcome assessment				-	
Outcome: Tongue mobility, protrusion					+
Appropriate measure for outcome assessment					+
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation					
Appropriate measure for outcome assessment					
Outcome: Beneficial					
Appropriate measure for outcome assessment					
Consistent implementation of outcome assessment	+	+	+	+	+
Appropriate measures for confounding variables assessment	-	-	-	NR	+
Consistent assessment of confounding variables	-	NR	-	NA	+
Secular trends and regression to the mean accounted for	-	AN	-	-	-
Pre-specified potential outcomes	+	+	+	-	+
Pre-specified harms	-	-	-	-	-
Reporting of all pre-specified outcomes	+	+	+	NA	+
Reporting of all pre-specified harms	AN	AN	AN	AN	AN

Author, Year	Lalakea et al. 2003[37]	Ballard et al. 2002[38]	Messner et al. 2002[39]	Masaitis et al. 1996[40]
Confounding and modifying variables accounted	-	-	-	-
Concurrent intervention/unintended exposure ruled out	+	-	-	NA
Study free from variations from protocol	+	+	+	+
Low rate (≤20%) attrition	+	+	+	+
Attrition did not result in difference in groups baseline & followup	NA	NA	NA	NR
Outcome assessors blinded	-	-	-	NA
Clearly stated inclusion/exclusion criteria	+	-	+	-
Measures implemented consistently	+	-	+	+
Appropriate measures for assessing interventions/exposures	+	+	+	+
Interventions implemented consistently		+	+	+
Outcome: Latch		+		
Appropriate measures for outcome assessment		+		
Outcome: Nipple Pain		+		
Appropriate measures for outcome assessment		+		
Outcome: breastfeeding		+		+
Appropriate measures for outcome assessment		+		+
Outcome: feeding outcomes				
Appropriate measures for outcome assessment				
Outcome: infant growth				-
Appropriate measures for outcome assessment				+
Outcome: speech		+	+	
Appropriate measures for outcome assessment		+	+	
Outcome: Tongue mobility, protrusion	+		+	+
Appropriate measure for outcome assessment	+		+	+
Outcome: Oral hygiene				
Appropriate measure for outcome assessment				
Outcome: reoperation				
Appropriate measure for outcome assessment				
Outcome: Beneficial				
Appropriate measure for outcome assessment				
Consistent implementation of outcome assessment	+	+	+	+
Appropriate measures for confounding variables assessment	NR	NR	+	NA
Consistent assessment of confounding variables	NA	-	NA	NA
Secular trends and regression to the mean accounted for	-	-	NR	-
Pre-specified potential outcomes	+	+	+	+
Pre-specified harms	-	-	+	-
Reporting of all pre-specified outcomes	+	+	+	+
Reporting of all pre-specified harms	NA	NA	NA	NA

Author, Year	Confounding and modifying variables accounted	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20%) attrition	Attrition did not result in difference in groups baseline & followup	Outcome assessors blinded	Clearly stated inclusion/exclusion criteria	Measures implemented consistently	Appropriate measures for assessing interventions/exposures	Interventions implemented consistently	Outcome: Latch	Appropriate measures for outcome assessment	Outcome: Nipple Pain	Appropriate measures for outcome assessment	Outcome: breastfeeding	Appropriate measures for outcome assessment	Outcome: feeding outcomes	Appropriate measures for outcome assessment	Outcome: infant growth	Appropriate measures for outcome assessment	Outcome: speech	Appropriate measures for outcome assessment	Outcome: Tongue mobility, protrusion	Appropriate measure for outcome assessment	Outcome: Oral hygiene	Appropriate measure for outcome assessment	Outcome: reoperation	Appropriate measure for outcome assessment	Outcome: Beneficial	Appropriate measure for outcome assessment	Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Pre-specified harms	Reporting of all pre-specified outcomes	Reporting of all pre-specified harms
Godley. 1994[41]	-	+	NR	+	NA	-	-	NR	+	+													-	-							NR	-	NA	-	-	-	NA	Na

*No discrete outcomes measured;
NA=Not applicable; NR=Not reported

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Appendix G. Case Reports Harms

Table G-1. Harms of frenectomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae	Other/comments
Santos et al. 2012[1] Brazil	12 years					✓	✓	Mucocele post-surgery
Cunha et al. 2008[2] Brazil	3 months	✓						
Fleiss et al.1990[3] U.S.	13 years							Lisp post-surgery
Tuli et al. 2010[4] India	5 years					✓		
Reddy et al. 2014[5] India	NR		✓		✓			

Table G-2. Harms of frenotomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae	Other/comments
Opara et al. 2012[6] Nigeria (case 1)	1 day	✓						Continued bleeding for one day post intervention; sepsis
Opara et al. 2012[6] Nigeria (case 2)	3 days	✓						Continued bleeding for three days post-intervention
Mathewson et al. 1966[7] U.S.	16 years							Scar band formed post-surgery

Table G-3. Harms of frenulectomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae	Other/comments
Isaiah et al. 2013[8] U.S.	2 years			✓	✓			Fever and drooling
Nicholson 1991[9] Australia	44 hours							Slight bruising under tongue for three to four days.

Table G-4. Harms of frenuloplasty described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae
Sirinoglu et al. 2013[10] Turkey	3 years				✓		
Chu et al. 2009[11] U.S.	4 weeks	✓					
Lin et al. 2009[12] U.S.	13 years		✓	✓	✓		

Table G-5. Harms of frenulotomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae
Berg. 1990[13] U.S.	12.5 weeks	✓					
Huggins. 1990[14] U.S.	2 weeks	✓					
Good. 1987[15] U.S.	7 months	✓					

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Appendix H. Conference Abstracts

We searched for abstracts/proceedings within PubMed, CINAHL, EMBASE, Web of Science, Science Direct and websites and journal publications of pediatric, dental, orthodontic and lactation societies and organizations from 1980 to the present. Organizations included the Academy of Breastfeeding Medicine (ABM), American Academy of Pediatric Dentistry (AAPD), American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), American Association of Orthodontists (AAO), American Association of Pediatrics (AAP), American Orthodontic Society (AOS), American Speech-Language-Hearing Association (AHSA), College of Lactation Consultants of Western Australia (CLCWA), International Lactation Consultant Association (ILCA), Lactation Consultants of Australia and New Zealand (LCANZ), and Pediatric Academic Societies (PAS).

We identified over 20 abstracts, a number of which reported on incidence or prevalence rates or rates of surgical procedures or provided summaries of studies included in the full review. Abstracts that address outcomes related to breastfeeding, feeding, and speech or social concerns are outlined in H-1.

Table H-1. Relevant conference abstracts

Abstract	Key outcomes
4th Congress of the European Academy of Paediatric Societies, Istanbul, Turkey, 2012.	
Post E. et al. "Snipping of a tongue-tie in neonates" with ankyloglossia and breastfeeding problems: Outcomes and complications.	• 117/132 (89%) mothers whose infant (<3 months of age) underwent frenotomy reported breastfeeding improvements (latch and decreased nipple pain). Specific assessment tools are not reported. • 12/132 (9%) mothers reported no improvement • Minor brief bleeding post intervention and pain were reported in five patients .
Matthews E. et al. An audit of impacts of frenulectomy in breast feeding.	• Results of a questionnaire administered to mothers approximately three weeks after infant (mean age of 6.6 weeks) underwent frenulectomy. Mothers reported decreased latch difficulties (reduction from 16/26 (62%) to 2/26 (8%)) and nipple/breast pain (from 13/26 (50%) to 5/26(19%)). Breastfeeding exclusively increased to 61% (16/26) from pre-intervention 46% (12/26).
4th British Academic Conference in Otolaryngology, Glasgow, UK, 2012	
Dhillon B. Audit of division of tongue ties in a single consultant's clinic.	• 77% of mothers (90/118) reported improved breast feeding immediately following infant tongue tie division.
10th World Conference of Perinatal Medicine. Punta del Este, Uruguay, 2011.	
Alvarez V. et al. Breastfeeding and tongue tie.	• 69/75 infants referred for frenotomy due to breastfeeding difficulties underwent procedure. • Mothers reported immediate improved breastfeeding. No associated complications occurred.

Abstract	Key outcomes
Annual Scientific Meeting of the British Association of Oral and Maxillofacial Surgeons (BAOMS) 2011 Nice France.	
Cottom H. Division of ankyloglossia- Its effectiveness in improving associated breastfeeding difficulties.	• All 40 mothers whose infants were referred for frenulotomy reported improvement in breastfeeding evaluated on a scale of zero (impossible) to 10 (no feeding problems) and 40% reported total resolution.
2009 International Lactation Consultant Association (ILCA) Conference	
Felc Z. Ankyloglossia: incidence and effect of neonatal frenotomy on breastfeeding.	• 60/3383 consecutively screened infants experienced breastfeeding problems due to ankyloglossia. Thirty-five of the sixty infants (58%) underwent frenotomy. In 24/35 (68.6%) of the infants, latch, milk transfer, nipple pain improved. No complications occurred.

Appendix I. Applicability Tables

Table I-1. Applicability for KQ 1

Domain	Description of applicability of evidence
Population	Studies examining the effectiveness of ankyloglossia treatment had significant differences in population. Specifically, there was age heterogeneity between the 3 good quality trials: ranging from group means of 28d and 33d for patients treated with frenotomy versus sham in one study[1], an overall median 6d +/- 6.9 in another [2], and group medians 11d (IQR 8 – 14) and 11d (IQR 8 – 16) in the third.[3] Gender distribution was ~2:1 in 2 trials,[1, 2] and not reported in the third. [3] Finally, ankyloglossia severity was only rated in 1 trial, which also excluded the most severe cases (HATLFF > 6), thus potentially biasing its results toward the null hypothesis[3].
Intervention	All comparative studies assessed the role of surgical intervention. Procedural specifics were consistent across studies although tongue-tie division terminology differed (i.e. frenotomy, frenulotomy). No comparative study considered alternative treatments for ankyloglossia and its effect on breastfeeding.
Comparators	Two comparators were used: sham[1, 2] and no intervention[3]. These are synonymous except in relation to blinding of participants since no intervention was performed even in either group. No treatment is a common alternative to frenotomy and therefore its use is broadly applicable to the overall population at risk for ankyloglossia and its sequelae.
Outcomes	There was fair homogeneity among outcome measures used in these studies, which consisted of assessment of breastfeeding effectiveness and maternal nipple pain. However, the means of measuring breastfeeding effectiveness differed among studies. In one RCT, effectiveness was assessed both by maternal-report and objective observer immediately after frenotomy or sham.[1] A second RCT employed an objective observer to assess breastfeeding effectiveness (IBFAT) compared to sham immediately post-procedure.[2] The third RCT had an objective observer score breast latch using the LATCH and IBFAT outcome measures.[3] Nipple pain was assessed using either a visual analog scale (VAS) or the Short-form Montreal Pain Questionnaire (SF-MPQ). While VAS-type scales are commonly used for pain, specific levels may not be widely applicable to other populations of women breastfeeding a newborn with ankyloglossia.
Setting	The setting was variably reported in these studies. Frenotomy were performed in tertiary care hospitals and clinics and performed by pediatric surgeons, lactation consultants, and otolaryngologists. Two of three RCTs were not explicit whether frenotomy was performed as an inpatient or outpatient.

Table I-2. Applicability for KQ 2a

Domain	Description of applicability of evidence compared to question
Population	Neonates born with congenital ankylglossia between January 2010 and December 2010
Intervention	Frenotomy within first month of life
Comparators	Offered but declined frenotomy within first month of life; may or may not have received non-surgical interventions
Outcomes	Paternal (typically maternal) report of the 3 year old's difficulty: (1) cleaning teeth with the tongue, (2) licking the outside of the lips, and (3) eating ice cream
Timing	Outcomes measured at 3 years of age
Setting	Academic medical center hospital in a large, urban area

Table I-3. Applicability for KQ 2b

Domain	Description of applicability of evidence compared to question
Population	The study population primarily consisted of children with tongue-tie and perceived speech impairment, though inclusion criteria were not explicit. There was a small subset of pre-lingual patients who were treated for fear of speech impediment, though no speech concern had been diagnosed at the time of intervention.
Intervention	All interventions in this group were surgical. A variety of surgical techniques were utilized, included simple division with scalpel, scissors, and CO2 laser [4], frenulectomy/frenulotomy,[5] frenuloplasty,[6, 7] and the addition of genioglossus myotomy.[8]
Comparators	The majority of studies were non-comparative case series. Among the comparative studies, two cohort studies compared children with ankyloglossia after surgical management to those with ankyloglossia without surgical management and non-tongue-tied controls. A single RCT compared 4-flap frenuloplasty to horizontal to vertical frenuloplasty
Outcomes	Follow-up intervals ranged from several months to 3 years. Many studies evaluated speech improvement using parental self-report, including one of the cohort studies.[9] The second cohort study[10] measured articulation, and speech understandability with word, sentence and connected speech, as evaluated by blinded speech pathologists.
Setting	The setting was varied and variably reported in these studies. Procedures were performed in nurseries, outpatient clinics and in operating rooms, with no anesthetic, local and general anesthetic all being used. Pediatric surgeons, plastic surgeons and otolaryngologists performed the surgeries. Most studies were based in the United States, with a single study from each India, Korea, China and the United Kingdom.

Table I-4. Applicability for KQ 3

Domain	Description of applicability of evidence for a key question
Population	The population studied in the question of benefit of ankyloglossia repair for social concerns included children and adults with wide variation in ages. The patients were selected either by retrospective chart review or as they presented to otolaryngology clinics.
Intervention	Surgical repair only
Comparators	None
Outcomes	Outcomes measured were not consistent between studies with social concerns measured as a secondary outcome and the types of social outcomes considered were not consistent
Setting	Setting was inconsistently reported but most often surgeries occurred in outpatient settings.

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Section 3.0

New Discussion Items

Teledentistry

Coverage Question: Should the telehealth guideline be modified to specify when various teledentistry services are covered?

Question source: Holly Jo Hodges, CCO medical director

Background: Dr. Hodges is part of the Oregon Health Leadership Council (OHLC), which has been looking at dental telehealth. Dr. Hodges noted that no current teledentistry codes are included in the current telehealth guideline and she is requesting guidance on when CCOs/DCOs should cover teledentistry.

The OHLC is considering the following services as possibly appropriate for teledentistry:

1) Preventive dental or oral health screenings for children: the OHLC is looking for guidance on the following CDT codes:
    a. D1206 Fluoride varnish application
    b. D1310 Nutritional counseling
    c. D1320 Tobacco counseling
    d. D1321 High-risk counseling
    e. D1330 Oral hygiene instruction
2) Emergency department follow-up for non-traumatic dental conditions: the OHLC is looking for guidance on CDTs:
    a. D0190 Screening of a patient
    b. D0191 Assessment of a patient
    c. D1310 Nutritional counseling for the control of dental disease
    d. D1320 Tobacco counseling for the control and prevention of oral disease
    e. D1321 Counseling for the control and prevention of adverse oral, behavioral, and systemic health effects associated with high-risk substance use
    f. D1330 Oral hygiene instruction
    g. D9991-D9994: Dental case management
    h. D9997 Dental case management - patients with special health care needs
3) Certain services are appropriate for facilitated telehealth visits where a dental professional, such as an expanded practice dental hygienist (EPDH) or dental therapist, is located with the patient while the treating or consulting provider is in a separate location. Services that should be considered for these visits are (but are not necessarily limited to): CDT D0120-D0180

OHLC is considering the following recommendations for in-person visits:

1) Assessments for children in DHS custody: recommending an in-person visit with a dental professional
2) Oral evaluations for adults with diabetes: recommending an in-person visit with a dental professional

Teledentistry

Teledentistry, according to the ADA's Comprehensive Policy Statement on Teledentistry, refers to the use of telehealth systems and methodologies in dentistry. Teledentistry can include patient care and education delivery using, but not limited to, the following modalities:

- Live video (synchronous): Live, two-way interaction between a person (patient, caregiver, or provider) and a provider using audiovisual telecommunications technology.
- Store-and-forward (asynchronous): Transmission of recorded health information (for example, radiographs, photographs, video, digital impressions and photomicrographs of patients) through a secure electronic communications system to a practitioner, who uses the information to evaluate a patient's condition or render a service outside of a real-time or live interaction.
- Remote patient monitoring (RPM): Personal health and medical data collection from an individual in one location via electronic communication technologies, which is transmitted to a provider (sometimes via a data processing service) in a different location for use in care and related support of care.
- Mobile health (mHealth): Health care and public health practice and education supported by mobile communication devices such as cell phones, tablet computers, and personal digital assistants (PDA).

Previous HSC/HERC reviews:

Teledentistry was discussed in 2017 by OHAP and VBBS/HERC in relation to review of new CDT codes for teledentistry. During that review, OHAP members asked for limitations on the types of services that could be provided with these codes. HSD was charged with creating rules regarding teledentistry.

Current Oregon Administrative Rules on teledentistry (available at https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=285136) allow D0191 (assessment of a patient), D0120-D0180 (oral evaluations), and D9995-D9996 (teledentistry). "As stated in ORS 679.543 and this rule, payment for dental services may not distinguish between services performed using teledentistry, real time, or store-and-forward and services performed in-person."

Current Prioritized List/Coverage status:

CDT Code	Code Description	Current Line(s)
D0120-D0180	Oral evaluation	D0120, D0145, D0150, D0180: 53 PREVENTIVE DENTAL SERVICES D0140, D0160, D0170: 54 DENTAL CONDITIONS (E.G., INFECTION, PAIN, TRAUMA) D0171: Excluded
D0190	Screening of a patient	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
D0191	Assessment of a patient	3, 53
D1206	Topical application of fluoride varnish	3, 53
D1310	Nutritional counseling for the control of dental disease	53

Teledentistry

D1320	Tobacco counseling for the control and prevention of oral disease	5 TOBACCO DEPENDENCE
D1321	Counseling for the control and prevention of adverse oral, behavioral, and systemic health effects associated with high-risk substance use	53
D1330	Oral hygiene instruction	53
D9991-D9994	Dental case management	NEVER REVIEWED
D9995	Teledentistry - synchronous; real-time encounter	54
D9996	Teledentistry - asynchronous; information stored and forwarded to dentist for subsequent review	54
D9997	Dental case management - patients with special health care needs	ANCILLARY PROCEDURES

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

Telehealth services include a variety of health services provided by synchronous or asynchronous electronic communications, including secure electronic health portal, audio, or audio and video and clinician-to-clinician virtual consultations.

Criteria for coverage

The clinical value of the telehealth service delivered must reasonably approximate the clinical value of the equivalent services delivered in-person.

Coverage of telehealth services requires the same level of documentation, medical necessity, and coverage determinations as in-person visits.

Examples of covered telephone or online services include but are not limited to:

A) Extended counseling when person-to-person contact would involve an unwise delay or exposure to infectious disease.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-covered telehealth services include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Services which are part of care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
F) Services which relate to or take place within the postoperative period of a procedure provided by the physician are not separately covered. (Such a service is considered part of the procedure and is not be billed separately.)

Teledentistry

Codes eligible for telehealth delivery include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. Additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 is covered only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

Clinician to Patient Services billed using specified codes indicating telephone or online service delivery

Covered telephonic and online services include services related to evaluation, assessment and management as well as other technology-based services (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063, G2251-G2252).

Covered telephone and online services billed using these codes do not include either of the following:

A) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
B) Services which result in the patient being seen within 24 hours or the next available appointment.

Clinician-to-Clinician Consultations (telephonic, online or using electronic health record)

Covered interprofessional consultations delivered online, through electronic health records or by telephone (CPT 99446-99449, 99451-99452).

Store and Forward

Store and forward codes (HCPCS G2010, G2250) are only covered when billed concurrently with a code that includes medical decision making and communication with the patient (for example, HCPCS G2012).

Expert guidelines:

1) ADA policy on teledentistry
    a) Available at: https://www.ada.org/en/about/governance/current-policies/ada-policy-on-teledentistry
        i) Accessed 2/9/2024
    b) The ADA believes that examinations performed using teledentisty can be an effective way to extend the reach of dental professionals, increasing access to care by reducing the effect of distance barriers to care.

Teledentistry

OHAP input:

HERC staff summary: The ADA recommends use of teledentistry as a way to extend the reach of dental professionals. The current telehealth guideline does not include any mention of teledentistry. In general, assessments and counseling appear to be reasonable services to be provided via teledentistry.

OHAP should advise HERC staff on whether to add a section on teledentistry; if so, what should this section contain?

HERC staff recommendation:

1) Consider modifying Ancillary Guideline A5 as shown below

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

Telehealth services include a variety of health services provided by synchronous or asynchronous electronic communications, including secure electronic health portal, audio, or audio and video and clinician-to-clinician virtual consultations.

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The clinical value of the telehealth service delivered must reasonably approximate the clinical value of the equivalent services delivered in-person.

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B) Scheduling a test.
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Teledentistry

Codes eligible for telehealth delivery include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. Codes eligible for teledentistry include D0190, D9191, D1310, D1320, D1321, D1330 and D9991-D9997. Services are appropriate for facilitated telehealth visits where a dental professional, such as an EPDH or dental therapist, is located with the patient while the treating or consulting provider is in a separate location include: D0120-D0170, D0180, and D1206. Additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 is covered only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

Clinician to Patient Services billed using specified codes indicating telephone or online service delivery

Covered telephonic and online services include services related to evaluation, assessment and management as well as other technology-based services (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063, G2251-G2252).

Covered telephone and online services billed using these codes do not include either of the following:

A) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
B) Services which result in the patient being seen within 24 hours or the next available appointment.

Clinician-to-Clinician Consultations (telephonic, online or using electronic health record)

Covered interprofessional consultations delivered online, through electronic health records or by telephone (CPT 99446-99449, 99451-99452).

Store and Forward

Store and forward codes (HCPCS G2010, G2250) are only covered when billed concurrently with a code that includes medical decision making and communication with the patient (for example, HCPCS G2012).

D9995 and D9996 – ADA Guide to Understanding and Documenting Teledentistry Events

Developed by the ADA, this guide is published to educate dentists and others in the dental community on these procedures and their codes first published in CDT 2018 and effective January 1, 2018.

Introduction

CDT 2018 marks the first time teledentistry codes have been added to the code set. Teledentistry provides the means for a patient to receive services when the patient is in one physical location and the dentist or other oral health or general health care practitioner overseeing the delivery of those services is in another location. This mode of patient care makes use of telecommunication technologies to convey health information and facilitate the delivery of dental services without the physical constraints of a brick and mortar dental office.

The two full CDT Code entries are:

D9995 teledentistry – synchronous; real-time encounter

Reported in addition to other procedures (e.g., diagnostic) delivered to the patient on the date of service.

D9996 teledentistry – asynchronous; information stored and forwarded to dentist for subsequent review

Reported in addition to other procedures (e.g., diagnostic) delivered to the patient on the date of service.

The following pages contain a number of Questions and Answers, and Scenarios, all intended to provide readers with insight and understanding of how care is delivered and reported when teledentistry is a facet of the process.

Questions and Answers

1. What is telehealth and teledentistry?

   Telehealth is not a specific service; it refers to a broad variety of technologies and tactics to deliver virtual medical, health, and education services. As an umbrella term, it is further defined when applied to specific health care disciplines, such as dentistry.

   Teledentistry, according to the ADA's *Comprehensive Policy Statement on Teledentistry*, refers to the use of telehealth systems and methodologies in dentistry. Teledentistry can include patient care and education delivery using, but not limited to, the following modalities:

   - Live video (synchronous): Live, two-way interaction between a person (patient, caregiver, or provider) and a provider using audiovisual telecommunications technology.
   - Store-and-forward (asynchronous): Transmission of recorded health information (for example, radiographs, photographs, video, digital impressions and photomicrographs of patients) through a secure electronic communications system to a practitioner, who uses the information to evaluate a patient's condition or render a service outside of a real-time or live interaction.
   - Remote patient monitoring (RPM): Personal health and medical data collection from an individual in one location via electronic communication technologies, which is transmitted

to a provider (sometimes via a data processing service) in a different location for use in care and related support of care.

- Mobile health (mHealth): Health care and public health practice and education supported by mobile communication devices such as cell phones, tablet computers, and personal digital assistants (PDA).

2. Why are there two teledentistry CDT Codes, but four delivery modalities?

   Delivery of Remote Patient Monitoring (RPM) and Mobile Health (mHealth) may occur in either a synchronous or asynchronous information exchange environment.

3. What prompts the need for teledentistry?

   Teledentistry is a means to an end – a patient's oral health. The reason or reasons why a teledentistry event occurs depends on the circumstances, such as when all persons who must be involved are not able to be in the same physical location. Another determining facet is the judgment of the dentist or other oral health or general health practitioner, all acting in accordance with applicable state law, regulation or licensure.

4. How is a teledentistry event affected when the health care practitioners are in different states?

   A teledentistry event is subject to applicable state law, regulation or licensure. All involved persons (the dentist or other oral health or general health care practitioner) must determine if a teledentistry event can occur when all participants are not in the same state.

5. What are the notable attributes of a synchronous encounter reported with D9995, and asynchronous teledentistry reported with C9996?

   Synchronous teledentistry (D9995) is delivery of patient care and education where there is live, two-way interaction between a person or persons (e.g., patient; dental, medical or health caregiver) at one physical location, and an overseeing supervising or consulting dentist or dental provider at another location. The communication is real-time and continuous between all participants who are working together as a group. Use of audiovisual telecommunications technology means that all involved persons are able to see what is happening and talk about it in a natural manner.

   Asynchronous teledentistry (D9996) is different as there is no real-time, live, continuous interaction with anyone who is not at the same physical location as the patient. Also known as store-and-forward, asynchronous teledentistry involves transmission of recorded health information (e.g., radiographs, photographs, video, digital impressions and photomicrographs of patients) through a secure electronic communications system to another practitioner for use at a later time.

6. Who would document and report a D9995 or D9996 CDT Code?

   The dentist who oversees the teledentistry event, and who via diagnosis and treatment planning completes the oral evaluation, documents and reports the appropriate teledentistry CDT code. Applicable state regulations may also determine the oral health or general health practitioner who documents and reports these codes.

   As noted in their descriptors, either one or the other teledentistry code is reported in addition to other procedures delivered to the patient on the date of service. In addition, both the individuals collecting records in the off-site setting and the dentist reviewing the records should document those activities in the progress notes in the patient's chart.

7. Are there CDT Codes for: a) documenting collection and transmission of information in a teledentistry event; and b) for receipt of the information?

   There are no such discrete codes. As noted in the answer to question #6, the collection, transmission and receipt actions should be noted in the patient's record. An unspecified procedure by report code may also be used as part of this documentation, with the required narrative report containing the pertinent information.

8. Who would document and report other procedures delivered during a teledentistry event?

   The dentist or other oral health or general health practitioner acting in accordance with applicable state law, regulation or licensure, reports the appropriate CDT Code for these procedures, such as prophylaxis, topical fluoride application, diagnostic images. Supervision requirements within a state practice act determine whether the dentist must document and report all the other procedures, or if they may be reported whole or in part by another type of licensed practitioner.

   More than one claim submission may be necessary when:

   - there is a continuum of care that begins with a teledentistry encounter at a remote location, and continues with other services being delivered at a dental practice location, or
   - state practice acts permit different licensed health care practitioners to submit claims for the particular services they provided during the teledentistry encounter.

   Notes:

   a) Teledentistry is a mode of dental service delivery that, when applicable, is reported in addition to the other procedures provided to the patient.

   b) Procedure delivery is by a natural person (e.g., dentist); the billing entity may be a natural person or a legal person (i.e., the facility where the service is delivered).

   c) The ADA's "Comprehensive Policy Statement on Teledentistry" states that dentists and allied dental personnel who deliver services through teledentistry modalities must be licensed or credentialed in accordance with the laws of the state in which the patient receives service. The delivery of services via teledentistry must comply with the state's scope of practice laws, regulations or rules.

9. Who has responsibility for services delivered via teledentistry?

   Responsibility, and liability, for services delivered is determined by applicable state law and regulations. Each dentist, hygienist and others involved in a teledentistry appointment should become familiar with applicable state or federal regulations to determine their liability exposure, and whether or not the person receiving care becomes their patient of record. Please note that "patient of record" may be defined differently under applicable state regulations. This could be a factor to consider in a teledentistry event where the patient and some members of the team of providers are in different states.

10. With responsibility comes potential liability – what should I do to protect myself and my practice when I engage in teledentistry?

    As noted in the answer to question #9 (immediately above) liability is determined by applicable state law and regulations. This concern should be discussed with your personal legal counsel and insurance advisor to determine whether or not your existing liability insurance policies cover

this risk. Additional personal, professional and practice insurance coverage may be needed to address any coverage gaps.

11. How would D9995 or D9996 be reported on a dental claim submission?

    A claim submission includes the services provided to one patient. Each claim detail line identifies the particular procedure and the date it was delivered to the patient. D9995 or D9996 are reported in addition to the codes for other procedures (e.g., prophylaxis; diagnostic imaging) reported separately when the patient presents for care.

    Appendix 1 contains special claim completion instructions for the ADA Dental Claim Form (©2012). These instructions are envisioned as the model for reporting teledentistry CDT Codes on the HIPAA standard electronic dental claim transaction (837Dv5010).

12. Are D9995 and D9996 used when a claim for teledentistry is submitted to a medical benefit plan?

    D9995 and D9996 are CDT Codes that are applicable to claims filed against a dental benefit plan. Dental claim content, format and completion instructions differ from claims filed against a medical benefit plan. Claims filed against a medical benefit plan use a unique format, are prepared with different code sets, and follow their own completion instructions. Medical benefit claims are outside the scope of this guide.

13. What documentation should I maintain in my patient records, and what will be needed on a claim submission when reporting D9995 and D9996?

    The patient record must include the CDT Code that reflects the type of teledentistry encounter, and there may be additional state documentation requirements to satisfy. A claim submission must include all required information as described in the completion instructions for the ADA paper claim form and the HIPAA standard electronic dental claim. Some government programs (e.g., Medicaid) may have additional claim reporting requirements.

14. What dental benefit plan coverage – commercial or governmental – is anticipated?

    Current dental benefit plan coverage and reimbursement provisions should apply to services delivered in-office and via teledentistry. However, there is no expectation that commercial and government dental benefit plans must create new coverage provisions pertaining to teledentistry. Further, coverage and reimbursement for D9995 and D9996 is likely to vary between commercial benefit plan offerings and by state for government programs (e.g. Medicaid).

    The ADA's "Comprehensive Policy Statement on Teledentistry" sets an expectation of consistent and equitable coverage for all procedures associated with teledentistry services – as noted in the following extract.

    > **Reimbursement:** Dental benefit plans and all other third-party payers, in both public (e.g. Medicaid) and private programs, shall provide coverage for services using teledentistry technologies and methods (synchronous or asynchronous) delivered to a covered person to the same extent that the services would be covered if they were provided through in-person encounters. Coverage for services delivered via teledentistry modalities will be at the same levels as those provided for services provided through in-person encounters and not be limited or restricted based on the technology used or the location of either the patient or the provider as long as the health care provider is licensed in the state where the patient receives service.

This policy statement concerns equitable application of existing coverage and reimbursement provisions, and recognizes that dental benefit plan coverage and reimbursement provisions are likely to vary.

15. How would dental benefit plan reimbursements, meaning claim payments, be processed when more than one oral health or medical health practitioner is involved in a teledentistry encounter?

    Dental benefit plan reimbursements are, as today, payable to the billing entity on the claim submission, who may be a natural person (e.g., dentist) or a legal person (e.g., dental practice). Allocation of reimbursements is subject to the business relationships between the reimbursement's recipient and other oral health or medical health practitioners involved in the teledentistry event – such relationships are outside the scope of this guide.

Coding Scenarios

Note: These two scenarios assume that the persons and services involved are in accordance with local state practice act, laws, rules, and regulations

1. Assessments at Senior Living Facility – A "Real-Time" Teledentistry Encounter

A hygienist is scheduled to meet with residents of a local senior living facility in order to assess their potential need for dental treatment. The facility does not have dedicated space or equipment for dental assessments, so the hygienist brings a laptop computer and an intraoral camera. This equipment is used to enable information capture and a real-time connection with the dentists via a HIPAA-compliant (Security and Privacy) connection that uses encryption and a secure "cloud" server.

During her or his visit the hygienist records patient information that includes perio probing and charting, a visual oral cancer examination, and capture of high-quality intraoral diagnostic images. The dentist through this real-time connection sees 10 patients exhibiting evidence of the need for immediate or further care (e.g., restorations; soft tissue biopsies). Several of the senior living facility residents schedule their care at the affiliated brick and mortar dental practice.

What CDT Codes would be used to document the services provided on the day of this real-time encounter?

In this scenario patients present for diagnostic and evaluative procedures. The dentist is at a different physical location with complete and immediate access to patient information being captured, and the ability to interact vocally and visually with the patient

The following procedure codes are reported by the oral health or general health practitioner, as applicable, **for each patient** who received the services described.

D0191 assessment of a patient

D0350 2D oral/facial photographic image obtained intra-orally or extra-orally

D0351 3D photographic image

Note: The types of diagnostic image (2-D or 3-D), as well as the number of separate images captured would be determined by the dentist to adequately document the clinical condition.

D01xx (oral evaluation CDT Code – determined and reported by the dentist – or by another oral health or general health practitioner in accordance with applicable state law**)**

D9995 teledentistry – synchronous; real-time encounter

Note: D9995 is reported once for each patient, in the same manner as CDT Code "D9410 house/extended care facility call" (once per date of service per patient) to document the type of teledentistry interaction in this setting on the date of service.

2. Screening Services at an Off-Site Setting - A "Store and Forward" Teledentistry Encounter

A hygienist in an off-site setting collects a full set of electronic dental records as allowed in the state where the facility is located. These records include radiographs, photographs, charting of dental conditions, health history, consent, and applicable progress notes. This stored information is forwarded to the dentist via a HIPAA-compliant (Security and Privacy) connection that uses encryption and a secure "cloud" server. At a later time the dentist completes a comprehensive oral examination, diagnosis, and treatment plan.

What CDT Codes would be used to document the services provided in this scenario?

In this scenario the individual interacts only with the hygienist. Information collected is conveyed to the dentist for diagnosis, evaluation and treatment planning at a later time, and possibly at a different location. This dentist has no live vocal or visual interaction with the individual or hygienist during information collection.

The following procedure codes are reported, as applicable, **for each individual** who received the services described above.

D0190 screening of a patient

D0350 2D oral/facial photographic image obtained intra-orally or extra-orally

D0351 3D photographic image

Note: The types of diagnostic image (2-D or 3-D), as well as the number of separate images captured would be determined by the clinical condition being documented.

D9996 teledentistry – asynchronous; information stored and forwarded to dentist for subsequent review

Note: D9996 is reported once for each individual to document the type of teledentistry interaction in this setting on the date of service.

Appendix 1

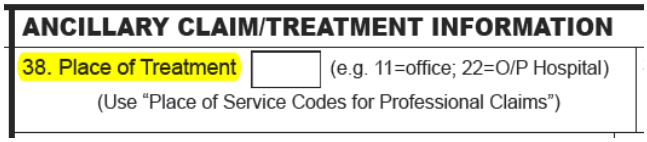
Special Claim Completion Instructions – Coding a Teledentistry Event

A teledentistry event claim or encounter submission involves reporting the appropriate Place of Service (POS) code and CDT Code.

- POS code **02** (Telehealth – the location where health services and health related services are provided or received, through telecommunication technology) was added to that code set effective January 1, 2017.
- CDT Codes **D9995** and **D9996** are effective January 1, 2018. These codes are reported in addition to other services (e.g., diagnostic) reported separately when the patient presents for care. They document services provided by the dentist, or other practitioner providing care, who is not in direct contact with the patient at the time of the encounter.

These instructions apply only to the ADA Dental Claim Form. Please contact your practice management system vendor for guidance when reporting D9995 or D9996 on the HIPAA standard electronic dental claim (837D v 5010).

POS code **02** is recorded in Item # 38 on the claim form.



Note: POS is at the Claim level for dental services, which means it pertains to all services reported on the claim submission.

D9995 or **D9996** is recorded on **any** unused line (1 through 10) in the 'Record of Services Provided' section of the form.

RECORD OF SERVICES PROVIDED

	24. Procedure Date (MM/DD/CCYY)	25. Area of Oral Cavity	26. Tooth System	27. Tooth Number(s) or Letter(s)	28. Tooth Surface	29. Procedure Code	29a. Diag. Pointer	29b. Qty.	30. Description	31. Fee
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

The following special instructions for Items 24 - 31 apply to the service line on which D9995 or D9996 is reported.

24. Procedure Date (MM/DD/CCYY): **Enter** date the dental procedures delivered in the teledentistry encounter were performed. The date must have two digits for the month, two for the day, and four for the year.

25. Area of Oral Cavity: Not Used

26. Tooth System: Not Used

27. Tooth Number(s) or Letter(s): Not Used

28. Tooth Surface: Not Used

29. Procedure Code: **Enter** D9995 or D9996 as applicable. Only one type of teledentistry service may be reported for the encounter.

    29a Diagnosis Code Pointer: Not Used

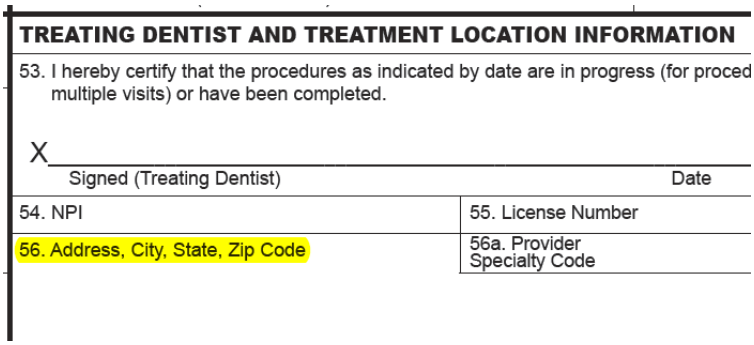
    29b Quantity: Cannot be greater than "1"

30. Description: **Enter** "Teledentistry – Synchronous" or "Teledentistry – Asynchronous" as applicable.

31. Fee: **Enter** the full fee for the reported teledentistry procedure that is related to the other procedures delivered in the encounter.

    Note: A full fee may be zero dollars.

In addition to the above, Item # 56 in the claim's "Treating Dentist and Treatment Location" block is the location where the patient being treated is physically located, and may differ from the where the "treating dentist" is located.



TREATING DENTIST AND TREATMENT LOCATION INFORMATION	
53. I hereby certify that the procedures as indicated by date are in progress (for proced multiple visits) or have been completed.	
X_____ Signed (Treating Dentist)	Date
54. NPI	55. License Number
56. Address, City, State, Zip Code	56a. Provider Specialty Code

56. Address, City, State, Zip Code: Enter the physical location where the treatment was rendered. Must be a street address, not a Post Office Box.

Questions or Assistance?

Call 800-621-8099 or send an email to dentalcode@ada.org

Notes:

- This document includes content from the ADA publication – *Current Dental Terminology (CDT)* ©2017 American Dental Association (ADA). All rights reserved.
- This document includes content from the ADA publication – *ADA Dental Claim Form* ©2012 American Dental Association (ADA). All rights reserved.
- Version History

Date	Version	Remarks – Change Summary
07/17/2017	1	Initial publication

Fluoride Varnish Frequency

Coverage Question: Should the guideline regarding fluoride varnish be updated to clarify the number of covered applications per year?

Question source: Metrics and Scoring Committee

Background:

The Metrics & Scoring Committee is looking at possibly including topical fluoride varnish for kids. It's a national measure and requires two applications. Currently, the guideline on fluoride varnish allows two applications per year for average risk children and up to 4 per year for high risk children. It was discussed at OHAP in the past that Medicaid eligibility (i.e. low socioeconomic status) is one of the qualifying definitions of moderate to high risk for which varnish is indicated. All patients under OHP would thus meet this definition of risk. Metrics and Scoring would like clarification of the number of covered applications per year.

Previous HSC/HERC reviews:

The fluoride varnish guideline was last reviewed in 2013. At that time, a 2009 MED report and the 2006 ADA guideline were reviewed. Both of these sources recommended fluoride varnish twice per year.

Current Prioritized List/Coverage status:

Code	Code Description	Current Lines(s)
D1206	Topical application of fluoride varnish	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 53 PREVENTIVE DENTAL SERVICES
D1208	Topical application of fluoride excluding varnish	53 PREVENTIVE DENTAL SERVICES

GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE

Lines 3,53

Dental cleaning is limited to once per 12 months for adults and twice per 12 months for children up to age 19 (D1110, D1120). More frequent dental cleanings may be required for certain higher risk populations.

Fluoride varnish (99188) is included on Line 3 for use with children 18 and younger during well child preventive care visits. Fluoride treatments (D1206 and D1208) are included on Line 53 PREVENTIVE DENTAL SERVICES for use with adults and children during dental visits. The total number of fluoride applications provided in all settings is not to exceed four per twelve months for a child at high risk for

dental caries and two per twelve months for a child not at high risk. The number of fluoride treatments is limited to once per 12 months for average risk adults and up to four times per 12 months for high-risk adults.

Evidence:

1) **Chou 2023**, USPSTF review of preventive interventions for oral health in children and adolescents aged 5 to 17 years
    a. A good-quality systematic review (searches through May 2013) included 14 trials of fluoride varnish vs placebo or no varnish in children 5 years or older (n = 6965)
        i. Fluoride varnish was most commonly administered as 5% sodium fluoride varnish (22 600 ppm) every 6 months
        ii. In all trials, varnish was applied by dental professionals in schools or local clinics
    b. The systematic review found fluoride varnish associated with a DMFS/DFS-prevented fraction of 0.43 (95% CI, 0.30-0.57) at 1 to 4.5 years (14 trials; n = 3419)
    c. When administered by dental professionals or in school settings, fluoride supplements compared with placebo or no intervention were associated with decreased change from baseline in the number of decayed, missing, or filled permanent teeth (DMFT index) or decayed or filled permanent teeth (DFT index) (mean difference, −0.73 [95% CI, −1.30 to −0.19]) at 1.5 to 3 years (6 trials; n = 1395)
    d. The harms of preventive interventions were sparsely reported, although serious harms were not described
    e. Conclusions: Administration of fluoride supplements, fluoride gels, varnish, and sealants in dental or school settings improved caries outcomes
2) **Chou 2021**, USPSTF review of preventive interventions for oral health in children and adolescents under age 5
    a. Fifteen trials evaluated topical fluoride. Sample sizes ranged from 123 to 2536 (total 9541 participants)
        i. Three trials were rated good quality and the rest fair quality
        ii. Fluoride varnish was most commonly administered as 5% sodium fluoride every 6 months. Topical fluoride was administered by a dental health professional in all trials in which this information was reported
    b. Topical fluoride was associated with significant decreased caries increment (13 trials, n = 5733; mean difference, −0.94 [95% CI, −1.74 to −0.34]
    c. Topical fluoride was associated with improved outcomes, with a number needed to treat to prevent 1 child with incident caries of about 14 (95% CI, 8 to 50)
    d. Limited evidence on harms associated with topical fluoride indicated no increased risk of fluorosis or adverse events vs placebo. Serious adverse events were not reported, though some children had difficulty tolerating the varnish application because of odor or taste
    e. Conclusion: Dietary fluoride supplementation and fluoride varnish were associated with improved caries outcomes in higher-risk children and settings

Expert guidelines:

1) **American Academy of Pediatric Dentistry 2023,** fluoride therapy

Fluoride Varnish Frequency

a. Recommends professionally-applied topical fluoride treatments such as five percent NaFV or 1.23 percent F gel preparations at least twice per year to reduce incidence of dental caries.

2) **USPSTF 2023**, Screening and Preventive Interventions for Oral Health in Children and Adolescents Aged 5 to 17 Years
    a. The evidence is insufficient to assess the balance of benefits and harms of preventive interventions performed by primary care clinicians for oral health conditions, including dental caries
        i. I recommendation
3) **USPSTF 2021**, Screening and Interventions to Prevent Dental Caries in Children Younger Than 5 Years
    a. Apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption
        i. B level recommendation
4) **American Dental Association 2013**, fluoride guideline
    a. For patients at elevated risk of developing caries
        i. Younger than 6 years: 2.26 percent fluoride varnish at least every three to six months
            1. Moderate certainty evidence; benefit outweighs potential harms
        ii. 6-18 years: 2.26 percent fluoride varnish at least every three to six months or 1.23 percent fluoride (APF*) gel for four minutes at least every three to six months
            1. Moderate certainty evidence; benefit outweighs potential harms
        iii. Older than 18 years: 2.26 percent fluoride varnish at least every three to six months or 1.23 percent fluoride (APF*) gel for four minutes at least every three to six months
            1. Based on expert opinion

OHAP input:

HERC staff summary:

Systematic reviews from a highly trusted source (USPSTF) found evidence of reduced caries incidence with the use of fluoride varnish. The studies included in these reviews generally applied varnish every 6 months. Expert guidelines all recommend the use of fluoride varnish “at least every 6 months” in children, with the ADA recommending varnish “at least every 3 to 6 months.”

HERC staff recommend considering modifications to guideline note 17 to clarify that coverage of fluoride varnish is covered up to 4 times a year for children.

HERC staff recommendation:

Fluoride Varnish Frequency

1) Modify GN17 as shown below

GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE

Lines 3,53

Dental cleaning is limited to once per 12 months for adults and twice per 12 months for children up to age 19 (D1110, D1120). More frequent dental cleanings may be required for certain higher risk populations.

Fluoride varnish (99188) is included on Line 3 for use with children 18 and younger during well child preventive care visits. Fluoride treatments (D1206 and D1208) are included on Line 53 PREVENTIVE DENTAL SERVICES for use with adults and children during dental visits. The total number of fluoride applications provided in all settings is not to exceed four per twelve months for children up to age 19 ~~a child at high risk for dental caries and two per twelve months for a child not at high risk~~. The number of fluoride treatments is limited to once per 12 months for average risk adults and up to four times per 12 months for high-risk adults.

JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Screening, Referral, Behavioral Counseling, and Preventive Interventions for Oral Health in Children and Adolescents Aged 5 to 17 Years

A Systematic Review for the US Preventive Services Task Force

Roger Chou, MD; Christina Bougatsos, MPH; Jessica Griffin, MS; Shelley S. Selph, MD, MPH; Azrah Ahmed, BA; Rongwei Fu, PhD; Chad Nix, MSc; Eli Schwarz, DDS, MPH, PhD

IMPORTANCE Dental caries is common in children and adolescents aged 5 to 17 years and potentially amenable to primary care screening and prevention.

OBJECTIVE To systematically review the evidence on primary care screening and prevention of dental caries in children and adolescents aged 5 to 17 years to inform the US Preventive Services Task Force.

DATA SOURCES MEDLINE, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews (to October 3, 2022); surveillance through July 21, 2023.

STUDY SELECTION Diagnostic accuracy of primary care screening instruments and oral examination; randomized and nonrandomized trials of screening and preventive interventions and systematic reviews of such studies; cohort studies on primary care oral health screening and preventive intervention harms.

DATA EXTRACTION AND SYNTHESIS One investigator abstracted data; a second checked accuracy. Two investigators independently rated study quality. Random-effects meta-analysis was performed for fluoride supplements and xylitol; for other preventive interventions, pooled estimates were used from good-quality systematic reviews.

MAIN OUTCOMES AND MEASURES Dental caries, morbidity, functional status, quality of life, harms; diagnostic test accuracy.

RESULTS Three systematic reviews (total 20 684 participants) and 19 randomized clinical trials, 3 nonrandomized trials, and 1 observational study (total 15 026 participants) were included. No study compared screening vs no screening. When administered by dental professionals or in school settings, fluoride supplements compared with placebo or no intervention were associated with decreased change from baseline in the number of decayed, missing, or filled permanent teeth (DMFT index) or decayed or filled permanent teeth (DFT index) (mean difference, −0.73 [95% CI, −1.30 to −0.19]) at 1.5 to 3 years (6 trials; n = 1395). Fluoride gels were associated with a DMFT- or DFT-prevented fraction of 0.18 (95% CI, 0.09-0.27) at outcomes closest to 3 years (4 trials; n = 1525), fluoride varnish was associated with a DMFT- or DFT-prevented fraction of 0.44 (95% CI, 0.11-0.76) at 1 to 4.5 years (5 trials; n = 3902), and resin-based sealants were associated with decreased risk of carious first molars (odds ratio, 0.21 [95% CI, 0.16-0.28]) at 48 to 54 months (4 trials; n = 440). No trial evaluated primary care counseling or dental referral. Evidence on screening accuracy, silver diamine fluoride, xylitol, and harms was very limited, although serious harms were not reported.

CONCLUSIONS AND RELEVANCE Administration of fluoride supplements, fluoride gels, varnish, and sealants in dental or school settings improved caries outcomes. Research is needed on the effectiveness of oral health preventive interventions in primary care settings and to determine the benefits and harms of screening.

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Multimedia

Related article page 1666 and **JAMA Patient Page** page 1703

Supplemental content

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Oral health issues, most commonly due to dental caries, are common in children and adolescents and are often untreated.[1] Dental caries can lead to pain, disability, and decreased well-being.[2-5] Gaps exist in the provision of oral health services in school-aged children[6] and include disparities related to race and ethnicity, socioeconomic status, and other factors.[1,7] In school-aged children and adolescents, oral health screening and preventive interventions could potentially be provided in primary care settings and reduce associated negative health consequences and disparities. This evidence report was conducted to inform the US Preventive Services Task Force (USPSTF) for a new recommendation on primary care screening, dental referral, behavioral counseling, and preventive interventions for oral health in children and adolescents aged 5 to 17 years. This report does not address school- or community-based oral health interventions,[8] which are outside the USPSTF's scope. A complementary evidence report was conducted for the USPSTF on oral health screening and prevention in adults[9]; the USPSTF addressed oral cancer screening separately[10] and previously addressed screening and prevention of dental caries in children younger than 5 years.[11,12]

Methods

Scope of the Review

Detailed methods and evidence tables with additional study details are available in the full evidence report.[13] **Figure 1** and **Figure 2** show the analytic frameworks and key questions (KQs) that guided the review. Separate analytic frameworks were used to distinguish treatment of children and adolescents with existing dental caries or periodontal disease (screening) from treatment of those without those conditions (preventive interventions). The full report[13] includes findings for contextual questions (not systematically reviewed) on the association between dental caries and long-term health outcomes, oral health disparities, and primary care interventions to reduce disparities. In addition, this article focuses on results from 2 fair-quality trials of xylitol[15,16]; results of 8 poor-quality xylitol trials are described in the full report.[13]

Search Strategies

A research librarian searched MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews from inception to October 3, 2022 (eMethods 1 in the Supplement). Searches were supplemented by reference list review of relevant articles. Since October 3, 2022, ongoing surveillance was conducted through article alerts and targeted searches of journals to identify major studies published in the interim that could affect the conclusions or understanding of the evidence and the related USPSTF recommendation. The last surveillance was conducted on July 21, 2023, and identified no eligible randomized trials.

Study Selection

Two investigators independently reviewed titles, abstracts, and full-text articles using predefined eligibility criteria (eMethods 2 in the Supplement). The population was asymptomatic children and adolescents aged 5 to 17 years who were not selected on the basis of having existing dental caries. Screening and diagnostic accuracy studies conducted in primary care settings of oral health examination or risk assessment instruments were eligible. Studies of risk instruments not administered in primary care settings were also eligible if they were relevant to primary care (ie, did not involve a dental professional examination or specialty tests). Eligible preventive interventions were primary care oral health behavioral counseling, referral to a dental professional, and preventive medications potentially feasible for primary care administration (not requiring extensive dental training): topical fluoride (varnish, foam, or gel), silver diamine fluoride (SDF) topical solution, dental sealants, and xylitol. Comparisons were against placebo or no intervention.

The most commonly reported outcome was dental caries (incidence or caries burden, often measured as the number of decayed, missing, or filled permanent teeth [DMFT index] or surfaces [DMFS index]; decayed or filled teeth [DFT] or surfaces [DFS] were also used in children because missing permanent teeth were less common and might not be due to caries). Other outcomes included periodontal disease presence and severity, morbidity, quality of life, functional status, and harms. Randomized or nonrandomized trials and diagnostic accuracy studies were eligible; cohort studies were also eligible for screening and preventive intervention harms.

Data Abstraction and Quality Rating

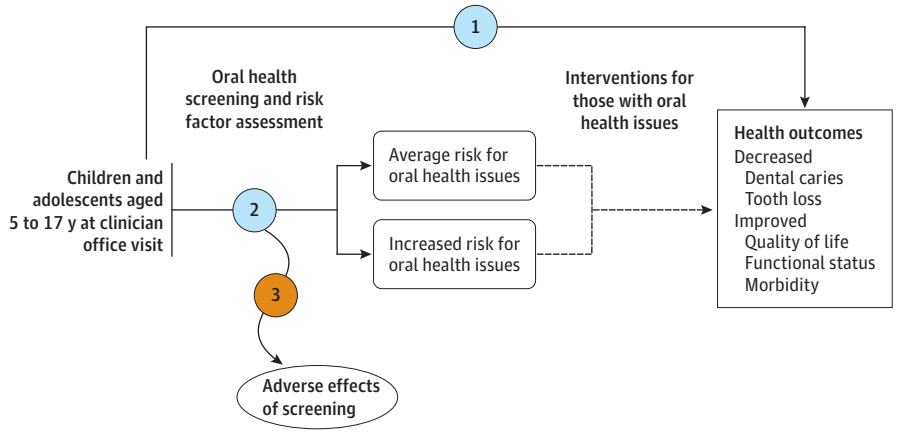
One investigator abstracted details about the study design, patient population, setting, interventions or screening instruments, analysis, follow-up, and results from each study. A second investigator reviewed abstracted data for accuracy. Two independent investigators assessed the quality of each study as good, fair, or poor using predefined criteria developed by the USPSTF (eMethods 3 in the Supplement). Discrepancies were resolved by consensus. In accordance with the USPSTF Procedure Manual,[14] studies rated poor quality were included only if higher-quality evidence was unavailable.

Data Synthesis

For all KQs, the overall quality of evidence was rated as "good," "fair," or "poor" based on study limitations, consistency, precision, reporting bias, and applicability, using the approach described in the USPSTF Procedure Manual.[14]

Meta-analyses of oral health preventive interventions from high-quality systematic reviews were reported when available. Systematic reviews measured caries burden based on the prevented fraction (caries index in control group minus intervention group, divided by the control group caries index) or (for sealants) likelihood of first carious molars. For fluoride supplements, which lacked high-quality systematic reviews, profile likelihood model random-effects meta-analysis using Stata/SE version 16.1 (StataCorp) was performed to summarize effects on caries burden, based on the difference in DMFT or DFT increment (ie, difference in change from baseline to follow-up between treatment vs placebo or no treatment in the DMFT or DFT index; see eMethods 4 in the Supplement for detailed meta-analytic methods). Analyses were conducted stratifying on relevant factors, including placebo or no treatment control; school or home setting; follow-up less than 3 years or 3 years or more; Europe or Canada vs other geographic region; high or low baseline caries burden; age 10 years or older or younger than 10 years; and study quality. All significance testing was 2-tailed; *P* values of .05 or less were considered statistically significant. Assessment for

Figure 1. Analytic Framework and Key Questions: Screening for Oral Health in Children and Adolescents Aged 5 to 17 Years



Key questions

1. How effective is screening for oral health performed by a primary care clinician in preventing negative oral health outcomes?
2. How accurate is screening for oral health performed by a primary care clinician in identifying children and adolescents who
   a. Have oral health issues?
   b. Are at increased risk of future oral health issues?
3. What are the harms of screening for oral health performed by a primary care clinician?

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. A dashed line depicts a health outcome that follows an intermediate outcome. For additional information, see the USPSTF Procedure Manual.[14]

small study effects was not performed because the meta-analyses had fewer than 10 studies.[17]

Results

Across all KQs, 3 systematic reviews[18-20] (total of 20 684 participants) of 54 unique trials (53 publications)[21-73] and 23 additional studies (in 27 publications[15,16,74-98]; total of 15 026 participants) were included (**Figure 3**). One study assessed diagnostic accuracy of screening[74]; the systematic reviews[18-20] and other 22 studies (19 randomized clinical trials[15,16,75-91] and 3 nonrandomized trials[92-94]) addressed preventive interventions.

Screening

Key Question 1. How effective is screening for oral health performed by a primary care clinician in preventing negative oral health outcomes?

No study addressed this KQ.

Key Question 2a. How accurate is screening for oral health performed by a primary care clinician in identifying children and adolescents who have oral health issues?

For identification of untreated caries in children aged 5 to 12 years, 1 fair-quality study[74] found visual screening by a registered nurse (n = 219) following 5 hours of training associated with sensitivity of 0.92 (95% CI, 0.84-0.97) and specificity of 0.993 (95% CI, 0.96-0.9998), and a 17-item questionnaire completed by children's parents or guardians (n = 305) associated with sensitivity of 0.69 (95% CI, 0.60-0.77) and specificity of 0.88 (95% CI, 0.83-0.93) (eTables 1 and 2 in the Supplement). The reference standard was a full dentist examination.

Key Question 2b. How accurate is screening for oral health performed by a primary care clinician in identifying children and adolescents who are at increased risk for future oral health issues?

No study addressed this KQ.

Key Question 3. What are the harms of screening for oral health performed by a primary care clinician?

No study addressed this KQ.

Prevention

Key Question 1. How accurate is screening performed by a primary care clinician in identifying children and adolescents who are at increased risk of future oral health issues?

No study addressed this KQ.

Key Question 2. How effective is oral health behavioral counseling provided by a primary care clinician in preventing oral health issues?

No study addressed this KQ.

Key Question 3. How effective is referral by a primary care clinician to a dental health care provider in preventing oral health issues?

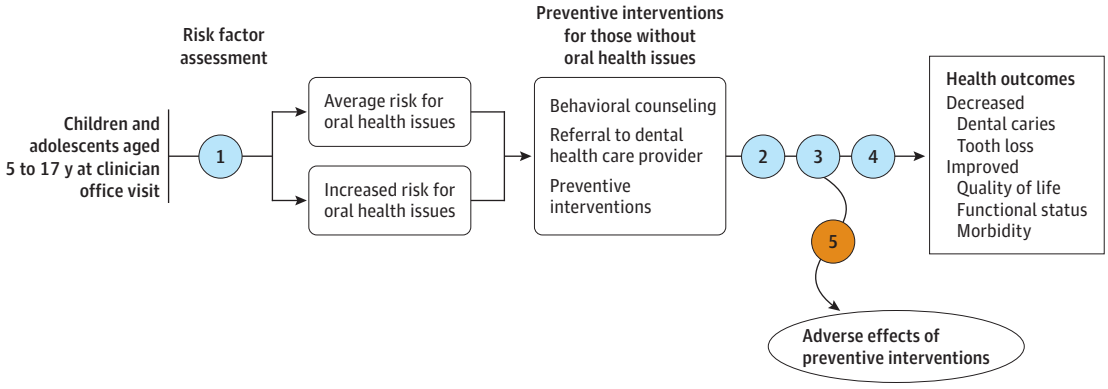
No study addressed this KQ.

Key Question 4. How effective are preventive interventions in preventing oral health issues?

Fluoride Supplements

Seven fair-quality trials (reported in 8 publications; n = 3382) evaluated fluoride supplements vs placebo or no supplement in children 5 years or older in settings with low socioeconomic status, nonfluoridated water, or high caries burden (eTables 3 and 4 in the Supplement).[75-81,95] Trials were conducted in the US (3 studies),

Figure 2. Analytic Framework and Key Questions: Interventions to Prevent Oral Health Issues in Children and Adolescents Aged 5 to 17 Years



Key questions

1. How accurate is screening for oral health performed by a primary care clinician in identifying children and adolescents who are at increased risk of future oral health issues?[a]
2. How effective is oral health behavioral counseling provided by a primary care clinician in preventing oral health issues?
3. How effective is referral by a primary care clinician to a dental health care provider in preventing oral health issues?
4. How effective are preventive interventions in preventing oral health issues?
5. What are the harms of specific interventions (behavioral counseling, referral, and preventive interventions) to prevent oral health issues?

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. For additional information, see the USPSTF Procedure Manual.[14]

[a] This is the same as KQ2b from the screening analytic framework (Figure 1).

the UK (3 studies), and Taiwan (1 study). All trials recruited children from schools and were published before 1990 except for 1 (published in 2013).[79] Fluoride supplements were administered daily as acidulated phosphate fluoride or sodium fluoride tablets. In 1 trial of older children (mean age, 12.5 years),[76] fluoride supplements were taken at home; all other trials evaluated supervised supplement administration at school. All trials had unclear randomization and allocation concealment methods and were rated fair-quality. Other methodological limitations included open-label design and high attrition.

Fluoride supplements were associated with a decreased DMFT or DFT increment compared with placebo or no supplement at 1.5 to 3 years (6 trials; effective n = 1395; mean difference, −0.73 [95% CI, −1.30 to −0.19]) (eFigure 1 in the Supplement); however, statistical heterogeneity was substantial (I^2 = 80%).[75-81,95] In a stratified analysis, supplements were not associated with reduced DMFT/DFT increment in 1 trial[76] of home administration in adolescents that reported low adherence (n = 178; mean difference, 0.13 [95% CI −0.38 to 0.64]), but all school-administered trials reported reduced DMFT/DFT increment (5 trials; effective n = 1217; pooled mean difference, −0.88 [95% CI, −1.43 to −0.40]; I^2 = 74%; P = .15 for interaction) (eFigure 2 in the Supplement). There were no statistically significant interactions between control type, follow-up duration, or age and effects of supplements on DMFT/DFT increment, although analyses were limited by small numbers of trials (eTable 5 in the Supplement).

Fluoride Gel

A good-quality systematic review[18] (searches through November 2014) included 26 randomized or quasirandomized trials (in 25 publications)[21-45] of fluoride gels vs placebo or no treatment in children 5 years or older (n = 8619) (eTables 6 and 7 in the Supplement). Baseline age and caries burden varied, and reporting of fluoride exposure, socioeconomic status, and provision of oral health education was suboptimal. Twelve trials were conducted in the US, 6 trials in Europe, 4 in Brazil, and 1 each in Canada, Israel, China, and Venezuela. Five trials were published from 1990 to 2005; the other trials were published between 1967 and 1988.

Fluoride gel was most commonly administered as acidulated phosphate fluoride (12 300 ppm F). Gels were applied in dental clinics or schools using a tray (19 trials), brush (6 trials), or floss (1 trial). In 15 trials, gels were applied by a dental professional (1-4 times per year) and in 11 trials, gels were self-applied (mostly 5 times per year) with dental hygienist or other adult supervision. Only 1 trial was assessed as low risk of bias.[44] Methodological limitations in the other trials included use of a quasirandomized design (7 trials),[21,22,29,31-33,38] unclear randomization or allocation concealment methods (19 trials), open-label design (10 trials), and high attrition (14 trials).

The systematic review found fluoride gels associated with reduced caries burden compared with no intervention or control based on a DMFT/DFT-prevented fraction of 0.32 (95% CI, 0.19-0.46) at outcomes closest to 3 years (10 trials; n = 3198). There was marked statistical heterogeneity (I^2 = 91%), with estimates that varied by

Figure 3. Literature Search Flow Diagram: Screening and Interventions to Prevent Oral Health Issues in Children and Adolescents Aged 5 to 17 Years

The sum of the number of studies per key question (KQ) exceeds the total number of studies because some studies were applicable to multiple KQs or systematic reviews. SDF indicates silver diamine fluoride.

[a] Fifty-four trials included in the systematic reviews (in 53 publications).

control type (placebo control–prevented fraction, 0.18 [95% CI, 0.09-0.27]; I^2 = 6%; 4 trials; n = 1525; no treatment control–prevented fraction, 0.43 [95% CI, 0.29-0.57]; I^2 = 90%; 6 trials; n = 1673). The systematic review found no statistically significant interactions between baseline caries level, exposure to fluoride, application method, application frequency, gel concentration, or follow-up duration and effects of gels. A supplemental analysis of data reported in the systematic review found similar estimates when children were stratified by baseline age younger than 10 years or 10 years or older (eFigure 3 in the Supplement). One subsequent good-quality trial[82] (n = 986) reported results consistent with the systematic review (eTables 8 and 9 in the Supplement).

Fluoride Varnish

A good-quality systematic review[19] (searches through May 2013) included 14 trials[46-59] of fluoride varnish vs placebo or no varnish in children 5 years or older (n = 6965) (eTables 10 and 11 in the Supplement). Baseline age, caries burden, and fluoride exposure varied. Eight trials were conducted in Europe, 2 trials each in Brazil and India, and 1 trial each in Canada and China. Four trials were published prior to 1990, 3 between 1990 and 1997, and 7 between 2005 and 2012. Fluoride varnish was most commonly administered as 5% sodium fluoride varnish (22 600 ppm) every 6 months. In all trials, varnish was applied by dental professionals in schools or local clinics. Ten trials were open-label or did not provide information on blinding, and 8 trials did not adequately randomize participants or had unclear randomization methods. Other methodological limitations included inadequate allocation concealment methods (79% of trials) and between-group baseline differences (21% of trials).

The systematic review found fluoride varnish associated with a DMFS/DFS-prevented fraction of 0.43 (95% CI, 0.30-0.57) at 1 to 4.5 years (14 trials; n = 3419), although statistical heterogeneity was present (I^2 = 75%). There were no statistically significant interactions between baseline caries severity, background fluoride exposure, varnish concentration, follow-up duration, application frequency, time since permanent teeth eruption, or control type and effects of varnish. Findings were similar when using the DMFT/DFT-prevented fraction (0.44 [95% CI, 0.11-0.76]; I^2 = 86%), which was reported in 5 trials (n = 3902). One subsequent fair-quality cluster randomized trial[83] of 6- and 7-year-old children in rural China (n = 5397) reported results consistent with the systematic review (eTables 12 and 13 in the Supplement).[83]

Sealants

One good-quality systematic review[20] (searches through August 2016) included 16 trials[54,58,60-73] of a sealant vs no sealant (eTables 14 and 15 in the Supplement). Fifteen trials (n = 4195) evaluated a resin-based sealant, and 3 trials (n = 905 participants) evaluated a glass ionomer sealant (2 trials evaluated both types[66,72]). Children were aged 6 to 10 years at baseline in all trials but 1 (12-13 years).[72] Baseline caries burden varied, and reporting of socioeconomic status and water fluoridation levels was suboptimal. Four trials were conducted in the US or Canada, 3 trials in China, 4 trials in Europe, and 1 trial each in Brazil, Colombia, New Zealand, and Thailand. Five trials were published between 2011 and 2014, 1 trial in 2005, and 10 trials between 1976 and 1995. In all trials, sealants were applied to occlusal surfaces of permanent premolar or molar teeth by dental professionals, except for 1 trial[72] in which sealants were administered by dentists or schoolteachers with 3 days of training. The trials were unable to effectively mask outcome assessors because sealant materials are visible; other methodological limitations included unclear or inadequate randomization (33% of trials), unclear allocation concealment methods (37% of trials), and high or unclear attrition (at 48-54 months; 60% of trials).

The systematic review found resin-based sealants associated with decreased risk of carious first molars at 24 months among children aged 5 to 10 years (7 trials; n = 1322; odds ratio [OR], 0.12 [95% CI, 0.08-0.19]; I^2 = 72%). Although statistical heterogeneity was present, estimates favored sealants in all trials (ORs ranged from 0.06 to 0.32). Based on the pooled estimate, the absolute risk difference ranged from 11% to 51%. Findings were similar at 36 months (7 trials; n = 1410; OR, 0.17 [95% CI, 0.11-0.27]; I^2 = 90%) and at 48 to 54 months (4 trials; n = 440; OR, 0.21 [95% CI, 0.16-0.28]; I^2 = 45%); 1 trial (n = 120) reported decreased risk at longer-term follow-up (OR at 9 years, 0.35 [95% CI, 0.22-0.55]).[61] One trial (n = 671) found resin-based sealants compared with no treatment associated with slightly decreased change from baseline in DMFS index among older (12-13 years) children (mean difference, −0.24 [95% CI, −0.36 to −0.12]).[72] Too few trials reported community water fluoridation levels to determine interaction with sealant effectiveness.

The systematic review found limited evidence on the effectiveness of glass ionomer sealants vs placebo, based on 2 trials with inconsistent findings (1 trial reported no benefit).[66,72] In 1 of the trials, outcomes were very similar when sealants were administered by a dentist or a schoolteacher. Two subsequent, fair-quality trials[84,85] (n = 187 and n = 50) also reported inconsistent findings for glass ionomer sealants vs no sealants (eTables 16 and 17 in the Supplement).

Silver Diamine Fluoride

One fair-quality trial (n = 452) evaluated SDF solution applied to primary canines and molars and occlusal surfaces of first permanent molars every 6 months vs no SDF for prevention of caries in 6-year-old schoolchildren in a setting with low community fluoridation (0.09 ppm F) and with high caries burden (mean DMFS, 3.6) in Cuba (eTables 18 and 19 in the Supplement).[86] The trial report did not describe how persons who administer SDF were trained. At 36 months, SDF use was associated with fewer new active (decayed or filled) deciduous caries surfaces (mean, 0.3 vs 1.4; P < .001), fewer active first permanent molar surfaces (mean, 0.4 vs 1.1; P < .001), and decreased likelihood of experiencing at least 1 new decayed or filled tooth (26.1% vs 49.7%; relative risk, 0.52 [95% CI, 0.40-0.70]).

Xylitol

Two fair-quality cluster-randomized trials[15,16] (n = 432 and n = 496) evaluated xylitol vs no xylitol in children 5 years or older (eTables 20 and 21 in the Supplement). Xylitol was administered in supervised school settings; in 1 trial, parents also administered xylitol when children were at home.[16] One trial was open-label[15]; neither trial adjusted for clustering, and both trials had unclear randomization methods.

One trial[15] enrolled 10-year-old children (n = 496) in Finland in an area with natural water fluoridation and low baseline caries burden. It found xylitol lozenges for 1 or 2 years associated with similar

effects on caries burden at 4 years vs no xylitol based on the D_3MFS (DMFS with caries lesions extending into the dentin) increment (mean, 3.02 for xylitol for 2 years vs 2.74 for no xylitol; $P > .05$) or likelihood of D_3MFS greater than 0 (vs placebo; adjusted OR, 1.01 [95% CI, 0.40-2.56]), although estimates were imprecise. Another cluster-randomized trial (n = 432)[16] evaluated children (mean age, 11.6 years) with high baseline caries burden (mean DMFS, 13.2-15.3) in a nonfluoridated setting in Lithuania. The trial found no difference between 5-times-daily use of xylitol gum vs placebo (nonxylitol gum in DMFS increment [all stages] at 3 years; mean, 8.1 vs 8.3; $P > .05$). However, xylitol gum was associated with decreased DMFS increment vs no gum (mean, 8.1 vs 12.4; $P < .05$). Xylitol and placebo gum were also associated with similar likelihood of experiencing a DMFS increment of 14 or greater.

Key Question 5. What are the harms of specific interventions (behavioral counseling, referral, and preventive interventions) to prevent oral health issues?

Evidence on harms of oral health preventive interventions was very limited. One trial of fluoride supplements (n = 349) reported no adverse events.[79] None of 26 trials of fluoride gels included in a good-quality systematic review[18] reported on tooth surface staining. Two trials in the systematic review reported on acute toxicity (nausea, gagging, or vomiting), with 1 trial reporting no events and a pooled analysis finding no difference between gel vs placebo or no treatment (n = 490; absolute risk difference, 0.01 [95% CI −0.01 to 0.02]; $I^2 = 0\%$).[30,38] The systematic review also found no difference between fluoride gel vs placebo in risk of study withdrawal (19 trials; n = 8695; relative risk, 1.03 [95% CI, 0.89-1.19]).

For fluoride varnish, 5 of 16 trials included in a good-quality systematic review[19] reported adverse events. Four trials[46,54,56,58] (n = 1704) reported no adverse events, and 1 trial[55] (n = 2967) reported 12 of 1473 children assigned to varnish reported adverse events (the most common adverse event was nausea, occurring in 7 children). All adverse events were described as self-limited, although 4 children were withdrawn due to mild adverse events. One subsequent trial of varnish (n = 5397) reported no adverse events.[83]

Only 3[54,61,67] of 16 trials of sealants vs no sealants included in a good-quality systematic review[20] reported harms. All (n = 775) evaluated a resin-based sealant and reported no adverse events. One trial (n = 452) found SDF associated with increased likelihood of black-stained inactive caries in deciduous teeth (97% vs 48%, $P < .001$) and in first permanent molars (86% vs 67%, $P < .001$),[86] and 1 trial (n = 296) of xylitol reported 1 withdrawal due to diarrhea.[15]

Discussion

The **Table** summarizes the evidence reviewed for this report. Evidence on screening was limited to 1 study[74] that found oral health visual screening by a trained nurse associated with high sensitivity and specificity for untreated caries and a parent- or guardian-reported questionnaire associated with moderate sensitivity and high specificity.

Several oral health preventive interventions improved caries outcomes when administered in school or dental settings. Supervised administration of fluoride supplements in school was associated with a small decrease in the DMFT/DFT increment (mean difference, <1 affected tooth) in settings with low socioeconomic status, nonfluoridated water, or high caries burden. Fluoride gels, fluoride varnish, and sealants were each associated with improved caries outcomes when administered in schools or in dental clinics. Gels were administered by dental professionals or were self-administered with supervision by a dental or nondental professional; varnish and sealants were administered by dental professionals. The reduction in caries burden was larger for varnish[19] than for gels,[18] and resin-based sealants were associated with a strong reduction in the likelihood of developing carious first molars.[20] Evidence on SDF for prevention was limited to a single trial[86] suggesting benefit in a setting with high baseline caries burden and with inadequate water fluoridation. Two fair-quality trials of xylitol either found no benefit of xylitol (vs no xylitol[15]) or reported results that varied depending on the control type (large benefit vs no gum but no benefit vs placebo gum[16]).

Evidence on the effectiveness of interventions administered in the home or primary care setting was lacking because few trials of limited quality were available. There were no eligible trials of primary care counseling or referral to a dental professional. Trials of preventive interventions did not evaluate health outcomes (eg, quality of life or function), and factors that could potentially affect the effectiveness of oral health preventive interventions—such as water fluoridation levels, provision of oral health education, and oral health behaviors—were not consistently reported.

The harms of preventive interventions were sparsely reported, although serious harms were not described. As reported in trials of SDF for arresting caries,[99] the single trial[86] of SDF for prevention reported increased risk of black staining of inactive caries lesions. No study evaluated the association between exposure to fluoride via oral health preventive interventions in children older than 5 years and adolescents and risk of fluorosis. Studies of fluorosis risk have focused on younger children, who are at increased risk due to being at earlier stages of enamel and neurocognitive development.[11,12]

Limitations

This review had several limitations. First, non–English-language articles were excluded. However, non–English-language articles likely to affect conclusions were not identified. Second, the review did not search for studies published only as abstracts and did not formally assess for publication bias with graphical or statistical methods for small sample effects when conducting meta-analysis, due to small numbers of studies with serious methodological limitations.[17] Third, previously published systematic reviews were used, rather than relying exclusively on primary studies. However, the systematic reviews were assessed as good-quality, and review findings were supplemented with subsequently published primary studies.[100] Fourth, the review did not evaluate the effectiveness of tooth brushing or flossing, as these are routinely recommended and performed outside the primary care setting. Rather, the review addressed the effectiveness of oral health counseling, which includes counseling on tooth brushing, flossing, and diet. Fifth, meta-analyses had substantial statistical heterogeneity. To address statistical heterogeneity, random-effects models were used and stratified analyses on study-level factors were examined for potential sources. Sixth, poor-quality trials of xylitol were included, due to few higher-quality studies. However, xylitol conclusions were based on fair-quality trials. Seventh, few trials of preventive interventions have

Table. Summary of Evidence: Oral Health Screening and Preventive Interventions in Children and Adolescents Aged 5 to 17 Years

Objective/ intervention	No. of studies; study design (No. of participants)	Summary of findings by outcome	Consistency/ precision; reporting bias	Overall quality	Body of evidence limitations	Strength of evidence	Applicability
Screening KQ1: Screening effectiveness							
	No studies	NA	NA	NA	NA	NA	NA
Screening KQ2: Screening accuracy							
A. In persons who have oral health issues B. In persons who are at increased risk for future oral health issues	A. 1 Cross-sectional study (n = 305) B. No studies	Visual screen by registered nurse: sensitivity, 0.92 (95% CI, 0.84-0.97) and specificity, 0.993 (95% CI, 0.96-0.9998) for untreated caries 17-Item questionnaire: sensitivity, 0.69 (95% CI, 0.60-0.77) and specificity, 0.88 (95% CI, 0.83-0.93) for untreated caries	Unable to assess consistency (1 study) Reasonably precise Reporting bias not detected	Fair	Single study with methodological limitations; results unvalidated	Low	Nurses received 5 h of training; questionnaire based on report by children's parents or guardians; study conducted in rural setting with high prevalence of untreated caries (35%)
Screening KQ3: Screening harms							
	No studies	NA	NA	NA	NA	NA	NA
Prevention KQ1: Screening accuracy (identification of persons at risk for future caries)[a]							
	No studies	NA	NA	NA	NA	NA	NA
Prevention KQ2: Behavioral counseling							
	No studies	NA	NA	NA	NA	NA	NA
Prevention KQ3: Referral							
	No studies	NA	NA	NA	NA	NA	NA
Prevention KQ4: Preventive interventions							
Supplements	7 Trials (n = 3382)	Fluoride supplements were associated with decreased DMFT/DFT increment at 1.5 y to 3 y (mean difference, −0.73 [95% CI, −1.30 to −0.19]; 6 trials) when administered in schools under supervision; however, the only trial in which fluoride supplements were administered at home reported low adherence and no benefit (mean difference, 0.13 [95% CI, −0.38 to 0.64])	Serious inconsistency No imprecision Reporting bias not suspected	Fair	All trials had methodological limitations; substantial statistical heterogeneity	Low	Supplements administered in school under supervision in all trials except 1; all trials published prior to 1990 except for 1; no trial of adolescents and all trials but 1 focused on children aged <10 y; trials conducted in settings with high caries burden, low SES, or low fluoridation levels; 6 trials conducted in the US or UK and 1 trial conducted in Taiwan
Fluoride gel	1 Systematic review (26 trials [n=8619]) and 1 subsequent RCT (n=986)	Systematic review found fluoride gels associated a DMFT/DFT-prevented fraction at outcomes closest to 3 y of 0.32 (95% CI, 0.19-0.46; I^2 = 91% [10 trials; n = 3198]); based on 4 placebo-controlled trials (n = 1525), the prevented fraction was 0.18 (95% CI, 0.09-0.27; I^2 = 6%) One subsequent trial reported consistent results	Consistent (based on placebo-controlled trials) No imprecision Reporting bias not suspected	Fair	Most trials had methodological limitations; statistical heterogeneity when all (placebo-controlled and non-placebo-controlled) trials pooled; few placebo-controlled trials	Moderate	Eighteen trials conducted in the US, Europe, or Canada; only 1 trial focused on adolescents; gels were applied by dental professional or under supervision and applied in dental clinics or schools; limited reporting of water fluoridation levels and SES; most trials conducted in settings with high caries burden; 22 trials published prior to 1990

(continued)

Table. Summary of Evidence: Oral Health Screening and Preventive Interventions in Children and Adolescents Aged 5 to 17 Years (continued)

Objective/ intervention	No. of studies; study design (No. of participants)	Summary of findings by outcome	Consistency/ precision; reporting bias	Overall quality	Body of evidence limitations	Strength of evidence	Applicability
Fluoride varnish	1 Systematic review (14 trials [n = 6965]) and 1 subsequent RCT (n = 5397)	Systematic review found fluoride varnish associated with a DMFS/DFS-prevented fraction of 0.43 (95% CI, 0.30-0.57; 14 trials); a DMFT/DFT-prevented fraction of 0.44 (95% CI, 0.11-0.76; 5 trials); and a reduced risk of developing ≥1 caries (RR, 0.75 [95% CI, 0.53-1.05]; I^2 = 89.2%; 5 trials) One subsequent trial reported results consistent with the systematic review	Some inconsistency present No imprecision Reporting bias not suspected	Fair	Most trials had methodological limitations; statistical heterogeneity present	Moderate	Nine trials conducted in Europe (no trials conducted in the US); no trial focused on adolescents; varnish applied by dental professionals at school or in dental clinics; limited reporting of water fluoridation levels and SES; 7 trials published prior to 1998
Sealants	Resin-based sealant: 1 systematic review (15 RCTs; n = 4195 children) and 1 supplemental RCT (n = 50 children) Glass ionomer sealant: 1 Systematic review (3 RCTs; n = 905) and 2 subsequent RCTs (n = 237)	Resin-based sealants: systematic review found resin-based sealants associated with decreased risk of carious first molars at 24 mo (7 trials; OR, 0.12 [95% CI, 0.08-0.19]), 36 mo (7 trials; OR, 0.17 [95% CI, 0.11-0.27]; I^2 = 90%), and 48 to 54 mo (4 trials; OR, 0.21 [95% CI, 0.16-0.28]; I^2 = 45%) Glass ionomer sealants: systematic review (2 trials) and 1 subsequent trial found inconsistent effects of glass ionomer sealants vs no sealants on caries outcomes	Resin-based sealants: No inconsistency No imprecision Glass ionomer sealants: Serious inconsistency Serious imprecision Reporting bias (all sealants) not suspected	Fair	Open-label design; few trials of glass ionomer sealants	Moderate	Nine trials conducted in the US, Europe, Canada, or New Zealand; limited information on SES and fluoridation levels; higher caries burden settings; variability in sealants evaluated; 10 trials published prior to 1996; sealants applied by dental professionals
Silver diamine fluoride	1 RCT (n = 452)	Silver diamine fluoride associated with fewer new surfaces with active caries in deciduous dentition (mean, 0.3 vs 1.4; P < .001) and first permanent molars (mean, 0.4 vs 1.1; P < .001), and decreased likelihood of ≥1 new decayed or filled teeth (26.1% vs 49.7%; RR, 0.52 [95% CI, 0.40-0.70])	Unable to assess consistency (1 trial) No imprecision Reporting bias not suspected	Fair	One trial with methodological limitations	Low	Trial conducted in Cuba in a setting with high caries burden in children aged 6 y; training of person administering SDF not reported; children received oral health education and performed fluoride mouth rinses
Xylitol	10 Trials (n = 4267)	One fair-quality trial found no difference between xylitol vs no xylitol in caries outcomes at 4 y, and 1 fair-quality trial found no difference between xylitol vs placebo in DMFS increment at 3 y but a decreased DMFS increment vs no xylitol Eight other trials found xylitol associated with reduced DMFS increment vs no xylitol (mean difference, −2.38 [95% CI, −3.66 to −1.15]), but had serious methodological limitations and were rated poor-quality	Some inconsistency No imprecision Reporting bias not suspected	Fair (based on fair-quality trials)	Only 2 fair-quality trials; potential differences in outcomes based on control type	Low	Six trials conducted in Europe (no trials in the US); no trial focused on adolescents; xylitol administered under supervision at school in all trials except 1; 4 trials published in or prior to 1991; fluoride exposure varied; information on SES not provided

(continued)

Table. Summary of Evidence: Oral Health Screening and Preventive Interventions in Children and Adolescents Aged 5 to 17 Years (continued)

Objective/ intervention	No. of studies; study design (No. of participants)	Summary of findings by outcome	Consistency/ precision; reporting bias	Overall quality	Body of evidence limitations	Strength of evidence	Applicability
Prevention KQ5: Harms of preventive interventions							
	Supplements: 1 trial (n = 349) Gel: 2 trials (n = 490) Varnish: 6 trials (n = 8574) Sealants: 3 trials (n = 775) SDF: 1 trial (n = 452) Xylitol: 1 trial (n = 296)	Supplements: 1 trial reported no adverse events Gels: no difference between gel vs placebo or no treatment in acute toxicity (nausea, gagging, or vomiting); absolute risk difference, 0.01 (95% CI, −0.01 to 0.02) Varnish: 5 trials reported no adverse events and 1 trial reported 0.04% of children allocated to varnish reported a self-limited adverse event (most commonly nausea), with 4 withdrawals due to mild adverse events Sealants: 3 trials of resin-based sealants reported no adverse events SDF: SDF associated with increased likelihood of inactive caries and black stain in deciduous teeth (97% vs 48%, $P < .001$) and first permanent molars (86% vs 67%, $P < .001$) Xylitol: 1 trial reported 1 withdrawal from xylitol due to diarrhea	Consistency uncertain, due to sparse data Serious imprecision Potential reporting bias, as few trials reported harms	Poor	Few trials reported harms or harms reporting was suboptimal	Low	Evidence on harms was very sparse, limiting assessments of applicability

Abbreviations: DFS, decayed or filled surfaces; DFT, decayed or filled teeth; DMFS, decayed, missing, or filled surfaces; DMFT, decayed, missing, or filled teeth; KQ, key question; NA, not applicable; OR, odds ratio; RCT, randomized clinical trial; RR, relative risk; SDF, silver diamine fluoride; SES, socioeconomic status.

[a] This is the same as KQ2b from the screening framework.

been published since 2000, potentially reducing applicability to current US practice.

Of note, all trials evaluated oral health preventive interventions administered by dental health professionals or in supervised school settings, with unknown effectiveness and feasibility in primary care. Barriers to provision of oral health preventive interventions in primary care include uncertain acceptability and uptake; potential need for additional training and equipment (particularly for sealants); and uncertain reimbursement. Some evidence indicates increased uptake in 2018 compared with 2008 of primary care administration of fluoride varnish in children younger than 5 years, suggesting feasibility for older children and adolescents,[101] and limited evidence indicates that applying SDF in primary care settings is feasible.[102]

Conclusions

Administration of fluoride supplements, fluoride gels, varnish, and sealants in dental or school settings improved caries outcomes. Research is needed on the effectiveness of oral health preventive interventions in primary care settings and to determine the benefits and harms of screening.

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Concept and design: Chou.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Chou, Bougatsos, Selph, Ahmed, Fu, Schwarz.
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JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Screening and Interventions to Prevent Dental Caries in Children Younger Than 5 Years

Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Roger Chou, MD; Miranda Pappas, MA; Tracy Dana, MLS; Shelley Selph, MD; Erica Hart, MBS; Rongwei F. Fu, PhD; Eli Schwarz, DDS, PhD, MPH

IMPORTANCE A 2014 review for the US Preventive Services Task Force (USPSTF) found that oral fluoride supplementation and topical fluoride use were associated with reduced caries incidence in children younger than 5 years.

OBJECTIVE To update the 2014 review on dental caries screening and preventive interventions to inform the USPSTF.

DATA SOURCES Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews (to September 2020); surveillance through July 23, 2021.

STUDY SELECTION Randomized clinical trials (RCTs) on screening, preventive interventions, referral to dental care; cohort studies on screening and referral; studies on diagnostic accuracy of primary care oral examination or risk assessment; and a systematic review on risk of fluorosis included in prior USPSTF reviews.

DATA EXTRACTION AND SYNTHESIS One investigator abstracted data; a second checked accuracy. Two investigators independently rated study quality.

RESULTS Thirty-two studies (19 trials, 9 observational studies, and 4 nonrandomized clinical intervention studies [total 106 694 participants] and 1 systematic review [19 studies]) were included. No study evaluated effects of primary care screening on clinical outcomes. One study (n = 258) found primary care pediatrician examination associated with a sensitivity of 0.76 (95% CI, 0.55 to 0.91) and specificity of 0.95 (95% CI, 0.92 to 0.98) for identifying a child with cavities, and 1 study found a risk assessment tool associated with sensitivity of 0.53 and specificity of 0.77 (n = 697, CIs not reported) for a child with future caries. No new trials of dietary fluoride supplementation were identified. For prevention, topical fluoride compared with placebo or no topical fluoride was associated with decreased caries burden (13 trials, n = 5733; mean caries increment [difference in decayed, missing, and filled teeth or surfaces], −0.94 [95% CI, −1.74 to −0.34]) and likelihood of incident caries (12 trials, n = 8177; RR, 0.80 [95% CI, 0.66 to 0.95]; absolute risk difference, −7%) in higher-risk populations or settings, with no increased fluorosis risk. Evidence on other preventive interventions was limited (education, xylitol) or unavailable (silver diamine fluoride), and no study directly evaluated primary care dentistry referral vs no referral.

CONCLUSIONS AND RELEVANCE There was no direct evidence on benefits and harms of primary care oral health screening or referral to dentist. Dietary fluoride supplementation and fluoride varnish were associated with improved caries outcomes in higher-risk children and settings.

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Dental caries is a common chronic disease that can cause pain and diminish function and quality of life.[1] Dental caries is the most common chronic disease of children in the US and disproportionately affects vulnerable and underserved children.[1,2] Children who lack access to a dentist often have encounters with a primary care clinician. Therefore, provision of oral care in primary care settings may improve access and facilitate provision of treatments to prevent or treat caries and improve outcomes.[3-5]

In 2014, the US Preventive Services Task Force (USPSTF) recommended that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride and apply fluoride varnish starting at the age of primary tooth eruption for all children (B recommendations).[6] The USPSTF found insufficient evidence to assess the benefits and harms of dental caries screening by primary care clinicians in children younger than 5 years (I statement). This evidence report was conducted to update the 2014 USPSTF review on dental caries screening and preventive interventions in children younger than 5 years,[7,8] to inform the USPSTF for an updated recommendation statement.

Methods

Scope of Review

Detailed methods and study details are available in the full evidence report.[9] **Figure 1** (screening) and **Figure 2** (preventive interventions) show the analytic frameworks and key questions (KQs) that guided the review. Separate analytic frameworks were used to distinguish treatment of children with existing caries (screening) from treatment of children without caries (preventive interventions).

Data Sources and Searches

Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews were searched from 2013 through September 2020 (see the Supplement for search strategies). Searches were supplemented by reference list review of relevant systematic reviews; studies from the prior USPSTF review[7,8] that met inclusion criteria were carried forward. Ongoing surveillance was conducted to identify major studies published since September 2020 that may affect the conclusions or understanding of the evidence and the related USPSTF recommendation. The last surveillance was conducted on July 23, 2021, and identified no studies affecting review conclusions.

Study Selection

Two investigators independently reviewed titles, abstracts, and full-text articles using predefined eligibility criteria. The population was children younger than 5 years. Screening and diagnostic accuracy studies conducted in primary care settings were eligible. Eligible preventive interventions were primary care feasible (not requiring extensive dental training): parental or caregiver education, referral to a dentist, dietary fluoride supplementation, topical fluoride application (varnish, foam, or gel), xylitol, and silver diamine fluoride. Comparisons were against placebo or no intervention. Outcomes were dental caries (incidence or caries burden, measured based on the number of decayed, missing, or filled teeth [dmft] or decayed, missing, or filled surfaces), morbidity, quality of life, and harms (including fluorosis).

Data Extraction and Quality Assessment

One investigator abstracted details about the study design, patient population, setting, interventions, analysis, follow-up, and results from each study. A second investigator reviewed abstracted data for accuracy. Two independent investigators assessed the quality of each study as good, fair, or poor using predefined criteria developed by the USPSTF (see the Supplement for quality rating criteria).[10] Discrepancies were resolved through consensus. In accordance with the USPSTF Procedure Manual,[10] studies rated poor quality owing to critical methodological limitations were excluded.

Data Synthesis and Analysis

For all KQs, the overall quality of evidence was rated "good," "fair," or "poor" based on study limitations, consistency, precision, reporting bias, and applicability, using the approach described in the USPSTF Procedure Manual.[10]

Meta-analysis was conducted only for topical fluoride, because of small numbers of trials of other preventive interventions with clinical and methodological heterogeneity. For topical fluoride, random-effects meta-analysis was performed to summarize the likelihood of incident caries or caries increment (difference in mean caries burden) vs placebo or no topical fluoride using a profile likelihood model in Stata/SE 16.1 (StataCorp). Statistical heterogeneity was assessed using the I^2 statistic.[11] Analyses were stratified by community fluoridation status (adequate [≥0.7 parts fluoride per million parts water {ppm F} vs nonadequate) and topical fluoride type (varnish vs foam or gel). Additional subgroup analyses were conducted on use of cluster randomization, follow-up duration, varnish frequency, use of additional oral health measures, very high Human Development Index (HDI) setting (based on a United Nations Development Programme HDI score of 0.800 or higher for the country or geographic setting),[12] conducted in preschool or daycare setting, conducted in high-risk population, and inclusion of children with caries at baseline. A random-effects meta-regression model was used to test subgroup differences. All significance testing was 2-tailed; *P* values of .05 or less were considered statistically significant.

Results

Across all KQs, 32 studies (reported in 35 publications, total 106 694 participants)[13-48] and 1 systematic review (19 studies)[49] were included (**Figure 3**). Seventeen studies[15,16,18-22,34-45,48] were new for this update and 16 studies (including the systematic review)[13,14,17,23-33,46,47,49] were carried forward from the previous USPSTF review.

Screening

Benefits of Screening

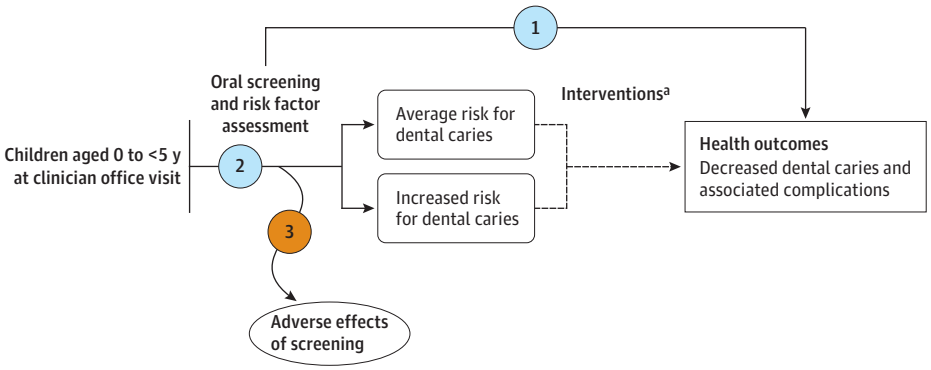
Key Question 1. How effective is oral screening (including risk assessment) performed by a primary care clinician in preventing dental caries in children younger than 5 years?

No study met inclusion criteria for this KQ.

Accuracy of Screening

Key Question 2a. How accurate is screening performed by a primary care clinician in identifying children younger than 5 years who have cavitated or noncavitated caries lesions?

Figure 1. Analytic Framework: Screening for Dental Caries in Children Younger Than 5 Years



Key questions

1 How effective is oral screening (including risk assessment) performed by a primary care clinician in preventing dental caries in children younger than 5 years?

2 How accurate is screening performed by a primary care clinician in identifying children younger than 5 years who
a. Have cavitated or noncavitated caries lesions?
b. Are at increased risk for future dental caries?

3 What are the harms of oral health screening performed by a primary care clinician in children younger than 5 years?

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. A dashed line indicates a health outcome that immediately follows an intermediate outcome. For additional information see the USPSTF Procedure Manual.[10]

[a] Interventions are provided to children found to have caries on screening.

No new study met inclusion criteria for this KQ. Two studies in the prior USPSTF review compared a pediatrician vs pediatric dentist oral examination (eTables 1 and 2 in the Supplement). One good-quality study of children younger than 36 months (n = 258) reported a sensitivity of 0.76 (95% CI, 0.55 to 0.91) and specificity of 0.95 (95% CI, 0.92 to 0.98) for identifying a child with 1 or more cavities and a sensitivity of 0.49 (95% CI, 0.37 to 0.60) and specificity of 0.99 (95% CI, 0.99 to 0.99) for identifying a tooth with a cavity.[13] A fair-quality study of children aged 18 to 36 months reported a sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries (n = 61, CIs not reported).[14]

Key Question 2b. How accurate is screening performed by a primary care clinician in identifying children younger than 5 years who are at increased risk for future dental caries?

One new fair-quality study (n = 1681) found a caries risk assessment tool administered by health visitor nurses in children aged 1 year associated with sensitivity of 0.53 and specificity of 0.77 (n = 697, CIs not reported) for predicting any $d_3$mft lesion (d_3 indicates dentin caries lesion) at age 4 years and sensitivity of 0.65 and specificity of 0.69 (n = 784, CIs not reported) for predicting presence of 3 or more $d_3$mft lesions (eTables 2 and 3 in the Supplement).[15]

Harms of Screening

Key Question 3. What are the harms of oral health screening performed by a primary care clinician in children younger than 5 years?

No study met inclusion criteria for this KQ.

Preventive Interventions

Accuracy of Screening

Key Question 1. How accurate is screening performed by a primary care clinician in identifying children younger than 5 years who are at increased risk of future dental caries?

See KQ2b for screening, which addresses the same question.

Benefits of Intervention

Key Question 2. How effective is parental or caregiver/guardian oral health education provided by a primary care clinician in preventing dental caries in children younger than 5 years?

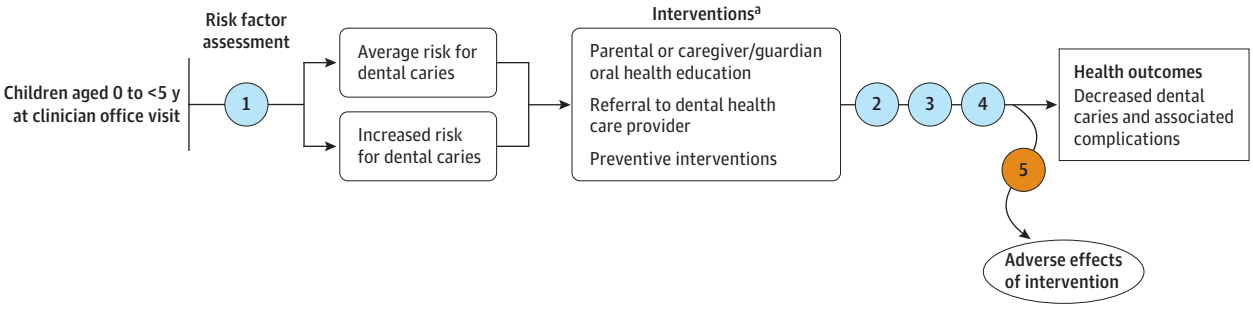
One new fair-quality trial (n = 104) found oral health education for mothers of caries-free children aged 12 to 36 months was associated with reduced risk of incident dental caries at 6 months vs usual care (13.5% vs 34.7%; relative risk [RR], 0.39 [95% CI, 0.18 to 0.85) (eTables 4 and 5 in the Supplement).[16]

Key Question 3. How effective is referral by a primary care clinician to a dental health care professional in preventing dental caries in children younger than 5 years?

No study directly evaluated the effects of referral by a primary care clinician to a dental care professional on caries incidence. Although 6 observational studies (n = 92 476) (1 included in the prior USPSTF review[17] and 5 new[18-22]) of children enrolled in Medicaid compared receiving a preventive dental visit from a dentist vs primary care clinician or earlier vs later first preventive dental visit, the studies were not designed to determine the referral source or effects of dental referral from primary care vs no referral (eTables 6 and 7 in the Supplement). In addition, results in some studies indicating an association between a dentist or earlier preventive visit and increased likelihood of subsequent caries-related treatment or caries burden are susceptible to confounding by indication related to the need for dental services.

Key Question 4. How effective are preventive interventions (dietary fluoride supplementation, topical fluoride application, silver diamine fluoride, or xylitol) in preventing dental caries in children younger than 5 years?

Figure 2. Analytic Framework: Interventions to Prevent Dental Caries in Children Younger Than 5 Years



Key questions

1. How accurate is screening performed by a primary care clinician in identifying children younger than 5 years who are at increased risk of future dental caries?[b]
2. How effective is parental or caregiver/guardian oral health education provided by a primary care clinician in preventing dental caries in children younger than 5 years?
3. How effective is referral by a primary care clinician to a dental health care professional in preventing dental caries in children younger than 5 years?
4. How effective are preventive interventions (dietary fluoride supplementation, topical fluoride application, silver diamine fluoride, or xylitol) in preventing dental caries in children younger than 5 years?
5. What are the harms of specific oral health interventions to prevent dental caries in children younger than 5 years (parental or caregiver/guardian oral health education, referral to a dental health care professional, and preventive interventions)?

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. For additional information see the USPSTF Procedure Manual.[10]

[a] Interventions are provided to children without caries.

[b] This is the same question as screening key question 2b.

Dietary Fluoride Supplementation

We identified no new trials published since the 2004 or 2014 USPSTF reviews.[8,50] One randomized trial of Taiwanese 2-year old children with cleft lip (n = 140, fluoridation <0.1 ppm F) found 0.25-mg fluoride drops or chews associated with significantly decreased caries increment vs no supplementation (mean dmft reduction, 72% [*P* = .001] and 52% [*P* = .01], respectively).[23] Four nonrandomized controlled intervention studies (n = 2273) included in the prior USPSTF review[8] also found dietary fluoride supplementation in settings with water fluoridation levels below 0.6 ppm F associated with decreased caries incidence vs no fluoride supplementation (mean dmft reduction, 32% to 69%).[24-28]

Topical Fluoride Application

Fifteen trials (5 trials[29-33] in the prior USPSTF review and 10 new trials[34-45]) evaluated topical fluoride (eTables 8 and 9 in the Supplement). Sample sizes ranged from 123 to 2536 (total 9541 participants). Two trials[33,44,45] (n = 1376) were conducted in communities with adequate drinking water fluoridation, defined as 0.7 ppm F or greater. The mean age of enrolled children was 1 year to younger than 2 years in 6 trials and 2 to 5 years in 9 trials (1 trial[31] did not report mean age). Five trials[30,34,38,39,42] were conducted in preschool or daycare settings and the others were conducted in clinics. Eight trials (including 6 of the new trials) were conducted in very high HDI countries or settings. All trials except for 1[44,45] evaluated children classified as being at higher risk, based on low socioeconomic status, high community prevalence of caries, high baseline caries burden, or low rates of oral health behaviors.

One trial[38] evaluated acidulated phosphate fluoride foam and the others evaluated fluoride varnish. Fluoride varnish was most commonly administered as 5% sodium fluoride every 6 months. Topical fluoride was administered by a dental health professional in all trials in which this information was reported. In all trials except for 3,[29,30,38] oral health education was provided in addition to the randomized intervention. The duration of follow-up ranged from 1 to 3 years.

Three trials were rated good quality[37,39,43] and the rest fair quality (eTable 5 in the Supplement). Methodological limitations in the fair-quality trials included unclear randomization or allocation concealment methods, open-label design, or high attrition.

Topical fluoride was associated with significant decreased caries increment (13 trials, n = 5733; mean difference, −0.94 [95% CI, −1.74 to −0.34]; I^2 = 86%) (**Figure 4**) and decreased likelihood of incident caries (12 trials, n = 8177; RR, 0.80 [95% CI, 0.66 to 0.95]; I^2 = 79%; absolute risk difference, −7% [95% CI, −12% to −2%]) (**Figure 5**) vs placebo or no varnish, with a number needed to treat to prevent 1 child with incident caries of 14 (95% CI, 8 to 50). Although statistical heterogeneity was present, results consistently favored topical fluoride in analyses stratified by use of cluster design, very high HDI setting, application frequency, preschool, baseline caries status, adequate community fluoridation, provision of additional oral health measures, risk of bias, or duration of follow-up, and

Figure 3. Literature Search Flow Diagram: Screening for Dental Caries in Children Younger Than 5 Years

KQ indicates key question.

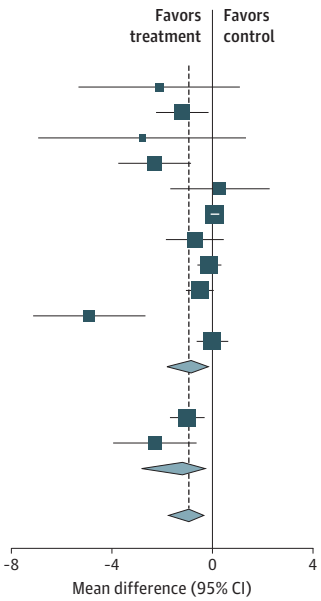
[a] Identified from reference lists, hand searching, suggested by experts, etc.

[b] Studies that provided data and contributed to the body of evidence were considered included.

[c] Studies may have contributed data for more than 1 KQ.

Figure 4. Pooled Analysis of Topical Fluoride vs Placebo or No Topical Fluoride on Mean Change in Number of Caries at Follow-up, by Fluoridation Status

Source	Mean age, y	Follow-up duration, y	Baseline caries	Continuous caries measure[a]	Treatment No.	Treatment Mean (SD)	Control No.	Control Mean (SD)	Mean difference (95% CI)
No adequate fluoridation									
Frostell et al,[29] 1991	4	2	Mean $dmfs_1$: 4.79	$dmfs_1$	93	6.6 (11.2)	113	8.7 (12.3)	-2.12 (-5.33 to 1.09)
Jiang et al,[30] 2005[b]	3.5	2	Mean dmft 1.6-1.7	dmfs	167	3.8 (0.9)	151	5.0 (1.0)	-1.20 (-2.24 to -0.16)
Lawrence et al,[31] 2008[b]	0.5-5	2	dmft >0: 72%	dmfs	832	11.0 (14.4)	328	13.5 (16.3)	-2.80 (-6.94 to 1.34)
Slade et al,[32] 2011[b]	2.8	2	≥1 Carious surface	dm_3fs	344	7.3 (10.4)	322	9.6 (10.1)	-2.30 (-3.75 to -0.85)
Agouropoulos et al,[34] 2014	3.4	2	dmfs1 >0: 38%	dmfs	175	5.8 (9.5)	154	5.5 (8.8)	0.30 (-1.68 to 2.28)
Jiang et al,[37] 2014	1.3	2	Mean dmft: 0.03	Cavitated dmft	137	0.2 (0.9)	144	0.1 (0.5)	0.10 (-0.07 to 0.27)
Oliveira et al,[43] 2014	2.4	2	Dentine caries: 24%	d_3mfs	89	1.8 (3.9)	92	2.5 (4.0)	-0.70 (-1.85 to 0.45)
Memarpour et al,[41] 2015	1.8	1	0	dmft	29	0.3 (0.9)	31	0.4 (1.0)	-0.12 (-0.60 to 0.36)
Muñoz-Millán et al,[42] 2018	2.7	2	0	dmft	131	1.6 (2.0)	144	2.1 (2.6)	-0.50 (-1.05 to 0.05)
Latifi-Xhemajli et al,[38] 2019	1.8	2	Mean dmfs: 1	dmfs	218	5.2 (10.5)	209	10.1 (12.9)	-4.90 (-7.14 to -2.66)
McMahon et al,[39] 2020	3.5	2	Caries: 17%	d_3mfs	577	3.5 (5.9)	573	3.5 (4.9)	0.00 (-0.63 to 0.63)
Subgroup: $I^2 = 87.2\%$; $P < .001$									-0.85 (-1.81 to -0.16)
Adequate fluoridation									
Weintraub et al,[33] 2006	1.8	2	0	$d_{2+}mfs$	187	0.7 (1.9)	93	1.7 (3.1)	-1.00 (-1.69 to -0.31)
Tickle et al,[45] 2017[b]	3.1	3	0	d_3mfs	187	7.2 (8.0)	213	9.6 (8.8)	-2.29 (-3.95 to -0.63)
Subgroup: $I^2 = 0.0\%$; $P = .16$ Heterogeneity between groups: $P = .54$									-1.19 (-2.81 to -0.29)
Overall: $I^2 = 85.7\%$; $P < .001$									-0.94 (-1.74 to -0.34)



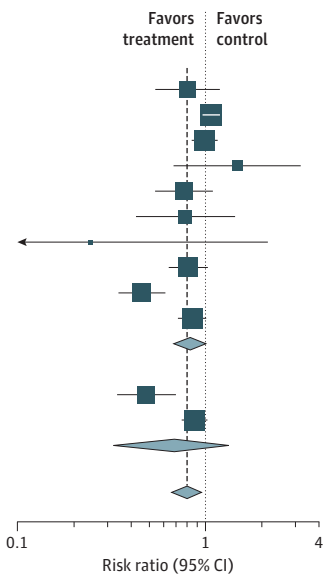
The size of the data markers indicates the weight of each study in the analysis. dmfs indicates decayed, missing, or filled surfaces; dmft, decayed, missing, or filled teeth.

[a] Subscripts indicate the extent of the caries lesion (eg, d_1 indicates noncavitated enamel lesion; d_2, cavitated enamel lesion; d_3, dentin lesion; d_4, lesion extending into pulp).

[b] Study adjusted for clustering design or other confounding variables.

Figure 5. Pooled Analysis of Topical Fluoride vs Placebo or No Topical Fluoride on Caries Development at Follow-up, by Fluoridation Status

Source	Mean age, y	Follow-up duration, y	Baseline caries	Outcome definition[a]	Treatment No.	Treatment Mean (SD)	Control No.	Control Mean (SD)	Risk ratio (95% CI)
No adequate fluoridation									
Jiang et al,[30] 2005[b]	3.5	2	Mean dmft 1.6-1.7	dmfs increase ≥6	47	167	53	151	0.80 (0.54 to 1.19)
Lawrence et al,[31] 2008[b]	0.5-5	2	dmft >0: 72%	New dmfs ≥1	595	832	247	328	1.07 (0.96 to 1.19)
Agouropoulos et al,[34] 2014	3.4	2	dmfs >0: 38%	dmfs >0	113	174	101	154	0.99 (0.85 to 1.16)
Jiang et al,[37] 2014	1.3	2	Mean dmft: 0.03	Incident caries	14	137	10	144	1.47 (0.68 to 3.20)
Oliveira et al,[43] 2014	2.4	2	Dentine caries: 24%	New caries lesion	32	89	43	92	0.77 (0.54 to 1.09)
Anderson et al,[36] 2016[b]	1	3	ICDAS 5-6: 0.2%	ICDAS 5 to 6	75	1231	99	1305	0.78 (0.43 to 1.44)
Memarpour et al,[40] 2016	1.7	1	0	dmft >0	1	87	4	85	0.24 (0.03 to 2.14)
Muñoz-Millán et al,[42] 2018	2.7	2	0	Cavitated caries	59	131	80	144	0.81 (0.64 to 1.03)
Latifi-Xhemajli et al,[38] 2019	1.8	2	Mean dmfs: 1.1	ICDAS 5 or 6	48	218	100	209	0.46 (0.34 to 0.61)
McMahon et al,[39] 2020	3.5	2	Caries: 17%	$d_3$mfs increment >0	165	577	193	573	0.85 (0.71 to 1.01)
Subgroup: I^2 = 75.4%; P <.001									0.83 (0.68 to 1.00)
Adequate fluoridation									
Weintraub et al,[33] 2006	1.8	2	0	Incident caries	37	163	42	90	0.49 (0.34 to 0.70)
Tickle et al,[45] 2017	3.1	3	0	Became caries active	187	549	213	547	0.87 (0.75 to 1.02)
Subgroup: I^2 = 76.2%; P = .003 Heterogeneity between groups: P = .43									0.68 (0.33 to 1.33)
Overall: I^2 = 79.3%; P <.001									0.80 (0.66 to 0.95)



The size of the data markers indicates the weight of each study in the analysis. dmfs indicates decayed, missing, or filled surfaces; dmft, decayed, missing, or filled teeth; ICDAS, International Caries Detection and Assessment System.

[a] Subscripts indicate the extent of the caries lesion (eg, d_1 indicates noncavitated enamel lesion; d_2, cavitated enamel lesion; d_3, dentin lesion; d_4, lesion extending into pulp).

[b] Study adjusted for clustering design or other confounding variables.

Table 1. Pooled Analyses of Mean Change in Number of Caries at Follow-up, Topical Fluoride vs Placebo or No Topical Fluoride

	No. of trials	Mean difference (95% CI)	I^2, %	*P* value for interaction
All studies	13[29-34,37-39,41-43,45]	−0.94 (−1.74 to −0.34)	86	
Fluoride type				
Sodium fluoride (5%) varnish	10[29,31-33,37,39,41-43,45]	−0.62 (−1.35 to −0.16)	75	.57
Other varnish	2[34,38]	−2.24 (−8.56 to 3.98)	83	
Foam	1[30]	−1.20 (−2.24 to −0.16)	NA	
Study quality				
Good	3[37,39,43]	0.08 (−0.28 to 0.27)	0	.13
Fair	10[29-34,38,41,42,45]	−1.33 (−2.36 to −0.54)	78	
Fluoridation status				
Adequate	2[33,45]	−1.19 (−2.81 to −0.29)	0	.54
Not adequate	11[29-32,34,37-39,41-43]	−0.85 (−1.81 to −0.16)	87	
Cluster enrollment				
Yes	3[30-32]	−1.63 (−3.04 to −0.64)	0	.27
No	10[29,33,34,37-39,41-43,45]	−0.72 (−1.66 to −0.09)	86	
Setting				
Preschool	5[30,34,38,39,42]	−1.04 (−2.90 to 0.57)	88	.94
Other	8[29,31-33,37,41,43,45]	−0.89 (−1.86 to −0.21)	80	
Mean age, y				
<2	4[33,37,38,41]	−1.26 (−3.24 to 0.74)	98	.93
≥2	9[29-32,34,39,42,43,45]	−0.89 (−1.70 to −0.30)	50	
High risk of caries				
Yes	12[29-34,37-39,41-43]	−0.81 (−1.64 to −0.24)	84	.34
No	1[45]	−2.29 (−3.95 to −0.63)	NA	
Caries-free at baseline				
Yes	5[33,37,41,42,45]	−0.43 (−1.24 to 0.06)	74	.33
No	8[29-32,34,38,39,43]	−1.40 (−2.74 to −0.29)	74	
High Human Development Index rating				
Yes	7[29,33,34,37,39,42,45]	−0.43 (−1.16 to 0.06)	64	.22
No	6[30-32,38,41,43]	−1.62 (−3.26 to −0.33)	81	
Additional oral health measures used				
Yes	10[31-34,37,39,41-43,45]	−0.53 (−1.18 to −0.10)	71	.07
No	3[29,30,38]	−2.57 (−5.45 to 0.03)	62	
Duration of follow-up, y				
1	2[34,41]	−0.09 (−0.73 to 0.71)	0	.35
2	11[29-34,37-39,42,43]	−0.95 (−1.87 to −0.28)	84	
3	1[45]	−2.29 (−3.95 to −0.63)	NA	
Application frequency				
Every 3 mo	1[38]	−4.90 (−7.14 to −2.66)	NA	.06
Every 4 mo	1[41]	−0.12 (−0.60 to 0.36)	NA	
Every 6 mo	11[29-34,37,39,42,43,45]	−0.73 (−1.40 to −0.24)	70	
Every 12 mo	1[33]	−1.00 (−1.72 to −0.28)	NA	

Abbreviation: NA, not applicable.

there were no statistically significant interactions on these factors and caries outcomes (**Table 1** and **Table 2**). Results were also similar when the trial of fluoride foam or the trial conducted in a non–high-risk population was excluded from the analysis. There was a significant interaction between age and effects of fluoride varnish on likelihood of incident caries but not caries increment. In trials in which the mean age was younger than 2 years, fluoride varnish was associated with significant decreased likelihood of incident caries (5 trials, n = 3669; RR, 0.60 [95% CI, 0.39 to 1.03]; I^2 = 49%),[33,36-38,40] with no significant difference in trials in which the mean age was 2 years or older (7 trials, n = 4508; RR, 0.92 [95% CI, 0.81 to 1.01]; I^2 = 42%; *P* = .008 for interaction).[30,31,34,39,42,43,45]

No trial evaluated effects of topical fluoride on quality of life, function, or other noncaries outcomes.

Xylitol

No new trials of xylitol vs no xylitol were identified. Two fair-quality trials (n = 115 and n = 44) included in the prior USPSTF review found

Table 2. Pooled Analyses of Risk of Caries Development at Follow-up, Topical Fluoride vs Placebo or No Topical Fluoride

	No. of trials	Relative risk (95% CI)	I^2, %	*P* value for interaction
All studies	12[30,31,33,34,36-40,42,43,45]	0.80 (0.66 to 0.95)	79	
Fluoride type				
Sodium fluoride (5%) varnish	11[31,33,34,36-40,42,43,45]	0.84 (0.69 to 0.99)	65	.79
Other varnish	2[34,38]	0.69 (0.27 to 1.71)	90	
Foam	1[30]	0.80 (0.54 to 1.19)	NA	
Quality				
Good	3[37,39,43]	0.85 (0.71 to 1.08)	0	.49
Fair	9[30,31,33,34,36,38,40,42,45]	0.77 (0.60 to 0.96)	84	
Fluoridation status				
Adequate	2[33,45]	0.68 (0.33 to 1.33)	76	.43
Not adequate	10[30,31,34,36-40,42,43]	0.83 (0.68 to 1.00)	75	
Cluster enrollment				
Yes	3[30,31,36]	1.04 (0.74 to 1.17)	0	.37
No	9[33,34,37-40,42,43,45]	0.76 (0.60 to 0.95)	78	
Setting				
Preschool	5[30,34,38,39]	0.77 (0.58 to 1.01)	83	.63
Other	7[31,33,36,37,40,42,43,45]	0.83 (0.61 to 1.08)	74	
Mean age, y				
<2	5[33,36-38,40]	0.60 (0.39 to 1.03)	49	.008
≥2	7[30,31,34,39,42,43,45]	0.92 (0.81 to 1.01)	42	
High risk of caries				
Yes	11[30,31,33,34,36-40,42,43]	0.79 (0.64 to 0.96)	80	.73
No	1[45]	0.87 (0.75 to 1.02)	NA	
Caries-free at baseline				
Yes	6[33,36,37,40,42,45]	0.77 (0.57 to 1.04)	48	.77
No	6[30,31,34,38,39,43]	0.82 (0.62 to 1.05)	86	
High Human Development Index rating				
Yes	7[33,34,36,37,39,42,45]	0.84 (0.69 to 1.00)	48	.57
No	5[30,31,38,40,43]	0.74 (0.47 to 1.07)	79	
Additional oral health measures used				
Yes	10[31,33,34,36,37,39,40,42,43,45]	0.86 (0.73 to 1.00)	64	.11
No	2[30,38]	0.59 (0.31 to 1.18)	59	
Duration of follow-up, y				
1	3[33,34,40]	0.71 (0.27 to 1.29)	58	.68
2	9[30,31,33,34,37-39,42,43]	0.79 (0.63 to 0.99)	84	
3	2[36,45]	0.87 (0.67 to 1.07)	0	
Application frequency				
Every 3 mo	1[38]	0.46 (0.35 to 0.61)	NA	.07
Every 6 mo	11[30,31,33,34,36,37,39,40,42,43,45]	0.88 (0.74 to 0.98)	52	
Every 12 mo	1[33]	0.60 (0.40 to 0.91)	NA	

Abbreviation: NA, not applicable.

xylitol tablets or wipes associated with decreased caries increment or likelihood or incident caries, but estimates were imprecise.[46,47]

Silver Diamine Fluoride

No study of silver diamine fluoride met inclusion criteria.

Harms of Intervention

Key Question 5. What are the harms of specific oral health interventions to prevent dental caries in children younger than 5 years (parental or caregiver/guardian oral health education, referral to a dental health care professional, and preventive interventions)?

The prior USPSTF review included a systematic review of 19 studies that found an association between early childhood fluoride supplementation and risk of fluorosis of the permanent dentition. Studies were observational and had methodological shortcomings, including use of recall to determine exposures.[49] In studies that recorded supplement use at the time of exposure, odds ratios for dental fluorosis ranged from 4.2 to 15.6. No new

Table 3. Summary of Evidence

Objective/intervention	Studies (No. of observations), study design	Summary of findings	Consistency and precision	Other limitations	Strength of evidence	Applicability
Screening KQ1 and KQ3: Effectiveness and harms of screening by PCP						
	No studies	NA	NA	NA	NA	NA
Screening KQ2a: Accuracy of screening by PCP						
Identifying caries lesion	2 (n = 368) diagnostic accuracy studies (both in prior USPSTF review)	Sensitivity of 0.76 and specificity of 0.95 for identifying a child with ≥1 cavities and sensitivity of 0.63 and specificity of 0.98 for identifying a child in need of a dental referral (1 study) Sensitivity of 1.0 and specificity of 0.87 for identifying nursing caries (1 study)	Unable to assess consistency due to differences between studies Precision low to moderate	Nursing caries study rated fair quality	Low	Primary care examiners underwent 2 or 4 h of training; both studies conducted in the US
Screening KQ2b: Accuracy of screening by PCP						
Predicting future caries	1 (n = 1681) diagnostic accuracy study (new)	Dundee Caries Risk Assessment Model associated with sensitivity of 0.53 and specificity of 0.77 for predicting future dentin caries in children aged 1 y	Unable to assess consistency (single study), precise	Fair quality; factors selected for model not predefined; no validation available	Low	Administered by health visitor nurses in Scotland
Prevention KQ1: Accuracy of screening by PCP[a]						
	See screening KQ2b	See screening KQ2b	See screening KQ2b	See screening KQ2b	See screening KQ2b	See screening KQ2b
Prevention KQ2: Educational interventions						
	1 (n = 104) RCT (new)	1 RCT found oral health education for mothers of caries-free children aged 12 to 36 mo associated with reduced risk of incident dental caries vs usual care at 6 mo (RR, 0.39 [95% CI, 0.18 to 0.85])	Unable to assess consistency (1 study), precise	Fair quality; dental health behaviors not reported at baseline or follow-up	Low	Conducted in Iran in region with inadequate fluoridation of drinking water
Prevention KQ3: Referral to a dentist by a PCP						
	6 (n = 92 476) observational studies; 1 study in prior review and 5 new	No study directly compared referral by primary care clinician to a dentist vs no referral Receiving a dental visit from a dentist associated with increased likelihood of subsequent caries-related treatment vs a dental visit from a primary care clinician (4 studies) Earlier vs later first preventive dental visit associated with no difference in rate of subsequent dental procedures, higher subsequent caries burden, and lower rates of untreated caries	Consistent, precise	Observational studies; fair quality; studies not designed to determine referral source or compare effects of referral vs no referral; findings susceptible to confounding by indication	Low	All studies conducted in US children enrolled in Medicaid; some overlap in study populations conducted within the same state

(continued)

Table 3. Summary of Evidence (continued)

Objective/intervention	Studies (No. of observations), study design	Summary of findings	Consistency and precision	Other limitations	Strength of evidence	Applicability
Prevention KQ4: Preventive interventions						
Dietary fluoride supplementation	1 (n = 140) RCT and 4 (n = 3172) nonrandomized controlled intervention studies (all in prior USPSTF review)	Dietary fluoride supplementation in settings with water fluoridation levels below 0.6 ppm F associated with decreased caries incidence vs no fluoridation (percentage reduction ranged from 48% to 72% for primary teeth and from 51% to 81% for primary tooth surfaces)	Consistent, precise	4 of 5 studies were nonrandomized	Moderate	2 Trials conducted in Asia; 1 trial conducted in children with cleft lip; 3 trials conducted between 1967 and 1972
Topical fluoride	15 (n = 9541) RCTs (5 in prior USPSTF review and 10 new)	Topical fluoride associated with decreased caries increment (13 trials; mean difference, −0.94 [95% CI, −1.74 to −0.34]) and decreased likelihood of incident caries (12 trials; RR, 0.80 [95% CI, 0.66 to 0.95]) vs placebo or no varnish	Inconsistent (high statistical heterogeneity), precise	11 Trials rated fair quality (2 rated good quality); open-label design in some trials	Moderate	Almost all trials conducted in higher-risk children or settings; almost all trials evaluated fluoride varnish; varnish applied by persons with dental training; some trials conducted in preschool or daycare setting; some trials conducted in non-very high Human Development Index settings; some trials included children with high baseline caries burden
Xylitol	2 (n = 159) RCTs (both in prior USPSTF review)	Estimates imprecise from 2 trials, but favored xylitol over placebo for caries outcomes	Consistent, imprecise	Trials rated fair quality	Low	Trials conducted in US and Sweden; 1 trial conducted in low socioeconomic status setting; xylitol administered as tablet or wipe
Silver diamine fluoride	No studies	NA	NA	NA	NA	NA
Prevention KQ5: Harms of interventions						
Dietary fluoride supplements	1 Systematic review of 19 observational studies (in prior USPSTF review)	Intake of fluoride supplements before age 7 y (primarily before age 3 y) associated with increased risk of mild to moderate fluorosis; odds ratio ranged from 1.1 to 10.8 in the studies that relied on retrospective recall and from 4.2 to 15.6 in the studies that recorded supplement use at the time of exposure	Consistent, precise	Observational studies; most studies relied on retrospective recall to determine fluoride exposure	Low-moderate	Studies conducted in a variety of settings and countries, variability in recommended levels of fluoride supplementation and water fluoridation levels
	4 (n = 4141) RCTs (all new)	No difference in risk of fluorosis or esthetically objectionable fluorosis (1 trial); no difference in risk of adverse events (1 trial); reports of disagreeable odor	Consistency cannot be determined (single trials reported different adverse events), precise	Harms not reported or suboptimal reporting in most trials	Low-moderate	See KQ4
Xylitol	No studies	RCTs of xylitol vs placebo or no xylitol did not report harms	NA	NA	NA	NA

Abbreviations: KQ, key question; NA, not applicable; PCP, primary care physician; ppm F, parts fluoride per million parts water; RCT, randomized clinical trial; RR, relative risk; USPSTF, US Preventive Services Task Force.

[a] Same question as screening KQ2b.

study evaluated the association between fluoride supplementation and risk of fluorosis.

Four new trials (n = 4141) reported no significant differences between fluoride varnish vs placebo or no varnish in risk of fluorosis or the likelihood of any adverse event.[34-36,44,45,48] Two studies (n = 2864) reported that children did not like the smell of the fluoride varnish, and 1 study reported that a few children vomited due to the smell, texture, or taste.[34-36]

Discussion

Table 3 summarizes the evidence reviewed for this update. As in the prior USPSTF review,[7,8] there remained no direct evidence on screening vs no screening for dental caries in children younger than 5 years. Evidence on the accuracy of primary care clinician examination in identifying caries lesions or predicting caries incidence in this population remained very limited, with no new studies. One new study found a novel caries risk assessment tool in 1-year-old children associated with suboptimal diagnostic accuracy for predicting future caries.[15] Although other caries risk assessment instruments are available, they did not meet inclusion criteria because they were not administered by primary care clinicians or in primary care settings. These instruments often incorporate findings from an oral examination by a dental health professional and include tests not commonly obtained or available in primary care.[51,52]

Evidence on the effectiveness of parental or caregiver oral health education also remains very limited. One new trial found oral health education for mothers of caries-free children associated with reduced risk of incident dental caries vs usual care, but the study was relatively small and conducted in Iran, potentially reducing applicability to the US.[16] No study directly evaluated effects of referral by a primary care clinician to a dentist. Observational studies that compared children enrolled in Medicaid who received a preventive dental visit from a dentist vs a pediatrician are available but difficult to interpret due to confounding related to need for dental services.[19-22] In addition, these studies did not evaluate referral source and did not compare dental referral vs no referral.

No new trial evaluated fluoride supplementation. Prior USPSTF reviews found dietary fluoride supplementation associated with reduced caries incidence in children younger than 5 years in settings primarily with water fluoridation levels less than 0.6 ppm F, largely based on nonrandomized controlled intervention studies.[53] There was also no new evidence on the association between early childhood intake of dietary fluoride supplementation and risk of enamel fluorosis. A systematic review included in the prior USPSTF review found an association between early childhood ingestion of systemic fluoride and enamel fluorosis of the permanent dentition.[49] Severe fluorosis remains uncommon in the US (prevalence <2%).[54]

Findings regarding topical fluoride are strengthened by the inclusion of 10 new trials. In addition to increasing the precision of estimates, 6 new trials were conducted in very high HDI settings (compared with 2 of 5 prior trials), potentially increasing applicability to US primary care settings. Topical fluoride was associated with improved outcomes, with a number needed to treat to prevent 1 child with incident caries of about 14 (95% CI, 8 to 50). Topical fluoride was administered as a varnish in all trials except for 1,[30] which used acidulated phosphate fluoride foam. Results were consistent in stratified analyses on multiple factors, including community water fluoridation status. Although there was a significant interaction between younger age and larger reduction in likelihood of incident caries with topical fluoride, there was no significant interaction between age and effects on caries burden. Because almost all trials were conducted in higher-risk children, the applicability of findings to children not at increased risk is uncertain. In all trials the varnish was applied by dental personnel, although fluoride varnish can be successfully applied easily and with minimal training.[55,56] Limited evidence on harms associated with topical fluoride indicated no increased risk of fluorosis[48] or adverse events[44,45] vs placebo. Serious adverse events were not reported, though some children had difficulty tolerating the varnish application because of odor or taste.

Evidence on other preventive interventions was limited or unavailable. There were no new trials of xylitol in children younger than 5 years, and evidence in the prior USPSTF review was limited to 2 trials with imprecise estimates.[46,47] Silver diamine fluoride has primarily been used as a treatment for arresting existing cavitated caries, but is also being evaluated for caries prevention. No trial evaluated silver diamine fluoride for prevention of caries in children younger than 5 years, although trials in US school-aged children are expected to be completed in 2023.[57,58]

Limitations

This review has several limitations. First, non–English-language articles were excluded. However, no non–English-language articles that appeared likely to affect conclusions were identified. Second, the review did not search for studies published only as abstracts and did not formally assess for publication bias with graphical or statistical methods because of differences in study design, populations, and outcomes assessed, with substantial statistical heterogeneity. Third, statistical heterogeneity was substantial in meta-analyses of topical fluoride. However, results were consistent in prespecified stratified analyses based on factors related to study design, population characteristics, intervention characteristics, and setting, and meta-analysis used a random-effects model. Fourth, some trials were conducted in countries and settings in which oral health care and behaviors may differ substantially from typical US primary care settings, potentially reducing applicability. Fifth, most studies had methodological limitations, reducing certainty in findings, and some KQs and interventions were addressed by little or no evidence.

Conclusions

There was no direct evidence on benefits and harms of primary care oral health screening or referral to dentist. Dietary fluoride supplementation and fluoride varnish were associated with improved caries outcomes in higher-risk children and settings.

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Editorial Disclaimer: This evidence report is presented as a document in support of the accompanying USPSTF Recommendation Statement. It did not undergo additional peer review after submission to *JAMA*.

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Fluoride Therapy

Latest Revision

2023

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Abstract

This best practice provides information for practitioners regarding the use of fluoride as an aid in preventing and controlling dental caries in pediatric dental patients. These recommendations address systemic fluoride (water fluoridation, dietary fluoride supplements), topical fluoride delivery via professional application (acidulated phosphate fluoride gel or foam, sodium fluoride varnish, silver diamine fluoride), and home-use products (toothpastes, mouthrinses) as well as the associated risks of fluoride agents. The standard level for community water fluoridation (0.7 parts per million fluoride) helps balance the risk of caries and the possibility of dental fluorosis from excessive fluoride ingestion during the early years of tooth development. Specific recommendations for dietary supplementation of fluoride for children ages six months through 16 years are based on fluoride levels in the drinking water, other dietary sources of fluoride, use of a fluoridated toothpaste, and caries risk. The specific needs of each patient determine the appropriate use of systemic and topical fluoride products, whether delivered in a professional clinical or a home setting. Fluoride has proven to be an effective therapy in reducing the prevalence of dental caries in infants, children, adolescents, and persons with special needs.

Through a collaborative effort of the American Academy of Pediatric Dentistry Councils on Clinical Affairs and Scientific Affairs, this best practice was revised to offer updated information and recommendations to assist healthcare practitioners and parents in using fluoride therapy for management of caries risk in pediatric patients.

KEYWORDS: ADOLESCENT; CHILD; FLUORIDATION; FLUORIDE; ORAL HEALTH; SILVER DIAMINE FLUORIDE; TOOTHPASTE

Purpose

The American Academy of Pediatric Dentistry intends these recommendations to help practitioners make decisions concerning appropriate use of fluoride as part of the comprehensive oral health care for infants, children, adolescents, and persons with special health care needs.

Methods

This document was initially developed by the Liaison with Other Groups Committee, adopted in 1967[1] and last revised by the Council on Clinical Affairs in 2018[2]. To update this guidance, an electronic search of the PubMed®/MEDLINE database was conducted using the terms: fluoride caries prevention, fluoridation, fluoride gel, fluoride varnish, fluoride toothpaste, fluoride therapy, silver diamine fluoride, and topical fluoride; fields: all; limits: within last five years, English. Because 4077 papers were identified through these electronic searches, an alternate strategy of limiting the information gathering to systematic review using the term fluoride caries prevention yielded 116 new systematic reviews or trials since 2017. Expert opinions and clinical practices also were relied upon for these recommendations.

Background

Fluoride has been a major factor in the decline in prevalence and severity of dental caries in the United States (**U.S.**) and other economically developed countries. It has several caries-protective mechanisms of action. Topically, low levels of fluoride in plaque and saliva inhibit the demineralization of sound enamel and enhance the remineralization of demineralized enamel.[3,4] The topical effect may be enhanced when combined with good oral hygiene practices at home and use of a fluoride dentifrice.[5] Fluoride also inhibits dental caries by affecting the metabolic activity of cariogenic bacteria.[6] High levels of fluoride, such as those attained with the use of topical gels or varnishes, produce a temporary layer of calcium fluoride-like material on the enamel surface. The fluoride is released when the pH drops in response to acid production and becomes available to remineralize enamel or affect bacterial metabolism.[7] Although fluoride-rich enamel is less acid-soluble than enamel with less fluoride, the topical and remineralization effects of fluoride have been found to have a greater impact on caries prevention than incorporation of fluoride into developing teeth.[8]

Community water fluoridation

Fluoridation of community drinking water is the most equitable and cost-effective method of delivering fluoride to all members of most communities.[9] As of 2018, 73 percent of the U.S. population on community water systems had access to fluoridated water.[10] Water fluoridation at the level of 0.7-1.2 milligrams (**mg**) fluoride ion per liter (i.e., parts per million fluoride [**ppm F**]) was introduced in the U.S. in the 1940s. Since community water is now one of several sources of fluoride,

ABBREVIATIONS

CaF: Calcium fluoride. **F:** Fluoride. **FSIQ:** Full scale intelligent quotient. **IQ:** Intelligence quotient. **mg:** Milligrams. **mg/kg:** Milligrams per kilogram. **NaFV:** Sodium fluoride varnish. **ppm F:** Parts per million fluoride. **SDF:** Silver diamine fluoride. **U.S.:** United States.

the U.S. Department of Health and Human Services revised these recommendations in 2015 to a standardized level of 0.7 ppm F to balance the benefits of preventing dental caries while reducing the chance of fluorosis.[11]

Community water fluoridation has been associated with the decline in caries prevalence in U.S. adolescents, from 90 percent in at least one permanent tooth in 12-17-year-olds in the 1960s, to 60 percent in a 1999-2004 survey,[12,13] with more recent estimates of 35 percent caries reduction in primary teeth and 26 percent in permanent teeth of children[14]. Additionally, a Cochrane review found that water fluoridation led to a 15 percent increase in caries-free children in primary dentition and 14 percent increase in caries-free children with permanent dentition.[14]

Consuming fluoridated drinking water is both safe and effective in preventing and controlling dental caries. Although adverse health effects (e.g., decreased cognitive ability, endocrine disruption, cancer) have been ascribed to the use of fluoride over the years, the preponderance of evidence from large cohort studies and systematic reviews does not support an association of such health issues and consumption of fluoridated water at the recommended concentration.[11] Regarding cognitive ability, a recent study of mothers' urinary fluoride levels and their child's intelligence quotient (**IQ**) levels suggested an association with exposure levels much greater than those recommended in the U.S. for water fluoridation.[15] Also utilizing maternal urinary fluoride levels, a multicenter prospective cohort study[16] followed children born in Canada between 2008 and 2012. Forty-one percent of followed patients lived in fluoridated communities. This study assessed IQ at ages three and four years using the Wechsler Preschool and Primary Scale of Intelligence with Full Scale Intelligence Quotient (**FSIQ**) as the primary outcome.[16] Results indicated that a one mg increase in daily fluoride intake (e.g., an extra six cups of optimally-fluoridated water each day) during pregnancy was associated with a 4.49 point lower FSIQ score in boys but did not significantly impact girls.[16] The study results suggested maternal exposure to high fluoride levels was associated with lower IQ scores in boys and girls; however, it overlooked confounding variables that did not adjust for differences in socioeconomic status or maternal IQ, and there was no IQ difference when evaluating the full population.[16] Moreover, a prospective study in New Zealand did not support an association between fluoridated water and IQ measurements[17], and a national sample in Sweden found no relationship between fluoride levels in water supplies and cognitive ability, noncognitive ability, and education[18]. The current evidence does not support that consuming water fluoridated at the level 0.7 ppm F is associated with reductions in IQ.

Repeated consumption of fluoride at levels higher than those recommended in this document during enamel development, however, can cause dental fluorosis (children 15-30 months of age being most susceptible for fluorosis of the permanent incisors).[19] The National Health and Nutrition Examination Survey (NHANES) 1999-2004 study found 23 percent of the U.S. population aged six through 49 had very mild or mild fluorosis.[20] Very mild and mild levels of fluorosis are associated with decreased caries experience and presents clinically as an increase in diffuse or lacy appearing white opacities of the enamel and generally are not considered an esthetic problem.[21,22] The Iowa Fluoride Study was a longitudinal study that gathered data on fluoride intake from multiple sources (water, beverages, foods, fluoride supplements, and dentifrices) on subjects from birth to 36 months.[23] Those subjects were examined at about age nine to assess permanent incisors and first molars for fluorosis using the Fluorosis Risk Index.[24] This study found the prevalence of mild fluorosis was 13 percent among those children with average fluoride intakes of 0.04 mg per kilogram (**mg/kg**) body weight and increased to 23 percent when intakes were between 0.04 to 0.06 mg/kg.[24] When fluoride intakes average 0.06 mg/kg or more per day, mild fluorosis prevalence was 38 percent.[24] A more recent study found mild fluorosis levels increased to over 60 percent for adolescents ages 16 and 17 in 2011-2012 compared to 29.4 percent in 2001-2002; this is a greater than 31 percent increase.[25]

Fluoride fluoridation, supplements, and infant formula

Fluoride supplements are effective in reducing prevalence of dental caries and may be considered for children at high caries risk who drink fluoride-deficient (less than 0.6 ppm F) water[26] (see Table). Fluoride supplementation schedules were last revised in the early 1990s[27] and have not been adjusted since 1) fluoride concentration in municipal water was standardized and 2) recommendations to use fluoridated toothpaste with the eruption of the first tooth were promulgated.

Before prescribing supplements, determination of dietary fluoride intake from all sources can help reduce intake of excess fluoride. Sources of dietary fluoride may include drinking water from home, day care, and school; beverages such as soda[28], juice[29], and infant formula[30]; prepared food[31]; and toothpaste. Concentrated infant formulas requiring reconstitution with water have raised concerns regarding an increased risk of fluorosis.[32] Infants may be particularly susceptible because of the large consumption of such liquid while the body weight is relatively low[4] and the enamel is mineralizing. An evidence-based review found that consumption of reconstituted

Table. DIETARY FLUORIDE SUPPLEMENTATION SCHEDULE

Age	<0.3 ppm F	0.3 to 0.6 ppm F	>0.6 ppm F
Birth to 6 months	0	0	0
6 months to 3 years	0.25 mg	0	0
3 to 6 years	0.50 mg	0.25 mg	0
6 to at least 16 years	1.00 mg	0.50 mg	0

Note: The recommendations in this table have not been revised since fluoride concentration in municipal water was standardized and use of fluoridated toothpaste for dentate infants was promulgated. All dietary sources of fluoride should be taken into consideration before recommending fluoride supplements for patients with fluoride-deficit community water.

infant formula can be associated with an increased risk of mild fluorosis but recommended the continued use of fluoridated water.[33] One study has shown that dental fluorosis levels do not vary in fluoridated areas regardless of premixed versus reconstituted formula.[34] Nevertheless, over-supplementation of fluoride, even for patients residing in areas with unfluoridated water, can cause fluorosis.[35] Since standardization of the optimal fluoride levels in drinking water to 0.7 ppm F in 2015, dental fluorosis is less likely to occur. However, caution is indicated when considering the use of fluoride supplements for children under age six due to their continued dental development and consumption of fluoride from a variety of sources.

Professionally-applied fluoride varnish, gel, and foam

Professionally-applied topical fluoride treatments are efficacious in reducing prevalence of dental caries. The most commonly used agents for professionally-applied fluoride treatments are five percent sodium fluoride varnish ([**NaFV**]; 2.26 percent fluoride [**F**], 22,600 ppm F) and acidulated phosphate fluoride ([APF]; 1.23 percent F, 12,300 ppm F). Meta-analyses of 23 clinical trials, most with twice yearly application, favors the use of fluoride varnish in primary and permanent teeth to prevent decay.[36] Fluoride varnish appears to be effective at preventing caries in higher-risk children younger than five years of age.[37] Unit doses of five percent fluoride varnish are the only professional topical fluoride agent recommended for children younger than age six for safety reasons.[36] Meta-analyses of placebo-controlled trials show that fluoride gels, applied at three-months to one-year intervals, also are efficacious in reducing caries in permanent teeth.[38,39] Some topical fluoride gel and foam products are marketed with recommended treatment times of less than four minutes, but there are no clinical trials showing efficacy of shorter than four-minute application times.[40] Evidence that topical fluoride foams are efficacious in children is limited.[36] Children at risk for caries should receive a professional fluoride treatment at least every six months.[40] In 2014, the U.S. Preventive Services Task Force recommended a schedule for fluoride varnish application specifically by non-dental personnel to provide this preventive strategy to children in medical settings, especially when children are more likely to see a medical provider rather than a dental provider.[41,42] Recent meta-analyses tried to determine whether professionally-applied fluoride can reverse incipient/white spot caries lesions[43-45] but, due to heterogeneity of studies included in the systematic review coupled with home use of fluoride dentifrices by research subjects, a valid conclusion could not be made[43]. Yet another study has shown that incipient enamel lesions (International Caries Detection and Assessment System Code 2) can be arrested with semiannual applications of five percent NaFV.[46]

Silver diamine fluoride

Thirty-eight percent silver diamine fluoride ([**SDF**]; five percent F, 44,800 ppm F) has been cleared by the U.S. Food and Drug Administration as a dentin desensitizer in adults.[47] It currently is used frequently to arrest cavitated caries lesions. SDF is thought to arrest caries by the antibacterial effect of silver and remineralization of enamel and dentin by fluoride.[48] Silver ions have an antimicrobial effect mainly in the treated carious dentin[49], and the combination of silver and fluoride in an alkaline solution have a synergistic effect that creates an unfavorable environment for collagen enzyme activation, thereby reducing dentin degradation.[50] Clinical trials show caries arrest rates ranging from 35 to 80 percent[51], but such studies have a high risk of bias and a high heterogeneity between them, leading to conditional recommendations for its use.[52] Numerous clinical trials conclude that biannual application of SDF results in higher caries arrest in dentin caries lesions as compared to fluoride varnish.[47,53] Thus, SDF is an important adjunct therapy in the individualized comprehensive care plan for children and adolescents for whom access to definitive dental restorative care may be limited for a variety of reasons or preferentially postponed. As the product is highly concentrated, less than a drop is needed to treat several caries lesions, making it cost-effective. SDF is best used as part of an ongoing caries management plan within the context of a dental home.[54,55]

SDF is safe to use in children and adults when delivered in accordance with dosing and application criteria.[56] While current data on the systemic effects of silver is limited[47], data supports a cytotoxic effect to the dental pulp cells when applied directly on pulp tissue[57-59]. SDF solution, when applied to deep caries lesions (0.25-0.5 millimeters dentin thickness remaining), can be rapidly absorbed into dentin and produce a mild inflammation.[60] Whether tertiary dentin formation is a response to cariogenic bacteria or to the SDF remains undetermined.[60] Two investigations[61,62] have evaluated SDF as an indirect pulp therapy medicament. One study[62] found application of SDF arrested further caries progression but did not significantly increase the amount of reparative dentin radiographically. Similarly, the other found no significant difference between SDF, SDF combined with potassium iodide, and the control (resin-modified glass ionomer) at preventing secondary caries.[61] The absence of postoperative pain and maintenance of tooth vitality indicated that SDF did not adversely affect the pulp when applied as an indirect pulp therapy agent.[61] The other reported side effects of SDF are that caries lesions stain black after treatment and skin and gingiva temporarily stain with contact.

Home-use fluoride products

The goal of home-use fluoride products for children is to maximize the time fluoride is in direct contact with the tooth surface, in lower-dose higher-frequency approaches.[63] In children having higher baseline levels of caries, utilizing higher concentrations of fluoride in the toothpaste, brushing with greater frequency, and having supervision of brushing were efficacious in reducing the prevalence of dental caries in permanent teeth.[64,65] A meta-analysis of eight clinical trials on caries increment in preschool children also shows that toothbrushing with fluoridated toothpaste significantly reduces dental caries prevalence in the primary dentition.[66] Using no more than a

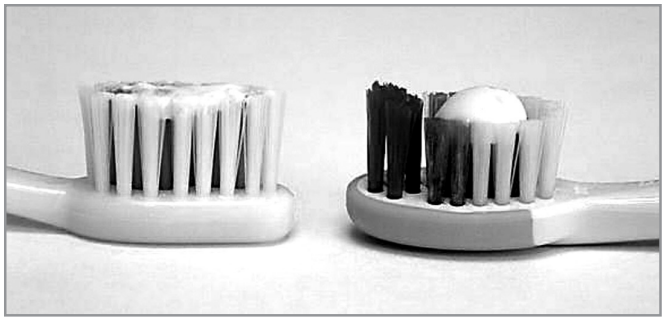

Figure. Comparison of a smear (left) with a pea-sized (right) amount of toothpaste.

smear or rice-sized amount (0.1 mg F) of fluoridated toothpaste for children less than three years of age may decrease risk of fluorosis. Using no more than a pea-sized amount (0.25 mg F) of fluoridated toothpaste is appropriate for children aged three to six[67,68] (see Figure). To maximize the beneficial effect of fluoride in the toothpaste, supervised toothbrushing should be done twice a day, and rinsing after brushing should be kept to a minimum or avoided altogether.[69] Other topical fluoride products (e.g., prescription-strength home-use 0.5 percent F gels and pastes; prescription-strength home-use 0.09 percent F mouthrinse) have benefit in reducing dental caries in those patients at higher risk, such as adolescents, adolescents with special health care needs, or patients with fixed orthodontic appliances; these products are recommended for use in children six years or older.[36] Having children spit after brushing and parents supervise the amounts administered to children will help avoid over-ingestion. Over-ingestion of fluoridated toothpaste combined with other dietary fluoride sources may lead to daily intake greater than the recommended amount and could lead to development of dental fluorosis.[4]

Over 20,000 reports per year regarding fluoride ingestion are received at poison control centers[70], and over 80 percent of suspected cases occur in the under-six-years age group[71]. The probably-toxic dose for fluoride is five mg/kg body weight.[72] Lower dosage may result in gastrointestinal disturbances with higher doses producing central nervous system side effects such as seizures or tetany.[73] Fifteen mg/kg body weight of fluoride likely could be fatal for a small child.[74] Over-the-counter toothpastes approved by the American Dental Association contain at least 1000 ppm F and less than 1500 ppm F.[75] Currently available prescription strength toothpastes may contain 5000 ppm F[75] or 605 mg F per 100 milliliters[76]. Parental dispensing of toothpaste for use by children under the age of three, supervised toothbrushing for all children unable to expectorate, and keeping prescription fluoride supplements and/or home-use fluoride products out of reach of young children can prevent unintended ingestion which has acute (toxicity) as well as chronic (fluorosis) implications.

Recommendations

The AAPD recommends:

1. the use of fluoride for the prevention and control of caries as it is both safe and highly effective in reducing dental caries prevalence.
2. consumption of optimally-fluoridated community water as a cost-effective method to prevent and control caries at the population level.
3. toothbrushing at least twice daily with an age-appropriate amount of over-the-counter fluoride-containing toothpaste to prevent caries as first line for caries prevention.
4. professionally-applied topical fluoride treatments such as five percent NaFV or 1.23 percent F gel preparations at least twice per year to reduce incidence of dental caries.
5. 38 percent SDF be used to arrest cavitated caries lesions in primary teeth and permanent teeth as part of a comprehensive caries management program.
6. prescription-strength home-use 0.5 percent F gels and pastes and 0.02-0.09 percent F mouth rinses to reduce dental caries in high-risk patients over six years of age.
7. decisions concerning the administration of fluoride be based on the unique needs of each patient, including the risks and benefits (e.g., risk of mild or moderate fluorosis versus the benefits of decreasing caries increment and, in some cases, preventing devastating dental disease).
8. fluoride dietary supplements be cautiously considered for children at caries risk who drink less than optimally-fluoridated water as supplementation, in the face of all other sources of fluoride, could exceed the recommended amount of daily fluoride intake.

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Clinician Summary of USPSTF Recommendation

Screening and Preventive Interventions for Oral Health in Children and Adolescents Aged 5 to 17 Years

November 2023

What does the USPSTF recommend?

I Statement

For asymptomatic children and adolescents aged 5 to 17 years:
The evidence is insufficient to assess the balance of benefits and harms of routine screening performed by primary care clinicians for oral health conditions, including dental caries.

I Statement

The evidence is insufficient to assess the balance of benefits and harms of preventive interventions performed by primary care clinicians for oral health conditions, including dental caries.

To whom does this recommendation apply?

This recommendation applies to children and adolescents aged 5 to 17 years.

What's new?

This is a new USPSTF recommendation.

How to implement this recommendation?

- The USPSTF found insufficient evidence to recommend for or against routine screening or preventive interventions for oral health conditions in the primary care setting for children and adolescents.
- The USPSTF is calling for more research on addressing oral health in nondental primary care settings, particularly in persons who are more likely to experience oral health conditions and on social factors that contribute to disparities in oral health.
- In the absence of evidence, primary care clinicians should use their clinical expertise to decide whether to perform these services.

What additional information should clinicians know about this recommendation?

- The USPSTF has a separate existing recommendation for children younger than 5 years that recommends prescribing oral fluoride supplements starting at age 6 months for children younger than 5 years whose water supply is deficient in fluoride and applying fluoride varnish to the primary teeth of all children younger than 5 years starting at the age of primary tooth eruption.
- Dental caries refers to a multifactorial disease process resulting in demineralization of the teeth.
- The evidence review focused on dental caries as the most common oral health condition and the most potentially amenable to primary care interventions.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.

U.S. Preventive Services TASK FORCE

Why is this recommendation and topic important?

- Dental caries is a common chronic condition of childhood; in 2011 in the US, more than 50% of children aged 6 to 11 years had dental caries in primary teeth and 17% had caries in permanent teeth.
- Developmental defects in teeth, inadequate salivary composition or flow, frequent intake of dietary sugars (in foods and beverages), suboptimal fluoride exposure, and oral hygiene practices (eg, lack of tooth brushing and flossing) can increase susceptibility to dental caries.
- In the US, oral health disparities are shaped by unequally affordable and accessible dental care and other disadvantages related to social determinants of health (eg, living in a rural area or immigration status).
- Dental caries disproportionately affects persons living in poverty; Asian, Black, Hispanic/Latino, Native American/Alaska Native, and Native Hawaiian/Pacific Islander children and adolescents; children with special health care needs; children experiencing homelessness; children living in urban or rural underserved areas; and children with public insurance or without insurance.

What are other relevant USPSTF recommendations?

The USPSTF has issued recommendations on screening and interventions to prevent dental caries in children younger than 5 years.

The USPSTF has issued recommendations on screening and preventive interventions for oral health in adults.

What are additional tools and resources?

- The Health Resources and Services Administration's oral health factsheet and report on *Integration of Oral Health and Primary Care Practice* emphasize optimal collaborations between primary care clinicians and oral health professionals.
- The US Department of Health and Human Services' *Report of the Surgeon General* and the National Institutes of Health's report *Oral Health in America: Advances and Challenges* comprehensively describe the importance of oral health to overall health and highlight advances and challenges toward improving oral health in the US.
- The Community Preventive Services Task Force recommends fluoridation of community water sources to reduce dental caries and school-based dental sealant delivery programs to prevent dental caries.

Where to read the full recommendation statement?

Visit the USPSTF website or the *JAMA* website to read the full recommendation statement. This includes more details on the rationale of the recommendation, including benefits and harms; supporting evidence; and recommendations of others.

Clinician Summary of USPSTF Recommendation

Screening and Interventions to Prevent Dental Caries in Children Younger Than 5 Years

December 2021

What does the USPSTF recommend?

Children younger than 5 years:

B Grade

Prescribe **oral fluoride supplementation** starting at age 6 months for children whose water supply is deficient in fluoride.

Children younger than 5 years:

B Grade

Apply **fluoride varnish** to the primary teeth of all infants and children starting at the age of primary tooth eruption.

Children younger than 5 years:

I Statement

The evidence is insufficient to assess the balance of benefits and harms of **routine screening** examinations for dental caries performed by primary care clinicians in children younger than 5 years.

To whom does this recommendation apply?

This recommendation applies to children younger than 5 years without signs or symptoms of dental caries.

What's new?

This recommendation is consistent with the 2014 USPSTF recommendation.

How to implement this recommendation?

- **Prescribe:** Prescribe oral fluoride supplementation beginning at age 6 months to children whose water supply is deficient in fluoride (<0.6 parts fluoride per million parts water [ppm F]).
- **Apply:** Apply topical fluoride varnish to the primary teeth in all infants and children once primary teeth erupt. Typically, fluoride varnish is applied with a small brush and is available as 5% sodium fluoride (2.26 F%).

Clinicians may consider using "My Water's Fluoride", a CDC tool that may assist in determining local water system fluoridation status.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.

U.S. Preventive Services TASK FORCE

www.uspreventiveservicestaskforce.org

What additional information should clinicians know about this recommendation?

- **Assessment of Risk:** Higher prevalence and severity of dental caries are found among specific racial and ethnic (e.g., Black and Mexican American) populations. Social determinants of health associated with increased caries risk include lack of access to dental care, low socioeconomic status, personal and family oral health history, dietary habits (especially frequent intake of dietary sugars in foods and beverages), fluoride exposure, and oral hygiene practices.

The USPSTF determined there was insufficient evidence to assess the balance of benefits and harms of performing **routine screening** examinations. In deciding whether to routinely perform screening examinations, clinicians may consider the following:

- **Potential preventable burden:** Dental caries is the most common chronic disease in children in the US and can cause pain and diminished quality of life. Of children living below the poverty threshold, 17% had untreated caries in 2011 to 2014. As soon as teeth erupt, all children are susceptible to dental caries.
- **Potential harms:** Primary care screening examinations for dental caries in children younger than 5 years are not invasive and unlikely to cause serious harms.
- **Current practice:** About half of pediatricians report examining the teeth of children between birth and age 3 years. Fewer report regularly applying fluoride varnish.

Why is this recommendation and topic important?

Dental caries in early childhood is associated with pain, loss of teeth, impaired growth, decreased weight gain, negative effects on quality of life, poor school performance, and future dental caries. According to the 2011–2016 National Health and Nutrition Examination Survey, approximately 23% of children aged 2 to 5 years have dental caries in their primary teeth. Prevalence is higher in Mexican American children (33%) and non-Hispanic Black children (28%) than in non-Hispanic White children (18%).

What are other relevant USPSTF recommendations?

Information on other oral health recommendations in adults and children older than 5 years from the USPSTF are available on the USPSTF website.

What are additional Tools and Resources?

- The Community Preventive Services Task Force recommends:
  - o Fluoridation of community water sources to reduce dental caries
  - o School-based dental sealant delivery programs to prevent caries
- The Health Resources and Services Administration's website contains various oral health program resources, including the "Bright Futures: Oral Health–Pocket Guide, 3rd edition," an overview of oral health prevention and interventions

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.

U.S. Preventive Services TASK FORCE
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Where to read the full recommendation statement?

Visit the USPSTF website or the *JAMA website* to read the full recommendation statement. This includes more details on the rationale of the recommendation, including benefits and harms; supporting evidence; and recommendations of others.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.

Abbreviations: NAAT, nucleic acid amplification test; STI, sexually transmitted infection, USPSTF, US Preventive Services Task Force.

NOTICE. The version of this article that was online from Oct. 31 until Nov. 26, 2013, contained an error repeated in several places in the text (pages 1279, 1281 and 1288). The article should have indicated that the recommended dosage of a prescription-strength, home-use fluoride gel or paste is 0.5 percent. The erroneous version of the article was removed Nov. 26; below is the corrected version. If you read or downloaded the article between Oct. 31 and Nov. 26, please review this corrected version. The print version of this article contained the same errors, and therefore an itemized notice of corrections appears in the December 2013 issue of JADA.

Topical fluoride for caries prevention

Executive summary of the updated clinical recommendations and supporting systematic review

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In 2006, the Council on Scientific Affairs (CSA) of the American Dental Association (ADA) published recommendations for the use of professionally applied topical fluorides for caries prevention.[1] It is ADA policy to start updating the evidence and clinical recommendations at five-year intervals. The objective of this report is to provide an update on professionally applied topical fluorides and address additional questions related to the use of prescription-strength, home-use topical fluorides for caries prevention. The panel evaluated sodium, stannous and acidulated phosphate fluoride (APF) for professional and prescription-strength home-use, including varnishes, gels, foams, mouthrinses and prophylaxis pastes. The panel did not include over-the-counter products, slow-release delivery devices, dental materials that release fluorides and products that contain sodium monofluorophosphate, silver diamine fluoride and titanium tetrafluoride in this report. Sodium monofluorophosphate is primarily a nonprescription, daily-use fluoride product. Silver diamine fluoride and titanium fluoride are not available in any products in the United States. For the remainder of this article, the term "topical fluoride agents" will be used to include professionally applied, as well as prescription-

ABSTRACT

Background. A panel of experts convened by the American Dental Association (ADA) Council on Scientific Affairs presents evidence-based clinical recommendations regarding professionally applied and prescription-strength, home-use topical fluoride agents for caries prevention. These recommendations are an update of the 2006 ADA recommendations regarding professionally applied topical fluoride and were developed by using a new process that includes conducting a systematic review of primary studies.

Types of Studies Reviewed. The authors conducted a search of MEDLINE and the Cochrane Library for clinical trials of professionally applied and prescription-strength topical fluoride agents—including mouthrinses, varnishes, gels, foams and pastes—with caries increment outcomes published in English through October 2012.

Results. The panel included 71 trials from 82 articles in its review and assessed the efficacy of various topical fluoride caries-preventive agents. The panel makes recommendations for further research.

Practical Implications. The panel recommends the following for people at risk of developing dental caries: 2.26 percent fluoride varnish or 1.23 percent fluoride (acidulated phosphate fluoride) gel, or a prescription-strength, home-use 0.5 percent fluoride gel or paste or 0.09 percent fluoride mouthrinse for patients 6 years or older. Only 2.26 percent fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from "in favor" to "expert opinion for." As part of the evidence-based approach to care, these clinical recommendations should be integrated with the practitioner's professional judgment and the patient's needs and preferences.

Key Words. Caries prevention; caries; evidence-based dentistry; fluoride; practice guidelines; preventive dentistry.
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TABLE 1

Definitions for levels of certainty.*

LEVEL OF CERTAINTY	DEFINITION
High	This statement is strongly established by the best available evidence; the conclusion is unlikely to be affected strongly by the results of future studies.
Moderate	This statement is based on preliminary determination from the current best available evidence; as more information becomes available, the magnitude or direction of the observed effect could change, and this change could be large enough to alter the conclusion.
Low	The available evidence is insufficient to support the statement, or the statement is based on extrapolation from the best available evidence; more information could allow a reliable estimation of effects on health outcomes.

* For more details, see American Dental Association Center for Evidence-Based Dentistry.[2] Adapted from the U.S. Preventive Services Task Force system.[3]

strength, home-use products.

The grading system[2] used in this report was adapted from the U.S. Preventive Services Task Force (USPSTF) system,[3] and it differs markedly from the system the previous panel used for the 2006 clinical recommendations.[1] One difference is that the current clinical recommendations are based on a synthesis of primary evidence collected by means of a de novo systematic review, whereas the previous clinical recommendations were based primarily on published systematic reviews. Another difference is that the current recommendations are based on the net benefit of the intervention (that is, a balance of benefits with potential harm) in conjunction with the level of certainty in the evidence, whereas the 2006 clinical recommendations were based solely on the study design.[4] These changes have resulted in some modifications to the strengths assigned to the individual recommendations for products reviewed in this report compared with recommendations for the products reviewed in the 2006 clinical recommendations report.

The current grading system includes the use of expert opinion as a means of determining whether to make clinical recommendations when evidence is lacking, contradictory or judged to have a high risk of bias (that is, a reliable estimate of the net benefit of the intervention is not possible). Practitioners should note the strength of the recommendations and endeavor to understand the underlying evidence in terms of the level of certainty and the balance of benefits with potential harm. They should discuss uncertainties in evidence with their patients, providing awareness that there usually is some level of uncertainty in the evidence used for making clinical decisions, in part arising from lack of clinical data, changes in product formulations across time and the availability of a wide variety of products.

The panel prepared this report to help practitioners make decisions about the use of topical fluoride caries preventive agents. (The full report, which includes more details, is available at http://ebd.ada.org//ClinicalRecommendations.aspx.) The recommendations in this report are not intended to define a standard of care but rather should be integrated with each practitioner's professional judgment and each patient's needs and preferences.

METHODS

The ADA CSA convened the panel, which was multidisciplinary and comprised subject matter and methodology experts, as well as representatives from various stakeholder groups. They addressed two clinical questions:

- In primary and permanent teeth, does the use of a topical fluoride agent reduce the incidence of new lesions in coronal caries, root caries or both compared with no topical fluoride use?
- Does the use of prophylaxis before application of topical fluoride reduce the incidence of caries to a greater extent than the application of topical fluoride without prophylaxis?

In the first part of the process, the authors conducted a systematic review of the literature. They then developed evidence statements based on a statistical evaluation of the evidence, as well as an assessment of their level of certainty in the statement (high, moderate, low), according to a standardized grading system (Table 1[2,3]).

In the second part of the process, the panel developed clinical recommendations and graded the strength of the recommendations, according to a standardized process. The panel ascertained the net benefit rating by judging the balance of benefits with potential harm. For example, if a topical fluoride agent was found to be effective, and the benefit was judged to outweigh the potential harm, the net benefit was "benefit outweighs potential harm." The panel

ABBREVIATION KEY. ADA: American Dental Association. **APF:** Acidulated phosphate fluoride. **CSA:** Council on Scientific Affairs. **USPSTF:** U.S. Preventive Services Task Force.

used the information in Table 2[3] to combine the level of certainty with the net benefit rating to arrive at the strength of the recommendation (strong, in favor, weak, expert opinion for, expert opinion against or against) to determine the strength of the clinical recommendation as defined in Table 1.[2,3] Table 3[3] shows the definitions of these recommendation strengths.

The panel approved the clinical recommendations by a simple majority vote. The panel sought comments on this report from other subject matter experts, methodologists, epidemiologists and end-users before finalizing the recommendations. The ADA CSA approved the final report for publication.

TABLE 2

Balancing level of certainty and net benefit rating to arrive at recommendation strength.*

LEVEL OF CERTAINTY	NET BENEFIT RATING		
	Benefit Outweighs Potential Harm	Benefit Balanced With Potential Harm	No Benefit, Potential Harm Outweighs Benefit
High	Strong	In favor	Against
Moderate	In favor	Weak	Against
Low	Expert opinion for† or expert opinion against†		

* Adapted from the U.S. Preventive Services Task Force (USPSTF) system.[3]
† The USPSTF system defines this category of evidence as "insufficient"; "grade I indicates that the evidence is insufficient to determine the relationship between benefits and harms (i.e., net benefit)." The corresponding recommendation grade "I" is defined as follows: "The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined."

TABLE 3

Definitions for the strength of clinical recommendations.*

RECOMMENDATION STRENGTH	DEFINITION
Strong	Evidence strongly supports providing this intervention.
In Favor	Evidence favors providing this intervention.
Weak	Evidence suggests implementing this intervention after alternatives have been considered.
Expert Opinion For†	Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation
Expert Opinion Against†	Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention.
Against	Evidence suggests not implementing this intervention or discontinuing ineffective procedures.

* Adapted from the U.S. Preventive Services Task Force (USPSTF) system.[3]
† The USPSTF system defines this category of evidence as "insufficient"; "grade I indicates that the evidence is insufficient to determine the relationship between benefits and harms (i.e., net benefit)." The corresponding recommendation grade "I" is defined as follows: "The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined."

CLINICAL RECOMMENDATIONS: SUMMARY

For people who are at an elevated risk of developing dental caries, the panel makes clinical recommendations for the use of specific topical fluoride agents (Table 4); these recommendations are based on the evidence statements and the balance of benefits with potential harm (Table 5,[5,6] pages 1284-1285). The panel recommends topical fluoride agents only for people what are at elevated risk of developing dental caries.

The panel recommends the following for people at risk of developing dental caries: 2.26 percent fluoride varnish or 1.23 percent fluoride (APF) gel, or a prescription-strength, home-use 0.5 percent fluoride gel or paste or 0.09 percent fluoride mouthrinse for patients 6 years or older. Only 2.26 percent fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from "in favor" to "expert opinion for."

The panel judged that the benefits outweighed the potential for harm for all professionally applied and prescription-strength, home-use topical fluoride agents and age groups except for children younger than 6 years. In these children, the risk of experiencing adverse events (particularly nausea and vomiting) associated with swallowing professionally applied topical fluoride agents outweighed the potential benefits of using all of the topical fluoride agents except for 2.26 percent fluoride varnish.

DISCUSSION OF EVIDENCE AND CLINICAL RECOMMENDATIONS

The panel included 71 trials in 82 published articles (some clinical studies were published in multiple articles) in its review and assessed the efficacy of various topical fluoride agents for preventing caries. Table 5[5,6] (pages 1284-1285) summarizes the expert panel's assessment of the evidence. There were some general considerations to take into account when reviewing the evidence. First, some of the studies were

TABLE 4

Clinical recommendations for use of professionally applied or prescription-strength, home-use topical fluorides for caries prevention in patients at elevated risk of developing caries.

Strength of recommendations: Each recommendation is based on the best available evidence. The level of evidence available to support each recommendation may differ.

Strong	In favor	Weak	Expert Opinion For	Expert Opinion Against	Against
Evidence strongly supports providing this intervention	Evidence favors providing this intervention	Evidence suggests implementing this intervention only after alternatives have been considered	Evidence is lacking; the level of certainty is low. Expert opinion guides this recommendation	Evidence is lacking; the level of certainty is low. Expert opinion suggests not implementing this intervention	Evidence suggests not implementing this intervention or discontinuing ineffective procedures

Age Group or Dentition Affected	Professionally Applied Topical Fluoride Agent	Prescription-Strength, Home-Use Topical Fluoride Agent
Younger Than 6 Years	2.26 percent fluoride varnish at least every three to six months ● In Favor	
6-18 Years	2.26 percent fluoride varnish at least every three to six months ● In Favor **OR** 1.23 percent fluoride (APF*) gel for four minutes at least every three to six months ● In Favor	0.09 percent fluoride mouthrinse at least weekly ● In Favor **OR** 0.5 percent fluoride gel or paste twice daily ● Expert Opinion For
Older Than 18 Years	2.26 percent fluoride varnish at least every three to six months ● Expert Opinion For **OR** 1.23 percent fluoride (APF) gel for four minutes at least every three to six months ● Expert Opinion For	0.09 percent fluoride mouthrinse at least weekly ● Expert Opinion For **OR** 0.5 percent fluoride gel or paste twice daily ● Expert Opinion For
Adult Root Caries	2.26 percent fluoride varnish at least every three to six months ● Expert Opinion For **OR** 1.23 percent fluoride (APF) gel for four minutes at least every three to six months ● Expert Opinion For	0.09 percent fluoride mouthrinse daily ● Expert Opinion For **OR** 0.5 percent fluoride gel or paste twice daily ● Expert Opinion For

Additional Information:

- 0.1 percent fluoride varnish, 1.23 percent fluoride (APF) foam or prophylaxis pastes are not recommended for preventing coronal caries in all age groups (● Expert Opinion Against or ● Against). The full report, which includes more details, is available at http://ebd.ada.org//ClinicalRecommendations.aspx.
- No prescription-strength or professionally applied topical fluoride agents except 2.26 percent fluoride varnish are recommended for children younger than 6 years (● Expert Opinion Against or ● Against), but practitioners may consider the use of these other agents on the basis of their assessment of individual patient factors that alter the benefit-to-harm relationship.
- Prophylaxis before to 1.23 percent fluoride (APF) gel application is not necessary for coronal caries prevention in all age groups (● Expert Opinion Against or ● Against). The full report, which includes more details, is available at http://ebd.ada.org//ClinicalRecommendations.aspx. No recommendation can be made for prophylaxis before application of other topical fluoride agents.

Patients at low risk of developing caries may not need additional topical fluorides other than over-the-counter fluoridated toothpaste and fluoridated water.

* APF: Acidulated phosphate fluoride.

conducted before the 1970s, when dental caries rates among children were higher,[7] the percentage of the population receiving fluoridated water was substantially lower,[8] and the percentage of people using fluoridated dentifrice was much lower.[9] Second, some studies were conducted in countries with different caries prevalence and different levels of background fluoride exposure and other caries prevention efforts. Third, the study populations often could not be categorized in terms of caries risk, and the panel could not assign risk categories to the populations as they are defined today. Therefore, caution is advised when extrapolating the results to today's high-risk populations, such as children at high risk of developing early childhood caries.

Table 6 (page 1286) presents the fluoride concentrations of each of topical fluoride agent evaluated, both as a concentration of fluoride ion and a concentration of sodium fluoride.

Varnish. There are more than 30 fluoride-containing varnish products on the market today, and they have varying compositions and delivery systems. These compositional differences lead to widely variable pharmacokinetics, the effects of which remain largely untested clinically. Through the literature search, the panel found clinical trials[10-38] regarding four brand-name products and decided to summarize the results of these trials on the basis of the percentage of fluoride, which was either 2.26 percent or 0.1 percent. Further research revealed that products identified with an identical brand name (Fluor Protector, Ivoclar Vivadent, Amherst, N.J.) underwent a compositional change in 1987 from 0.7 percent fluoride to 0.1 percent fluoride.[39] Because the 0.7 percent fluoride product no longer is available commercially, these trials[10-14] were not eligible for inclusion in this review. Therefore, the data are subdivided into 2.26 percent fluoride and 0.1 percent fluoride varnish categories.

2.26 percent fluoride varnish. The panel identified 17 randomized and five nonrandomized clinical trials that evaluated 2.26 percent fluoride varnish. There were six randomized[11-13,15-19] and two nonrandomized[20,21] clinical trials concerning the primary dentition, 11 randomized[11-13,22-32] and two nonrandomized[33,34] clinical trials concerning the permanent dentition and one controlled[35] clinical trial that combined results for both dentitions. The interventions for the control groups were no treatment, oral health counseling or placebo varnish. The studies were carried out in populations with various levels of dental caries. The studies were conducted in many countries (Brazil, Canada, Hong Kong, India, Kuwait, Netherlands, Poland, Spain, Sweden, United Kingdom and United States) in participants with and without additional fluoride use or other fluoride exposures (although most studies were conducted in low-fluoride areas) and with and without prior prophylaxis. The ages of the children at baseline varied from 6 months to 8 years for studies of the primary teeth; and from 5 to 15 years for studies of the permanent teeth. The panel identified two studies[30,31] of root caries. The age range in these two studies was 44 to 79 years. The varnish was applied professionally every three to 12 months; in most of studies, the varnish was applied every six months.

Because of the low risk of experiencing harm in children younger than 6 years, unit doses of 2.26 percent fluoride varnish are the only topical fluoride agents that are recommended for this age group, even though other topical fluorides may have some evidence of a benefit. The panel had a moderate level of certainty that there is a benefit of 2.26 percent fluoride varnish in the permanent teeth of children aged 6 through 18 years. Although there were no studies of coronal caries prevention in adults older than 18 years, the panel extrapolated the data from 6- through 18-year-olds to recommend using 2.26 percent varnish for this age group for both coronal and root caries. The benefits were judged to outweigh the potential for harm for all age groups.

0.1 percent fluoride varnish. The panel identified two nonrandomized clinical trials[36,37] in which investigators evaluated 0.1 percent fluoride varnish on the primary dentition and one randomized clinical trial[38] in which investigators evaluated 0.1 percent fluoride varnish in the permanent dentition. The control groups received oral hygiene instruction or no treatment. The studies were carried out in Germany and Sweden in populations with various baseline levels of dental caries. The ages of the children at baseline varied from 4 through 5 years for primary dentition and 9 through 12 years for permanent dentition. The varnish was applied professionally every six months in the primary dentition and every four months in the permanent dentition. Additional fluoride use or other fluoride exposure was variable, and all studies included prior prophylaxis.

The panel found evidence of no benefit from use of 0.1 percent fluoride varnish in children. Although there were no studies regarding coronal caries prevention in adults older than 18 years, the panel extrapolated the data from 6- through 18-year-olds that showed no benefit

TABLE 5

Evidence statements for professionally applied and prescription-strength, home-use topical fluorides used for caries prevention.

AGENT	AGE GROUP (YEARS) OR DENTITION AFFECTED	EVIDENCE STATEMENT
Varnish (2.26 Percent Fluoride)	Younger than 6	There is a benefit of 2.26 percent fluoride varnish application at least twice per year for caries prevention.
	6-18	There is a benefit of 2.26 percent fluoride varnish application at least twice per year for caries prevention.
	Adult root caries	There is a benefit of 2.26 percent fluoride varnish application at least twice per year for root caries prevention in adults.
Varnish (0.1 Percent Fluoride)	Younger than 6	There is no benefit of 0.1 percent fluoride varnish application twice per year for caries prevention.
	6-18	There is no benefit of applying 0.1 percent fluoride varnish three times per year for caries prevention.
APF* Gel (1.23 Percent Fluoride)	Younger than 6	There is a benefit of APF gel (1.23 percent fluoride) application up to every three months for four† minutes for caries prevention.
	6-18	There is a benefit of APF gel (1.23 percent fluoride) application up to every three months for four† minutes for caries.
	Adult root caries	There is a benefit of APF gel (1.23 percent fluoride) application twice per year for four† minutes to prevent root caries.
Prophylaxis Before APF Gel (1.23 Percent Fluoride) Application	Younger than 6	There is no benefit from conducting a prophylaxis prior to APF gel (1.23 percent fluoride) application for caries prevention.
	6-18	There is no benefit from conducting a prophylaxis prior to APF gel (1.23 percent fluoride) application for caries prevention.
APF Foam (1.23 Percent Fluoride)	Younger than 6	There is a benefit of APF foam (1.23 percent fluoride) application twice per year for four‡ minutes for caries prevention.
	6-18	There is no benefit of 1.23 percent APF foam application twice per year for four‡ minutes for caries prevention.
Prophylaxis Pastes Containing Fluoride	Younger than 6	There is no benefit of prophylaxis paste containing fluoride application for four minutes twice per year for caries prevention.
	6-18	There is no benefit of prophylaxis paste containing fluoride application for four minutes twice per year for caries prevention.
Prescription-Strength, Home-Use (0.5 Percent Fluoride) Gel or Paste	Younger than 6	There is a benefit of prescription-strength, home-use (0.5 percent fluoride) gel or paste application twice daily for caries prevention.
	6-18	There is a benefit of prescription-strength, home-use (0.5 percent fluoride) gel or paste application twice daily for caries prevention.
	Adult root caries	There is a benefit of prescription-strength, home-use (0.5 percent fluoride) gel or paste application twice daily in preventing root caries.
Prescription-Strength, Home-Use (0.09 Percent Fluoride) Mouthrinse	6-18	There is a benefit of using prescription-strength, home-use (0.09 percent fluoride) mouthrinse daily or weekly for caries prevention.
	Adult root caries	There is a benefit of using prescription-strength, home-use (0.09 percent fluoride) mouthrinse for root caries prevention among elderly people living in long-term care facilities.

* APF: Acidulated phosphate fluoride.
† No studies were found regarding professionally applied fluoride APF gels with an application time of less than three minutes.
‡ Two studies[5,6] regarding professionally applied fluoride (APF) foams used an application time of four minutes.

of 0.1 percent varnish for this age group. The panel was not comfortable extrapolating these results to root caries and gives no clinical recommendation for this form of the disease.

1.23 percent fluoride (APF) gel. The panel identified 11 randomized[5,40-50] and four nonrandomized[35,51-55] clinical trials that evaluated 1.23 percent fluoride (APF) gel quarterly, semiannually, annually or biannually (one application was observed after two years). The comparison groups received no treatment, a placebo, prophylaxis or a nonfluoride placebo gel. All studies except one[51] involved permanent teeth. In all of the studies, investigators applied fluoride gel for four minutes. All of the studies involved school-aged children (from 3 through 16 years) except for one.[49] This study involved noninstitutionalized adults who were at least 60 years of age, and investigators reported on root caries. Ten studies[40-45,48,49,51-55] were conducted in the United States and five elsewhere (India,[35,50] United Kingdom,[46] China[5] and Canada[47]).

TABLE 5 (CONTINUED)

LEVEL OF CERTAINTY	NET BENEFIT RATING
Moderate	Benefit outweighs potential harm
Moderate	Benefit outweighs potential harm
Low	Benefit outweighs potential harm
Moderate	No benefit
Low	No benefit
Low	Potential harm outweighs benefit
Moderate	Benefit outweighs potential harm
Low	Benefit outweighs potential harm
Low	No benefit
Moderate	No benefit
Low	Potential harm outweighs benefit
Low	No benefit
Low	No benefit
Moderate	No benefit
Low	Potential harm outweighs benefit
Low	Benefit outweighs potential harm
Low	Benefit outweighs potential harm
Moderate	Benefit outweighs potential harm
Low	Benefit outweighs potential harm

Although the panel had a low level of certainty that there was a benefit in using 1.23 percent fluoride (APF) gel in the primary dentition of children younger than 6 years, they judged that the potential for harm associated with swallowing APF gel could outweigh these benefits. The panel had a moderate level of certainty that there was a benefit of using 1.23 percent fluoride (APF) gel in the permanent teeth of children aged 6 through 18 years. The panel found no studies regarding the effect of 1.23 percent fluoride (APF) gel on coronal caries of adults older than 18 years, but they extrapolated the evidence from permanent teeth of children 6 through 18 years of age to recommend (at the strength of expert opinion) for this age group.

Prophylaxis before APF gel application. Although the panel searched the literature for prophylaxis before any topical fluoride application (per the second clinical question), it only found studies regarding prophylaxis before application of 1.23 percent fluoride (APF) gel. The panel identified two randomized[56-58] and one nonrandomized[59] clinical trials in which investigators assessed whether prophylaxis before professional application of APF gel affects its efficacy. Two studies were conducted in the United States,[57-59] and one was conducted in Canada.[56] All of the studies involved children aged 6 through 14 years at baseline. Investigators for both studies reported data regarding permanent teeth, and investigators for one[56] also reported data regarding primary teeth.

The panel found no benefit for performing prophylaxis before the application of 1.23 percent fluoride (APF) gel for the primary and permanent dentition of children. Although no studies were found in this category regarding adult populations, the panel extrapolated the evidence from the permanent teeth of children aged 6 through 18 years to coronal caries in adults, but it was not comfortable doing so for root caries and gives no clinical recommendation for this form of the disease.

1.23 percent fluoride (APF) foam. The panel identified two randomized clinical trials[5,6] that evaluated 1.23 percent fluoride (APF) foam in children aged 3 through 7 years at baseline. One study involved the primary dentition[6] and the other the permanent dentition.[5] The comparison groups received either no treatment or placebo. Both studies were conducted in China.

Although a benefit was found with using 1.23 percent fluoride (APF) foam in children younger than 6 years, the panel judged that the potential for harm—including swallowing APF foam—outweighed this benefit. The panel found no benefit regarding caries prevention in the permanent dentition of children. The panel extrapolated this finding to permanent teeth in adults and does not recommend foam use in adults older than 18 years. The panel was not comfortable extrapolating these results to root caries and gives no clinical recommendation for this form of the disease.

Prophylaxis pastes containing fluoride. The panel identified three randomized[60-62] and three nonrandomized[63-65] clinical trials in which investigators evaluated the annual or semiannual application of prophylaxis pastes, most of

TABLE 6

Fluoride ion and sodium fluoride concentrations in topical fluoride agents.

TOPICAL FLUORIDE AGENT	FLUORIDE ION, %	SODIUM FLUORIDE, %
Professionally Applied		
2.26 Percent fluoride varnish	2.26	5.0
APF* gel (with 0.1 molar phosphoric acid)	1.23	2.7
APF foam (with 0.1 M phosphoric acid)	1.23†	2.7†
Prophylaxis paste containing fluoride (most as APF)	1.23	2.7
0.1 Percent fluoride varnish	0.1‡	Not applicable
Prescription Strength, Home Use		
Prescription-strength gels or pastes with or without acidulation (0.1 M phosphoric acid)	0.5	1.1
Prescription-strength mouthrinses	0.09	0.2

* APF: Acidulated phosphate fluoride.
† Concentration of fluoride before being dispensed. When delivered as a foam by combining gel with air, the total amount of fluoride in the foam product is reduced.
‡ The fluoride ion form was 0.09 percent difluorsilane.

which contained 1.23 percent fluoride (APF), for caries prevention. These studies were conducted between 1966 and 1980. The comparison groups received placebo prophylaxis pastes. All studies except one[65] (regarding children aged 3-5 years at baseline) involved the permanent teeth of children aged 8 through 16 years at baseline.

The panel found no benefit of using prophylaxis pastes containing fluoride on the primary or permanent teeth of children. Although no studies were found regarding adult populations, the panel extrapolated the evidence of no benefit to coronal caries in adults but was not comfortable doing so for root caries and gives no clinical recommendation for this form of the disease.

Prescription-strength, home-use (0.5 percent fluoride) gels or pastes. The panel reviewed the data for prescription-strength, home-use gels and pastes together. The primary difference between gels and pastes is that pastes contain a small amount of an abrasive component. The panel noted that investigators in only one study[66] evaluated prescription-strength fluoride paste or gel (in this case, it was paste) in an unsupervised home environment, rather than by professional application in trays or with floss or in a supervised school setting. These products are often used at home and applied with a toothbrush.

The panel identified eight randomized[66-75] and one nonrandomized[76] clinical trials that met the inclusion criteria regarding prescription-strength (0.5 percent fluoride) paste or gel for home use. Six of the studies[66,69-73,75,76] involved permanent teeth, one[67] involved root caries, and two[71,72,74] involved primary teeth. The comparison group for all studies was either placebo, 0.125-0.145 percent fluoride paste or no treatment. The baseline age range of children was 2 through 15 years for most of the studies, and one study included participants older than 75 years.[67] The studies were performed in Denmark, French Polynesia, Netherlands, Sweden and the United States.

Although the panel found a benefit with 0.5 percent fluoride paste or gel treatment in children younger than 6 years, it judged that the potential for harm—including swallowing gels or pastes—outweighed this benefit. The panel had a low level of certainty regarding the benefit of 0.5 percent fluoride paste or gel on the permanent teeth of children and on root caries because there were few data on the home use of these products. However, the panel judged that the benefits outweighed potential harm. Although the panel found no studies in this category regarding permanent teeth in adults, the panel extrapolated the available evidence and judged that the benefits outweighed the potential for harm in this age group.

Prescription-strength, home-use (0.09 percent fluoride) mouthrinse. The panel identified 10 randomized[77-88] and two nonrandomized[89,90] clinical trials in which investigators evaluated 0.09 percent fluoride mouthrinse applications with daily, weekly or biweekly applications. Investigators in most of the studies compared the intervention with placebo mouthrinses, although some compared the intervention with no treatment[85,89] or oral hygiene instruction and prophylaxis.[79] All studies were conducted on permanent teeth. All of the studies but one[87] were conducted in school-aged children (5 through 12 years). No adult populations were studied except elderly people living in long-term care facilities (mean age, 83 years) in one study.[87] In most studies, the children's teachers supervised the use of the fluoride rinse. In only one study[88] were children enrolled on the basis of their caries risk status. Four of the studies[77,78,80-82,84] were conducted in the United States. The other studies were conducted in Canada,[87] Denmark,[83] New Zealand,[79-88] Philippines,[90] South Africa[86,89] and Sweden.[85]

The panel judged that the benefits outweighed the potential for harm in children 6 years or older and adults. Although there were

no studies regarding the effect of 0.09 percent fluoride mouthrinse on caries in children younger than 6 years, the panel judged that the risk of swallowing mouthrinse outweighed the potential for unknown benefits. Although there were no studies regarding coronal caries in adults older than 18 years, the panel extrapolated the results from children aged 6 through 18 years to arrive at a clinical recommendation based on expert opinion.

GENERAL REMARKS ON CLINICAL RECOMMENDATIONS

A practitioner should consider a patient's risk of experiencing disease when developing an optimal caries-prevention plan. Part of a patient's risk status includes whether the patient lives in an optimally fluoridated community and uses fluoridated toothpaste. Patients at low risk of developing caries may not need additional fluoride interventions, whereas caries in people at high risk of developing caries appears at times to be refractory to additional intensive preventive interventions.[91,92]

Professional judgment is required to interpret the clinical relevance of preventive measures for individual patients. The combination of evidence from clinical studies, the patient's caries risk status, the practitioner's professional judgment and the patient's needs and preferences should guide decision making. Patient education, assessment of readiness for change, dietary advice, other preventive modalities and periodic clinical examinations should be considered as a part of the caries-prevention plan. In public health care settings, additional considerations include the feasibility and cost of the proposed intervention. The panel did not consider these issues when providing its clinical recommendations.

The panel noted that clinical trials generally test the efficacy of an intervention, which results in the best possible outcome for the intervention because of the controlled nature of the trial and strict inclusion and exclusion criteria for participants. These results do not necessarily reflect the effectiveness of an intervention (that is, how the intervention works in routine practice), which typically includes patients with comorbidities who may be taking multiple medications. Under controlled study conditions, the efficacy is almost always higher than the effectiveness because of the presence of idealized conditions.

The panel has reported on several different topical fluoride agents, including those planned for home use. Practitioners can expect different compliance with treatment plans incorporating home-use products than with professionally applied products. Cost, efficacy or effectiveness related to the intended usage environment also may vary.

When considering any intervention, the practitioner and patient must balance the potential benefits with the potential harm. The panel considered harm reported by investigators of the included articles as well as known potential harm of fluoride use. Potential harm of topical fluorides includes, but may not be limited to, nausea and vomiting associated with the ingestion of topical fluorides[93] and dental fluorosis (an esthetic concern) while tooth enamel is developing (until about age 6 years) due to daily ingestion of topical fluoride, such as from toothpaste or from prescription-strength, home-use gels. There is less of a concern about professionally applied topical fluorides for which there are longer intervals between applications.[94] Fluoride varnish dispensed in unit doses has lower potential for harm than do other forms of high-concentration topical fluoride agents, because the amount of fluoride that is placed in the mouth by means of fluoride varnish is approximately one-tenth that of other professionally applied products.[95]

FUTURE RESEARCH

The panel recommends that multiple well-designed, appropriately powered, placebo-controlled randomized trials that follow the Consolidated Standards of Reporting Trials guidelines[96] with standardized reporting according to age, dentition and caries risk status be conducted in the United States. Standard methodologies for caries and fluoride randomized controlled trials should be developed. The panel recommends that future trials be registered with ClinicalTrials.gov or equivalent registries. Specific areas of research recommendations are as follows:

- **Mechanisms of fluoride action and effects.** Research is needed regarding various topical fluorides to determine their mechanism of action and caries-preventive effects when in use at the current level of background fluoride exposure (that is, fluoridated water and fluoride toothpaste) in the United States. Studies regarding strategies for using fluoride to induce arrest or reversal of caries progression, as well as topical fluoride's specific effect on erupting teeth, also are needed.
- **Populations.** Research is needed concerning the following subpopulations: adults aged 18 through 65 years, high-risk adults older than 65

(including those living in long-term care facilities) who are at high risk of developing caries, children and adults who are at extremely high risk of developing caries, U.S.-specific populations, special needs populations (for example, those with cognitive disabilities, compromised self-care abilities or physical disabilities) and populations with chronic diseases (such as Sjögren syndrome). Comparative effectiveness studies of different fluoride strategies in these populations, as well as studies regarding strategies to manage xerostomia-induced coronal and root caries also are needed.

- **Products and usage.** Research is needed concerning the effectiveness and risks of specific products in the following areas: self-applied, prescription-strength, home-use fluoride gels, toothpastes or drops; 2 percent professionally applied sodium fluoride gel; alternative delivery systems, such as foam; optimal application frequencies for fluoride varnish and gels; one-minute applications of APF gel; and combinations of products (home-use and professionally applied).
- **Measurement and outcomes.** Development of measurements to evaluate caries arrest and reversal are needed.
- **Economics.** Studies regarding caries prevention and the economic benefit of topical fluoride in different caries risk populations are needed.
- **Dissemination and implementation.** Research on the best ways to help practitioners incorporate clinical recommendations into practice are needed.

CONCLUSIONS

The panel recommends the following for people at risk of developing dental caries: 2.26 percent fluoride varnish or 1.23 percent fluoride (APF) gel; or prescription-strength, home-use 0.5 percent fluoride gel or paste or 0.09 percent fluoride mouthrinse for patients 6 years or older. Only 2.26 percent fluoride varnish is recommended for children younger than 6 years. The strengths of the recommendations for the recommended products varied from "in favor" to "expert opinion for." As part of the evidence-based approach to care, these clinical recommendations should be integrated with the practitioner's professional judgment and the patient's needs and preferences. ■

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Dental Coding Review

Coverage Question: Should any changes be made in the current placement of various dental codes?

Question source: multiple stakeholders

Background: At the request of multiple stakeholders, OHA convened the Oral Health Forum (OHF), which is a workgroup that reviewed the placement of current CDT codes and their relationship to dental rules. This workgroup has completed their review of codes and has made recommendation for addition of some previously excluded codes and for movement of some currently covered codes.

OHAP input:

HERC staff summary:

HERC staff have compiled the OHA dental code workgroup recommendations for review by OHAP. HERC staff recommend that OHAP provide input on the codes suggested for movement, which are presented in next two code tables. OHAP members may also review all of the codes considered by OHF, which are presented on two additional code tables and suggest any additional codes for movement.

HERC staff recommendation:

1) Review the covered codes review document and the excluded codes review document
2) Additional full review documents included if any member wishes to pull out additional codes to review

OHF recommended changes to covered codes (with HERC staff recommendations)						
Code	**Code description**	**Current Placement**	**HERC Staff Recommended**	**Rationale/Notes from OHA workgroup**	**OAR update, other comments**	**OHAP input**
D0190	Screening of a patient	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	Diagnostic Procedures File	to align w/CDT groupings; per CDT line is Diagnostic File (align w/D0191 3,53)		
D4346	Scaling in presence of generalized moderate or severe gingival inflammation - full	53 PREVENTIVE DENTAL SERVICES	217 DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE)	Periodontal code		
D4355	Full mouth debridement to enable a comprehensive	53	217	Periodontal code		
D9920	Behavior management, by report	53	Ancillary	D9920 - behavior management was established as a means to assure comprehensive oral health care for persons with developmental disabilities (DD). This code allows for additional compensation to a dentist who is treating persons with developmental disabilities due to the increased time, staffing, expertise, and adaptive equipment required for treatment	define in OAR when code is appropriate	
D7997	Appliance removal (not by dentist who placed appliance), includes removal of archbar	54	265 DENTAL CONDITIONS (TIME SENSITIVE EVENTS) Treatment URGENT			

OHF recommended changes to covered codes (with HERC staff recommendations)						
Code	**Code description**	**Current Placement**	**HERC Staff Recommended**	**Rationale/Notes from OHA workgroup**	**OAR update, other comments**	**OHAP input**
D7962	Lingual frenectomy (frenulectomy)	18 FEEDING PROBLEMS IN NEWBORNS 597 TONGUE TIE AND OTHER ANOMALIES OF TONGUE	OHF recommended; 341 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) Treatment ORAL SURGERY. See issue summary for HERC staff recommendation	oral surgery, covered benefit on dental	OHF comment: Guideline Note 48 applies only to D7961. See separate issue document.	
D7280	Exposure of an unerupted tooth	254 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION 611 DENTAL CONDITIONS (E.G., MALOCCLUSION)	254, 341	618 = uncovered by dental; is covered for HCM should also be on a covered dental line 341 (in addition to 256)		
D7283	Placement of device to facilitate eruption of impacted tooth	254,636	254, 341	618 = uncovered by dental; is covered for HCM should also be on a covered dental line 344 (in addition to 254)		

OHF codes recommended for movement from Excluded file to Prioritized List (with HERC staff recommendations)					
Code	**Code description**	**Current placement**	**HERC staff recommended placement**	**Rationale/OHA workgroup Notes/other comments**	**OHAP input**
D0171	Re-evaluation - post-operative office visit	Excluded (Group 1118)	341 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) Treatment ORAL SURGERY	Possibly "not to be billed separately" as this service is included in treatment/service provided. (410-123-1200 not eligible for separate reimbursement) 1. Exam code, should be moved to be consistent w/OARs. 2.	
D0391	Interpretation of diagnostic image by a practitioner not associated with capture of the image, including report	Excluded (Group 1118)	53 PREVENTIVE DENTAL SERVICES	Possibly "not to be reimbursed separately" as this service is included in treatment/service provided. (410-123-1200 not eligible for separate reimbursement)	
D0460	Pulp vitality tests	Excluded (Group 1118)	54 DENTAL CONDITIONS (E.G., INFECTION, PAIN, TRAUMA)	Diagnostic	
D4921	Gingival irrigation with a medicinal agent - per quadrant	Not open for pymt	217 DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE)	Is this open for encounter data? (update OAR? Can be billed) "not to be billed separately"	

OHF codes recommended for movement from Excluded file to Prioritized List (with HERC staff recommendations)					
Code	**Code description**	**Current placement**	**HERC staff recommended placement**	**Rationale/OHA workgroup Notes/other comments**	**OHAP input**
D7922	Placement of intra-socket biological dressing to aid in hemostasis or clot stabilization, per site	Excluded (Group 1118)	341	Clinical need. Part of procedure, not separately reimbursed. Dr. Geisler input: Used for bleeding, may reduce ED visits and other complications. These materials are	
D7993	Surgical placement of craniofacial implant - extra oral	Excluded (Group 1118)	612 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment IMPLANTS	implant Dr. Geisler input: May be used for treatment of severe facial trauma or congentital defects that require extensive reconstruction.	
D7994	Surgical placement: zygomatic implant	Excluded (Group 1118)	612	Dr. Geisler input: May be used for creation of substrate for dentures in a person who had all teeth pulled as a young person	
D9210	Local anesthesia not in conjunction with operative or surgical procedures	Excluded (Group 1118)	54	Palliative, could be urgent, or emergent (needs GN). Add situation to 123-1200 re: local anesthesia	

OHF codes recommended for movement from Excluded file to Prioritized List (with HERC staff recommendations)					
Code	**Code description**	**Current placement**	**HERC staff recommended placement**	**Rationale/OHA workgroup Notes/other comments**	**OHAP input**
D9219	Evaluation for moderate sedation, deep sedation or general anesthesia	Excluded (Group 1118)	54, 341	add to "not to be reimbursed separately" (bundle w/oral surgery procedures)	
D9613	Infiltration of sustained release therapeutic drug, per quadrant	Excluded (Group 1118)	341	gets billed, but not paid. Should be either "not paid separate" or have a guideline (e.g. Exporel)	

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D0190	Screening of a patient	3	per CDT line is Diagnostic File (align w/D0191 3,53)	to align w/CDT groupings		
D1701	Pfizer-biontech covid-19 vaccine administration - first dose	3		Per CDT line is preventative- stay		
D1702	Pfizer-biontech covid-19 vaccine administration - second dose	3		Per CDT line is preventative- stay		
D1703	Moderna covid-19 vaccine administration - first dose	3		Per CDT line is preventative- stay		
D1704	Moderna covid-19 vaccine administration - second dose	3		Per CDT line is preventative- stay		
D1705	Astrazeneca covid-19 vaccine administration - first dose	3		Per CDT line is preventative- stay		
D1706	Astrazeneca covid-19 vaccine administration - second dose	3		Per CDT line is preventative- stay		
D1707	Janssen COVID-19 vaccine administration	3		Per CDT line is preventative- stay		
D1708	Pfizer-biontech covid-19 vaccine administration - third dose	3		Per CDT line is preventative- stay		
D1709	Pfizer-biontech covid-19 vaccine administration - booster dose	3		Per CDT line is preventative- stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D1710	Moderna covid-19 vaccine administration - third dose	3		Per CDT line is preventative- stay		
D1711	Moderna covid-19 vaccine administration - booster dose	3		Per CDT line is preventative- stay		
D1712	Janssen Covid-19 vaccine administration - booster dose	3		Per CDT line is preventative- stay		
D1713	Pfizer-biontech covid-19 vaccine administration tris-sucrose pediatric - first dose	3		Per CDT line is preventative- stay		
D1714	Pfizer-biontech covid-19 vaccine administration tris-sucrose pediatric - second dose	3		Per CDT line is preventative- stay		
D1781	Vaccine administration - human papillomavirus - dose 1	3		Per CDT line is preventative- stay		
D1782	Vaccine administration - human papillomavirus - dose 2	3		Per CDT line is preventative- stay		
D1783	Vaccine administration - human papillomavirus - dose 3	3		Per CDT line is preventative- stay		
D1320	Tobacco counseling for the control and prevention of oral disease	5		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D0120	Periodic oral evaluation - established patient	53		stay	align w/ESPDT age limitations	
D0145	Oral evaluation for a patient under three years of age and counseling with primary caregiver	53		stay	align w/ESPDT age limitations	
D0150	Comprehensive oral evaluation - new or established patient	53		stay	align w/ESPDT age limitations	
D0180	Comprehensive periodontal evaluation - new or established patient	53		stay	align w/ESPDT age limitations	
D0601	Caries risk assessment and documentation, with a finding of low risk	53		stay	Codes currently aren't listed in rule	
D0602	Caries risk assessment and documentation, with a finding of moderate risk	53		stay	Codes currently aren't listed in rule	
D0603	Caries risk assessment and documentation, with a finding of high risk	53		stay	Codes currently aren't listed in rule	
D1110	Prophylaxis - adult	53		stay	dentition, not age	
D1120	Prophylaxis - child	53		stay	dentition, not age	
D1208	Topical application of fluoride - excluding varnish	53		stay		
D1310	Nutritional counseling for the control of dental disease	53		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D1321	Counseling for the control and prevention of adverse oral, behavioral, and systemic health effects associated with high-risk substance use	53		stay		
D1330	Oral hygiene instruction	53		stay		
D1351	Sealant-per tooth	53		stay	consider adjusting age to allow for primary dentition and premolars	
D1355	Caries preventive medicament application - per tooth	53		stay		
D1510	Space maintainer - fixed, unilateral - per quadrant	53		stay		
D1516	Space maintainer - fixed - bilateral, maxillary	53		stay		
D1517	Space maintainer - fixed - bilateral, mandibular	53		stay		
D1520	Space maintainer - removable, unilateral - per quadrant	53		stay		
D1526	Space maintainer - removable - bilateral, maxillary	53		stay		
D1527	Space maintainer - removable - bilateral, mandibular	53		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D1551	Re-cement or re-bond bilateral space maintainer - maxillary	53		stay		
D1552	Re-cement or re-bond bilateral space maintainer - mandibular	53		stay		
D1553	Re-cement or re-bond unilateral space maintainer - per quadrant	53		stay		
D1556	Removal of fixed unilateral space maintainer - per quadrant	53		stay		
D1557	Removal of fixed bilateral space maintainer - maxillary	53		stay		
D1558	Removal of fixed bilateral space maintainer - mandibular	53		stay		
D1575	Distal shoe space maintainer - fixed, unilateral - per quadrant	53		stay		
D4346	Scaling in presence of generalized moderate or severe gingival inflammation - full mouth, after oral evaluation	53	218	Perio code,		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D4355	Full mouth debridement to enable a comprehensive periodontal evaluation and diagnosis on a subsequent visit	53	218	Perio code,		
D5986	Fluoride gel carrier	53		stay		
D9920	Behavior management, by report	53	(discussion re Ancillary)		define in OAR when code is appropriate	
D0140	Limited oral evaluation - problem focused	54		Stay		
D0160	Detailed and extensive oral evaluation - problem focused, by report	54		Stay		
D0170	Re-evaluation-limited, problem focused (established patient; not post-operative visit)	54		Stay		
D3110	Pulp cap-direct (excluding final restoration)	54		Stay		
D3221	Pulpal debridement, primary and permanent teeth	54		stay		
D7261	Primary closure of a sinus perforation	54		stay		
D7270	Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth	54		Stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7510	Incision and drainage of abscess-intraoral soft tissue	54		Stay		
D7520	Incision and drainage of abscess-extraoral soft tissue	54		stay		
D7530	Removal of foreign body from mucosa, skin, or subcutaneous alveolar tissue	54		stay		
D7560	Maxillary sinusotomy for removal of tooth fragment or foreign body	54		stay		
D7670	Alveolus - closed reduction, may include stabilization of teeth	54		stay		
D7770	Alveolus - open reduction stabilization of teeth	54		stay		
D7910	Suture of recent small wounds up to 5 cm	54		stay		
D7911	Complicated suture-up to 5 cm	54		stay		
D7997	Appliance removal (not by dentist who placed appliance), includes removal of archbar	54	move from emergency line to urgent line, 265			
D9110	Palliative treatment of dental pain - per visit	54		stay		
D9410	House/extended care facility call	54		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D9420	Hospital or ambulatory surgical center call	54		stay		
D9440	Office visit-after regularly scheduled hours	54		stay		
D9610	Therapeutic parenteral drug, single administration	54		stay		
D9612	Therapeutic parenteral drugs, two or more administrations, different medications	54		stay		
D9995	Teledentistry - synchronous; real-time encounter	54		stay		
D9996	Teledentistry - asynchronous; information stored and forwarded to dentist for subsequent review	54		stay		
D5937	Trismus appliance (not for tm treatment)	71		stay		
D5934	Mandibular resection prosthesis with guide flange	200		stay		
D5935	Mandibular resection prosthesis without guide flange	200		stay		
D9947	custom sleep apnea appliance fabrication and placement	202		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D9948	adjustment of custom sleep apnea appliance	202		stay		
D9949	repair of custom sleep apnea appliance	202		stay		
D9953	reline custom sleep apnea appliance (indirect)	202		stay		
D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth or tooth bounded spaces per quadrant	218		stay		
D4211	Gingivectomy or gingivoplasty - one to three contiguous teeth or tooth bounded spaces per quadrant	218		stay		
D4212	Gingivectomy or gingivoplasty to allow access for restorative procedure, per tooth	218		stay		
D4341	Periodontal scaling and root planing - four or more teeth per quadrant	218		stay		
D4342	Periodontal scaling and root planing - one to three teeth, per quadrant	218		stay		
D4910	Periodontal maintenance	218		stay		
D5988	Surgical splint	228		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D0364	Cone beam ct capture and interpretation with limited field of view - less than one whole jaw	254	Review for additional line			
D0365	Cone beam ct capture and interpretation with field of view of one full dental arch - mandible	254	Review for additional line			
D0366	Cone beam ct capture and interpretation with field of view of one full dental arch - maxilla, with or without cranium	254	Review for additional line			
D0367	Cone beam ct capture and interpretation with field of view of both jaws, with or without cranium	254	Review for additional line			
D0801	3d dental surface scan - direct	256		stay		
D0802	3d dental surface scan - indirect	256		stay		
D5919	Facial prosthesis	256		stay		
D5924	Cranial prosthesis	256		stay		
D5925	Facial augmentation implant prosthesis	256		stay		
D5929	Facial prosthesis, replacement	256		stay		
D5931	Obturator prosthesis, surgical	256		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D2910	Re-cement or re-bond inlay, onlay, veneer or partial coverage restoration	267		Stay		
D2915	Re-cement or re-bond indirectly fabricated or prefabricated post and core	267		Stay		
D2920	Re-cement or re-bond crown	267		Stay		
D2921	Reattachment of tooth fragment, incisal edge or cusp	267		Stay		
D2940	Protective restoration	267		Stay		
D3120	Pulp cap-indirect (excluding final restoration)	267		stay		
D3220	Therapeutic pulpotomy (excluding final restoration) removal of pulp coronal to the dentinocemental junction and application of medicament	265		stay	clarify age and teeth # in rule 1260 (7)	
D3222	Partial pulpotomy for apexogenesis - permanent tooth with incomplete root development	267		Stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D3230	Pulpal therapy (resorbable filling)-anterior, primary tooth (excluding final restoration)	267		Stay		
D3240	Pulpal therapy (resorbable filling)-posterior, primary tooth (excluding final restoration)	267		stay		
D3351	Apexification/recalcification - initial visit (apical closure/calcific repair of perforations, root resorption, etc.)	267		stay		
D3352	Apexification/recalcification - interim medication replacement (apical closure/calcific repair of perforations, root resorption, pulp space disinfection, etc.)	267		stay		
D3353	Apexification/recalcification-final visit (includes completed root canal therapy-apical closure/calcific repair of perforations, root resorption, etc.)	267		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D4920	Unscheduled dressing change (by someone other than treating dentist or their staff)	267		stay		
D5410	Adjust complete denture - maxillary	267		stay		
D5411	Adjust complete denture - mandibular	267		stay		
D5421	Adjust partial denture - maxillary	267		stay		
D5422	Adjust partial denture - mandibular	267		stay		
D5850	Tissue conditioning, maxillary	267		stay		
D5851	Tissue conditioning, mandibular	267		stay		
D6930	Re-cement or re-bond fixed partial denture	267		stay		
D8695	Removal of fixed orthodontic appliances for reasons other than completion of treatment	267		stay		
D9120	Fixed partial denture sectioning	267		stay		
D9951	Occlusal adjustment-limited	267		stay		
D5983	Radiation carrier	287		stay		
D5985	Radiation cone locator	287		stay		
D5932	Obturator prosthesis, definitive	300		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D5954	Palatal augmentation prosthesis	300		stay		
D5955	Palatal lift prosthesis, definitive	300		stay		
D5958	Palatal lift prosthesis, interim	300		stay		
D5959	Palatal lift prosthesis, modification	300		stay		
D5960	Speech aid prosthesis, modification	300		stay		
D5987	Commissure splint	300		stay		
D7983	Closure of salivary fistula	323		stay		
D1354	Application of caries arresting medicament - per tooth	343		stay		
D2140	Amalgam-one surface, primary or permanent	343		stay		
D2150	Amalgam-two surfaces, primary or permanent	343		stay		
D2160	Amalgam-three surfaces, primary or permanent	343		stay		
D2161	Amalgam-four or more surfaces, primary or permanent	343		stay		
D2330	Resin-one surface, anterior	343		stay		
D2331	Resin-two surfaces, anterior	343		stay		
D2332	Resin-three surfaces, anterior	343		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D2335	Resin-four or more surfaces or involving incisal angle (anterior)	343		stay		
D2390	Resin-based composite crown, anterior	343		stay		
D2391	Resin-based composite - one surface, posterior	343		stay		
D2392	Resin-based composite - two surfaces, posterior	343		stay		
D2393	Resin-based composite - three surfaces, posterior	343		stay		
D2394	Resin-based composite - four or more surfaces, posterior	343		stay		
D2930	Prefabricated stainless steel crown-primary tooth	343		stay		
D2931	Prefabricated stainless steel crown-permanent tooth	343		stay		
D2932	Prefabricated resin crown	343		stay		
D2933	Prefabricated stainless steel crown with resin window	343		stay		
D2941	Interim therapeutic restoration - primary dentition	343	move to urgent, 265			
D2951	Pin retention-per tooth, in addition to restoration	343		stay		
D2954	Prefabricated post and core in addition to crown	343		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D2957	Each additional prefabricated post - same tooth	343		stay		
D2980	Crown repair necessitated by restorative material failure	343		stay		
D6980	Fixed partial denture repair necessitated by restorative material failure	343		stay		
D6096	Remove broken implant retaining screw	344		stay		
D7241	Removal of impacted tooth-completely bony, with unusual surgical complications	344		Stay		
D7251	Coronectomy - intentional partial tooth removal, impacted teeth only	344		stay		
D7310	Alveoloplasty in conjunction with extractions - four or more teeth or tooth spaces, per quadrant	344		Stay	currently not covered, should stay as not covered. Should be on Not to be billed seperately list.	

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7311	Alveoloplasty in conjunction with extractions - one to three teeth or tooth spaces, per quadrant	344		Stay		
D7320	Alveoloplasty not in conjunction with extractions - four or more teeth or tooth spaces, per quadrant	344		stay	lots of requests for. Covered for under 21 and preg adults. Budget review if can be available for non-pregnant adults. (oral surgeons may sometimes substitute and submit claim for exostosis) If funded, would need GN similar to GN117 when medically needed for prostetic.	

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7321	Alveoloplasty not in conjunction with extractions - one to three teeth or tooth spaces, per quadrant	344		stay	lots of requests for. Covered for under 21 and preg adults. Budget review if can be available for non-pregnant adults. (oral surgeons may sometimes substitute and submit claim for exostosis)	
D7450	Removal of benign odontogenic cyst or tumor-lesion diameter up to 1.25 cm	344		stay		
D7451	Removal of benign odontogenic cyst or tumor-lesion diameter greater than 1.25 cm	344		stay		
D7465	Destruction of lesion(s) by physical or chemical methods, by report	344		stay		
D7471	Removal of lateral exostosis (maxilla or mandible)	344		stay	providers may use this instead of alveloplasty; covered service, used frequently	
D7509	marsupialization of odontogenic cyst	344		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7540	Removal of reaction-producing foreign bodies-musculoskeletal system	344		stay		
D7550	Partial ostectomy/sequestrectomy for removal of non-vital bone	344		stay		
D7963	Frenuloplasty	344		stay	needs more extensive guideline note	
D7971	Excision of pericoronal gingiva	344		stay		
D9930	Treatment of complications (postsurgical) - unusual circumstances, by report	344		stay		
D7810	Open reduction of dislocation	359		stay	(medical line?)	
D7820	Closed reduction of dislocation	359		stay	(medical line?)	
D7830	Manipulation under anesthesia	359		stay	(medical line?)	

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D3310	Endodontic therapy, anterior tooth (excluding final restoration)	384			look at lines, verify why the endodontic therapy treatments are on different line #s. Possibly history of variable benefits.	
D3320	Endodontic therapy, premolar tooth (excluding final restoration)	411			look at lines, verify why the endodontic therapy treatments are on different line #s. Possibly history of variable benefits.	

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D3330	Endodontic therapy, molar tooth (excluding final restoration)	444			look at lines, verify why the endodontic therapy treatments are on different line #s. Possibly history of variable benefits. (confirm clinical criteria for endo in molars, in addition to age/tooth number etc)	
D5110	Complete denture - maxillary	454		stay	review frequency limitation	
D5120	Complete denture - mandibular	454		stay		
D5130	Immediate denture - maxillary	454		stay		
D5140	Immediate denture - mandibular	454		stay		
D5211	Maxillary partial denture - resin base (including, retentive/clasping materials, rests, and teeth)	454		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D5212	Mandibular partial denture - resin base (including, retentive/clasping materials, rests and teeth)	454		stay		
D5221	Immediate maxillary partial denture - resin base (including retentive/clasping materials, rest and teeth)	454		stay		
D5222	Immediate mandibular partial denture - resin base (including retentive/clasping materials, rests and teeth)	454		stay		
D5511	Repair broken complete denture base, mandibular	454		stay		
D5512	Repair broken complete denture base, maxillary	454		stay		
D5520	Replace missing or broken teeth-complete denture (each tooth)	454		stay		
D5611	Repair resin partial denture base, mandibular	454		stay		
D5612	Repair resin partial denture base, maxillary	454		stay		
D5621	Repair cast partial framework, mandibular	454		stay		
D5622	Repair cast partial framework, maxillary	454		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D5630	Repair or replace broken retentive clasping materials - per tooth	454		stay		
D5640	Replace broken teeth-per tooth	454		stay		
D5650	Add tooth to existing partial denture	454		stay		
D5660	Add clasp to existing partial denture - per tooth	454		stay		
D5670	Replace all teeth and acrylic on cast metal framework (maxillary)	454		stay		
D5671	Replace all teeth and acrylic on cast metal framework (mandibular)	454		stay		
D5710	Rebase complete maxillary denture	454		stay		
D5711	Rebase complete mandibular denture	454		stay		
D5720	Rebase maxillary partial denture	454		stay		
D5721	Rebase mandibular partial denture	454		stay		
D5730	Reline complete maxillary denture (direct)	454		stay		
D5731	Reline lower complete mandibular denture (direct)	454		stay		
D5740	Reline maxillary partial denture (direct)	454		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D5741	Reline mandibular partial denture (direct)	454		stay		
D5750	Reline complete maxillary denture (indirect)	454		stay		
D5751	Reline complete mandibular denture (indirect)	454		stay		
D5760	Reline maxillary partial denture (indirect)	454		stay		
D5761	Reline mandibular partial denture (indirect)	454		stay		
D5765	Soft liner for complete or partial removable denture - indirect	454		stay		
D5820	Interim partial denture (including retentive/clasping materials, rests, and teeth), maxillary	454		stay		
D5821	Interim partial denture (including retentive/clasping materials, rests, and teeth), mandibular	454		stay		
D5876	add metal substructure to acrylic full denture (per arch)	454		stay		
D7472	Removal of torus palatinus	454		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7473	Removal of torus mandibularis	454		stay		
D7970	Excision of hyperplastic tissue-per arch	454		stay		
D3346	Retreatment of previous root canal therapy-anterior	456		stay		
D3410	Apicoectomy - anterior	456		stay		
D2710	Crown - resin-based composite (indirect)	469		stay	Review limitations	
D2712	Crown - 3/4 resin-based composite (indirect)	469		stay	Review limitations	
D2740	Crown - porcelain/ceramic	469		stay	Review limitations	
D2751	Crown-porcelain fused to predominantly base metal	469		stay	Review limitations	
D2752	Crown-porcelain fused to noble metal	469		stay	Review limitations	
D7962	Lingual frenectomy (frenulectomy)	18,597	341	oral surgery, covered benefit on dental	(GN48 currently applies only to D7961)	
D7440	Excision of malignant tumor-lesion diameter up to 1.25 cm	200,287		stay		
D7441	Excision of malignant tumor-lesion diameter greater than 1.25 cm	200,287		stay		
D7912	Complicated suture-greater than 5 cm	207,300		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D5933	Obturator prosthesis, modification	256,300		stay		
D7220	Removal of impacted tooth-soft tissue	256,344		stay		
D7230	Removal of impacted tooth-partially bony	256,344		stay		
D7240	Removal of impacted tooth-completely bony	256,344		stay		
D5915	Orbital prosthesis	256,484		stay		
D5928	Orbital prosthesis, replacement	256,484		stay		
D7940	Osteoplasty-for orthognathic deformities	256,617		stay		
D7941	Osteotomy - mandibular rami	256,617		stay		
D7943	Osteotomy - mandibular rami with bone graft; includes obtaining the graft	256,617		stay		
D7944	Osteotomy-segmented or subapical	256,617		stay		
D7945	Osteotomy-body of mandible	256,617		stay		
D7946	Lefort i (maxilla-total)	256,617		stay		
D7947	Lefort i (maxilla-segmented)	256,617		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7948	Lefort ii or lefort iii (osteoplasty of facial bones for midface hypoplasia or retrusion)-without bone graft	256,617		stay		
D7949	Lefort ii or lefort iii-with bone graft	256,617		stay		
D7280	Exposure of an unerupted tooth	254,618	341	618 = uncovered by dental; is covered for HCM should also be on a covered dental line 344 (in addition to 256)		
D7283	Placement of device to facilitate eruption of impacted tooth	254,618	341	618 = uncovered by dental; is covered for HCM should also be on a covered dental line 344 (in addition to 256)		
D7951	Sinus augmentation with bone or bone substitutes via a lateral open approach	256,619		stay		
D7952	Sinus augmentation via a vertical approach	256,619		stay		
D7955	Repair of maxillofacial soft and/or hard tissue defect	256,643		Review why this on the TMJ line? (643)		
D7950	Osseous, osteoperiosteal, or cartilage graft of the mandible or maxilla - autogenous or nonautogenous, by report	256,646		review 646 placement, most often in conjunction w/implants (619)		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7953	Bone replacement graft for ridge preservation - per site	256,646		Stay; consider adding to implant line (619)		
D2950	Core build-up, including any pins when required	267,343		stay	verify if limitations are correct either in GN or OAR. Only to be used in conjuction w/crown	
D7250	Removal of residual tooth roots (cutting procedure)	300,344		stay	GN 34 is specific to removal of impacted third molars. Review GN 34 and OAR regarding impacted teeth. Should be additional GN to allow for other roots than only third molars.	
D7340	Vestibuloplasty-ridge extension (second epithelialization)	300,586		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7350	Vestibuloplasty-ridge extension (including soft tissue grafts, muscle re-attachments, revision of soft tissue attachment, and management of hypertrophied and hyperplastic tissue)	300,586		stay		
D7982	Sialodochoplasty	323,500		stay		
D6100	Surgical removal of implant body	344,619		stay		
D6105	Removal of implant body not requiring bone removal or flap elevation	344,619		stay		
D7961	Buccal / labial frenectomy (frenulectomy)	344,661		stay	review GN 48 to have it also address D7962, D7963	
D7140	Extraction, erupted tooth or exposed root (elevation and/or forceps removal)	54,256,300		stay		
D7260	Oral antral fistula closure	54,300,577		stay		
D5984	Radiation shield	#########		stay		
D7920	Skin graft (identify defect covered, location, and type of graft)	#########		stay		
D7111	Extraction, coronal remnants - primary tooth	#########		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D3332	Incomplete endodontic therapy; inoperable, unrestorable or fractured tooth	#########		stay		
D3331	Treatment of root canal obstruction; non-surgical access	#########		stay		
D3333	Internal root repair of perforation defects	#########		stay		
D3430	Retrograde filling-per root	#########		stay		
D7298	removal of temporary anchorage device [screw retained plate], requiring flap	#########		stay	Review: database says "not to be billed separately", but this not stated in OAR. 123-1200	
D7299	removal of temporary anchorage device, requiring flap	#########		stay	Review: database says "not to be billed separately", but this not stated in OAR.	
D7300	removal of temporary anchorage device without flap	#########		stay	Review: database says "not to be billed separately", but this not stated in OAR.	

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D8010	Limited orthodontic treatment of the primary dentition	#########		stay		
D8020	Limited orthodontic treatment of the transitional dentition	#########		stay		
D8030	Limited orthodontic treatment of the adolescent dentition	#########		stay		
D8040	Limited orthodontic treatment of the adult dentition	#########		stay		
D8070	Comprehensive orthodontic treatment of the transitional dentition	#########		stay		
D8080	Comprehensive orthodontic treatment of the adolescent dentition	#########		stay		
D8090	Comprehensive orthodontic treatment of the adult dentition	#########		stay		
D8210	Removable appliance therapy	#########		stay		
D8220	Fixed appliance therapy	#########		stay		
D8660	Pre-orthodontic treatment examination to monitor growth and development	#########		stay		
D8670	Periodic orthodontic treatment visit	#########		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D8680	Orthodontic retention (removal of appliances, construction and placement of retainer(s))	#########		stay		
D8681	Removable orthodontic retainer adjustment	#########		stay		
D8696	Repair of orthodontic appliance - maxillary	#########		stay		
D8697	Repair of orthodontic appliance - mandibular	#########		stay		
D8698	Re-cement or re-bond fixed retainer - maxillary	#########		stay		
D8699	Re-cement or re-bond fixed retainer - mandibular	#########		stay		
D8701	Repair of fixed retainer, includes reattachment - maxillary	#########		stay		
D8702	Repair of fixed retainer, includes reattachment - mandibular	#########		stay		
D8703	Replacement of lost or broken retainer - maxillary	#########		stay		
D8704	Replacement of lost or broken retainer - mandibular	#########		stay		

OHF review of covered codes						
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**OAR update, other comments**	**Participant Notes**
D7210	Extraction, erupted tooth requiring removal of bone and/or sectioning of tooth, and including elevation of mucoperiosteal flap if indicated	#########		stay		
D7981	Excision of salivary gland, by report	#########		stay on medical		
D5992	Adjust maxillofacial prosthetic appliance, by report	#########		stay on medical		
D5993	Maintenance and cleaning of a maxillofacial prosthesis (extra- or intra-oral) other than required adjustments, by report	#########		stay on medical		
D3911	intraorifice barrier	384, 411, 444, 456, 507, 538		"not to be billed separately" 123-1200		
D3921	decoronation or submergence of an erupted tooth	384, 411, 444, 456, 507, 538		stay		
D0191	Assessment of a patient	3,53		stay		
D1206	Topical application of fluoride varnish	3,53		stay		

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0171	Re-evaluation - post-operative office visit	Excluded (Group 1118)	343 (exam line)	possibly "not to be billed separately" as this service is included in treatment/service provided. (410-123-1200 not eligible for separate reimbursement) 1. Exam code, should be moved to be consistent w/OARs. 2. should stay as "not to be reimbursed separately." Add to post-operative rule.	Per OAR 410-120-1200		1/1/2019
D0368	Cone beam ct capture and interpretation for tmj series including two or more exposures	Excluded (Group 1118)		only Cone Beam call out of TMJ . Limited specifications (possibly add GN for cone beams). Possibly revisit, conduct another evidence review. Review the other cone beams, keep this on Excluded.	Per OAR 410-120-1200		1/1/2013

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0369	Maxillofacial mri capture and interpretation	Excluded (Group 1118)		MRI = medical ? Could be used by oral surgeons but would use medical code. Keep on excluded	Per OAR 410-120-1200		1/1/2013
D0370	Maxillofacial ultrasound capture and interpretation	Excluded (Group 1118)		MRI = medical ? Could be used by oral surgeons but would use medical code. Keep on excluded	Per OAR 410-120-1200		1/1/2013
D0371	Sialoendoscopy capture and interpretation	Excluded (Group 1118)		MRI = medical ? Could be used by oral surgeons but would use medical code. Keep on excluded	Per OAR 410-120-1200		1/1/2013
D0372	Intraoral tomosynthesis - comprehensive series of radiographic images	Excluded (Group 1118)		New technology, inadequate research, (consider putting in re-evaluation cycle)	Per OAR 410-120-1200		1/1/2023
D0373	Intraoral tomosynthesis - bitewing radiographic image	Excluded (Group 1118)		New technology, inadequate research, (consider putting in re-evaluation cycle)	Per OAR 410-120-1200		1/1/2023
D0374	intraoral tomosynthesis - periapical radiographic image	Excluded (Group 1118)		New technology, inadequate research, (consider putting in re-evaluation cycle)	Per OAR 410-120-1200		1/1/2023

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0380	Cone beam ct image capture with limited field of view - less than one whole jaw	Excluded (Group 1118)		Recommend evidence review	Per OAR 410-120-1200		1/1/2013
D0381	Cone beam ct image capture with field of view of one full dental arch - mandible	Excluded (Group 1118)		Recommend evidence review	Per OAR 410-120-1200		1/1/2013
D0382	Cone beam ct image capture with field of view of one full dental arch - maxilla, with or without cranium	Excluded (Group 1118)		Recommend evidence review	Per OAR 410-120-1200		1/1/2013
D0383	Cone beam ct image capture with field of view of both jaws, with or without cranium	Excluded (Group 1118)		Recommend evidence review	Per OAR 410-120-1200		1/1/2013
D0384	Cone beam ct image capture for tmj series including two or more exposures	Excluded (Group 1118)		Stay on Excluded. (Related to TMJ)	Per OAR 410-120-1200		1/1/2013
D0385	Maxillofacial mri image capture	Excluded (Group 1118)		medical use; keep on excluded. (Check if there's a coordinated CPT code)	Per OAR 410-120-1200		1/1/2013

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0386	Maxillofacial ultrasound image capture	Excluded (Group 1118)		medical use; keep on excluded. (Check if there's a coordinated CPT code)	Per OAR 410-120-1200		1/1/2013
D0387	Intraoral tomosynthesis - comprehensive series of radiographic images - image capture only	Excluded (Group 1118)		New technology, inadequate research, (consider putting in re-evaluation cycle)	Per OAR 410-120-1200		1/1/2023
D0388	Intraoral tomosynthesis - bitewing radiographic image - image capture only	Excluded (Group 1118)		New technology, inadequate research, (consider putting in re-evaluation cycle)	Per OAR 410-120-1200		1/1/2023
D0389	Intraoral tomosynthesis - periapical radiographic image - image capture only	Excluded (Group 1118)		New technology, inadequate research, (consider putting in re-evaluation cycle)	Per OAR 410-120-1200		1/1/2023
D0391	Interpretation of diagnostic image by a practitioner not associated with capture of the image, including report	Excluded (Group 1118)	53	possibly "not to be reimbursed separately" as this service is included in treatment/service provided. (410-123-1200 not eligible for separate reimbursement)	Per OAR 410-120-1200		1/1/2013
D0416	Viral culture	Excluded (Group 1118)		medical in nature	Per OAR 410-120-1200		1/1/2005

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0417	Collection and preparation of saliva sample for laboratory diagnostic testing	Excluded (Group 1118)		medical in nature	Per OAR 410-120-1200		1/1/2009
D0418	Analysis of saliva sample	Excluded (Group 1118)		Saliva=dental health-related, medical in nature. Carries risk assessment.	Per OAR 410-120-1200		1/1/2009
D0419	Assessment of salivary flow by measurement	Excluded (Group 1118)		Saliva=dental health-related, medical in nature. Carries risk assessment.	Per OAR 410-120-1200		1/1/2020
D0422	Collection and preparation of genetic sample material for laboratory analysis and report	Excluded (Group 1118)		Stay	GL Note 173		1/1/2019
D0423	Genetic test for susceptibility to diseases – specimen analysis	Excluded (Group 1118)		Stay	GL Note 173		1/1/2019
D0425	Caries susceptibility tests	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2000

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0431	Adjunctive pre-diagnostic test that aids in detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0460	Pulp vitality tests	Excluded (Group 1118)	54	Diagnostic	Per OAR 410-120-1200		1/1/2000
D0470	Diagnostic casts	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/1995
D0475	Decalcification procedure	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0476	Special stains for microorganisms	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0477	Special stains, not for microorganisms	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0478	Immunohistochemical stains	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0479	Tissue in-situ hybridization, including interpretation	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0481	Electron microscopy	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0482	Direct immunofluorescence	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D0483	Indirect immunofluorescence	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0484	Consultation on slides prepared elsewhere	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0485	Consultation, including preparation of slides from biopsy material supplied by referring source	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D0600	Non-ionizing diagnostic procedure capable of quantifying, monitoring, and recording changes in structure of enamel, dentin, and cementum	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2017
D0605	Antibody testing for a public health related pathogen, including coronavirus	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2021
D0803	3d facial surface scan - direct	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2023
D0804	3d facial surface scan - indirect	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2023
D0999	Unspecified diagnostic procedure, by report	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2000

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D1352	Preventive resin restoration in a moderate to high caries risk patient - permanent tooth	Excluded (Group 1118)		Public health method, less invasive. What is evidence? (Table for more research, ask Dr. Allen's opinion) could take place of sealants for adults. If covered, what would be the frequency? (if billed, cant bill sealant/composite on same date/same tooth). Some commercial plans cover, w/clinical rules. no age limitation listed. (Possibly offer to ages 16+). Dr. Allen skeptical, some controversy, as decay can be sealed over. (review what overall utilization is). **STAY**	Per OAR 410-120-1200		1/1/2011

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D1353	Sealant repair - per tooth	Excluded (Group 1118)		Some commercial plans cover, w/limitations. Limitations = time since first sealed, if cavitated. (Table for more research, ask Dr. Allen's opinion)	Per OAR 410-120-1200		1/1/2019
D1999	Unspecified preventive procedure, by report	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2019
D2975	Coping	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2005
D4265	Biologic materials to aid in soft and osseous tissue regeneration, per site	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2003
D4266	Guided tissue regeneration, natural teeth - resorbable barrier, per site	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2000
D4267	Guided tissue regeneration, natural teeth - non-resorbable barrier, per site	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2000

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D4921	Non-autogenous connective tissue graft (including recipient site and donor material) first tooth, implant, or edentulous tooth position in graft	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2019
D7295	Combined connective tissue and pedicle graft, per tooth	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2011
D4921	Gingival irrigation with a medicinal agent - per quadrant	Not open for pymt	Perio procedure, Line 218	Is this open for encounter data? (update OAR? Can be billed) "not to be billed separately"			
D7295	Harvest of bone for use in autogenous grafting procedure	Not open for pymt Excluded		(move to Excluded) Stay			
D7411	Excision of benign lesion greater than 1.25 cm	Excluded (Group 1118)		Stay (consider revising OAR. Not always most appropriate to be limited to medical codes. Coordinating care becomes complex. Could be helpful for oral surgeons to use these codes).	Per OAR 410-120-1200		1/1/2003

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D7412	Excision of benign lesion, complicated	Excluded (Group 1118)		Stay (consider revising OAR. Not always most appropriate to be limited to medical codes. Coordinating care becomes complex. Could be helpful for oral surgeons to use these codes). Bring this to OHAP to discuss medical/dental care coordination. Get oral surgeon input (lived experiences for council on how). OHA guidance could cause confusion, not recommended.	Per OAR 410-120-1200		1/1/2003

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D7413	Excision of malignant lesion up to 1.25 cm	Excluded (Group 1118)		Stay (consider revising OAR. Not always most appropriate to be limited to medical codes. Coordinating care becomes complex. Could be helpful for oral surgeons to use these codes)	Per OAR 410-120-1200		1/1/2003
D7414	Excision of malignant lesion greater than 1.25 cm	Excluded (Group 1118)		Stay (consider revising OAR. Not always most appropriate to be limited to medical codes. Coordinating care becomes complex. Could be helpful for oral surgeons to use these codes)	Per OAR 410-120-1200		1/1/2003

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D7415	Excision of malignant lesion, complicated	Excluded (Group 1118)		Stay (consider revising OAR. Not always most appropriate to be limited to medical codes. Coordinating care becomes complex. Could be helpful for oral surgeons to use these codes)	Per OAR 410-120-1200		1/1/2003
D7485	Reduction of osseous tuberosity	Excluded (Group 1118)		Oral surgery. Stay on excluded	Per OAR 410-120-1200		1/1/2003
D7671	Alveolus - open reduction, may include stabilization of teeth	Excluded (Group 1118)		Trauma-related. Stay	Per OAR 410-120-1200		1/1/2003
D7771	Alveolus, closed reduction stabilization of teeth	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2003
D7921	Collection and application of autologous blood concentrate product	Excluded (Group 1118)		Stay, or on non-covered line. Questionable evidence to support	Per OAR 410-120-1200		1/1/2013

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D7922	Placement of intra-socket biological dressing to aid in hemostasis or clot stabilization, per site	Excluded (Group 1118)	move to 344	Clinical need. Part of procedure, not separately reimbursed. Should discuss whether this ought to be reimbursed separately.	Per OAR 410-120-1200		1/1/2020
D7993	Surgical placement of craniofacial implant - extra oral	Excluded (Group 1118)	move to 619	implant	Per OAR 410-120-1200		1/1/2021
D7994	Surgical placement: zygomatic implant	Excluded (Group 1118)	more to 619		Per OAR 410-120-1200		1/1/2021
D8999	Unspecified orthodontic procedure, by report	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2012
D9210	Local anesthesia not in conjunction with operative or surgical procedures	Excluded (Group 1118)	54	Palliative, could be urgent, or emergent (needs GN). Add situation to 123-1200 re: local anesthesia	Per OAR 410-120-1200		1/1/2000
D9215	Local anesthesia in conjunction with operative or surgical procedures	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2000

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D9219	Evaluation for moderate sedation, deep sedation or general anesthesia	Excluded (Group 1118)	54, 344	add to "not to be reimbursed separately" (bundle w/oral surgery procedures)	Per OAR 410-120-1200		1/1/2019
D9450	Case presentation, subsequent to detailed and extensive treatment planning	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2003
D9613	Infiltration of sustained release therapeutic drug, per quadrant	Excluded (Group 1118)	344	gets billed, but not paid. Should be either "not paid separate" or have a guideline (eg, Exporel). Discuss if should be paid separately	Per OAR 410-120-1200		1/1/2019
D9932	Cleaning and inspection of the removable complete denture, maxillary	Excluded (Group 1118)		Stay (173 GN) per OHAP in 2019	GL Note 173		1/1/2019
D9933	Cleaning and inspection of the removable complete denture, mandibular	Excluded (Group 1118)		Stay	GL Note 173		1/1/2019
D9934	Cleaning and inspection of the removable complete denture, mandibular	Excluded (Group 1118)		Stay	GL Note 173		1/1/2019

OHF review of excluded codes							
Code	**Code description**	**Current placement**	**If rec'd move, line/group destination**	**Rationale/Notes**	**Applicable OARs/GNs**	**Participant Notes**	**Excluded since**
D9935	Cleaning and inspection of the removable complete denture, mandibular	Excluded (Group 1118)		Stay	GL Note 173		1/1/2019
D9961	duplicate/copy patient's records	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2019
D9985	Sales tax	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2019
D9986	Missed appointment	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2020
D9987	Cancelled appointment	Excluded (Group 1118)		Stay	Per OAR 410-120-1200		1/1/2019