



Draft

Pressure Reducing Support
Surfaces for Pressure Ulcers

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Produced by:

The Health Resources Commission
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Health Resources Commission

The State of Oregon's Health Resources Commission is a volunteer commission appointed by the Governor. The Health Resources Commission provides a public forum for discussion and development of conclusions regarding significant emerging issues related to medical technology. Created by statute in 1991, it consists of four physicians experienced in health research and the evaluation of medical technologies and clinical outcomes; one representative of hospitals; one insurance industry representative; one business representative; one representative of labor organizations; one consumer representative and two pharmacists. All Health Resources Commissioners are selected with conflict of interest guidelines in mind. Any minor conflict of interest is disclosed.

The Commission is charged with conducting medical assessment of selected technologies, including prescription drugs. The commission may use advisory committees or subcommittees, the members to be appointed by the chairperson of the commission subject to approval by a majority of the commission. The appointees have the appropriate expertise to develop a medical technology assessment. Subcommittee meetings and deliberations are public, where public testimony is encouraged. Subcommittee recommendations are presented to the Health Resources Commission in a public forum. The Commission gives strong consideration to the recommendations of the advisory subcommittee meetings and public testimony in developing its final reports.

Overview

In 2007 the Oregon Health Resources Commission (HRC) appointed a technology subcommittee to perform evidence-based reviews of medical technologies. Members of the subcommittee for this review consisted of five physicians, and an attorney who serves as the consumer representative. All meetings were held in public with appropriate notice provided. The technologies chosen for review are chosen by the HRC which takes into account stakeholder input when deciding on topics to consider. The HRC utilizes source documents from sources previously approved by the Commission. In conducting the review process and working with our source providers the HRC defines the patient populations of interest, technologies to be studied and outcome measures for analysis, considering both effectiveness and safety. Evidence is specifically sought for subgroups

of patients based on race, ethnicity and age, demographics. Using standardized methods, the subcontractors review systematic databases, and the medical literature. Inclusion and exclusion criteria were applied to titles and abstracts, and each study was assessed for quality according to predetermined criteria.

The HRC utilized materials from Hayes, Inc. to complete the report, “Pressure-Reducing Support Surfaces for Pressure Ulcers”, November, 2010”. This report was circulated to subcommittee member. The subcommittee met to review the document and this report is the consensus result of those meetings and input from the HRC. Time was allotted for public comment, questions and testimony.

This report does not recite or characterize all the evidence that was discussed by the source documents, the subcommittee or the HRC. This report is not a substitute for any of the information provided during the subcommittee process, and readers are encouraged to review the source materials. This report is prepared to facilitate the HRC in providing recommendations to the Department of Human Services. This report may be updated if indicated at the discretion of the Health Resources Commission

Information regarding the Oregon Health Resources Commission and its subcommittee policy and process can be found on the Office for Oregon Health Policy & Research website: <http://www.oregon.gov/DAS/OHPPR/HRC/index.shtml>

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There will be a charge for copying and handling in providing hard copy documents from the Office of Oregon Health Policy & Research. Source Documents should be obtained from their listed source.

Source Documents

1. *Pressure-Reducing Support Surfaces for Pressure Ulcers*. Hayes Directory, Hayes Inc. May 24, 2010

Critical Policy

Health Resources Commission

- “Clinical outcomes are the most important indicators of comparative effectiveness”
- “If evidence is insufficient to answer a question, neither a positive nor a negative association can be assumed.”

Scope and Key Questions

Evidence evaluated for this report was obtained from a search in the MEDLINE, EMBASE, and Cochrane Library electronic databases. The search was designed to identify randomized trials that compared pressure-reducing support surfaces with standard hospital mattresses or other support surfaces, that included at least 50 adult patients and that were published between April 2000 and April 2010.

The following questions pertaining to pressure ulcer support surfaces were used to help guide the review:

1. Which pressure ulcer support surfaces are effective in *preventing* pressure ulcer development compared with standard care or other appropriate comparators?
2. Which pressure ulcer support surfaces are effective in *treating* pressure ulcers compared with standard care or other appropriate comparators?
3. Is there a difference in effectiveness of the support surfaces according to wound severity?
4. Are there adverse effects associated with the use of pressure ulcer support surfaces?
5. Have definitive patient selection criteria been established for pressure ulcer support surfaces?

Clinical Overview

Pressure-reducing support surfaces are used to relieve pressure in patients at risk of developing pressure ulcers, and to promote healing of existing pressure ulcers.

A pressure ulcer, also referred to as a decubitus ulcer, pressure sore, or bedsore, is a localized injury to the skin or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear or friction. Prolonged, uninterrupted pressure is the primary cause of pressure ulcers, and impaired mobility is the most common reason that people are exposed to unrelieved pressure. Other factors that predispose people to pressure ulcer formation are poor nutrition, poor sensation, urinary and fecal incontinence, a healed ulcer, and poor overall physical and mental health. The sacrum and heel are the most common location for pressure ulcers (Allman, 1989; Woodbury and Houghton, 2004).

There are various risk assessment tools to identify patients at risk of developing pressure ulcers. The Braden risk scale is a commonly used scale estimating risk based on sensory perception, activity, mobility, moisture, nutrition and friction/shearing forces applied to the skin (Bergstrom et al., 1987). The score ranges between 6 and 23. Patients with Braden scores from 6 to 12 are considered at high risk for developing pressure ulcers. Patients with scores of 13 to 14 are considered at moderate risk for developing pressure ulcers (Bergstrom et al., 1987; Capobianco and McDonald, 1996). Another recognized risk assessment tool is the Norton risk score, which comprises five items: general physical condition; mental condition; activity; mobility; and incontinence (Norton, 1975). The score ranges from 5 to 20. While these tools are available and used their predictive value is low (Defloor et al., 2005). Pressure ulcers can be classified according to severity. Most physicians and nurses use the North American National Pressure Ulcer Advisory Panel (NPUAP) system or the European equivalent, the European Pressure Ulcer Advisory Panel (EPUAP) system. Stage 1 usually refers to a change in the skin without breakage; stage 2 refers to a shallow ulcer with partial-thickness skin loss; stages 3 and 4

are considered advanced ulcers with full-thickness skin loss affecting tissues beneath the dermis. A new category, Unstageable, was recently added to represent the damage of underlying soft tissues while the skin remains intact. Since pressure ulcers do not heal by regeneration and various strata are not replaced, pressure ulcers should not be reverse staged as they heal.

A review of 60 studies of pressure ulcer prevalence in the United Kingdom, United States, and Canada reported prevalence rates ranging from 4.7% to 32.1% for hospital populations, 4.4% to 33% for community care populations, and 4.6% to 20.7% for nursing home populations (Kaltenthaler et al., 2001). Pressure ulcers are associated with an increased risk of mortality amongst geriatric patients, increased frequency and duration of hospitalization, and decreased quality of life (Aronovitch, 1999).

Furthermore, as pressure ulcers increase in severity, the probability of healing decreases, while morbidity and mortality increase (Allman, 1997). Pressure ulcers impose a significant health and economic burden that, to a large extent, can be prevented by good care; therefore, the incidence and prevalence rates are now put forward by many healthcare, professional, and governmental organizations as an indicator of the quality of healthcare. In addition, development of pressure ulcers while in a hospital is considered a “never event”; therefore, Medicare and some private payers will not reimburse the hospital for treatment of this condition (CMS, 2008). Utilizing pressure-reducing support surfaces is one way to impact prevention and healing of pressure ulcers.

Pressure ulcer prevention strategies aim to reduce the magnitude and duration of pressure (including shear and friction) between a patient and their support surface (the interface pressure). This may be achieved by regular manual repositioning (e.g., 2-hourly turning) or by using pressure-reducing support surfaces such as cushions, mattress overlays, replacement mattresses, or whole bed replacements. Pressure-reducing cushions, beds, and mattresses either distribute the patient’s weight over a larger area (constant low-pressure devices) or mechanically vary the pressure beneath the patient, so reducing the duration of the applied pressure (alternating pressure devices) (Bliss and Thomas, 1993). Pressure ulcer management depends on the ulcer stage and usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in stage 3 and 4 ulcers, wound cleansing, control of infection, dealing with the edge effect (when the edge fails to close), and dressings that promote a moist wound environment (Diegelmann and Evans, 2004; MAS, 2009a).

Support Devices

Pressure-reducing support surfaces can be divided into two categories: low-tech and high-tech devices. Low-tech devices, also called static devices, are defined as conforming surfaces that distribute the body weight over a large area. Various types of foam, gel, fiber, water, air, beads, or silicone are used to construct these support surfaces. High-tech devices, also called dynamic pressure-reducing devices, are electrically powered, air-filled mattresses in which adjacent cells inflate and deflate reciprocally underneath the patient. They vary in the type of materials used, the number of cells that inflate and deflate during one cycle, the amount of pressure inside the cells during the peak inflation and deflation phases, the alternation cycle times, and the rate at which pressure is ramped up and down during inflation and deflation.

Pressure reducing support surfaces are regulated by the FDA as class II (moderate risk) devices. An extensive list of commercially available pressure-reducing support surfaces has been approved for marketing by the FDA under the 510(k) clearance process to treat or prevent bedsores (FDA, 2010).

Conclusions

Limitations of the Evidence

1. There was a lack of blinding of nursing staff and patients after randomization.
2. Some studies lacked intention to treat analysis or were insufficiently powered to detect clinically significant differences between the modalities.
3. In at least some studies there were potential conflicts of interest.
4. Overall quality of evidence was moderate for high-specification foam mattresses and low for all other devices.
5. Heterogeneity among studies was caused by variations in length of follow-up, extent of blinding of allocation and/or outcome assessment, range of included pressure ulcer stages, lack of a uniform pressure ulcer risk assessment tool, and variation between interventions.
6. The literature provided very little information on adverse events

Conclusions

1. No evidence was found to support the use of pressure reducing surfaces for individuals not at risk for pressure ulcer development.
2. Limited evidence fails to show a difference between most of the included interventions and nursing care.

KQ1. Which pressure ulcer support surfaces are effective in *preventing* pressure ulcer development compared with standard care or other appropriate comparators?

1. Moderate-quality evidence showed a beneficial effect of VEP foam support surfaces on pressure ulcer incidence compared with standard hospital mattresses; however one small study did not show a difference between these groups.
2. Low quality evidence showed no difference in pressure ulcer incidence for other high-specification foam support surfaces.
3. Low quality evidence was contradictory regarding efficacy of pressure support surfaces for reducing incidence of pressure ulcers compared to static foam mattresses.
4. Low quality evidence showed that medical sheepskins placed on a standard hospital mattress reduced pressure ulcer incidence compared with a standard hospital mattress alone
5. Low quality evidence did not show significant differences between study groups investigating special bed units or heel protector cushions.
6. Low quality evidence indicates that VEP foam support surfaces led to more pressure ulcers compared to a standard OR table set up. (N=175, study terminated early based on interim analysis).

KQ2. Which pressure ulcer support surfaces are effective in *treating* pressure ulcers compared with standard care or other appropriate comparators?

1. Low quality evidence indicates that therapeutic seats improved healing of advanced pressure ulcers compared with total bed rest. Further studies are needed to confirm these results.

KQ3. Is there a difference in effectiveness of the support surfaces according to wound severity?

1. Evidence from two RCTs comparing the healing rate of advanced pressure ulcers using a generic total contact seat (GTCS) or low-air-loss bed in long-term care patients indicated time to ulcer healing was reduced in the group that used the seat. Further studies are needed to confirm these results.

KQ4. Are there adverse effects associated with the use of pressure ulcer support surfaces?

1. Isolated cases of reported adverse events included slipping off the bed, and issues related to comfort.

KQ5. Have definitive patient selection criteria been established for pressure ulcer support surfaces.

1. Generally accepted, but not validated risk factors for developing pressure ulcers include immobility, cognitive impairment, heavy sedation, old age, diabetes, urinary and fecal incontinence, circulatory impairment, or poor nutrition.
2. Consensus regarding critical risk factors has not been established, a fact reflected in the lack of a uniform risk assessment tool.
3. Pressure ulcer risk assessment tools used today have a rather low predictive value.
4. There were no definitive patient selection criteria for utilization or selection of pressure ulcer support surfaces for patients at risk for pressure ulcer development identified.

Supporting Evidence

Existing Guidelines

National Institute for Health and Clinical Excellence (NICE):

NICE published a guideline on the use of pressure-reducing devices for the prevention of pressure ulcers in primary and secondary care (NICE, 2005). The guideline provides specific recommendations regarding the use of pressure-reducing devices (beds, mattresses, and overlays). Pressure reducing aids, including water-filled gloves, sheepskins, donut-type devices, cushions, limb protectors, and seats were not considered. The ratings range from A (based directly on category 1 evidence) to D (based directly on category 4 evidence or extrapolated recommendation from category 1, 2, or 3 evidence) NICE recommends (NICE, 2005):

- Use of a high-specification foam mattress with pressure-reducing properties for all individuals at risk for pressure ulcers (B rating).
- Use of alternating pressure or other high-tech pressure-relieving interventions:
 - (1) as first-line preventive strategy for at-risk patients;
 - (2) when previous history indicates that they should be cared for with a high-tech device;
 - or (3) when a low-tech device has failed. This recommendation is assigned a D rating as it is based on professional consensus without supportive research evidence.

- Use of high-specification foam mattress or another pressure-reducing surface for surgery patients who are considered vulnerable to pressure ulcers (D rating).
- Provision of pressure-reducing devices requires a 24- hour approach (D rating), with repositioning occurring when individuals are on pressure-reducing devices (D rating).

European Pressure Ulcer Advisory Panel (EPUAP) and National Pressure Ulcer Advisory Panel (NPUAP):

EPUAP and NPUAP released a quick reference guide that contains specific recommendations for pressure ulcer prevention (EPUAP and NPUAP, 2009). The strength of evidence ratings ranges from A to C, with A ratings supported by direct scientific evidence from Level 1 studies; B ratings supported by direct scientific evidence from Level 2, 3, 4, or 5 studies; and C ratings supported by indirect evidence and/or expert opinion.

EPUAP and NPAUP recommend (EPUAP and NPUAP, 2009):

- Use of high-specification foam mattress instead of a standard foam mattress for individuals at risk for pressure ulcer development (A rating).
- Use of an active support surface (mattress or overlay) for patients at risk for pressure ulcer development for whom frequent repositioning is not possible (B rating).
- Use of a pressure-redistributing seat cushion for individuals sitting in a chair whose mobility is reduced and who are, therefore, at risk for pressure ulcer development (B rating).
- Use of natural sheepskin pads (B rating).
- Use of a pressure-reducing mattress prior to and after surgery (C rating), and during the operation (B rating), for individuals at risk for pressure ulcer development.
- Avoiding use of synthetic sheepskin pads; cutout ring or donut-type devices; water-filled gloves; and small cell alternating pressure mattresses or overlays (C rating).

Other Systematic Reviews

Three recent high-quality systematic reviews are summarized here.

Cullum and Petherick (2008) conducted a systematic review with the objective to evaluate evidence of pressure ulcer interventions to prevent and to treat pressure ulcers. This review searched the medical literature up to February 2007 and found 60 systematic reviews or randomized controlled trials (RCTs) (absolute numbers not reported). With respect to preventive interventions the authors concluded:

- High-specification foam alternatives are more effective than standard foam mattresses.
- Low-air-loss beds in the intensive care unit (ICU) compared with standard ICU beds, and medical sheepskin overlays compared with standard care, may be more effective in preventing pressure ulcers.
- Low-air-loss hydrotherapy beds compared with other pressure-relieving surfaces are not likely to be beneficial.
- There are no significant differences between alternating pressure surfaces versus standard foam mattresses or constant low-pressure supports; hydrocellular heel supports versus orthopedic wool padding; and operating tables with pressure-relieving overlays versus operating tables without overlay. Also, no significant differences were shown

between different seat cushions, electric profiling beds, or low tech constant low-pressure supports.

With respect to treatment for pressure ulcers the authors concluded:

- Air-fluidized supports are more effective than standard care.
- There are no significant differences between alternating pressure surfaces, low-air-loss beds, low-tech constant low-pressure supports, and seat cushions.

The Medical Advisory Secretariat (MAS) and the Ontario Ministry of Health and Long-term Care (OHTAC) evaluated evidence of pressure ulcer prevention interventions and pressure ulcer treatment interventions, presented as two separate reviews (MAS, 2009a; MAS, 2009b).

1. For the pressure ulcer prevention review the medical literature reviewed was searched up to and including October 2007, presenting updated meta-analyses, when appropriate. This review selected two systematic reviews and five additional RCTs. MAS concluded that (MAS, 2009b):

- High-specification foam alternatives are more effective in pressure ulcer prevention than standard foam mattresses.
- Alternating pressure surfaces, sheepskin overlays, low-air-loss mattresses, air suspension beds, or VEP overlays, compared with standard foam mattresses, may be more effective in pressure ulcer prevention.
- Low-air-loss hydrotherapy beds compared with other pressure-relieving surfaces are not likely to be beneficial.
- There are no significant differences between any particular type of alternative foam mattress, any type of pressure-reducing cushion, or alternating pressure mattress and alternating pressure overlay.

2. For the pressure ulcer treatment report the medical literature was searched up to and including March 2008, presenting updated meta-analyses, when appropriate. The review selected 18 systematic reviews, 104 RCTs, 5 comparative trials, and 1 case series. MAS concluded that (MAS, 2009a):

- Air-fluidized supports are more effective in pressure ulcer healing compared with standard care.
- Profiling beds, alternating pressure mattresses for heel ulcers, and generic total contact seats, compared with standard support surfaces, may be more effective in pressure ulcer healing.
- There are no significant differences between alternating pressure surfaces and other alternating pressure systems, or between standard mattresses, low-air-loss beds, foam mattresses, low-pressure mattresses, and seat cushions.

Literature Review

The literature search identified 16 studies evaluating pressure-reducing support surfaces that met the criteria for review. The majority of studies were performed in Europe (11 studies). The other studies were performed in Asia (1 study), Australia (1 study), or North America (3 studies). The support surfaces that were studied included low-tech support surfaces (high-specification foam mattresses or overlays; medical sheepskins; heel and seat cushions) and high-tech support surfaces (alternating pressure surfaces; constant low pressure surfaces; pulsating low-air-loss surfaces; profiling beds; water-filled warming

mattresses). The therapeutic support surfaces were compared with standard surfaces and standard care, or with each other. In most studies, patients were followed for a preset period of time during which the development of pressure ulcers was recorded. Few studies followed patients until hospital discharge, death, or pressure ulcer healing. All studies had a prospective, randomized controlled design, including one control group and one or two experimental groups. The studies included patients in acute, postacute, or long-term care. A total of 8003 patients were included in the 16 studies (range, 62 to 1972 patients), either at risk of developing pressure ulcers, or presenting with existing pressure ulcers. The approximate mean age of the study population was 72 years (range, 64 to 84 years). Studies assessing the efficacy of support surfaces to prevent pressure ulcers used pressure ulcer incidence and pressure ulcer severity as main outcomes. Studies evaluating the effectiveness of support surfaces for pressure ulcer treatment used time to complete healing, change in pressure ulcer area or volume over time, or healing rate as outcome measures. Also, some studies evaluated comfort perception, nutritional status, interface pressure, functional capacity, or cost-effectiveness of the interventions. Standardized risk assessment tools were used. All studies used blinded randomization procedures to ensure allocation concealment. After randomization, blinding of patients and nursing staff was difficult given obvious differences between support surfaces. Some studies used independent investigators for analysis of the data, while others were single blind.

Prevention and management of pressure ulcers was the objective of the 16 selected RCTs comparing efficacy of high- or low-tech support surfaces. The studies evaluated the following comparisons:

Low-tech support surfaces:

- Viscoelastic polyurethane (VEP) foam mattress versus standard hospital mattress (Russell et al., 2003; Gunningberg et al., 2000; Defloor et al., 2005).
- Transfoam Wave mattress versus Transfoam mattress (Gray and Smith, 2000).
- Foam block mattress versus standard hospital mattress (Berthe et al., 2007).
- Standard hospital mattress with or without an Australian medical sheepskin overlay (Jolley et al., 2004).
- Three heel protector cushions (bunny boot; egg crate; foot waffle) versus each other (Gilcreast et al., 2005).

High-tech and low-tech support surfaces:

- Double- or single-layer alternating pressure overlay versus standard hospital mattress (Sanada et al., 2003).
- Alternating pressure mattress versus VEP foam mattress (Vanderwee et al., 2005).
- Alternating pressure mattress versus standard hospital bed (Russell and Lichtenstein, 2000).
- High-tech mattress with alternating pressure and continuous low-pressure modes versus high-specification foam mattress (Cavicchioli and Carella, 2007).
- Profiling bed with pressure-reducing foam mattress versus flat-base bed with pressure reducing foam mattress (Keogh and Dealey, 2001).
- Standard operating room table (water-filled warming mattress) with or without a VEP foam overlay (Feuchtinger et al., 2006).
- Generic total contact seats versus low-air-loss bed or medium-density open-cell VEP foam overlay (Rosenthal et al., 2003).

High-tech support surfaces:

- Alternating pressure mattress versus a standard mattress with an alternating pressure overlay (Nixon et al., 2006a).
- High-tech stand-alone bed unit with low air-loss mattress versus standard ICU bed/mattress configuration (high-tech mattress with alternating pressure and continuous lowpressure modes on standard ICU bed) (Theaker et al., 2005).

Efficacy:

High-Specification Foam Support Surfaces:

Three studies, including 2107 patients, compared efficacy of a VEP mattress versus a standard hospital mattress to prevent pressure ulcers (Gunningberg et al., 2000; Russell et al., 2003; Defloor et al., 2005).

On behalf of the British Prevention of Pressure Ulcers (PPUS-1) Study Group, Russell et al. (2003) compared the use of a VEP foam mattress versus a standard hospital mattress among > 1000 acute care elderly patients, assessing pressure ulcer incidence. A significantly lower incidence rate of stage 1 pressure ulcers was shown in patients on a VEP mattress compared with patients on a standard hospital mattress (26.7% versus 19.6%; $P=0.004$). A difference between groups regarding stage 2 pressure ulcer incidence rates was not statistically significant (41.0% versus 43.6%; $P=0.66$) (Russell et al., 2003). Defloor et al. (2005) compared four different preventive regimes involving either frequent turning (2-, 3-hourly) or the use of a VEP mattress with less frequent turning (4-, 6-hourly). This study included 838 geriatric nursing home patients. There was no significant difference between groups regarding grade 1 pressure ulcer incidence. However, the incidence of grade 2 or higher pressure ulcers in the VEP mattress group (3%) was significantly lower compared with incidence rates in the other groups, varying between 14.3% and 24.1% (Defloor et al., 2005).

Swedish investigators investigated efficacy of VEP and standard hospital mattresses among 101 patients with hip fractures preoperatively, peri-operatively, and post-operatively. No difference in pressure ulcer incidence between the study groups was found. However, there was a trend of more serious pressure ulcers in control patients (Gunningberg et al., 2000).

One study including 447 patients compared efficacy of a VEP foam mattress combined with a 4-hour turning protocol, versus an alternating pressure air mattress for prevention of pressure ulcers. In this Belgian multicenter study the two study groups had similar pressure ulcer (grade 2 to 4) incidence rates, i.e., 15.6% versus 15.3% ($P=1$). However, there were significantly more heel pressure ulcers in the VEP foam mattress group compared with the alternating pressure air mattress group (45.7% versus 14.7%; $P=0.006$) (Vanderwee et al., 2005).

One study including 175 cardiac surgery patients compared efficacy of a VEP foam overlay on an operating room table with a standard operating room table configuration (operating room table with water-filled warming mattress) A stipulated interim analysis population was set at 175 patients. In this population, pressure ulcer incidence was 11.1% for the standard table group and 17.6% for the VEP foam overlay table group (chi-square test, $P=0.22$). The study executives and data monitoring committee decided to halt the study. The majority of the observed pressure ulcers were skin changes from grade 0 preoperatively to grade 1 postoperatively (88%). The others were grade 2 ulcers. Of the

17 pressure ulcers that were grade 1 immediately after the surgical procedure, 14 had resolved by postoperative day 1 (Feuchtinger et al., 2006).

Three studies investigated the efficacy of a high specification foam mattress other than VEP, compared with a standard hospital mattress (Berthe et al., 2007), another high-specification foam mattress (Gray and Smith, 2000), and a high-tech mattress (Cavicchioli and Carella, 2007).

Belgian investigators compared the efficacy of a foam block mattress versus a standard hospital mattress among 1729 clinical patients. The foam block mattress has never been used in the United States. The overall pressure ulcer incidence rate was low (2.4%) with no difference between the two study groups; pressure ulcer incidence rates were 3.2% versus 1.9% in the foam block mattress and control mattress group, respectively. Time to develop a pressure ulcer was delayed on the experimental mattress compared with the standard hospital mattress (31 days versus 18 days; $P > 0.001$) (Berthe et al., 2007).

A small British study with 100 patients compared the efficacy of two types of Transfoam mattresses in a hospital setting (Gray and Smith, 2000). Given the small study size and low overall pressure ulcer incidence rate (2%), the investigators could not statistically analyze the findings.

The effectiveness of a high-specification foam mattress versus a high-tech mattress with alternating pressure and continuous low-pressure modes was investigated by Italian investigators in 173 high-risk patients. The high tech mattress was more effective than the high-specification foam mattress in preventing pressure ulcers; a 36.4% incidence of new grade 1 pressure ulcers was observed in the foam mattress group, versus 2.5% and 1.4% in the alternating pressure and continuous low-pressure study groups, respectively. During the 2-week follow-up, none of the preexisting pressure ulcers of patients on the foam mattresses healed, whereas 33% to 100% of the preexisting pressure ulcers of patients on the high-tech mattress healed (Cavicchioli and Carella, 2007). Lack of statistical power and serious methodological flaws limit the interpretation of these findings.

Alternating Pressure Surfaces:

Six studies compared an alternating pressure support surface with standard hospital support surfaces or other high-tech support surfaces (Russell and Lichtenstein, 2000; Sanada et al., 2003; Theaker et al., 2005; Vanderwee et al., 2005; Nixon et al., 2006a; Cavicchioli and Carella, 2007).

Canadian investigators compared pressure ulcer incidence among 198 cardiovascular surgery patients randomized to conventional management (gel pad during operation followed by standard hospital mattress) or an alternating pressure mattress pre-, peri- and postoperatively (Russell and Lichtenstein, 2000). There was a trend of more pressure ulcers among patients receiving conventional management compared with those using alternating pressure mattresses, but the difference was not significant.

An Italian study including 173 high-risk patients compared high-specification foam with alternating low pressure mattresses and with continuous low-pressure mattresses. A high-tech mattress was more effective than a high-specification foam mattress in preventing pressure ulcers; a 36.4% incidence of new grade 1 pressure ulcers was observed in the foam mattress group, versus 2.5% and 1.4% in the alternating pressure and continuous low-pressure study groups, respectively. The two low-pressure modes of the high-tech mattress were similarly effective in preventing pressure ulcers. During the 2-week

follow-up, 33% and 100% of preexisting pressure ulcers healed in the alternating pressure and continuous low-pressure study groups, respectively (Cavicchioli and Carella, 2007). Lack of statistical power and serious methodological flaws limit the interpretation of these findings.

A multicenter Belgian study with 447 patients compared efficacy of a VEP foam mattress combined with a 4-hour turning protocol versus an alternating pressure air mattress for prevention of pressure ulcers. This study did not show a significant difference in pressure ulcer incidence (grade 2 to 4) between the two study groups (15.6% in alternating pressure group, 15.3% in VEP foam group; $P=1.0$) (Vanderwee et al., 2005).

A Japanese study evaluated efficacy of three support surfaces to prevent pressure ulcers: a double-layer air-cell alternating pressure overlay; a single-layer air-cell alternating pressure overlay; and a standard hospital bed. The study included 82 bed-bound patients from a general hospital ward with a Braden scale score of ≤ 16 , requiring head elevation. A significantly lower percentage of patients using the double-layer air-cell overlay developed pressure ulcers (3.4%), compared with 19.2% and 37% for those patients using the single-layer air-cell overlay and standard hospital mattress, respectively. The difference in pressure ulcer incidence between the double-layer air-cell overlay and single-layer air-cell overlay was not significant. The pressure ulcers for all groups were either stage 1 or 2 (Sanada et al., 2003).

Nixon et al. presented findings of the Pressure Relieving Support Surfaces trial (PRESSURE), a multicenter RCT conducted in 11 hospitals in 6 UK National Health Service (NHS) trusts. This study included 1972 hospitalized patients randomized to an alternating pressure mattress or an alternating pressure overlay. The proportion of patients developing a new pressure ulcer of grade 2 or more was similar in both study groups (10.7% in overlay group, 10.3% in mattress group; $P=0.75$). At randomization 113 patients had pressure ulcers; of these, 35% healed during the trial: 34% in the overlay group, 35% in the mattress group. No statistically significant difference was found between the groups for median time to healing (20 days in both groups; $P=0.86$) (Nixon et al., 2006a).

A high-tech stand-alone bed unit with an incorporated low air-loss mattress was compared with a standard ICU bed configuration (including mattress with alternating pressure and continuous low-pressure mode) in a small study including 62 critically ill ICU patients. Three patients developed a pressure ulcer on the stand-alone bed unit, versus 6 patients on the standard ICU configuration. This difference was not significant. Eight patients developed a grade 2 or 3 pressure ulcer on their heel (Theaker et al., 2005). Whether alternating pressure or continuous low pressure was more effective in reducing the pressure ulcer incidence in these high-risk patients was not investigated.

Bed Units:

Two small British studies compared efficacy of a bed unit (bed plus mattress) to prevent pressure ulcers (Keogh and Dealey, 2001; Theaker et al., 2005).

One small study including 70 hospitalized patients investigated the efficacy of a profiling bed covered with a pressure-reducing foam mattress (experimental group), compared with a standard flat-base hospital bed covered with a pressure-reducing foam or a pressure-redistributing alternating mattress (control group). During the short follow up (5 to 10 days) none of the patients developed a pressure ulcer. In the experimental group 4 patients (11.4%) had a grade 1 pressure ulcer on initial assessment; all ulcers healed

during follow-up. In the control group 10 patients (28.5%) had a grade 1 pressure ulcer on initial assessment, 2 of which healed during follow-up (Keogh and Dealey, 2001). The study was underpowered to compare pressure ulcer incidence rates.

Prevention of pressure ulcers among ICU patients was investigated by Theaker et al. (2005). They compared a high-tech profiling bed with an incorporated low-air-loss mattress with a standard ICU bed configuration (including mattress with alternating pressure and continuous low pressure mode). The study included 62 critically ill ICU patients. Three patients developed a pressure ulcer on the stand-alone bed unit, versus 6 patients on the standard ICU configuration. This difference was not significant (see also Alternating pressure surfaces) (Theaker et al., 2005).

Australian Medical Sheepskin Mattress Overlay:

Australian investigators examined the efficacy of an Australian medical sheepskin in preventing pressure ulcers. A hospital population including 441 patients was randomly allocated to receive a sheepskin mattress overlay for the duration of their hospital stay or a standard hospital mattress with or without other low-tech pressure-reducing support surfaces. Pressure ulcer incidence was significantly lower in the sheepskin group than in the control group. All pressure ulcers were grade 1 or 2 ulcers (Jolley et al., 2004).

Heel Pressure Relief Devices:

One study compared three heel pressure relief devices to prevent heel ulcers. A total of 240 moderate- to high-risk patients were randomly assigned to a High-Cushion Kodel Heel Protector (bunny boot), Egg Crate Heel Lift Positioner (egg crate), or EHOB Foot Waffle Air Cushion (foot waffle), all available in the United States.

Three ulcers occurred in 77 (3.9%) patients wearing the bunny boot, 4 developed in 87 (4.6%) wearing the egg crate, and 5 occurred in 76 (6.6%) wearing the foot waffle. Differences between groups were not significant (Gilcreast et al., 2005). The study was confounded by nurses adding pillows to the bunny boot group.

Therapeutic Seats:

American researchers compared the healing rate of advanced pressure ulcers using a generic contact seat or low-air-loss bed treatment among 207 long-term care patients. Rosenthal et al. (2003) presented findings of two separate RCTs. The effect of a therapeutic seat versus total bed rest on stage 3 and 4 pressure ulcer healing rates was investigated. The first study randomized patients to 4 hours per day sitting on a generic total contact seat (GTCS), lying on a low-air-loss bed, or upgraded bed overlay. In the second study patients were allocated to a GTCS or a low-air-loss bed. Patients were followed for 6 months or until they were totally healed. After 4 weeks, pressure ulcer status scores were lowest for the GTCS group compared with the other surfaces ($P < 0.0001$). Total healing of pressure ulcers occurred as early as 4 weeks in 8 patients using a GTCS, and in none of the other patients. Even at 8 weeks, total healing was primarily seen with use of the seat. Consequently, the total time to healing differed between groups: 3.33 ± 0.12 months in the GTCS groups; 4.38 ± 0.14 months in the low-air-loss groups; and 4.55 ± 0.22 months in the overlay group. The use of a GTCS promoted total healing of stage 3 or 4 pressure ulcers compared with low-air-loss bed treatments (Rosenthal et al. 2003).

Efficacy According to Wound Severity:

The majority of new ulcers were classified as grade 1 or grade 2 pressure ulcers. Most statistical analyses pooled new ulcers, irrespective of wound severity. Only two studies

performed separate analyses for grade 1 and grade 2 ulcers (Russell et al., 2003; Defloor et al., 2005). Both studies compared efficacy of a VEP mattress versus a standard hospital mattress to prevent pressure ulcers. The first study showed a significantly lower incidence rate of stage 1, but not of stage 2, pressure ulcers in patients on a VEP mattress compared with patients on a standard hospital mattress. The second study showed a significantly lower incidence rate of stage 2, but not of stage 1, pressure ulcers in patients on a VEP mattress compared with patients randomized to the standard mattress/frequent turning protocol. These findings provide contradictory evidence with respect to efficacy of preventive pressure ulcer support surfaces according to wound severity.

Comfort Perception:

Eight studies assessed patient comfort perception of the support surfaces (Gray and Smith, 2000; Gunningberg et al., 2000; Keogh and Dealey, 2001; Russell et al., 2003; Jolley et al., 2004; Gilcreast et al., 2005; Nixon et al., 2006a; Cavicchioli and Carella, 2007).

Patients perceived a traditional Transfoam mattress as similarly comfortable as a more advanced Transfoam Wave mattress (Gray and Smith, 2000). Also, a standard hospital mattress was perceived as similarly comfortable as a VEP mattress (Gunningberg et al., 2000; Russell et al., 2003). Patients on a standard flat-base bed complained considerably more about slipping down the bed than patients on a profiling bed (Keogh and Dealey, 2001).

In a study comparing the use of an alternating pressure mattress versus an alternating overlay, more patients in the overlay group requested one or more changes for comfort and other device-related reasons (23.3% in the overlay group versus 18.9% in the mattress group; $P=0.02$) (Nixon et al., 2006a).

In a study comparing alternating support surfaces with a standard mattress, almost 5% of patients allocated to an alternating low-pressure or continuous low pressure mattress did not complete the study because of noncompliance. There was no difference in the number of dropouts between the alternating pressure and continuous low-pressure groups (Cavicchioli and Carella, 2007).

Compliance in wearing a heel device to prevent pressure ulcers was an issue in a study by Gilcreast et al (2005). Approximately 16% of patients did not wear the prevention device for at least 48 hours, and another 15% of patients did not comply in wearing the device during the study. Patients stated that the devices did not allow them to move as freely in the bed as they would like. Among patients using sheepskin overlays to prevent pressure ulcers, almost 5% complained about its comfort (too hot, sensitive to wool, uncomfortable) and requested removal (Jolley et al., 2004).

Adverse Events

The PRESSURE trial reported incidental device-related adverse events (Nixon et al., 2006a; Nixon et al, 2006b): 4 falls from an alternating pressure mattress; 3 cot-side incidents (2 patients on an alternating pressure overlay and 1 patient on an alternating pressure mattress); 1 suspected contact dermatitis in a patient on a mattress; and 1 incident where a patient caught his/her back on the bed rail as the mattress deflated during transfer. No other studies reported device-related adverse events.

Average Hospital Length of Stay:

The length of hospital stay is generally prolonged if pressure ulcers occur; therefore, pressure-relieving surfaces have the potential to decrease length of stay in patients at high

risk of pressure ulcers. However, a significant impact on hospital length of stay was not demonstrated in the reviewed studies.

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APPENDIX I DESCRIPTIONS OF SPECIFIC SUPPORT SURFACES

Air-fluidized support: Membranes that cover a layer of particles that are fluidized by having air forced through them. The airflow can be turned off, which makes the surface solid again, to allow the person to be moved. People find it difficult to get in and out of these beds independently; therefore, they are usually reserved for individuals who spend most of the day in bed.

Alternating pressure surface: Electronically powered mattresses or overlays made of one or two layers of parallel air sacs. Alternate sacs are inflated and deflated, providing alternating pressure and release for each area of skin.

Dynamic surface: Surface designed to change its support characteristics in a cyclic fashion.

Low-air-loss support: Mattresses that consist of inflatable upright sacs of semipermeable fabric. Inflation of the sacs increases the area of contact between the individual and the support surface and reduces the pressure on the skin. People find it difficult to get in and out of these beds independently; therefore, they are usually reserved for individuals who spend most of the day in bed.

Low-air-loss hydrotherapy beds: A mattress that consists of cushions covered by a permeable, fast-drying filter sheet, through which air is circulated. The bed also contains a urine-collecting device.

Mattress replacement system: Mattress with pressure-reducing or pressure-relieving features that can be placed on an existing bed frame. The mattress is at least 8 inches thick.

Overlay: Support surface placed on top of a standard hospital mattress.

Pressure-reducing surface: Static or dynamic surface that reduces pressure from the level found with a standard mattress or (wheelchair) cushion, but does not consistently maintain interface pressures below normal capillary closing pressures.

Pressure-relieving surface: Surface that consistently maintains interface pressures below normal capillary closing pressures. Pressure-relieving devices are always dynamic.

Profiling beds (turning beds/frames): Beds that either aid manual repositioning of the patient or repositioning of the patient by motor-driven turning and tilting.

Static surface: Surface designed to provide support that remains constant, i.e., does not cycle in time.

Total contact seat: Seat that redistributes weight from pressure-sensitive bony prominences onto less pressure-sensitive areas.