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Pressure Ulcer Prevention

An Evidence-Based Analysis

April 2009

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About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series*.

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practising medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

If you are aware of any current additional evidence to inform an existing evidence-based analysis, please contact the Medical Advisory Secretariat: MASinfo.moh@ontario.ca. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html.

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Executive Summary

In April 2008, the Medical Advisory Secretariat began an evidence-based review of the literature concerning pressure ulcers.

Please visit the Medical Advisory Secretariat Web site, http://www.health.gov.on.ca/english/providers/program/mas/tech/tech_mn.html to review these titles that are currently available within the Pressure Ulcers series.

1. *Pressure ulcer prevention: an evidence based analysis*
2. *The cost-effectiveness of prevention strategies for pressure ulcers in long-term care homes in Ontario: projections of the Ontario Pressure Ulcer Model (field evaluation)*
3. *Management of chronic pressure ulcers: an evidence-based analysis (anticipated pubicstion date - mid-2009)*

Purpose

A pressure ulcer, also known as a pressure sore, decubitus ulcer, or bedsore, is defined as a localized injury to the skin/and or underlying tissue occurring most often over a bony prominence and caused by pressure, shear, or friction, alone or in combination. (1) Those at risk for developing pressure ulcers include the elderly and critically ill as well as persons with neurological impairments and those who suffer conditions associated with immobility. Pressure ulcers are graded or staged with a 4-point classification system denoting severity. Stage I represents the beginnings of a pressure ulcer and stage IV, the severest grade, consists of full thickness tissue loss with exposed bone, tendon, and or muscle. (1)

In a 2004 survey of Canadian health care settings, Woodbury and Houghton (2) estimated that the prevalence of pressure ulcers at a stage 1 or greater in Ontario ranged between 13.1% and 53% with nonacute health care settings having the highest prevalence rate (Table 1).

Executive Summary Table 1: Prevalence of Pressure Ulcers*

Setting	Canadian Prevalence, % (95% CI)	Ontario Prevalence, Range % (n)
Acute care	25 (23.8–26.3)	23.9–29.7 (3418)
Nonacute care†	30 (29.3–31.4)	30.0–53.3 (1165)
Community care	15 (13.4–16.8)	13.2 (91)
Mixed health care‡	22 (20.9–23.4)	13.1–25.7 (3100)
All health care settings	26 (25.2–26.8)	13.1–53.3 (7774)

*CI indicates confidence interval.

†Nonacute care included sub-acute care, chronic care, complex continuing care, long-term care, and nursing home care.
‡Mixed health care includes a mixture of acute, nonacute, and/or community care health care delivery settings.

Pressure ulcers have a considerable economic impact on health care systems. In Australia, the cost of treating a single stage IV ulcer has been estimated to be greater than $61,000 (AUD) (approximately $54,000 CDN), (3) while in the United Kingdom the total cost of pressure ulcers has been estimated at £1.4–£2.1 billion annually or 4% of the National Health Service expenditure. (4)

Because of the high physical and economic burden of pressure ulcers, this review was undertaken to determine which interventions are effective at preventing the development of pressure ulcers in an at-risk population.

Review Strategy

The main objective of this systematic review is to determine the effectiveness of pressure ulcer preventive interventions including Risk Assessment, Distribution Devices, Nutritional Supplementation, Repositioning, and Incontinence Management.

A comprehensive literature search was completed for each of the above 5 preventive interventions. The electronic databases searched included MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature. As well, the bibliographic references of selected studies were searched. All studies meeting explicit inclusion and exclusion criteria for each systematic review section were retained and the quality of the body of evidence was determined using the Grading of Recommendation Assessment, Development, and Evaluation (GRADE) system. (5) Where appropriate, a meta-analysis was undertaken to determine the overall estimate of effect of the preventive intervention under review.

Summary of Findings

Risk Assessment

There is very low quality evidence to support the hypothesis that allocating the type of pressure-relieving equipment according to the person's level of pressure ulcer risk statistically decreases the incidence of pressure ulcer development. Similarly, there is very low quality evidence to support the hypothesis that incorporating a risk assessment into nursing practice increases the number of preventative measures used per person and that these interventions are initiated earlier in the care continuum.

Pressure Redistribution Devices

There is moderate quality evidence that the use of an alternative foam mattress produces a relative risk reduction (RRR) of 69% in the incidence of pressure ulcers compared with a standard hospital mattress. The evidence does not support the superiority of one particular type of alternative foam mattress.

There is very low quality evidence that the use of an alternating pressure mattress is associated with an RRR of 71% in the incidence of grade 1 or 2 pressure ulcers. Similarly, there is low quality evidence that the use of an alternating pressure mattress is associated with an RRR of 68% in the incidence of deteriorating skin changes.

There is moderate quality evidence that there is a statistically nonsignificant difference in the incidence of grade 2 pressure ulcers between persons using an alternating pressure mattress and those using an alternating pressure overlay.

There is moderate quality evidence that the use of an Australian sheepskin produces an RRR of 58% in the incidence of pressure ulcers grade 1 or greater. There is also evidence that sheepskins are uncomfortable to use. The Pressure Ulcer Advisory Panel noted that, in general, sheepskins are not a useful preventive intervention because they bunch up in a patient's bed and may contribute to wound infection if not properly cleaned, and this reduces their acceptability as a preventive intervention.

There is very low quality evidence that the use of a Micropulse System alternating pressure mattress used intra operatively and postoperatively produces an RRR of 79% in the incidence of pressure ulcers compared with a gel-pad used intraoperatively and a standard hospital mattress used postoperatively (standard care). It is unclear if this effect is due to the use of the alternating pressure mattress intraoperatively or postoperatively or if indeed it must be used in both patient care areas.

There is low quality evidence that the use of a vesico-elastic polymer pad (gel pad) on the operating table for surgeries of at least 90 minutes' duration produces a statistically significant RRR of 47% in the incidence of pressure ulcers grade 1 or greater compared with a standard operating table foam mattress.

There is low quality evidence that the use of an air suspension bed in the intensive care unit (ICU) for stays of at least 3 days produces a statistically significant RRR of 76% in the incidence of pressure ulcers compared with a standard ICU bed.

There is very low quality evidence that the use of an alternating pressure mattress does not statistically reduce the incidence of pressure ulcers compared with an alternative foam mattress.

Nutritional Supplementation

There is very low quality evidence supporting an RRR of 15% in the incidence of pressure ulcers when nutritional supplementation is added to a standard hospital diet.

Repositioning

There is low quality evidence supporting the superiority of a 4-hourly turning schedule with a vesico-elastic polyurethane foam mattress compared with a 2-hourly or 3-hourly turning schedule and a standard foam mattress to reduce the incidence of grade 1 or 2 pressure ulcers.

Incontinence Management

There is very low quality evidence supporting the benefit of a structured skin care protocol to reduce the incidence of grade 1 or 2 pressure ulcers in persons with urinary and/or fecal incontinence.

There is low quality evidence supporting the benefit of a pH-balanced cleanser compared with soap and water to reduce the incidence of grade 1 or 2 pressure ulcers in persons with urinary and fecal incontinence.

Conclusions

There is moderate quality evidence that an alternative foam mattress is effective in preventing the development of pressure ulcers compared with a standard hospital foam mattress.

However, overall there remains a paucity of moderate or higher quality evidence in the literature to support many of the preventive interventions. Until better quality evidence is available, pressure ulcer preventive care must be guided by expert opinion for those interventions where low or very low quality evidence supports the effectiveness of such interventions.

Abbreviations

CI	Confidence interval
GRADE	Grading of Recommendation Assessment, Development, and Evaluation
ICU	Intensive care unit
MAS	Medical Advisory Secretariat
NPUAP	National Pressure Ulcer Advisory Panel
RAS	Risk assessment scale
RCT	Randomized controlled trial
RNAO	Registered Nurses Association of Ontario
RR	Relative risk
RRR	Relative risk reduction

Systematic Review

Overall Objective

The main objective of this systematic review is to determine the effectiveness of pressure ulcer preventive interventions. The following preventive interventions are reviewed in this report:

1. Risk Assessment
2. Distribution Devices
3. Nutritional Supplements
4. Repositioning
5. Incontinence Management

Methods

A comprehensive literature search was completed for each of the above 5 preventive interventions. The electronic databases searched included MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature. In addition, the bibliographic references of selected studies were searched. All search strategies are presented in full in Appendices 1 through 5. After a review of the title and abstracts, relevant studies were obtained and the full report evaluated. All studies meeting explicit inclusion and exclusion criteria for each preventive intervention systematic review section were retained and the quality of the body of evidence, defined as 1 or more relevant studies, was determined using GRADE. (5) Where appropriate, a meta-analysis was undertaken to determine the overall estimate of effect of the preventive intervention under review.

Assessment of Quality of Evidence

The quality of the body of evidence was examined according to the GRADE Working Group criteria. (5) Quality refers to criteria such as the adequacy of allocation concealment, blinding, and losses to follow-up and completion of an intention to treat analysis. Consistency refers to the similarity of effect estimates across studies. If there is important unexplained inconsistency in the results, confidence in the estimate of effect for that outcome decreases. Differences in the direction of effect, the size of the effect, and the significance of the differences guide the decision about whether important inconsistency exists. Directness refers to the extent to which the interventions, population, and outcome measures are similar to those of interest.

The GRADE Working Group used the following definitions in grading the quality of the evidence:

High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

Results of Evidence-Based Analyses

The following results of the evidence-based analysis for each preventive intervention will be reported:

- results of literature search
- characteristics of included studies
- quality assessment of individual studies
- results including meta-analysis (where applicable)
- GRADE evidence profile
- summary of results

Risk Assessment Scales

Research Question

The literature was searched to determine the effect of using a pressure ulcer risk assessment tool on the incidence of pressure ulcers. The search strategy is presented in Appendix 1.

Methods

Inclusion Criteria

- systematic reviews (with/without meta-analysis), randomized controlled trials (RCTs), and nonrandomized controlled clinical trials
- studies involving a population at risk for developing pressure ulcers
- studies evaluating the use of any risk assessment scale (RAS) for pressure ulcer development compared with not using an RAS or with clinical judgment
- studies reporting the incidence of new pressure ulcer measured as the number (proportion) of persons developing a new pressure ulcer
- studies reporting the stage of pressure ulcer or in which the stage can be inferred from the description of the ulcer

Exclusion Criteria

- studies determining the validity and reliability properties of an RAS
- studies reporting only the number of pressure ulcers (number of wounds) as an outcome measure

Primary Outcome Measure

The primary outcome measure was the incidence of pressure ulcers measured as the number (proportion) of persons developing a new pressure ulcer.

Results of Literature Search

Two systematic reviews (6;7) and 3 non-RCT studies (8-10) were obtained from the literature search strategy (Table 1). The objective of both systematic reviews was to determine the effectiveness of using a pressure ulcer RAS to reduce the incidence of pressure sores. McGough (6) searched the literature up to June 1997, and Pancorbo-Hidalgo et al. (7) searched up to 2003. McGough (6) limited the literature search to RCT designs and reported that there were no RCTs found that determined the effectiveness of RASs on the incidence of pressure ulcers. Pancorbo-Hidalgo et al. (7) did not limit their search to a specific study design and found 3 non-RCTs. The Medical Advisory Secretariat completed an updated literature search from 2003 to February 2008 and did not find additional studies to add to the body of evidence reported by Pancorbo-Hidalgo et al. (7) What follows is a report and evaluation of the 3 non-RCT studies described in the systematic review by Pancorbo-Hidalgo et al. (7)

Table 1: Quality of Evidence of Included Studies – Risk Assessment*

Study Design	Level of Evidence†	Number of Eligible Studies	MAS Update to Systematic Review
Systematic reviews of RCT	1	2	0
or			
Large RCT	1		
Large RCT unpublished but reported to an international scientific meeting	1(g)		0
Small RCT	2		0
Small RCT unpublished but reported to an international scientific meeting	2(g)		0
Non-RCT with contemporaneous controls	3a	3	0
Non-RCT with historical controls	3b		0
Non-RCT presented at international conference	3(g)		0
Surveillance (database or register)	4a		0
Case series (multisite)	4b		0
Case series (single site)	4c		0
Retrospective review, modeling	4d		0
Case series presented at international conference	4(g)		0

*MAS indicates Medical Advisory Secretariat; RCT, randomized controlled trial.
†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (11) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meeting. (11)

Characteristics of Included Studies

Table 2 reports the characteristics of the studies included in this systematic review. Gunningberg et al. (9) used a prospective controlled study design (contemporaneous controls), whereas the studies completed by both Hodge et al. (10) and Bale (8) used a before-and-after study design. The mean ages in this body of evidence ranged from 60 to 80 years. All studies used different RASs as well as different pressure ulcer classification systems to measure the study outcome. The characteristics of the RASs used are reported in Table 3.

Table 2: Characteristics of Included Studies – Risk Assessment*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Gunningberg et al.,1999 Prospective controlled design Consecutive admissions	124	Persons with hip fractures Mean age: 82 y	n = 58 Daily risk assessment score (RAS) completed on all participants. All patients with a Modified Norton Scale of < 21 (considered high risk for developing a pressure ulcer) were identified with a risk alarm sticker stating "Pressure ulcer prevention; active nursing care"	n = 66 Participants in this group received ordinary pressure prevention (e.g., cushions, turning) and no RAS was competed	Discharge and 2 weeks post operatively	Number of persons with new pressure ulcers Surrey Pressure Ulcer Classification system
Bale, 1995 Before-and-afterstudy design Consecutive admissions	223	Palliative care/ hospice setting Mean age: 67 y (*SD ±12)	n = 104 (phase 2) Participants in this group received a pressure support system allocated according to the Adapted Norton RAS where persons with a score of: i) ≤ 10 received a hollow core fiber overlay ii) 11–15 received an alternating air mattress overlay iii) ≥ 16 received an alternating pressure mattress This group also received ordinary pressure prevention (cushions, regular repositioning)	n = 161 (phase 1) Participants in this group received a hollow core fiber overlay or at the request of the patient continued using the same overlay/mattress used before admission. If they were considered by the nurse to be at high risk, a more sophisticated alternating pressure mattress replacement was allocated. Allocation was based on the opinion of the attending nurse and not on the results of an RAS. This group also received ordinary pressure prevention (cushions, regular repositioning).	Risk assessment was done every 48 hours for each group until participant died or was discharged Mean follow-up: 12 days	Number of persons with new pressure ulcers Torrence Pressure Ulcer Classification system

(continued)

Table 2: Characteristics of Included Studies – Risk Assessment (continued)*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Hodge et al., 1990 Before-and-after study design Consecutive enrollment	181	Neuro-surgery, general medicine, orthopedic, and oncology units Median age range: 60–69 y	n = 89 (phase 2) Norton Risk Assessment Scale used Staff received 3 weeks of training and education on the use of the Norton Scale before using it	n = 92 (phase 1) Standard care No RAS used	10 days	Number of preventive interventions per patient Number of persons with worsening skin condition Shea Classification System

*SD indicates standard deviation

Table 3: Characteristics of the Risk Assessment Scales

Study	Risk Assessment Scale	Scale Variables
Gunningberg et al., 1999	Modified Norton	Mental condition Physical activity Mobility Food intake Fluid intake Incontinence General physical condition
Bale, 1995	Adapted Norton	General physical condition Mobility Nutritional status Pain continence Special risk factors
Hodge et al., 1990	Norton	Physical condition Mental condition Activity Mobility Incontinence

Quality Assessment of Included Studies

The quality assessment for each of the 3 studies included in this review is reported in Table 4. Gunningberg et al. (9) used a prospective controlled study design with consecutive sampling and an alternate allocation scheme to assign participants to either the treatment or control interventions. Important study limitations included that the outcome measure of new pressure ulcers was not assessed independently of the treatment exposure status and that there was greater loss to follow-up in the control group compared with the treatment group at both discharge (41% vs. 8%, respectively) and 2 weeks postoperatively (53% vs. 26%, respectively). This latter limitation could possibly account for the lack of a statistically significant difference in the incidence of pressure ulcers between treatment groups.

Bale (8) used a before-and-after study design with consecutive enrollment and therefore the participants allocated to phase 1 (control) were different than those allocated to phase 2 (treatment). Major methodological limitations included the use of an adaptive version of the Norton RAS that had not been

validated, and, like Gunningberg et al., (9) an outcome measure that was not assessed independently of the treatment exposure status. Interestingly, however, the patients in phase 2 (treatment) had higher risk assessment scores, indicating an increased risk for developing a pressure ulcer, than participants in phase 1 (control). It is likely this would have biased the results in favor of fewer pressure ulcers in the control group; however, instead there were statistically significantly more new pressure ulcers in the control group compared with the treatment group (22.4% vs. 2.5%).

Hodge et al. (10) also used a before-and-after study design with consecutive enrollment. Therefore, there were different participants allocated between phase 1 (control) and phase 2 (treatment). Hodge et al. did not report the incidence of pressure ulcers as a primary outcome but instead the purpose of the study was to investigate the effect on nursing practice and patients' skin condition of using an RAS compared with not using an RAS. This was a well-conducted study with few if any methodological limitations biasing the study results. Unlike Gunningberg et al. (9) and Bale, (8) Hodge et al. (10) did assess the outcome measure independently of the treatment exposure status. In phase 1 the nurses caring for the study participants were unaware of the purpose of the study. In phase 2, the Norton RAS was done independently from the collection of the outcome measure (number of treatment interventions per patient). Finally, a standardized checklist of nursing interventions was used for data collection.

Table 4: Individual Study Quality Assessment – Risk Assessment*

Study	Inclusion/ Exclusion Criteria Stated	Consecutive Sampling Used	Are Baseline Characteristics in Groups Similar?	Is Treatment Valid and Reliable?	Is a Reliable and Valid Outcome Measure Used?	Is Outcome Measure Done Independently of Exposure Status?	Is Duration of Follow-Up Adequate?	Loss to Follow-Up, %
Gunningberg et al., 1999	✓	✓ Floor 1 was allocated to treatment and floor 2 to control. Each floor was sent every fourth patient with a hip fracture as a study participant.	✓ There were no significant differences in age or gender between groups.	✓ Modified Norton RAS	✓	x	✓	x Total study population: 26% loss to follow-up at discharge 40% loss to follow-up at 2 weeks postop By group: loss to follow-up at 2 weeks 53% in control group and 26% in treatment group Loss to follow-up at discharge 8% in treatment group and 41% in control group

Table 4: Individual Study Quality Assessment – Risk Assessment (continued)*

Study	Inclusion/ Exclusion Criteria Stated	Consecutive Sampling Used	Are Baseline Characteristics in Groups Similar?	Is Treatment Valid and Reliable?	Is a Reliable and Valid Outcome Measure Used?	Is Outcome Measure Done Independently of Exposure Status?	Is Duration of Follow-Up Adequate?	Loss to Follow-Up, %
Bale, 1995	✓	✓	✓ Demographic details of the patients did not differ between the 2 phases. Both groups were well matched for age, total days studied, and reason for terminating the study. There was a higher percentage of men included in phase 2 than in phase 1. Women were noted to have a 2-fold chance of developing pressure sores. Patients in phase 2 had higher risk assessment scores (increased risk of pressure ulcers) than in phase 1. This should have biased results in favor of less pressure ulcers in the control group.	x The RAS had not been formally evaluated in its modified form.	✓	x	✓	0

Table 4: Individual Study Quality Assessment – Risk Assessment (continued)*

Study	Inclusion/ Exclusion Criteria Stated	Consecutive Sampling Used	Are Baseline Characteristics in Groups Similar?	Is Treatment Valid and Reliable?	Is a Reliable and Valid Outcome Measure Used?	Is Outcome Measure Done Independently of Exposure Status?	Is Duration of Follow-Up Adequate?	Loss to Follow-Up, %
Hodge et al., 1990	✓	✓	✓ Demographic data were similar between groups. The experimental group had higher Norton Scale scores (13.53) than did the control group (12.18), indicating that the experimental group had better initial skin condition.	✓	✓	✓ Outcome measure independent of treatment exposure. A standardized checklist of nursing interventions was used as a reference for recording outcome measure of occurrence of interventions. In phase 1 the nature of the research was not known to the nursing careers. Norton ratings were done independent of data collection of the outcome measure in phase 2.	✓	0

*RAS indicates risk assessment scale.

Results

The main findings from each of these 3 studies are reported in Table 5. The individual study results were not amenable to meta-analysis because of the different study designs and outcome measures used between studies. Gunningberg et al. (9) did not find a significant difference between the treatment and control groups in the incidence of pressure ulcers. The high rate of attrition from the control group in the Gunningberg et al. (9) study may have contributed to the negative results of that study.

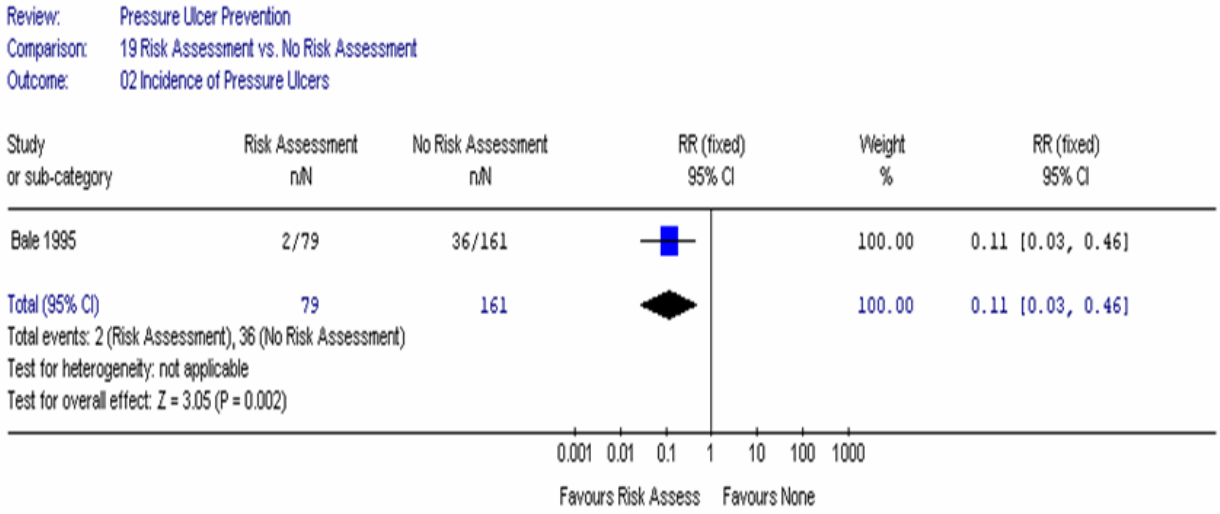
Bale (8) reported that using an RAS significantly reduced the incidence of pressure ulcers compared with not using one (22.4% vs. 2.5%, control vs. treatment, $P < .0001$). The significant result from Bale (8) may be due to the tailoring of the type of pressure-relieving preventive intervention to the person's risk level. Figure 1 presents the results reported by Bale.

Hodge et al. (10) reported that there was on average a significantly higher number of preventative interventions used per person ($P < .0001$) when an RAS was incorporated into nursing practice compared with not doing so. Furthermore, preventive interventions were used earlier in the hospital stay for persons receiving an RAS compared with the group that did not have an RAS completed ($P < .002$). However, there was no difference reported in the incidence of pressure ulcers between treatment groups.

Table 5: Study Results – Risk Assessment

Study	Treatment	Control	Conclusions
Gunningberg et al., 1999	Incidence of pressure ulcers: At discharge 20/51 (39.2%) At 2 weeks postop. 15/43 (34.9%)	Incidence of pressure ulcers: At discharge 17/48 (35.4%) At 2 weeks postop 16/41 (39%)	Incidence of pressure ulcers at discharge is not significantly different between groups. The intervention does not reduce the risk of developing pressure ulcers
Bale, 1995	Incidence of pressure ulcers: 2/79 (2.5%)	Incidence of pressure ulcers: 36/161 (22.4%)	The intervention significantly reduces the incidence of pressure ulcers ($P < .0001$) (RR, 0.11; 95% CI, 0.03–0.46).
Hodge et al.,1990	Average of 18.96 prevention interventions/patient	Average of 10.75 prevention interventions/patient	There was a significant difference in preventative interventions/patient between groups ($P < .001$). Interventions were used earlier for treatment group vs. control group (on day 1, 61% vs. 50%, $P < .002$). No significant difference in the incidence of pressure ulcers between treatment and control groups Less deterioration in elbow skin condition in treatment vs. control ($P < .05$)

CI indicates confidence interval; RR, relative risk.



CI indicates confidence interval; RR, relative risk.

Figure 1: Risk Assessment Versus No Risk Assessment

Grade of Evidence

The overall quality of evidence using the GRADE assessment method is reported by outcome measure in Tables 6 and 7. Because of the serious limitations in attrition rate in the study by Gunningberg et al., (9) only the Bale (8) study was considered as the body of evidence for the outcome of incidence of pressure ulcers. The quality of evidence is very low, indicating an estimate of effect that is uncertain. The study by Hodge et al. (10) formed the body of evidence for the outcome "number of preventive interventions used per person." The quality of evidence is also very low for this outcome, indicating that the estimate of effect is very uncertain.

Table 6: GRADE Evidence Profile – Risk Assessment Versus No Risk Assessment Outcome: Incidence of Pressure Ulcers*

Study	Design	Quality†	Consistency	Directness	Other Modifying Factors‡	No. of Patients			
						RAS	No RAS	RR (95% CI)	Quality/ Importance
Bale, 1995	Observa-tional	Some serious limitations	N/A	No uncertainty about directness		161	104	0.11 (0.03–0.46)	**Very Low**/ Critical
	LOW	**VERY LOW**	**VERY LOW**	**VERY LOW**	**VERY LOW**				

*CI indicates confidence interval; N/A, not applicable; RAS, risk assessment scale; RR, relative risk.
†Version of Norton Scale used in study was not validated, †outcome measure not obtained independently of treatment exposure (−1).
‡Possible confounding should bias in favor of control but it did not (+1).
Sparse data (−1).

Table 7: GRADE Evidence Profile – Risk Assessment Versus No Risk Assessment Outcome: Number of Preventive Interventions Used*

Study	Design	Quality	Consistency	Direct-ness†	Other Modifying Factors†	No. of Patients			
						RAS	No RAS	Mean No. of Interventions per Patient	Quality/ Importance
Hodge et al., 1990	Observ-ational	None	N/A	No uncertainty about directness		92	89	10.75 (control) vs. 18.96 (treatment)	**Very Low**/ Important
	LOW	**LOW**	**LOW**	**LOW**	**VERY LOW**				

*N/A indicates not applicable; RAS, risk assessment scale.
†Sparse data.

Summary of Results

There is very low quality evidence to support the hypothesis that allocating the type of pressure-relieving equipment according to the person's level of pressure ulcer risk statistically decreases the incidence of pressure ulcers. Similarly, there is very low quality evidence to support the hypothesis that incorporating an RAS into nursing practice increases the number of preventative measures used per person and that these interventions are initiated earlier in the care continuum. However, completing a risk assessment did not affect the incidence of pressure ulcers.

Pressure Redistribution Devices

Research Question

The literature was searched to determine the effect of using various pressure redistribution devices including mattresses, overlays, and sheepskins on the incidence of pressure ulcers in a population at risk for developing pressure ulcers. The search strategy is presented in Appendix 2.

Methods

Inclusion Criteria

- systematic reviews (with/without meta-analysis) or RCTs
- studies involving a population at risk for developing pressure ulcers
- studies evaluating the use of static or dynamic mattresses and/or mattress overlays compared with standard foam and/or other static of dynamic distribution devices
- studies evaluating the use of sheepskins compared with a standard foam mattress or other static or dynamic distribution devices
- studies reporting the incidence of pressure ulcers measured as the number (proportion) of persons developing a new pressure ulcer
- studies reporting the stage of pressure ulcer or in which the stage can be inferred from the description of the ulcer

Types of Devices

For the purpose of this review, dynamic pressure redistribution devices (also called high tech) were defined as alternating devices where cells in the mattress surface alternately inflate and deflate. Static devices (also called low tech) were defined as conforming surfaces that distribute the body weight over a large area.

Studies evaluating any of the following distribution devices were included in this review:

High-Tech Surfaces (Dynamic Surfaces)

- alternating pressure
- low air loss beds
- air fluidized beds
- turning beds/frames (profiling beds)

Low-Tech Surfaces (Static Surfaces)

- alternative foam (e.g., convoluted/cubed, high density foam)
- gel-filled
- fiber-filled
- water-filled
- air-filled
- bead-filled
- silicore-filled

- sheepskins

Exclusion Criteria

- studies in which the type of redistribution support surface could not be determined

Primary Outcome Measure

The primary outcome measure was the incidence of pressure ulcers measured as the number (proportion) of participants developing a new pressure ulcer.

Results of Literature Search

One systematic review (12) and 1 systematic review with meta-analysis (13) were each obtained from the literature search strategy (Table 8). The objective of both systematic reviews was to determine the effectiveness of pressure redistribution surfaces on the incidence of pressure ulcers. Cullum et al. (13) searched the medical literature up to and including January 2004, limiting the search to RCTs comparing the effectiveness of beds, mattresses, and cushions on the incidence of pressure ulcers. A total of 41 RCTs were retrieved from the literature. Reddy et al. (12) searched the medical literature up to and including June 2006, also limiting the search to RCTs with clinically relevant outcome measures. An additional 5 RCTs to those retrieved by Cullum et al. (13) were obtained. Cullum et al. (13) completed a meta-analysis of the evidence whereas Reddy et al. (12) did not. Table 9 reports the results of the meta-analyses completed by Cullum et al. (13)

We completed an updated literature search to that completed by Reddy et al. (12) and Cullum et al., (13) up to and including October 2007. Five new RCTs (2 large (14;15) and 3 small (16-18)) were obtained. We report in this review 3 statistically significant meta-analyses from the Cullum et al. (13) review as well as 3 updated meta-analyses to those completed by Cullum et al. (13)(Table 9. In addition to these 6, we report 3 new comparisons not reported by Cullum et al. (13) (Table 10). In total, the 9 comparisons reported in this review include:

Acute Care Setting

Comparison 1: Alternative Foam Versus Standard Foam
Comparison 2: Alternative Foam Versus Alternative Foam
Comparison 3: Alternating Pressure Mattress or Overlay Versus Standard Foam Mattress
Comparison 4: Alternating Pressure Mattress Versus Alternating Pressure Overlay
Comparison 5: Australian Sheepskin Versus Standard Treatment
Comparison 6: Alternating Pressure Mattress (Micropulse System) Versus Standard Care

Peri-Operative and Operative Setting

Comparison 7: Dry Vesico-Elastic Polymer Pad Versus Standard Operating Table Foam Mattress
Comparison 8: Air Suspension Bed Versus Standard Intensive Care Unit (ICU) Bed

Intensive Care Unit Setting

Comparison 9: Alternating Pressure Mattress Versus Alternative Foam

Table 8: Quality of Evidence of Included Studies – Pressure Redistribution Devices*

Study Design	Level of Evidence	Number of Eligible Studies	MAS Update to Systematic Review
Systematic reviews of RCT or	1	2 systematic reviews	
Large RCT,			2
Large RCT unpublished but reported to an international scientific meeting	1(g)†		0
Small RCT	2		3
Small RCT unpublished but reported to an international scientific meeting	2(g)		0
Non-RCT with contemporaneous controls	3a		0
Non-RCT with historical controls	3b		
Non-RCT presented at international conference	3(g)		
Surveillance (database or register)	4a		
Case series (multisite)	4b		
Case series (single site)	4c		
Retrospective review, modeling	4d		
Case series presented at international conference	4(g)		

*MAS indicates Medical Advisory Secretariat; RCT, randomized controlled trial.
†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (11) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meeting. (11)

Table 9: Results of Meta-Analyses Completed by Cullum et al.*

Comparison	No. of Studies	No. of Participants	Outcome	Results RR (95% CI)	MAS Update to Analysis
Constant low pressure supports vs. standard foam mattresses	7	1,166	Incidence of pressure ulcers	Studies too heterogenous Meta-analysis not done	No
Alternative foam mattress vs. standard foam mattress	5	2,016	Incidence of pressure ulcers	0.40 (0.21–0.74)	Yes 1 new study Berthe et al., 2007
Comparisons between alternative foam supports	3	629	Incidence of pressure ulcers	Meta-analysis not done	Yes 1 new study Gray and Smith, 2000
Comparisons between CLP supports	6	592	Incidence of pressure ulcers	Meta-analysis not done	No
AP vs. standard foam mattress	1	327	Incidence of pressure ulcers	0.32 (0.14–0.74)	Yes 1 new study Sanada et al., 2003

(continued)

Table 9: Results of Meta-Analyses Completed by Cullum et al. (continued)*

Comparison	No. of Studies	No. of Participants	Outcome	Results RR (95% CI)	MAS Update to Analysis
AP vs. constant low pressure	8	1,019	Incidence of pressure ulcers	0.82 (0.57–1.19)	No
i) AP devices vs. silicore or foam overlay	4	331	Incidence of pressure ulcers	0.91 (0.71–1.17)	No
ii) AP devices vs. water or static air mattress	3	458	Incidence of pressure ulcers	1.26 (0.60–2.61)	No
AP and CLP in ICU/post-ICU (factorial design)	6	936	Incidence of pressure ulcers	Not statistically significant	No
Comparison between AP devices					
i) Airwave. vs. large cell ripple	1	62	Incidence of pressure ulcers (all comparisons)	0.42 (0.17–1.04)	No
ii) Airwave vs. Pegasus Carewave	1	75		Not estimable	No
iii) Trinova vs. control	1	44		0.20 (0.01–3.94)	No
Air suspension bed vs. standard bed	1	98	Incidence of pressure ulcers	0.24 (0.11–0.53)	No
Air-fluidized therapy vs. dry flotation	1	12	Rate of wound breakdown	1.00 (0.20–4.95)	No
Kinetic treatment table vs. standard	1	2	Incidence of pressure ulcers	Meta-analysis not done	No
Operating table gel overlay vs. no overlay	1	416	Incidence of pressure ulcers	0.53 (0.33–0.85)	No
AP mattress (Micropulse System) / overlay vs. standard care intraoperatively and postoperatively	2	368	Incidence of pressure ulcers	0.21 (0.06–0.70)	No
Seat cushions	3	441	Incidence of pressure ulcers	Meta-analysis not done	Not done

*AP indicates alternating pressure; CI, confidence interval; CLP, constant low pressure; ICU, intensive care unit; MAS, Medical Advisory Secretariat; RR, relative risk.
Source: Cullum et al. (13)

Table 10: New Meta-Analyses Not Found in Cullum et al.

Comparison	No. of Studies	No. of Participants	Results RR (95% CI)
Alternating pressure mattress vs. alternating pressure overlay	1	1,972	0.96 (0.74–1.24)
Sheepskin vs. standard treatment	2	738	0.42 (0.22–0.81)
Alternate pressure vs. alternate foam	2	151	0.89 (0.54–1.47)

Comparison 1: Alternative Foam Mattress Versus Standard Foam Mattress

Characteristics of Included Studies

Six studies compared alternative foam mattresses with standard foam mattresses. (14;19-23) The study characteristics are reported in Table 11. All studies included patients admitted to an acute care setting. A variety of alternative foam mattresses were used in the treatment group. Standard mattresses in the control group were described by all included studies other than Berthe et al. (14) The author was contacted for this information but a response was not received. The follow-up study period in these 6 studies ranged from 10 days to 7 months. Four studies used an explicit pressure ulcer grading system (Table 12): 2 used different versions of the Torrence scale, the third used a modification of the Shea Scale, and the fourth used a grading system developed at the Dutch consensus meeting from 1985. Variations in the scales included grade 1 ranging from persistent erythema to blanching erythema and grade 2 from blister formation and nonblanching erythema. Collier (19) reported on the outcome of deterioration in skin condition, and Gray and Campbell (20) reported the incidence of pressure ulcers but did not report using an explicit grading system.

Of note, the study by Russell et al. (22) used a vesico-elastic and polyurethane (CONFOR-Med Mattress) foam mattress in the treatment group and 5 different types of mattresses as the control. Among the 5 different types of mattress, Russell included the transfoam mattress, which both Collier (19) and Santy et al. (23) used as the treatment (alternative foam) group. As well, the Softfoam appears to be a high-density foam mattress and thus more like an alternative foam mattress than a standard foam mattress.

Table 11: Study Characteristics – Alternative Foam Versus Standard Foam*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Collier, 1996	99	General medical ward patients	7 types of new foam mattresses: Clinifloat Omnifoam Softform STMS Therarest Transfoam Vapourlux	Standard 130 mm mattress (NHS Contract)	6 months	Deterioration in skin condition No pressure ulcer grading system reported
Gray and Campbell, 1994	170	Ortho, trauma, vascular, and medical oncology patients Waterlow score ≥ 15 No existing pressure ulcers	Softform	Standard 130 mm mattress	10 days	Incidence of pressure ulcers No pressure ulcer grading system reported
Hofman et al., 1994	36	Patients with femoral neck # Pressure ulcer risk score ≥ 8	Comfortex DeCube mattress	Standard polyproleen SG 40 mattress	2 weeks	Incidence of pressure ulcers ≥ grade 2 (blister formation) Grading system according to the Dutch consensus meeting for the prevention of pressure ulcers 1985
Russell et al., 2003	1168	Acute care, ortho, and rehab patients ≥ 65 y Waterlow score 15–20	CONFOR-Med mattress (Vesico-elastic and polyurethane foam)	Standard hospital mattress (5 types): Transfoam Softfoam Linknuse KingsFund with Spenco or Propad overlay	8–17 days (median days in study)	Incidence of Torrance grade 2 (nonblanching erythema) or worse Torrance Grading system
Santy et al., 1994	552	Hip # patients > 55 years No pressure ulcer stage ≥ 3	4 types of foam mattresses: CliniFloat Transfoam Therarest Vaperm	Standard 150 mm mattress (NHS contract mattress)	2 weeks	Skin deterioration or stage 3 pressure ulcer Adapted Torrance grading system
Berthe et al., 2007	1,729	Patients admitted to medical or surgical departments in acute care hospital	Kliniplot mattress	Standard hospital mattress (not described)	7 months	Development of pressure ulcer grade 1 or greater on the modified Shea scale

NHS indicates National Health Service.

Table 12: Pressure Ulcer Classification Systems – Studies of Alternative Foam Versus Standard Foam

Scale	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Dutch consensus meeting for the prevention of pressure ulcers 1985	Normal skin	Persistent erythema	Blister formation	Superficial (sub)cutaneous necrosis	Deep subcutaneous necrosis	N/A
Torrance	N/A	Blanching erythema	Non blanching erythema	N/A	N/A	N/A
Modified Torrance	Normal skin	Blanching hyperemia	Non blanching hyperemia	Ulceration through sub-cutaneous tissue	Lesion extends into subcutaneous fat	N/A
Modified Shea	Normal skin	Persistent erythema of the skin (> 24 h)	Blister formation	Dry pressure sore	Subcutaneous necrosis	Granulating wound

N/A indicates not applicable.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 13. Only 2 studies, Russell et al. (22) and Gray and Campbell, (20) explicitly describe allocation concealment methods. Santy et al. (23) was contacted and confirmed that allocation concealment was maintained by using sealed opaque envelopes. Similarly, other than Collier, (19) appropriate blinding of the patient or outcome assessor was not completed in any study.

Table 13: Individual Study Quality Assessment – Alternative Foam Versus Standard Foam*

Study	RCT†	Concealment‡	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Collier, 1996	x	x	x	Unclear	9%	x
Gray and Campbell, 1994	✓	✓	x	x	0%	✓
Hofman et al., 1994	✓	Unclear	✓	x	22%	x
Santy et al., 1994	✓	✓	✓	x	26%	✓
Russell, 2003	✓	✓	✓	x	23%	✓
Berthe et al., 2007	✓	x	✓	x	0%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.
†The study methods must establish that the randomization scheme used allowed each participant an equal chance of getting any of the study interventions. Therefore, the study was accepted as an RCT if the report stated either that the treatments were “randomly allocated” or that a random number table was used.
‡Concealment was adequate if the authors stated that opaque envelopes were used or there was evidence of a third party involvement for treatment allocation.

Results

The analysis completed by Cullum et al. (13;24) included the study by Russell et al. (22) (Figure 2); however, this analysis may be criticized as the control group in the study by Russell et al. (25) included an alternative foam mattress and is therefore dissimilar to the control groups of the other studies in the meta-analysis. Given this, the resultant relative risk (RR) estimate may represent an underestimate of the effect of an alternative foam mattress. It also may account for the large statistical heterogeneity in the analysis (I^2 = 77.3%). We completed a meta-analysis but removed the study by Russell et al. (22) (Figure 3). The resultant RR (random effects model) was 0.31 (95% confidence interval [CI], 0.21–0.46) with a corresponding I^2 value of 0%. Because the type or description of standard mattresses was not reported by Berthe et al., (14) we did not include this study in our meta-analysis. The author of the study was contacted for this information but did not reply.

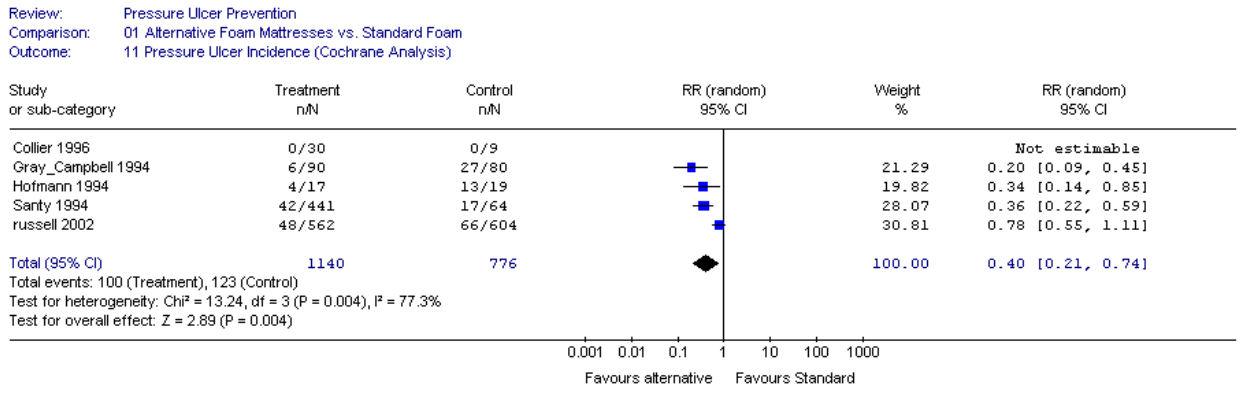
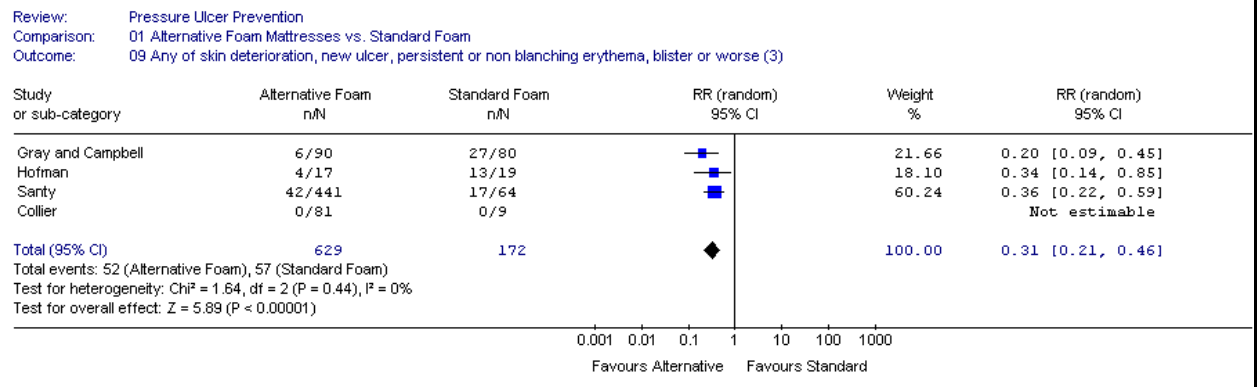


Figure 2: Alternative Foam Versus Standard Foam – Cullum et al. Meta-Analysis

Source: Cullum et al. (13;24)



CI indicates confidence interval; RR, relative risk.

Figure 3: Medical Advisory Secretariat Meta-Analysis – Alternative Foam Versus Standard Foam

Grade of Evidence

Table 14 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of alternative foam mattresses compared with standard foam hospital mattresses. The quality of the body of evidence is moderate.

Table 14: GRADE Evidence Profile – Alternative Foam Versus Standard Foam* Mattress Outcome: Any of Skin Deterioration, Mew Ulcer, Persistent or Nonblanching Erythema, Blister or Worse

Studies	Design	Quality†	Consistency	Directness	Other Modifying Factors‡	No. of Patients			
						AF	SF	RR (95% CI)	Quality/ Importance
Collier, 1996	RCT	Some serious limitations	No important inconsistency	No uncertainty about directness		629	172	.31 (0.21–0.46)	**MOD/** Critical
Gray and Campbell, 1994	RCT								
Hoffman et al., 1994	RCT								
Santy et al., 1994	RCT								
	HIGH	**LOW**	**LOW**	**LOW**	**MOD**				

*AF indicates alternative foam; MOD, moderate; RCT, randomized controlled trial; RR, relative risk; SF, standard foam.
†Unclear concealment methods (Hoffman); unblinded outcome assessment (all studies); moderate loss to follow-up (Santy) (−1).
‡Strong association (RR < 0.5) (+1).

Summary of Results

There is high quality evidence that the use of an alternative foam mattress produces an RRR of 69% in the incidence of pressure ulcers.

Comparison 2: Alternative Foam Mattress Versus Alternative Foam Mattress

Characteristics of Included Studies

Cullum et al. (13) reported 3 studies comparing different types of alternative foam mattresses including that completed by Santy et al., (23) Kemp et al., (26) and Vyhlidal et al. (27) However, the study by Santy et al. (23) was incorporated into the analysis of alternative foam mattresses compared with standard mattresses, so it is unclear why it was included in this comparison of alternative foam mattress versus alternative foam mattress. Therefore, we removed this study from the analysis. Our literature search found 1 additional study completed by Gray and Smith (16) comparing different types of alternative foam mattresses. This study was added to the body of evidence for this comparison. The study characteristics are reported in Table 15. All studies included patients admitted to an acute care setting. A variety of alternative foam mattresses were used in the treatment and control groups. All studies used an explicit pressure ulcer grading system (Table 16).

Table 15: Characteristics of Included Studies – Alternative Foam Versus Alternative Foam*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Kemp et al., 1993	84	General medicine, acute geriatric medicine and long-term care 65 years or older Braden score of < 6 Free of pressure ulcers on admission	Foam 1: Convoluted foam overlay (3–4 inches thick); these were the standard overlays used in the hospital	Foam 2: Solid foam overlay (4 inches solid sculptured overlay)	1 month	Incidence of pressure ulcers grade 1 or greater NPUAP 1989 scale used
Vyhlidal et al., 1997	40	Musculoskeletal, cardiovascular, neurological	Foam 1: Maxifloat solid foam mattress with heel insert, 1.5 inches thick	Foam 2: Iris 3000 (4-inch dimpled foam overlay)	10–21 days	Incidence of pressure ulcers stage I or greater Bergstrom Skin Assessment used
Gray and Smith, 2000	33	Admitted for bed rest or surgery	Foam 1: Transfoam wave mattress	Foam 2: Transfoam mattress	10 days	Incidence of pressure ulcers (all grades) Torrance Scale used

*NPUAP indicates National Pressure Ulcer Advisory Panel.

Table 16: Pressure Ulcer Classification System – Alternative Foam Versus Alternative Foam*

Scales	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
NPUAP Scale 1989	N/A	Nonblanchable erythema of intact skin	Break in skin (blister or abrasion)	Break in skin exposing subcutaneous tissue	Break in skin exposing muscle or bone	N/A
Bergstrom Skin Assessment	No redness or breakdowns	Erythema only, redness does not disappear for 24 hours after pressure is relieved	Break in skin such as blisters or abrasions	Break in skin exposing subcutaneous tissue	Break in skin extending through tissue and subcutaneous layers, exposing muscle or bone Dark necrotic tissue	N/A
Torrance Scale 1983	N/A	Area of blanching hyperemia	Nonblanching hyperemia	Ulceration progresses through the dermis to subcutaneous tissue	Ulceration extends into the subcutaneous fat, muscle becomes inflamed	Infective necrosis affects the deeper fascia and muscle

*N/A indicates not applicable; NPUAP, National Pressure Ulcer Advisory Panel.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 17. Of the 3 studies comprising the body of evidence, only 1, that by Gray and Smith, (16) reported adequate methods for both treatment allocation concealment and blinding the outcome assessments. None of the studies determined a sample size a priori. Loss to follow-up was negligible in all studies.

Table 17: Quality Assessment of Included Studies*

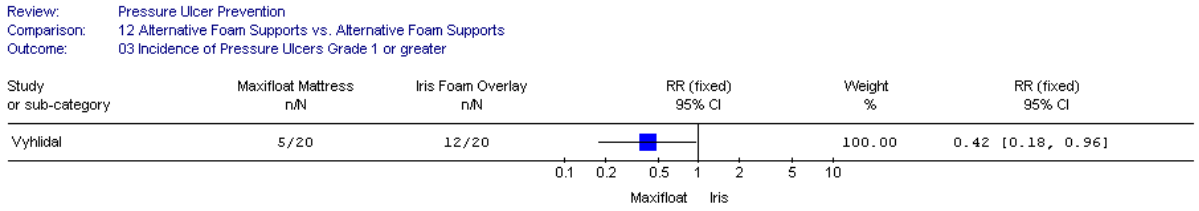
Study	RCT†	Concealment‡	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Kemp et al., 1993	✓	x	x	unclear	0%	✓
Vyhlidal et al., 1997	✓	x	x	unclear	0%	✓
Gray and Smith, 2000	✓	✓	x	✓	0%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.
†Accepted as an RCT if report stated study was "randomly allocated" or used a random number table. The study methods must establish that the randomization scheme used allowed each participant an equal chance of getting any of the study interventions.
‡Concealment was adequate if the authors stated that opaque envelopes were used or there was evidence of a third party involvement for treatment allocation.

Results

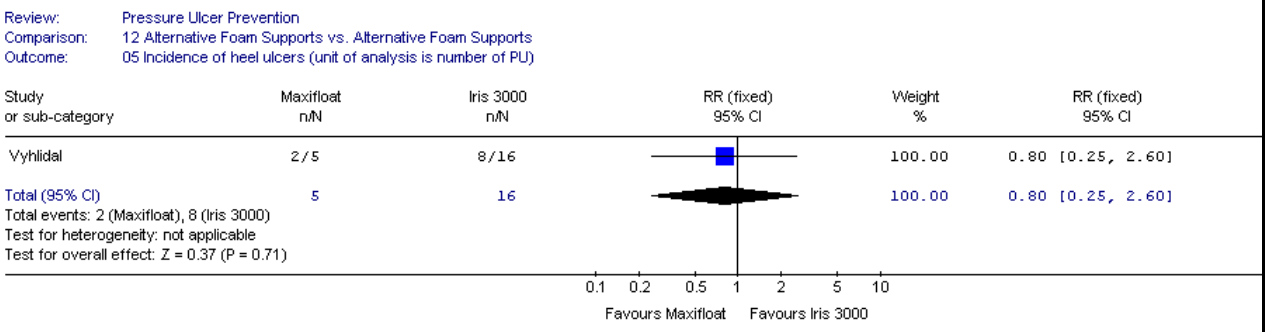
A meta-analysis for this comparison was not completed because of the variety of mattress types included in the individual studies. Figure 4 reports the results of the study completed by Vyhlidal et al. (27) Results indicate that the Maxifloat mattress statistically significantly decreases the incidence of grade 1 pressure ulcers compared with the Iris Foam Mattress. However, the Maxifloat group was significantly heavier than the Iris Foam group (body mass index 35 vs. 29, respectively) which may have lowered the risk for developing a pressure ulcer in the Maxifloat group. As well, the Maxifloat group also used heel guards. Because of this, we analyzed the study results to determine if there were fewer heel ulcers in the Maxifloat group accounting for an overall lower incidence of pressure ulcers between the Maxifloat and the Iris mattresses. Results indicated that there was no statistically significant difference in heel ulcers between groups (RR [fixed], 0.80; 95% CI, 0.25–2.60) (Figure 5). Therefore, the small sample size as well as the aforementioned issues regarding baseline characteristics of the groups may have biased the results of the study in favor of the Maxifloat mattress and thus the results of this study should be interpreted with caution.

The results of the studies by Kemp et al. (26) and Gray and Smith (16) are reported in Figures 6 and 7, respectively. Both studies report a statistically nonsignificant result.



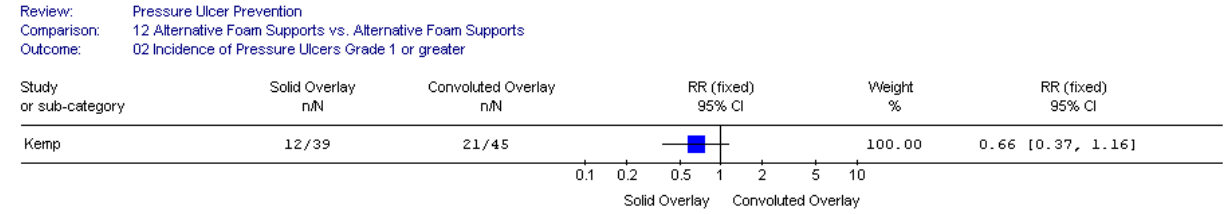
CI indicates confidence interval; RR, relative risk.

Figure 4: Alternative Foam Mattress Versus Alternative Foam Mattress – Vyhlidal et al. – Incidence of Pressure Ulcers



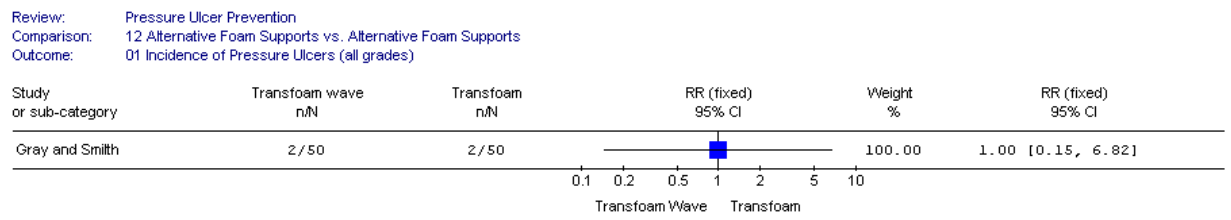
CI indicates confidence interval; PU, pressure ulcers; RR, relative risk.

Figure 5: Alternative Foam Mattress Versus Alternative Foam Mattress – Vyhlidal et al. – Incidence of Heel Ulcers



CI indicates confidence interval; RR, relative risk.

Figure 6: Alternative Foam Mattress Versus Alternative Mattress – Kemp et al.



CI indicates confidence interval; RR, relative risk.

Figure 7: Alternative Foam Mattress Versus Alternative Mattress – Gray and Smith

Grade of Evidence

Table 18 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of alternative foam mattresses (Foam 1) compared with alternative foam mattresses (Foam 2). The quality of the body of evidence is very low for the outcome of incidence of pressure ulcers grade 1 or greater.

Table 18: GRADE Evidence Profile – Alternative Foam Alternative Foam Versus Alternative Foam* Outcome: Incidence of Pressure Ulcers Grade 1 or Greater

Studies	Design	Quality†	Consistency‡	Direct-ness§	Other Modifying Factors‖	No. of Patients		RR, (95% CI)	Quality/ Importance
						Foam 1	Foam 2		
Vyhlidal et al., 1997	RCT	Some serious limitations	Important inconsistency	Some uncertainty about directness	Yes	5 39	16 45	0.42 (0.18–0.96)	**Very Low/** Critical
Kemp et al., 1993	RCT					50	50	0.66 (0.37–1.16)	
Gray and Smith, 2000	RCT **HIGH**	**MOD**	**LOW**	**VERY LOW**	**VERY LOW**			1.00 (0.15–6.82)	

*CI indicates confidence interval; MOD, moderate; RCT, randomized controlled trial; RR, relative risk.
†Kemp, Vyhlidal: no concealment and unclear if outcome assessor was blinded (−1).
‡Differences in size of effect between studies (−1).
§Different types of mattresses compared. Uncertain how to generalize comparisons (−1).
‖One small trial for each foam mattress type comparison (−1).

Summary of Results

The evidence does not support the superiority of any one type of alternative foam mattress. The quality of this evidence is very low.

Comparison 3: Alternating Pressure Mattress or Overlay Versus Standard Foam Mattress

Characteristics of Included Studies

In the systematic review by Cullum et al., (13) only the study by Andersen et al. (28) was reported comparing an alternating pressure mattress with a standard foam mattress. We found 1 additional RCT to add to this body of evidence, that completed by Sanada et al. (18) Therefore, 2 studies comprise the body of evidence comparing an alternating pressure mattress or overlay with a standard foam mattress. The study characteristics are reported in Table 19. All studies included patients admitted to an acute care setting. The follow-up study period was 10 days in the Andersen et al. (28) study. Sanada et al. (18) reported that follow-up was continued until a pressure ulcer developed. Both studies used an explicit but different pressure ulcer grading system (Tables 20 and 21).

Table 19: Characteristics of Included Studies – Alternating Pressure or Overlay Versus Standard Foam*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Andersen et al., 1982	482	Patients with acute conditions selected from emergency admissions	1. Alternating pressure air mattress. Alternating in 5-minute intervals N = 166 2. Water-filled mattress N = 155	Standard mattress (no details given) N = 166	10 days	Changes in skin integrity recorded as nondecubitus or decubitus
Sanada et al., 2003	123	Persons who have had a stroke, general surgery patients, and terminally ill patients who require head elevation (45 degrees)	1. Single-layer (1-cell) air cell overlay 2. Double-layer (2-cell) air cell overlay Cell pressure alternating in 5-minute intervals	Standard mattress (Paracare® made of polyester)	Until pressure ulcer developed	Incidence of stage I and stage II pressure ulcers using NPUAP classification

* NPUAP indicates National Pressure Ulcer Advisory Panel.

Table 20a: Pressure Ulcer Classification System Used by Andersen et al., 1982 – Alternating Pressure or Overlay Versus Standard Foam

Scale/Study	Nondecubitus	Decubitus
Changes in skin integrity / Andersen et al., 1982	Normal skin, redness, and infiltration, extravasations	Bullae, black necrosis, skin defect

Source: Andersen et al., 1982 (28)

Table 20b: Pressure Ulcer Classification System Used by Sanada et al., 2003 – Alternating Pressure or Overlay Versus Standard Foam*

Scale/Study	Grade 1	Grade 2	Grade 3	Grade 4
NPUAP Scale, 1989 / Sanada et al., 2003	N/A	Nonblanchable erythema of intact skin.	Break in skin (blister or abrasion)	Break in skin exposing subcutaneous tissue

*N/A indicates not applicable; NPUAP, National Pressure Ulcer Advisory Panel.
Source: Sanada et al., 2003 (18)

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 21. Of the 2 studies comprising the body of evidence, only 1, that by Sanada et al., (18) reported adequate allocation concealment methods and also completed a sample size calculation a priori. Neither study used a blinded assessment method for the outcome measure. Loss to follow-up ranged from 20% to 24%.

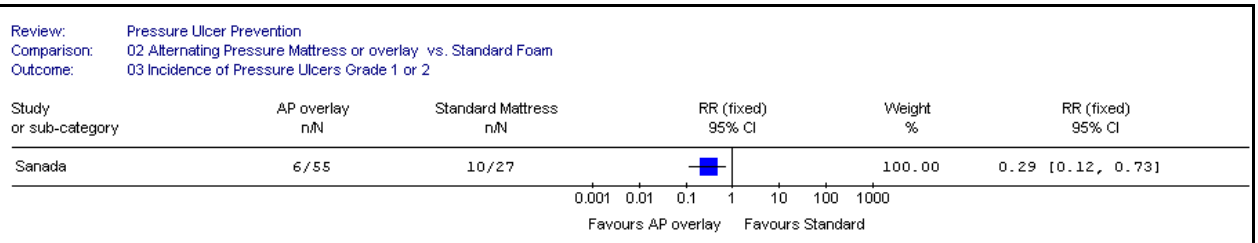
Table 21: Quality Assessment of Included Studies – Alternating Pressure or Overlay Versus Standard Foam*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Andersen et al., 1982	Unclear	x	✓	x	20%	x
Sanada et al., 2003	✓	✓	x	x	24%	x

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

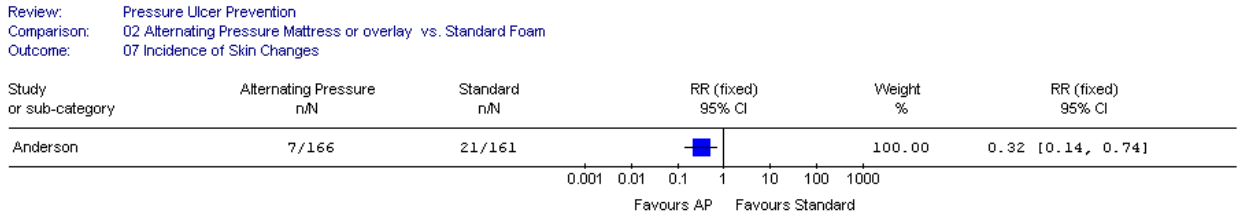
Results

A meta-analysis was not completed because of the different outcome measures used between studies (incidence of stage 1 and 2 pressure ulcers vs. changes in skin integrity). The results of each study are reported in Figures 8 and 9, respectively. Both studies report similar RR (fixed) estimates and 95% CIs.



AP indicates alternating pressure; CI, confidence interval; RR, relative risk.

Figure 8: Alternating Pressure or Overlay Versus Standard Foam – Sanada et al.



AP indicates alternating pressure; CI, confidence interval; RR, relative risk.

Figure 9: Alternating Pressure or Overlay Versus Standard Foam – Anderson et al.

Grade of Evidence

Tables 22 and 23 report the GRADE evidence profile for the body of evidence evaluating the effectiveness of an alternating pressure mattress or overlay versus a standard foam mattress. Table 22 reports that the quality of evidence is very low for the outcome of the incidence of grade 1 or 2 pressure ulcers, and Table 23 reports low quality of evidence for the outcome of changes in skin integrity.

Table 22: GRADE Evidence Profile – Alternating Pressure Overlay Versus Standard Foam Mattress
Outcome: Incidence of Grade 1 or 2 Pressure Ulcer*

Studies	Design	Quality†	Consistency‡	Directness¶	Other Modifying Factors#	No. of Patients			
						APO	SFM	RR (95% CI)	Quality/ Importance
Sanada et al., 2003	RCT	Some very serious limitations	N/A	Some uncertainty about directness	Sparse data	55	27	0.29 (0.12–0.73)	**Very Low**/ Critical
	HIGH	**LOW**	**LOW**	**VERY LOW**	**VERY LOW**				

*APO indicates alternating pressure overlay; CI, confidence interval; N/A, not applicable; RR, relative risk; SFM, standard foam mattress.
†Follow-up period unclear, unblinded outcome assessment and 24% dropout rate. (Sanada) (−2).
‡Not applicable (1 study).
¶Results obtained from a Japanese study population (−1).
#No difference between 1-cell mattress and either control or 2-cell mattress. However, the 2-cell group is significantly different from the control. Sanada et al. combined the results of the 1-cell mattress group and the 2-cell mattress group and compared this combined group with the control group. Since 1 cell is no different from control, combining 1-cell data with the 2-cell data (which is different from control) should bias the alternating pressure group in favor of control diluting the effect of the AP mattress. But the effect was not diluted and therefore GRADE is increased by 1 because all plausible confounders would have reduced the effect but didn't (+1).
#Sparse data (−1).

Table 23: GRADE Evidence Profile – Alternating Pressure Mattresses Versus Standard Foam Mattress
Outcome: Changes in Skin Integrity*

Studies	Design	Quality†	Consistency	Directness	Other Modifying Factors	No. of Patients			
						AP	SFM	RR (95% CI)	Quality/ Importance
Andersen et al., 1982	RCT	Some very serious limitations	Not applicable	No uncertainty about directness	None	166	161	0.32 (0.14–0.74)	**Low**/ Important
	HIGH	**LOW**	**LOW**	**LOW**	**LOW**				

*AP indicates alternating pressure; CI, confidence interval; RCT, randomized controlled trial; RR, relative risk; SFM, standard foam mattress.
†Unclear if this is a true RCT, inadequate concealment, unblinded outcome assessments (−2).

Summary of Results

There is very low quality evidence that the use of an alternating pressure overlay is associated with an RRR of 71% in the incidence of grade 1 or 2 pressure ulcers compared with a standard foam mattress.

There is low quality evidence that the use of an alternating pressure mattress is associated with an RRR of 68% in the incidence of skin changes compared with a standard foam mattress.

Comparison 4: Alternating Pressure Mattress Versus Alternating Pressure Overlay

Characteristics of Included Studies

One study compared the use of an alternating pressure mattress with an alternating pressure overlay. (29) The study characteristics are reported in Table 24. This comparison is not reported in the review by Cullum et al. (13) The study by Nixon et al. (29) included patients admitted to an acute care setting. The median follow-up time period was 9 days. An explicit pressure ulcer classification system was used to measure the outcome (Table 25).

Table 24: Characteristics of Included Study – Alternating Pressure Mattress Versus Alternating Pressure Overlay

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Nixon et al., 2006 N = 1972	1,972	Acute or elective vascular, orthopedic, medical, or care of elderly admissions Existing pressure ulcer of grade 2 or less	Alternating pressure mattress	Alternating pressure overlay	30 days and 60 days Median was 9 days	New pressure ulcer of grade 2 or worse Skin classification system

Table 25: Skin Classification System – Study of Alternating Pressure Mattress Versus Alternating Pressure Overlay

Scale/Study	Grade 0	Grade 1a	Grade 1b	Grade 2	Grade 3	Grade 4	Grade 5
Skin classification system	No skin changes	Redness to skin (blanching)	Redness to skin (nonblanching)	Partial thickness wound involving epidermis or dermis only	Full thickness wound involving sub-cutaneous tissue	Full thickness wound through sub-cutaneous tissue to muscle or bone	Black eschar

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 26. The study by Nixon et al. (29) was well conducted. Methodological limitations include only an unblinded outcome assessment.

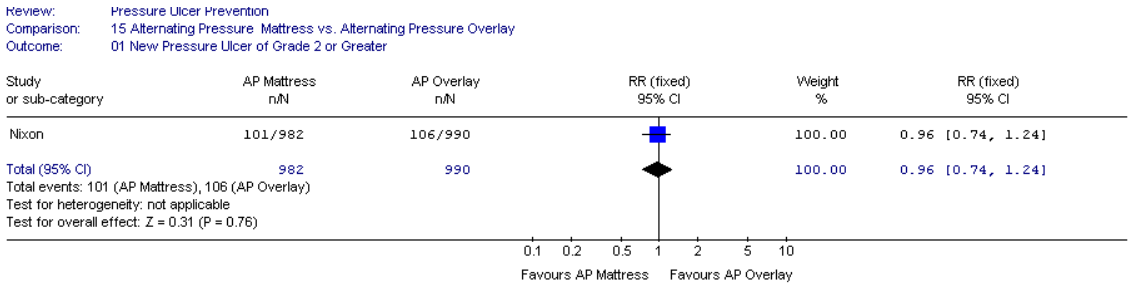
Table 26: Quality Assessment of Included Study – Alternating Pressure Mattress Versus Alternating Pressure Overlay

Study	RCT	Concealment	Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Nixon et al., 2006	✓	✓	✓	x	6%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

The results of the study completed by Nixon et al. (29) are reported in Figure 10. There was no statistically significant difference between alternating pressure mattress and an alternating pressure overlay in the incidence of pressure ulcers grade 2 or greater.



AP indicates alternating pressure; CI, confidence interval; RR, relative risk.

Figure 10: Alternating Pressure Mattress Versus Alternating Pressure Overlay

Grade of Evidence

Table 27 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of an alternating pressure mattress compared with an alternating pressure overlay. The quality of evidence is moderate for the outcome of incidence of grade 2 or greater pressure ulcers.

Table 27: GRADE Evidence Profile – Alternating Pressure Mattresses Versus Alternating Pressure Overlay
Outcome: Incidence of Pressure Ulcers Grade 2 or Greater*

Studies	Design	Quality†	Consistency	Directness	Other Modifying Factors	No. of Patients			
						APM	APO	RR (95% CI)	Quality/ Importance
Nixon et al., 2006	RCT	Some serious limitations	Not applicable (1 study)	No uncertainty about directness	None	982	990	0.96 (0.74–1.24)	**MOD/** Critical
	HIGH	**MOD**	**MOD**	**MOD**	**MOD**				

*APM indicates alternating pressure mattress; APO, alternating pressure overlay; CI, confidence interval; MOD, moderate; RCT, randomized controlled trial; RR, relative risk.
†Unblinded assessment (−1).

Summary of Results

There is moderate quality evidence that there is a statistically nonsignificant difference in the incidence of grade 2 or greater pressure ulcers between persons using an alternating pressure mattress and using an alternating pressure overlay.

Comparison 5: Australian Sheepskin Versus Standard Treatment

Characteristics of Included Studies

Two studies compared the use of an Australian sheepskin overlay and sheepskin heel and elbow protectors with the use of a standard hospital mattress and other constant low pressure devices as needed. (17;30) The study characteristics are reported in Table 28. All studies included patients admitted to an acute care setting, and treatment and control interventions were exactly the same in both studies. In the study by McGowan et al., (30) patients were followed until discharge from hospital; however, the authors did not report the average length of hospital stay for the study population. Jolley et al. (17) reported the follow-up period to be 7 days. Both studies used the same pressure ulcer classification system (Table 29).

Table 28: Characteristics of Included Studies – Australian Sheepskin Versus Standard Treatment*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
McGowan et al., 2000	297	Emergency and elective patients admitted to orthopedic wards	Australian sheepskin overlay, sheepskin heel and elbow protectors as needed	Standard hospital mattress, CLP device as needed	Study endpoint was discharge from hospital or transfer to a rehab ward Mean time (days) to study endpoint was not reported	Incidence of pressure ulcers stage I or greater Used the US Agency for Health Care Policy and Research Scale
Jolley et al., 2004	441	Patients at low to moderate risk of developing a pressure ulcer on the Braden Pressure Ulcer Risk Assessment scale	Australian sheepskin overlay, sheepskin heel and elbow protectors as needed	Standard hospital mattress, CLP device as needed	7 days	Incidence of pressure ulcers stage I or greater Used the US Agency for Health Care Policy and Research Scale

*CLP indicates constant low pressure; US, United States.

Table 29: Pressure Ulcer Classification System – Studies of Australian Sheepskin Versus Standard Treatment

Scale/Study	Grade 1	Grade 2	Grade 3	Grade 4
US Agency for Health Care Policy and Research Scale McGowan et al., 2000	Nonblanching erythema or erythema not resolving within 30 minutes of pressure relief. Epidermis remains intact. Reversible with intervention	Partial thickness loss of skin layers involving epidermis and possibly penetrating into but not through dermis. May present as blistering with erythema and/or induration; wound base moist and pink; painful; free of necrotic tissue	Full thickness tissue loss extending through dermis to involve subcutaneous tissue. Presents as shallow crater unless covered by eschar. May include necrotic tissue, undermining, sinus tract formation, exudate, and/or infection. Wound base is usually not painful.	Deep tissue destruction extending through subcutaneous tissue to fascia and may involve muscle layers, joint, and/or bone. Presents as a deep crater. May include necrotic tissue, undermining, sinus tract formation, exudate, and/or infection. Wound base is usually not painful.
US Agency for Health Care Policy and Research Scale Jolley et al., 2004	Nonblanchable erythema or intact skin	Partial thickness skin loss involving epidermis, dermis, or both	Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to but not through underlying fascia	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures

*US indicates United States.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 30. Both studies are methodologically sound except for using an unblinded outcome assessment process.

Table 30: Quality Assessment of Included Studies – Australian Sheepskin Versus Standard Treatment*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
McGowan et al., 2000	✓	✓	✓	x	6%	x
Jolley et al., 2004	✓	✓	✓	x	18%	✓

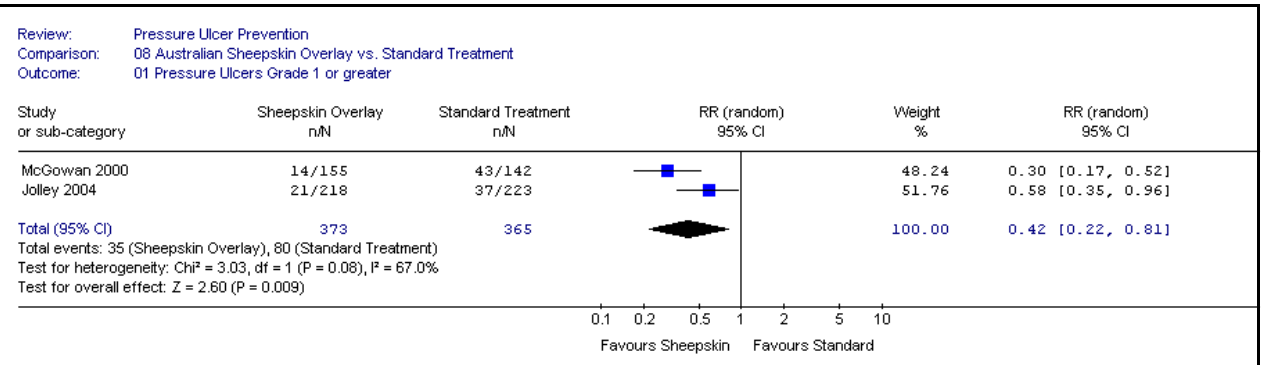
*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

Figure 11 reports the result of the meta-analysis for this body of evidence. There is a statistically significant reduction in the RR of pressure ulcers grade 1 or greater in persons using an Australian sheepskin compared with persons using standard treatment. This corresponds to an RRR of 58%. The I^2 value is 67%, indicating moderate statistical heterogeneity in the analysis.

Complications with sheepskins were also reported in both studies. Jolley et al. (17) reported that 10 patients using sheepskins complained that the sheepskin was uncomfortable and too hot. Sensitivity to the wool surface was also reported. Participants in the McGowan et al. (30) study reported that the sheepskins were hot and curled up in the bed. Six participants withdrew before completion of the study because the sheepskin caused an irritation and was too hot or uncomfortable.

To contextualize the evidence, the secretariat convened a Pressure Ulcer Advisory Panel comprised of clinical experts in pressure ulcer management. This advisory panel noted that in general sheepskins are not an acceptable preventive intervention because they bunch up in the patient's bed and may contribute to wound infection if not properly cleaned.



CI indicates confidence interval; RR, relative risk.

Figure 11: Australian Sheepskin Overlay Versus Standard Treatment

Grade of Evidence

Table 31 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of the Australian sheepskin compared with standard care. The quality of evidence is moderate for the outcome of incidence of pressure ulcers grade 1 or greater.

Table 31: GRADE Evidence Profile – Australian Sheepskin Versus Standard Treatment Outcome: Incidence of Pressure Ulcers Grade 1 or Greater*

Studies	Design	Quality†	Consistency	Directness	Other Modifying Factors‡	No. of Patients			
						AS	SC	RR (95% CI)	Quality/ Importance
Jolley et al., 2004 McGowan et al., 2000	RCT	Some very serious limitations	No important inconsistency	No uncertainty about directness	Strong association	373	365	0.42 (0.22–0.81)	**Moderate**/ Critical
	HIGH	LOW	LOW	LOW	MOD				

*AS indicates Australian sheepskin; CI, confidence interval; MOD, moderate; RCT, randomized controlled trial; RR, relative risk; SC, standard care.
†Studies not blinded, McGowan et al. did not complete an intention-to-treat analysis (−2)
‡Strong association (< 0.5)

Summary of Results

There is moderate quality evidence that the use of an Australian sheepskin produces an RRR of 58% in the incidence of pressure ulcers grade 1 or greater. There is also evidence that sheepskins are uncomfortable to use. The Pressure Ulcer Advisory Panel noted that in general sheepskins are not a useful preventive intervention because they bunch up in a patient's bed and may contribute to wound infection if not properly cleaned, and this reduces their acceptability as a preventive intervention.

Comparison 6: Alternating Pressure Mattress (Micropulse System) Versus Standard Care

Characteristics of Included Studies

Two studies compared the Micropulse System alternating pressure mattress with standard care. (31;32) The study characteristics are reported in Table 32. Both studies included patients having surgery for 2 or more hours. The follow-up study period was 7 days for both studies. Both studies used the National Pressure Ulcer Advisory Panel (NPUAP) pressure ulcer classification system (Table 33).

Table 32: Characteristics of Included Studies – Alternating Pressure Mattress (Micropulse System) Versus Standard Care*

Study	Population	Treatment	Control	Follow-Up	Outcome
Aronovitch et al., 1999	Elective surgery for 3 hours' duration	Micropulse System AP intraoperatively and postoperatively	Gel pad in OR and pressure Guard II hospital replacement mattress postop.	7 days	Incidence of pressure ulcers grade 1 or greater NPUAP (1989) Scale and the wound ostomy, and continence nurses Society staging system used
Russell and Lichtenstein, 2000	Cardiothoracic surgery for at least 4 hours	AP Micropulse System intraoperatively and postoperatively	Gel pad intraop. and standard mattress postop.	7 days	Development of pressure ulcers grade 1 or greater NPUAP scoring system used

*AP indicates alternating pressure mattress; NPUAP, National Pressure Ulcer Advisory Panel; OR, operating room.

Table 33: Pressure Ulcer Classification System – Alternating Pressure Mattress (Micropulse System) Versus Standard Care*

Scale / Study	Grade 1	Grade 2	Grade 3	Grade 4
NPUAP, 1989	Nonblanchable erythema of intact skin	Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents as an abrasion blister or shallow crater.	Full thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to but not through underlying fascia. The ulcer presents as a deep crater with or without undermining of adjacent tissue.	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures

*NPUAP indicates National Pressure Ulcer Advisory Panel.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 34. The study by Aronovitch et al. (31) did not satisfy any of the quality assessment criteria. Similarly, other than using an adequate allocation concealment process and proper randomization methodology, Russell and Lichtenstein (32) also did not satisfy many of the quality assessment criteria.

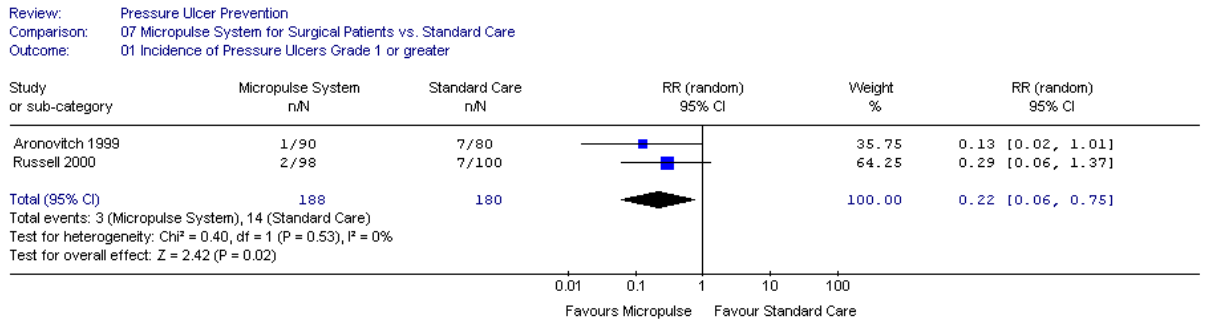
Table 34: Quality Assessment of Included Studies – Alternating Pressure Mattress (Micropulse System) Versus Standard Care*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Aronovitch et al., 1999	x Randomization by week	x	x	x Not reported	x	x
Russell and Lichtenstein, 2000	✓	✓ Opaque envelopes	x	x	x Not reported	✓

* ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

Figure 12 reports the results of the meta-analysis of the Aronovitch et al. and Russell and Lichtenstein studies. (31;32) There is a statistically significant reduction in the incidence of pressure ulcers (RR, 0.21; 95% CI, 0.06–0.70), suggesting an RRR in pressure ulcers of 79%. A limitation of the study design in both studies is that the Micropulse System alternating pressure mattress was used both intraoperatively and postoperatively. Because of this, it is unknown if the effect of this system is due to its use intraoperatively or postoperatively, or indeed if it needs to be used in both phases.



CI indicates confidence interval; RR, relative risk.

Figure 12: Alternating Pressure Mattress (Micropulse System) Versus Standard Care

Grade of Evidence

Table 35 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of the alternating pressure Micropulse System (AP) compared with a gel-pad intraoperatively and a standard mattress postoperatively (Standard care, SC) . The quality of evidence is very low for the outcome of incidence of pressure ulcers grade 1 or greater pressure.

Table 35: GRADE Evidence Profile – Alternating Pressure Mattress Intraoperatively and Postoperatively Versus a Gel Pad Intraoperatively and a Standard Mattress Postoperatively Outcome: Incidence of Pressure Ulcers Grade 1 or Greater*

Studies	Design	Quality†	Consistency	Directness‡	Other Modifying Factors§	No. of Patients			
						AP	SM	RR (95% CI)	Quality/ Importance
Aronovitch et al., 1999 Russell and Lichtenstein, 2000	RCT **HIGH**	Some very serious limitations **LOW**	No important inconsistency **LOW**	Some uncertainty about directness **VERY LOW**	**VERY LOW**	188	180	0.21 (0.06–0.70)	**Very Low/** Critical

*AP indicates alternating pressure; CI, confidence interval; RCT, randomized controlled trial; RR, relative risk; SM, standard mattress.
†Aronovitch used randomization by week, had inadequate allocation concealment, did not report using a blind outcome assessment procedure, did not report losses to follow-up, and did not complete an intention-to-treat analysis (−2). Russell did not report using a blind outcome assessment procedure and did not report losses to follow-up.
‡Unclear if standard treatment of gel pad intraoperatively can be generalized to the Ontario context (−1).
Standard postoperative mattress not described by Aronovitch.
§Strong evidence of association but sparse data (+1/-1).

Summary of Results

There is very low quality evidence that the use of an alternating pressure Micropulse System used intraoperatively and postoperatively produces an RRR of 79% in the incidence of pressure ulcers compared with a gel-pad intraoperatively and a standard mattress postoperatively (standard care). It is unclear if the effect is due to the use of the alternating pressure mattress intra operatively or postoperatively, or if indeed it must be used in both patient care areas.

Comparison 7: Dry Vesico-Elastic Polymer Pad Versus Standard Operating Table Foam Mattress

Characteristics of Included Studies

One study compared an operating table vesico-elastic polymer pad (gel pad) with a standard operating room table foam mattress. (32;33) The study characteristics are reported in Table 36. The follow-up study period was 1 postoperative day. The Torrance pressure ulcer classification grading system was used to measure the outcome (Table 37). Of note, in this classification system a grade 1 pressure ulcer includes blanching erythema.

Table 36: Characteristics of Included Studies – Dry Vesico-Elastic Polymer Pad Versus Standard Operating Table Foam Mattress

Study	Population	Treatment	Control	Follow Up	Outcome
Nixon et al., 1998	Vascular, general, or gynecological surgery Pressure ulcer of stage 2a or greater	Dry vesico-elastic polymer pad in operating room	Standard operating room table 3-inch foam mattress covered in a thick impervious material	Day 1 postop	Pressure ulcers stage 1 or greater

Table 37: Pressure Ulcer Classification System – Study of Dry Vesico-Elastic Polymer Pad Versus Standard Operating Table Foam Mattress

Scale/ Study	Grade 0	Grade 1	Grade 2a	Grade 2b	Grade 3	Grade 4	Grade 5
Torrance Scale / Nixon et al., 1998	No skin discoloration	Redness to the skin Blanching occurs	Redness to the skin Nonblanch-ing area	Superficial damage to epidermis	Ulceration progressed through the dermis	Ulceration extended into subcutaneous fat	Necrosis penetrating the deep fascia and extending to muscle

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 38. The study by Nixon et al. (33) satisfied all 6 quality assessment criteria.

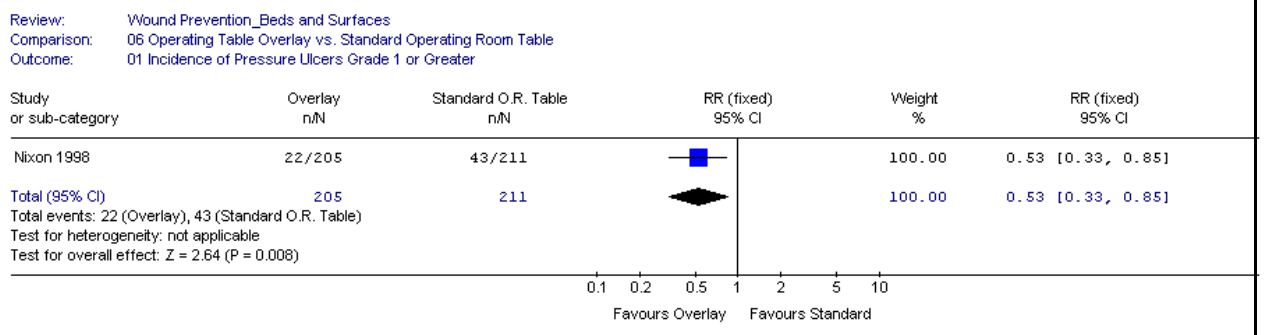
Table 38: Quality Assessment of Included Studies*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Nixon et al., 1998	✓	✓	✓	✓	8%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

The results of the study by Nixon et al. (33) are reported in Figure 13. There is a statistically significant reduction in the incidence of pressure ulcers grade 1 or greater in person using an operating table gel pad (RR, 0.53; 95% CI, 0.33–0.85) corresponding to an RRR of 47%. Of note, 20% of participants had a surgical time less than 90 minutes including 23% of persons in the treatment group compared with 18% in the control group. There was also a trend for the control group to have a longer duration of surgery and to spend more time in a hypotensive state intraoperatively. These variables may have increased the risk for developing pressure ulcers in the control group compared with the treatment group.



CI indicates confidence interval; O.R., operating room; RR, relative risk.

Figure 13: Operating Table Overlay Versus Standard Operating Room Table

Grade of Evidence

Table 39 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of a vesico-elastic polymer pad compared with a standard operating 3-inch foam mattress (standard care). The quality of evidence is low for the outcome of incidence of grade 1 or greater pressure ulcers.

Table 39: GRADE Evidence Profile – Dry Vesico-Elastic Polymer Pad Versus Standard 3-Inch Foam Mattress on Operating Table
Outcome: Incidence of Pressure Ulcers Grade 1 or Greater*

Studies	Design	Quality	Consistency	Directness†	Other Modifying Factors‡	No. of Patients			
						PP	SF	RR (95% CI)	Quality/ Importance
Nixon et al., 1998	RCT	No serious limitations	N/A	Some uncertainty about directness	Sparse data	205	211	0.53 (0.33–0.85)	**LOW/** Critical
	HIGH	**HIGH**	**HIGH**	**MOD**	**LOW**				

*CI indicates confidence interval; MOD, moderate; PP, polymer pad; RCT, randomized controlled trial; RR, relative risk; SF, standard foam.
†Grade 1 included blanching erythema. International consensus for grade 1 is nonblanching erythema (−1). The duration of follow up is 1 day. The study was not downgraded for this; however, some clinical experts believe this is not a sufficient length of follow-up to measure the outcome of grade 1 or greater pressure ulcers.
‡Only 1 study (−1).

Summary of Results

There is low quality evidence that the use of a vesico-elastic polymer pad (gel pad) on the operating table for surgeries of at least 90 minutes' duration produces a statistically significant RRR of 47% in the incidence of pressure ulcers grade 1 or greater compared with a standard operating table foam mattress.

Comparison 8: Air Suspension Bed Versus Standard Intensive Care Unit Bed

Characteristics of Included Studies

One study compared an air suspension bed with a standard intensive care unit (ICU) bed. (34) The study characteristics are reported in Table 40. The follow-up study period was 17 days on average. The Shea pressure ulcer classification grading system (35) was used to measure the outcome measure (Table 41).

Table 40: Characteristics of Included Studies – Air Suspension Bed Versus Standard Intensive Care Unit Bed*

Study	Population	Treatment	Control	Follow-Up	Outcome
Inman et al., 1993	ICU admissions > 3 days	Air suspension bed	Standard ICU bed	17 days (mean)	Incidence of pressure ulcers Shea classification system used

*ICU indicates intensive care unit.

Table 41: Table Pressure Ulcer Classification System – Study of Air Suspension Bed Versus Standard Intensive Care UnitBed

Scale/ Study	Grade 1	Grade 2	Grade 3	Grade 4	Closed
Shea 1975 / Inman et al., 1993	Indurated area of swelling, heat, and erythema with a superficial breakdown limited to the epidermis	Involves all soft tissue presenting with a full thickness skin ulcer extending to the underlying subcutaneous fat	A necrotic, foul smelling, infected ulcer limited by the deep fascia but extensively involving the fat with undermining of the skin. There is muscle, periosteum and joint involvement.	Pressure ulcer penetrates the deep fascia causing extensive soft tissue spread with osteomyelitis and septic, dislocated joints	Closed pressure sore conceals a deep lesion

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 42. The study by Inman et al. (34) satisfied 4 of the 6 quality assessment criteria; allocation concealment methods were not reported and the outcome assessments were not done in a blinded fashion.

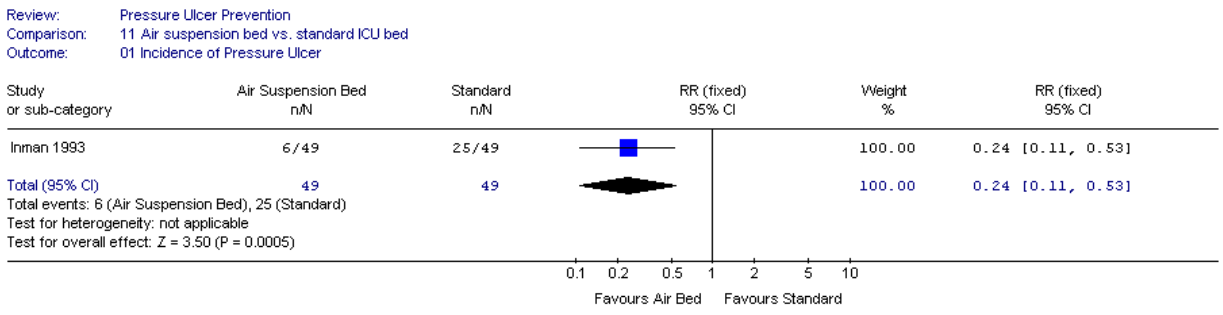
Table 42: Quality Assessment of Included Studies – Air Suspension Bed Versus Standard Intensive Care Unit Bed

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Inman et al., 1993	✓	Unknown	✓	x	2%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

The results of the study by Inman et al. (34) are reported in Figure 14. There is a statistically significant reduction in the incidence of pressure ulcers in person using an air suspension bed in the ICU (RR, 0.24; 95% CI, 0.11–0.53) corresponding to an RRR in the incidence of pressure ulcers of 76%.



CI indicates confidence interval; ICU, intensive care unit; RR, relative risk.

Figure 14: Air Suspension Bed Versus Standard Intensive Care Unit Bed

Grade of Evidence

Table 43 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of an air suspension bed in the ICU versus a standard ICU mattress. The quality of evidence is low for the outcome of incidence of pressure ulcers.

Table 43: GRADE Evidence Profile – Air Suspension Bed Versus Standard Intensive Care Unit Bed
Outcome: Incidence of Pressure Ulcers*

Studies	Design	Quality†	Consistency‡	Directness	Other Modifying Factors§	No. of Patients			
						Air	SM	RR (95% CI)	Quality/ Importance
Inman et al., 1993	RCT	Some serious limitations	N/A	No uncertainty about directness	Sparse data	49	49	0.24 (0.11–0.53)	**Low/** Critical
	HIGH	**MOD**	**MOD**	**MOD**	**LOW**				

*Air indicates air suspension bed; CI, confidence interval; MOD, moderate; RCT, randomized controlled trial; RR, relative risk; SM, standard ICU mattress.
†Unclear allocation concealment, outcome assessor not blinded to treatments.
‡Not applicable because there is 1 study.
§One study.

Summary of Results

There is low quality evidence that the use of an air suspension bed in the ICU for ICU stays of at least 3 days produces a statistically significant RRR of 76% in the incidence of pressure ulcers compared with a standard ICU bed.

Comparison 9: Alternating Pressure Mattress Versus Alternative Foam

Characteristics of Included Studies

Two studies compared alternating pressure mattresses with an alternate foam mattress. The study characteristics are reported in Table 44. The follow-up study period was 8 days in the study conducted by Whitney et al.; (36) however, the duration of follow-up was not clearly reported in the study by Stapleton. (37) A different pressure ulcer classification grading system was used to measure the study outcome in each study (Tables 45 and 46).

Table 44: Characteristics of Included Studies – Alternating Pressure Mattress Versus Alternative Foam*

Study	N	Population	Treatment	Control	Follow-Up	Outcome
Whitney et al., 1984	51	Medical-surgical units Patients in bed for 20 hours daily, ages 19–91 years with a mean of 63 years of age 60% of patients were confused, lethargic, and stuporous, and 40% were mentally alert 61% of patients were bedfast.	Alternating pressure consisting of 132 3-inch diameter air cells with 2.5 inch lift and micro air vents for air circulation. The air cells inflated and deflated every 3 minutes. Patient received routine nursing care including turning every 2 hours.	4-inch polyurethane convoluted foam mattress (eggcrate foam mattress)	8 days	Incidence skin breakdown Skin assessment tool
Stapleton, 1986	100	Female elderly patients with fractured neck of femur without existing pressure ulcers Age 65 or greater Scored 14 or less on the Norton scale No pre-existing pressure ulcers. Average age: 81 years	Large Cell Ripple (AP)	Polyether foam pad (CLP) Spenco Pad (CLP)	Unclear	Pressure ulcers of grade 2 or greater Categories from the Border study Category A: superficial/blister Category B-break in skin (no crater) Category C: a break in skin (with crater) Category D: blackened tissue

*AP indicates alternating pressure; CLP, constant low pressure.

Table 45: Pressure Ulcer Classification System Used by Whitney et al., 1984

Scale/Study	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Skin assessment tool Whitney et al., 1984	No redness or skin breakdown	Skin redness, fades in 15 minutes or less	Inflammation of the skin, fading time exceeds 15 minutes, less than 1 hour	Inflammation of the skin fading time exceeds 1 hour	Skin break with redness of surrounding skin: redness fades longer than 1 hour

Source: Whitney et al., 1984 (36)

Table 46: Pressure Ulcer Classification System Used by Stapleton, 1986

Scale/Study	Category A	Category B	Category C	Category D
Pressure ulcer grading Stapleton, 1986	Superficial/blister	A break in skin (no crater)	A break in skin (with crater)	Blackened tissue

Source: Stapleton, 1986 (37)

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 47. The methods of randomization were unclearly reported by Whitney et al. Stapleton allocated patients to the first 2 groups by lottery, and thereafter patients were allocated systematically in rotation. Overall, the quality of both studies was poor.

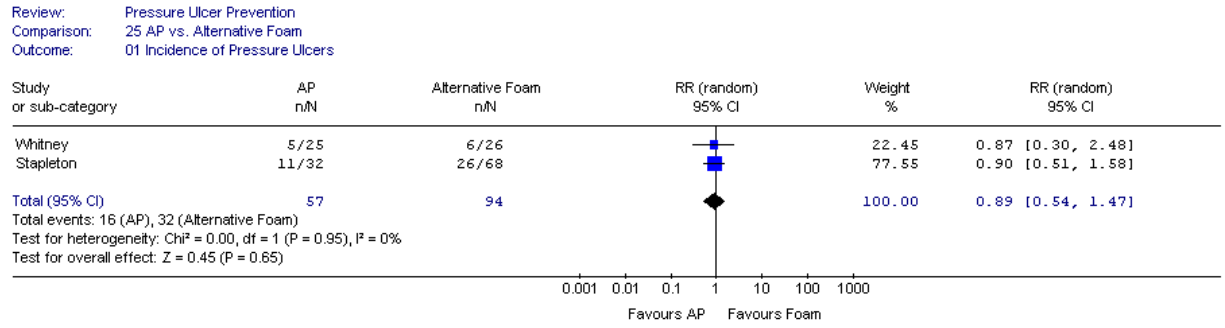
Table 47: Quality Assessment of Included Studies – Alternating Pressure Mattress Versus Alternative Foam*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Whitney et al., 1984	x Methods of randomization unclear	x	x	x Not blinded	None	✓
Stapleton, 1986	x	x	x	x	2%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

The results of the studies by Whitney et al. (36) and Stapleton (37) were pooled and the overall estimate of clinical effect is reported in Figure 15. There is a statistically nonsignificant reduction in the incidence of pressure ulcers in person using an alternating pressure mattress compared with an alternative foam mattress (RR, 0.89; 95% CI, 0.54–1.47).



AP indicates alternating pressure; CI, confidence interval; RR, relative risk.

Figure 15: Alternating Pressure Mattress Versus Alternative Foam

Grade of Evidence

Table 48 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of an alternating pressure mattress compared with an alternative foam mattress. The quality of evidence is very low for the outcome of incidence of pressure ulcers.

Table 48: GRADE Evidence Profile – Alternating Pressure Mattress Versus Alternative Foam Outcome: Incidence of Pressure Ulcers*

Studies	Design	Quality†	Consistency	Directness‡	Other Modifying Factors§	No. of Patients			
						AP	AF	RR (95% CI)	Quality/ Importance
Whitney et al., 1984	RCT	Some serious limitations	No important inconsistency	Some uncertainty about directness	Sparse data	57	94	0.89 (0.54–1.47)	**Very Low/** Critical
Stapleton, 1986	**HIGH**	**LOW**	**LOW**	**VERY LOW**	**VERY LOW**				

*AF indicates alternative foam mattress; AP, allternating pressure; CI, confidence interval; RCT, randomized controlled trial; RR, relative risk.
†Unclear allocation concealment, outcome assessor not blinded to treatments, methods of randomization inadequate in Stapleton (37) and unclear in Whitney et al. (36) (−2).
‡Studies were published 20 years ago; it is unknown if the quality and type of alternating pressure mattress is generalizable to that available today (−1).
§Pooled sample size is still small (−1).

Summary of Results

The use of an alternating pressure mattress does not statistically reduce the incidence of pressure ulcers compared with an alternative foam mattress. The quality of evidence supporting this conclusion is very low.

Nutritional Supplementation

Research Question

The literature was searched to determine the effect of using various nutritional supplementation regimens on the incidence of pressure ulcers in a population at risk for developing pressure ulcers. The search strategy is presented in Appendix 3.

Methods

Inclusion Criteria

- systematic reviews (with/without meta-analysis) or RCTs
- studies involving a population at risk for developing pressure ulcers
- studies evaluating the use of nutritional supplementation plus the standard hospital diet compared with the standard hospital diet only
- studies reporting the number (proportion) of persons developing a new pressure ulcer
- studies reporting the stage of pressure ulcer or in which the stage can be inferred from the description of the ulcer (nonblanchable erythema, blisters)

Exclusion Criteria

- studies that looked at discrete dosages of nutritional supplementation (e.g., different dosages of vitamin C or magnesium)

Primary Outcome

The primary outcome was the incidence of pressure ulcers measured as the number (proportion) of participants developing a new pressure ulcer.

Results of Literature Search

Two systematic reviews were obtained from the literature search strategy. (38;39) Langer et al. (38) searched the electronic databases up to 2003 and retrieved 4 relevant RCTs. Stratton et al. (39) searched up to 2004 and retrieved 1 additional relevant RCT. Our search strategy did not retrieve any relevant RCTs in addition to those reported by Stratton et al. and Langer et al. (38;39) (Table 49). Therefore, in total there are 5 relevant RCTs comparing the effectiveness of nutritional supplementation in addition to the standard hospital diet compared with the standard hospital diet alone.

Table 49: Quality of Evidence of Included Studies – Nutritional Supplementation*

Study Design	Level of Evidence	Number of Eligible Studies	MAS Update to Systematic Review
Systematic reviews of RCT	1	2	0
or			
Large RCT		2	
Large RCT unpublished but reported to an international scientific meeting	1(g)†		0
Small RCT	2	3	0
Small RCT unpublished but reported to an international scientific meeting	2(g)		0
Non-RCT with contemporaneous controls	3a		0
Non-RCT with historical controls	3b		n/a
Non-RCT presented at international conference	3(g)		n/a
Surveillance (database or register)	4a		n/a
Case series (multisite)	4b		n/a
Case series (single site)	4c		n/a
Retrospective review, modeling	4d		n/a
Case series presented at international conference	4(g)		n/a

* MAS indicates Medical Advisory Secretariat; RCT, randomized controlled trial.
†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (11) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meeting. (11)

Characteristics of Included Studies

Five studies compared the effect of nutritional supplementation on the incidence of pressure ulcers with that of a standard hospital diet. (40-44) The study characteristics are reported in Table 50. Three of the 5 studies included persons with hip fractures. (41;43;44) Nutritional supplementation ranged from 1070 to 6300 kJ/day (254 to 1,500 c/day). The total energy intake in the standard hospital diet of the control groups was reported in only 2 studies. (40;42) The follow-up study period ranged from 2 weeks to 6 months. In the study by Hartgrink et al., (43) the nutritional supplementation was delivered via nasogastric tube. All studies used a different pressure ulcer classification system for the outcome measure (Table 51).

Table 50: Characteristics of Included Studies – Nutritional Supplementation

Study Year	N	Population	Treatment	Control	Follow-Up	Outcome
Delmi et al., 1990	59	Persons with femoral neck fractures after accidental fall > 60 years, mean age of 82	Standard Hospital diet with daily oral nutrition supplement (250 mL; 1060 kJ (254 c); 20.4 g protein; 29.5 g carbo_hydrates; 5.8 lipid; 525 mg calcium; 750 IU vitamin A; 25 IU vitamin D3, vitamin E, B1, B2, B6, B12, C, nicotinamide, folate, calcium panto-thenate, biotin, minerals) 1070 kJ/day (254 c/day)	Standard hospital diet	Up to 6 months post discharge	At 6 months Incidence of bedsores No classification system given
Hartgrink et al., 1998	140	Persons with hip fracture, pressure sore risk score of 8 points or greater and an increased pressure sore risk	Standard hospital diet and additional naso-gastric tube feeding with 1000 mL Nutrison Steriflo energy plus (6300 kJ/L [1,500 c/L] 60 g/L protein) administered with a feeding pump between 9 pm and 5 am 6300 kJ/day (1,500 c/day)	Standard hospital diet alone	2 weeks	Pressure ulcers grade 2 or greater Dutch consensus meeting for the prevention of pressure sores, 1992 pressure ulcer classifi-cation system
Bourdel-Marchasson, 2000	672	65 years of age, and older who were critically ill, immobile, and did not have a pressure ulcer	Standard diet (7500 kJ/day [1800 c/day]) and 2 oral supplements per day (each with 200 ml; 840 kJ (200 c); 30% protein; 20% fat; 50% carbohydrate; minerals and vitamins such as 1.8 mg zinc and 15 mg vitamin C) Persons also received standard pressure ulcer prevention program care (changing positions, special mattresses, cleaning care) 1700 kJ/day (400 c/day)	Standard diet (7500 kJ/day [1800 c/day]) Persons also received standard pressure ulcer prevention program care (changing positions, special mattresses, cleaning care)	15 days or until discharge	Incidence of pressure ulcers Agency for Health Care and Policy Research Pressure Ulcer Classification System
Houwing et al., 2003	103	Persons with a hip fracture	Standard hospital diet and 1 supplement daily (400 mL; 2100 kJ (500 c); 40 g protein; 6g/L arginine; 20 mg zinc; 500 mg vitamin C; 200 mg vitamin E; 4 mg cartenoids) 2100 kJ/day (500 c/day)	Standard hospital diet and noncaloric water-based placebo	Up to 28 days or at discharge	Incidence of pressure ulcer (highest stage was recorded) European Pressure Ulcer Advisory Panel 1998 pressure ulcer classification system

Table 50: Characteristics of Included Studies – Nutritional Supplementation (continued)

Study Year	N	Population	Treatment	Control	Follow-Up	Outcome
Ek et al., 1991	501	Persons newly admitted to long-term medical ward, remaining for at least 3 weeks	200 mL of liquid supplement given twice daily (4 g protein, 4 g fat, 11.8 h carbohydrates, 419 kJ and minerals and vitamins/100 mL) 1700 kJ/day (400 c/day)	Standard hospital diet (9200kJ/day [2,200 c/day])	26 weeks after admission to hospital	Incidence of pressure ulcers Nonspecific pressure ulcer classification system used Persistent discoloration (dark red, reddish-blue color) or epithelial damage or damage to the full thickness of the skin with or without cavity

Table 51: Table Pressure Ulcer Classification System – Studies of Nutritional Supplementation*

Study	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Delmi et al., 1990	N/A	N/A	N/A	N/A	N/A
Hartgrink et al., 1998	Normal skin	Persistent erythema of the skin	Blister formation	Superficial subcutaneous necrosis	Deep subcutaneous necrosis
Bourdel-Marchasson, 2000	N/A	Erythematous skin	Superficial layer of broken or blistered skin	Involves subcutaneous tissue	Ulcer extends into the muscle or bone
Houwing et al., 2003		Nonblanchable erythema of intact skin Discoloration of the skin, warmth, edema, induration, or hardness may also be used as indicators particularly on individuals with darker skin	Partial thickness skin loss involving epidermis, dermis, or both The ulcer is superficial and presents clinically as an abrasion or blister	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss

*N/A indicates not applicable.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 52. All studies were RCTs. The study by Bourdel-Marchasson (40) used a cluster randomization design. None of the studies reported adequate allocation concealment methods or a blinded outcome assessment process. Two studies, Hartgrink et al. (43) and Houwing et al., (45) completed a sample size calculation a priori. The losses to follow-up were greater than 30% in all studies except that completed by Houwing et al. (45)and Ek et al. (42) An intention-to-treat analysis was completed by Bourdel-Marchasson (40) only.

Of note, in the study by Bourdel-Marchasson (40) the study groups were not comparable at baseline with respect to pressure ulcer risk scores. Persons in the nutritional intervention group had lower pressure ulcer risk scores, were less dependent, and had lower serum albumin levels. A multivariate analysis found that patients receiving the intervention were significantly less likely to develop a pressure ulcer compared with controls.

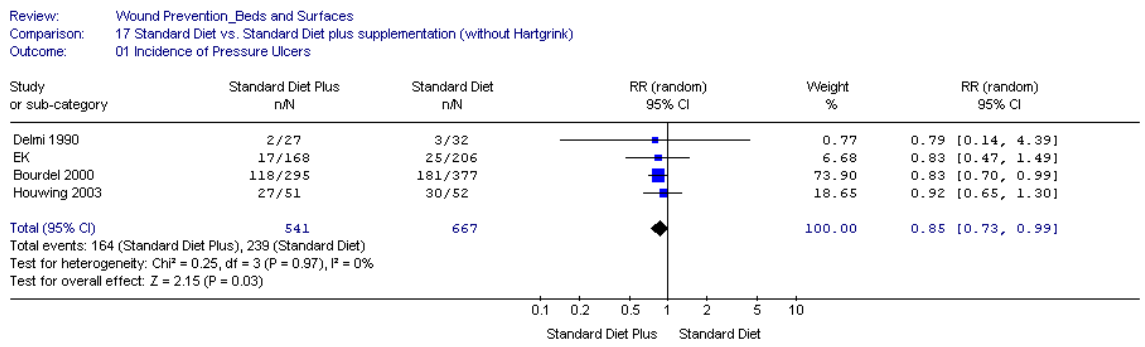
Table 52: Quality Assessment of Included Studies – Nutritional Supplementation*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Delmi et al., 1990	✓	x	x	x	60% at 6 months	Patients who died were not included in the analysis; 6 in the supple-mentation group and 4 in the controls
Hartgrink et al., 1998	✓	x	✓	x	Dropout rate in treatment group was 54% after 1 week because persons were intolerant of the naso-gastric tube feeding At 2 weeks the dropout rate was 33%	x
Bourdel-Marchasson, 2000	✓ (cluster randomization)	x	x	x	30%	✓
Houwing et al., 2003	✓	x	✓	x	3%	x 3 persons not included in analysis
Ek et al., 1991	✓	x	x	Unclear	1%	Missing information on 6 patients

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

Figure 16 reports the results of the meta-analysis of the studies comparing nutritional supplementation and a standard diet to a standard hospital diet alone. There is an overall statistically significant RRR of 15% in the incidence of pressure ulcers in favour of nutritional supplementation to a standard hospital diet. The effect estimate from the study by Hartgrink et al. (43) was not included in the meta-analysis as it was thought that the intervention of 6300 kJ/day (1,500 c/day) supplementation via nasogastric tube was clinically dissimilar to the interventions used in the other 4 studies.



CI indicates confidence interval; RR, relative risk.

Figure 16: Standard Diet Versus Standard Diet Plus Supplementation

Grade of Evidence

Table 53 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of nutritional supplementation plus a standard hospital diet compared with a standard hospital diet alone. The quality of evidence is very low for the outcome of incidence of pressure ulcers.

Table 53: GRADE Evidence Profile – Standard Hospital Diet Versus Standard Hospital Diet Plus Supplementation
Outcome: Incidence of Pressure Ulcers*

Studies	Design	Quality†	Consistency	Directness‡	Other Modifying Factors	No. of Patients			
						SD+	SD	RR (95% CI)	Quality/ Importance
Delmi et al., 1990 Hartgrink et al., 1998 Bourdel-Marchasson, 2000 Houwing et al., 2003	RCT	Some very serious limitations	No important inconsistency	Some uncertainty about directness	None	541	667	0.85 (0.73–0.99)	**Very Low/** Critical
	HIGH	**LOW**	**LOW**	**VERY LOW**	**VERY LOW**				

*CI indicates confidence interval; RCT, randomized controlled trial; RR, relative risk; SD, standard diet; SD+, standard diet plus nutritional supplementation.
†Inadequate allocation concealment, outcome assessor not blinded to treatments allocation, large losses to follow-up (−2).
‡Wide range in follow-up times and energy intake rate of nutritional supplementation, standard hospital diet not described (−1).

Summary of Results

There is very low quality evidence supporting an RRR of 15% in the incidence of pressure ulcers when nutritional supplementation is added to a standard hospital diet.

Repositioning

Research Question

The literature was searched to determine the effect of using different turning schedule frequencies on the incidence of pressure ulcers in a population at risk for developing pressure ulcers. The search strategy is presented in Appendix 4.

Methods

Inclusion Criteria

- systematic reviews (with/without meta-analysis), or RCTs
- studies involving a population at risk for developing pressure ulcers
- studies evaluating the use of various frequencies of turning compared with a standard 2-hour regimen for positioning frequency or other turning schedule frequencies
- studies reporting the number (proportion) of persons developing a new pressure ulcer
- studies reporting the stage of pressure ulcer or in which the stage can be inferred from the description of the ulcer

Exclusion Criteria

- studies evaluating the frequency of position changes with other preventive interventions (other than pressure redistribution surfaces) such that the effect of frequency cannot be determined

Primary Outcome Measure

The primary outcome measure was the incidence of pressure ulcers measured as the number (proportion) of participants developing a new pressure ulcer.

Results of Literature Search

One systematic review and 2 large RCTs were obtained from the literature search (Table 54). (46-48) The study by Vanderwee et al. (48) compared different turning frequencies and positioning, and the study by Defloor et al. (47) compared only different turning schedule frequencies. One Cochrane protocol was also found whose purpose was to conduct a systematic review of research evidence to determine the optimal turning schedule frequency. (49)

The systematic review by Buss et al. (46) determined the most effective time interval for repositioning persons at risk for pressure sore development. The investigators searched Medline, the Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature from the inception of these computerized databases up to the year 2000. Their literature search yielded 5 research reports, 1 of which was the study by Defloor et al. (47) The other 4 studies have not been included in our review for the following reasons: 2 evaluated small shifts in body position, 1 was a non-English thesis, and 1 was a non-RCT.

Table 54: Quality of Evidence of Included Studies – Repositioning*

Study Design	Level of Evidence	Number of Eligible Studies	MAS Update to Systematic Review
Systematic reviews of RCT or Large RCT	1	1	0
Large RCT unpublished but reported to an international scientific meeting	1(g)†		2
Small RCT	2		0
Small RCT unpublished but reported to an international scientific meeting	2(g)		0
Non-RCT with contemporaneous controls	3a		N/A
Non-RCT with historical controls	3b		
Non-RCT presented at international conference	3(g)		
Surveillance (database or register)	4a		
Case series (multisite)	4b		
Case series (single site)	4c		
Retrospective review, modeling	4d		
Case series presented at international conference	4(g)		

* MAS indicates Medical Advisory Secretariat; N/A, not applicable; RCT, randomized controlled trial.
†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (11) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meeting. (11)

Characteristics of Included Studies

Table 55 reports the characteristics of the included studies (47;48) The mean age in both studies was 85 years. The follow-up period ranged from 15 days on average in the Vanderwee et al. (48) study to 4 weeks in the study completed by Defloor et al. (47) While both studies used a different pressure classification system for the outcome measure, the classification systems were comparable (Table 56).

Table 55: Characteristics of Included Studies – Repositioning*

Study	Population	Treatment	Control	Follow-Up	Outcome
Vanderwee et al., 2007 N = 235 RCT	Belgian geriatric nursing home residents Median age: 84 (IQR 83–89)	Repositioned with unequal time intervals according to the following sequence: semi-Fowler 30º, right-side lateral position 30º, semi-Fowler 30º, left-side lateral position 30º. Persons lay for 4 hours in a semi-Fowler 30º position and 2 hours in a lateral position 30º. The semi-Fowler was a 30º elevation of the head end and the foot end of the bed. In the lateral position, the patient was rotated 30º with their back supported with an ordinary pillow. The group was lying on a visco-elastic foam overlay mattress (7 cm) The heels were elevated and a standardized sitting protocol was used Persons were asked to stand every 2 hours on their own or with help	Patients were repositioned according to the same turning scheme as used in the treatment group, but with equal time intervals of 4 hours in the lateral 30 and 4 hours in the semi-Fowler 30 position. The group was lying on a visco-elastic foam overlay mattress (7 cm) The heels were elevated and a standardized sitting protocol was used. Persons were asked to stand every 2 hours on their own or with help.	15 days on average	Grade 2–4 lesions European Pressure Ulcer Advisory Panel classification system 1999
Defloor et al., 2005 RCT N = 262 2 hours: n = 63 3 hours: n = 58 4 hours: n = 66 6 hours: n = 63	Geriatric nursing home patients in Belgium Mean age: 85 years (SD 8 years)	Turning every 4 hours Turning every 6 hours A visco-elastic polyurethane foam mattress was used	Turning every 2 hours Turning every 3 hours A standard hospital mattress was used	4 weeks	Grade 2 or greater pressure ulcers AHCPR classification system

*AHCPR indicates Agency for Health Care Policy and Research; IQR, interquartile range; RCT, randomized controlled trial; SD, standard deviation.

Table 56: Table Pressure Ulcer Classification System – Studies of Repositioning*

Study	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
European Pressure Ulcer Advisory Panel classification system 1999	N/A	Nonblanchable erythema	Abrasion or blister	Superficial ulcer	Deep ulcer
AHCPR classification system	N/A	Nonblanchable erythema	Blistering	Superficial ulcer	Deep ulcer

*AHCPR indicates Agency for Health Care Policy and Research; N/A, not applicable.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 57. All studies used a RCT design. The study by Vanderwee et al. (48) did not report using adequate allocation concealment methodology. Neither study used a blinded outcome assessment process.

Table 57: Quality Assessment of Included Studies – Repositioning

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Defloor et al., 2005	✓	✓	✓	x	4.5%	✓
Vanderwee et al., 2007	✓	x	✓	x	0%	✓

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

We could not pool the individual study results of the Defloor et al. (47) and the Vanderwee et al. (48) studies because the treatment and control groups received different interventions. Therefore, we will report on the individual study results.

Vanderwee et al. (48) reported no statistically significant difference in the incidence of pressure ulcers grade 2 or greater in the treatment group compared with the control group (RR, 0.66; 95% CI, 0.37–1.20). Both groups used an alternate foam mattress and were turned every 2 or 4 hours. The similarity in treatment protocols between groups may have contributed to the negative effects.

Defloor et al. (47) used multivariate logistic regression analyses using a standard-care group as a reference, and reported a statistically significant reduction in pressure ulcer lesions of grade 2 or greater in the 4-hourly turning protocol group which was using a pressure redistribution mattress (odds ratio, 0.12; 95% CI, 0.03–0.48).

We completed a subgroup analyses of the Defloor et al. (47) data and report the results in Table 58 and Figures 17 through 22. Results indicate that turning every 4 hours on a pressure redistribution mattress is associated with a 34% RRR in the incidence of grade 1 pressure ulcers compared with turning every 3 hours on a standard foam mattress (Figure 17). We found no difference between the incidence of grade 1 pressure ulcers using a 2-hourly turning schedule and a standard foam mattress compared with a 3-hour turning schedule and a standard foam mattress (RR, 0.90; 95% CI, 0.69–1.16). Therefore, we combined the incidence of grade 1 pressure ulcers for these 2 groups (2 h and 3 h and standard foam mattress) and compared the incidence of grade 1 pressure ulcers with that occurring in the 4-hourly

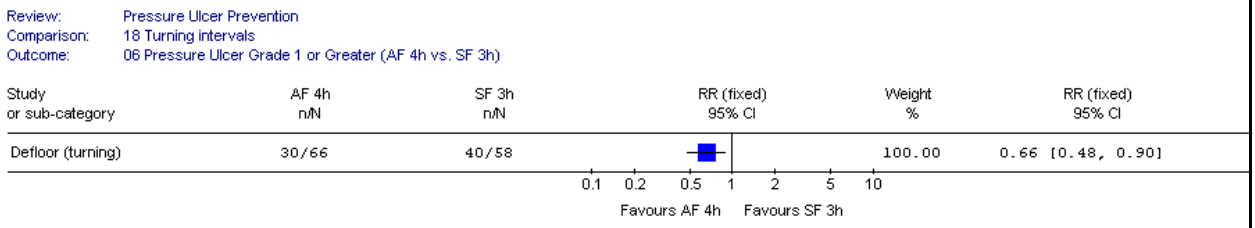
turning schedule group using a pressure redistribution mattress. Results indicate a statistically significant reduction in grade 1 pressure ulcers favoring a 4-hourly turning schedule with a pressure redistribution mattress (RR, 0.70; 95% CI, 0.5– 0.93) (Figure 18).

Similarly, we found a statistically significant reduction in pressure ulcers of grade 2 or greater using a 4-hourly turning schedule with a pressure redistribution mattress compared with either a 2-hourly (RRR of 79%) or 3-hourly (RRR of 87%) turning schedule with a standard foam mattress (Figure 19 and Figure 20). Likewise, a 4-hourly turning schedule with a pressure reducing mattress appears statistically superior to using a 6-hourly turning schedule with a pressure redistribution mattress (Figure 21). Again because there was no difference noted between the 2-hourly turning and 3-hourly turning schedules with a standard foam mattress we combined these 2 groups and compared the incidence of grade 2 or greater pressure ulcers with a 4-hourly turning schedule and a pressure redistribution mattress. Results indicate that a 4-hourly turning schedule was associated with a statistically significant RRR of 84% in grade 2 pressure ulcers compared with the combined incidence rate (RR, 0.16; 95% CI, 0.04–0.66) (Figure 22).

Table 58: Subgroup Analyses – Repositioning*

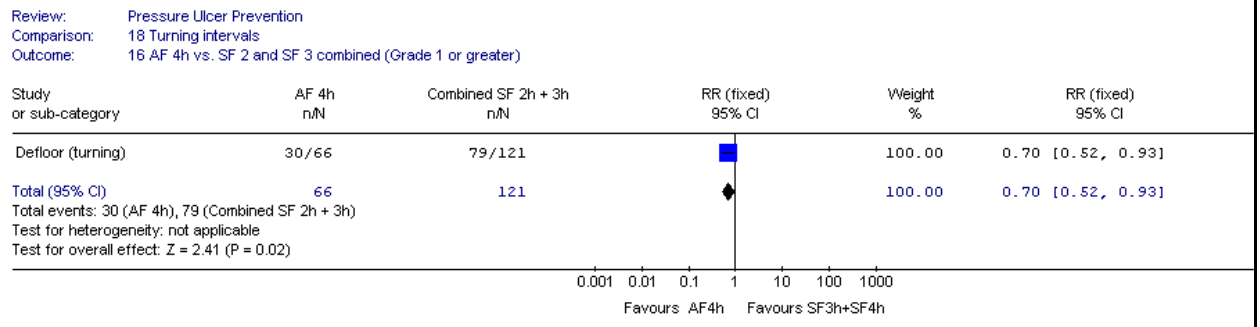
Comparison	RR (95% CI)† Grade 1	RR (95% CI) Grade 2
AF 4h vs. SF 2h	0.73 (0.53–1.02)	**0.21 (0.05–0.94)**
AF 4h vs. SF 3h	**0.66 (0.48–0.98)**	**0.13 (0.03–0.53)**
AF 4h vs. AF 6h	0.73 (0.53–1.02)	**0.19 (0.04–0.84)**
AF 4h vs. SF 2h + SF 3h	**0.70 (0.52–0.93)**	**0.16 (0.04–0.66)**
SF 2h vs. SF 3h	0.90 (0.69–1.16)	0.59 (0.28–1.26)
AF 6h vs. SF2h	1.00 (0.76–1.32)	1.11 (0.48–2.55)
AF 6h vs. SF 3h	0.90 (0.69–1.16)	0.66 (0.32–1.36)

*AF indicates alternative foam mattress (pressure redistribution mattress); CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.
†Fixed effects.



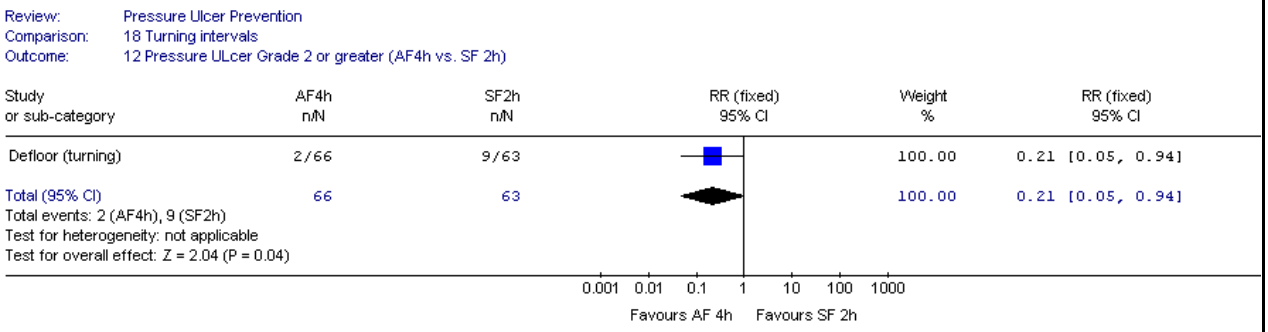
AF indicates alternative foam mattress; CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.

Figure 17: Alternate Foam Mattress and Turning 4-hourly Versus Alternate Foam Mattress Turning 3-hourly



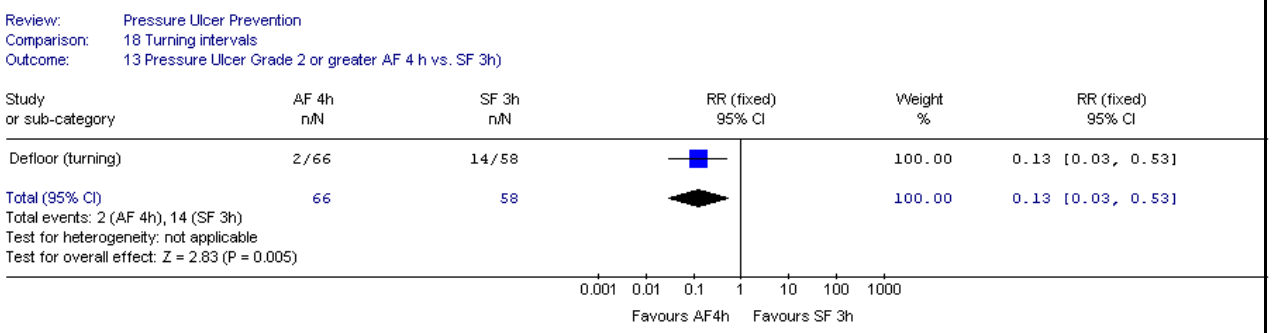
AF indicates alternative foam mattress; CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.

Figure 18: Alternate Foam Mattress and Turning 4-hourly Versus Standard Foam Mattress Turning 2-hourly and 3-hourly



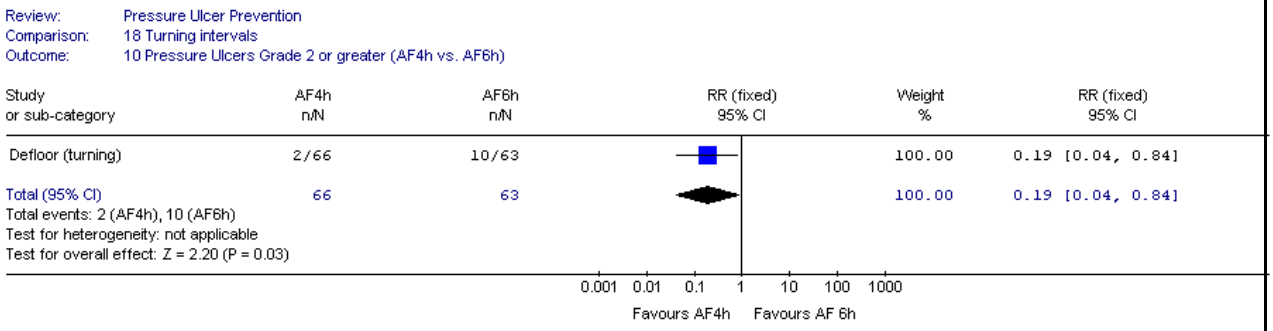
AF indicates alternative foam mattress; CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.

Figure 19: Alternate Foam Mattress and Turning 4-hourly Versus Standard Foam Mattress and Turning 2-hourly



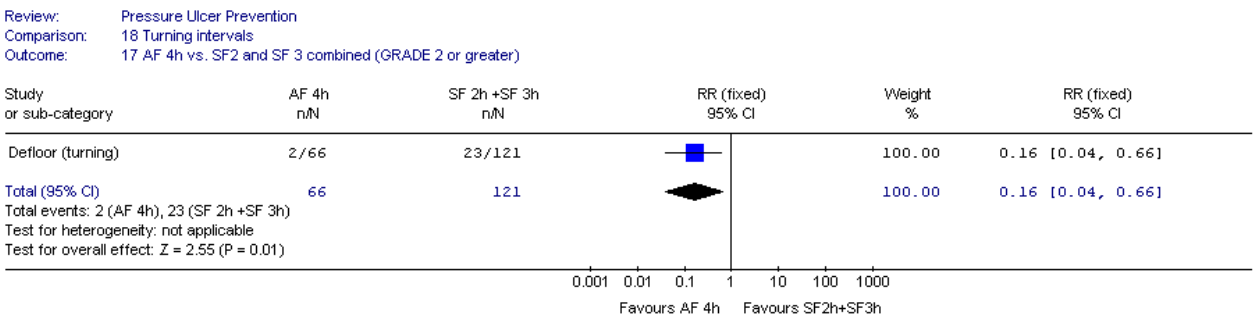
AF indicates alternative foam mattress; CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.

Figure 20: Alternate Foam Mattress and Turning 4-hourly Versus Standard Foam Mattress and Turning 3-hourly



AF indicates alternative foam mattress; CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.

Figure 21: Alternate Foam Mattress and Turning 4-hourly Versus Alternate Foam Mattress and Turning 6-hourly



AF indicates alternative foam mattress; CI, confidence interval; h, hours; RR, relative risk; SF, standard foam mattress.

Figure 22: Alternate Foam Mattress and Turning 4-hourly Versus Standard Foam Mattress and Turning 2-hourly and 3-hourly

Grade of Evidence

Tables 59 through 61 report the GRADE evidence profile for the body of evidence evaluating the effectiveness of a 4-hourly turning schedule with a pressure reducing mattress compared with a standard foam mattress and a 2-hourly and 3-hourly turning schedule to prevent grade 1 or greater or grade 2 or greater pressure ulcers. The quality of evidence is low.

Table 59: GRADE Evidence Profile – Turning Every 4 Hours Plus Pressure Redistribution Mattress Versus Turning Every 2 or 3 Hours on a Standard Foam Mattress *

Studies	Design	Quality	Consistency	Directness	Other Modifying Factors	No. of Patients		RR (95% CI)	Quality/ Importance
						4h +AP	2h + 3h +SFM		
Defloor et al., 2005	RCT	Some serious limitations†	N/A‡	No uncertainty about directness	Sparse data§	66	121	0.70 (0.52–0.93)	**LOW/** Critical
	HIGH	**MOD**	**MOD**	**MOD**	**LOW**				

*AP indicates alternating pressure; SFM, standard foam mattress; RR, relative risk; CI, confidence interval; RCT, randomized controlled trial; N/A, not applicable.
†Lacks blinded outcome assessment (−1)
‡Only 1 study
§Subgroup analyses (−1)

Table 60: GRADE Evidence Profile – Turning Every 4 Hours Plus Pressure Redistribution Mattress Versus Turning Every 2 Hours on a Standard Foam Mattress*

Studies	Design	Quality	Consistency	Directness	Other Modifying Factors	No. of Patients			
						4h +AP	2h +SFM	Relative (RR, 95% CI)	Quality/ Importance
Defloor et al., 2005	RCT	Some serious limitations†	N/A‡	No uncertainty about directness	Sparse data§	66	63	0.21 (0.05–0.94)	**LOW/** Critical
	HIGH	**MOD**	**MOD**	**MOD**	**LOW**				

*AP indicates alternating pressure; SFM, standard foam mattress; RR, relative risk; CI, confidence interval; RCT, randomized controlled trial; N/A, not applicable.
†Lacks blinded outcome assessment (−1)
‡One study
§Subgroup analyses (−1)

Table 61: GRADE Evidence Profile – Turning Every 4 Hours Plus Pressure-Reducing Mattress Versus Turning Every 2 or 3 Hours on a Standard Foam Mattress

Studies	Design	Quality	Consistency	Directness	Other Modifying Factors	No. of Patients			
						4h +AP	2h + 3h +SFM	RR (95% CI)	Quality/ Importance
Defloor et al., 2005	RCT	Some very serious limitations†	N/A‡	No uncertainty about directness	Sparse data§	66	121	0.16 (0.04–0.66)	**LOW/** Critical
	HIGH	**MOD**	**MOD**	**MOD**	**LOW**				

*AP indicates alternating pressure; SFM, standard foam mattress; RR, relative risk; CI, confidence interval; RCT, randomized controlled trial; N/A, not applicable.
†Lacks blinded outcome assessment (−1)
‡One study
§Subgroup analyses (−1)

Summary of Results

There is low quality evidence supporting the superiority of a 4-hourly turning schedule with a pressure redistribution mattress compared with a 2-hourly or 3-hourly turning schedule and a standard foam mattress to reduce the incidence of grade 1 or 2 pressure ulcers.

Incontinence Management

Research Question

- The literature was searched to determine:The effectiveness of using a structured skin care protocol compared with no structured skin care protocol in persons who have urinary and fecal incontinence
- The effectiveness of using a pH-balanced cleanser compared with soap and water to reduce the incidence of pressure ulcers in persons who have urinary and fecal incontinence.

The search strategy is presented in Appendix 5.

Methods

Inclusion Criteria

- systematic reviews (with/without meta-analysis), RCTs, and non-RCT study designs
- studies involving a population with urinary and fecal incontinence
- studies evaluating the use of a structured skin care protocol defined as having explicit components and a defined regimen of care
- studies comparing a pH-balanced cleanser with soap and water
- studies reporting the number (proportion) of persons developing a new pressure ulcer
- studies reporting the stage of pressure ulcer or in which the stage can be inferred from the description of the ulcer

Exclusion Criteria

- studies reporting only the incidence of dermatitis as an outcome measure

Primary Outcome Measure

The primary outcome measure was the incidence of pressure ulcers measured as the number (proportion) of participants developing a new pressure ulcer.

Results of Literature Search

Skin Care Protocol

Two reports describing the same observational research study were obtained from the literature search (Table 62). The objective of the study was to assess the effectiveness of a skin care protocol on the incidence of pressure ulcers in a geriatric population. The evaluation used a before-and-after research design.

pH-Balanced Cleanser Versus Soap and Water

One small RCT was obtained from the literature that determined the effectiveness of a pH-balanced cleanser for skin care compared with soap and water in persons with urinary and fecal incontinence (Table 62).

Table 62: Quality of Evidence of Included Studies – Incontinence Management*

Study Design	Level of Evidence	Number of Eligible Studies	Medical Advisory Secretariat Update to Systematic Review
Systematic reviews of RCT or Large RCT	1	0	0
Large RCT unpublished but reported to an international scientific meeting	1(g)†		0
Small RCT	2		1
Small RCT unpublished but reported to an international scientific meeting	2(g)		0
Non-RCT with contemporaneous controls	3a		2 (same study)
Non-RCT with historical controls	3b		
Non-RCT presented at international conference	3(g)		
Surveillance (database or register)	4a		
Case series (multisite)	4b		
Case series (single site)	4c		
Retrospective review, modeling	4d		
Case series presented at international conference	4(g)		

RCT indicates randomized controlled trial.
†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (11) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meeting. (11)

Comparison 1: Skin Protocols Versus Standard Care

Characteristics of Included Studies

Table 63 reports the characteristics of the included studies comparing the effectiveness of a skin care protocol with that of standard care. Both studies report on the same protocol. The mean age was 81 years. The duration of each study phase was 3 months. While both reports (50;51) described the same study, Hunter et al. (50) reported using the Agency for Health Care Policy and Research pressure ulcer classification system and Thompson et al. (51) using the NPUAP system (Table 64). We were unsuccessful at contacting the authors to reconcile this discrepancy.

Table 63: Characteristics of Included Studies – Skin Protocols Versus Standard Care

Study	Population	Treatment	Control	Follow-Up	Outcome
Hunter et al., 2003 Thompson et al., 2005 N = 136 Observational (before-and-after study design)	Residents in 2 long-term care facility in the US with at least 1-week stay with urinary and fecal incontinence. Incontinence was defined as 2 or more episodes of bladder or bowel incontinence in 1 week. Mean Age: Pre: 83 y Post: 80 y The majority of persons in the before phase of the study also participated in the after phase.	Body wash and skin protectant to routine care **Components** Educational session for nursing staff on how to assess stage I and stage II pressure ulcers, the physiology of ageing skin, the introduction of a nonirritating, pH-balanced, no-rinse cleanser/deodorizer body wash and a skin protectant (a fine grain emulsion consisting of 50% lanolin with beeswax and petrolatum additives) into skin care protocols Skin care protocols included skin assessment techniques, prevention and treatment for dry skin, identification of stage I and stage II pressure ulcers and skin protection and early intervention for incontinence. **Regimen** Cleanse skin with the body wash (Lantiseptic All Body Wash, Summit Industries, Inc, Marietta, GA) after each incontinent episode and to apply the skin protectant (Lantiseptic Skin Protectant, Summit Industries, Marietta, GA) to the skin. Skin protectant was to be applied at least every 8 hours and after every cleansing when incontinent. Check each incontinent resident's skin every 2 hours. Compliance Monitoring surveillance: directors and assistant directors of nursing monitored and reinforced protocol compliance	Completed 3 months before the treatment period. Documentation of skin assessment and pressure ulcer development, treatment, healing time and incontinence. Standard care at each agency included a skin care protocols based on the AHCPR guidelines. Agency skin care protocol included daily skin condition reports, weekly skin assessments, and dietary risk management. Briefs for incontinence were left open for air circulation; periwash and barrier cream were not used unless the resident was at moderate risk for skin breakdown.	3 months for each phase of the study	Incidence of stage 1 and 2 pressure ulcers Agency for Health Care Policy and Research, 1992 classification system And NPUAP definitions

* NPUAP indicates National Pressure Ulcer Advisory Panel.

Table 64: Table Pressure Ulcer Classification System – Studies of Skin Protocols Versus Standard Care*

Study	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
*Hunter et al., 2003 †Thompson et al., 2005	N/A	*Nonblanchable erythema of intake skin †Defined area of persistent redness in light skin. Persistent red, blue or purple in dark skin.	*Partial thickness skin loss involving epidemis and/or dermis. †Partial-thickness skin loss involving the loss of epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.	N/A for study	N/A for study

*N/A indicates not applicable.

Quality Assessment of Included Studies

The information in both the Thompson et al. (51) report and the Hunter et al. (50) report was used to complete the quality assessment of the study (Table 65). Of the 8 criteria used to assess the quality, 3 were not satisfied. The study used a convenience sample instead of consecutive enrollment. However, with the exception of 2 residents that declined participation, the study sample included all residents in both facilities that met the inclusion and exclusion criteria. It is unclear if the participants in both the pre phase and the post phase were comparable in terms of age and urinary and fecal incontinence status. However, it is reported that 77% of the study sample participated in both the pre- and post-study phases. Finally, the caregivers were the data collectors, and because of this the outcome measure was not assessed independently of the exposure status.

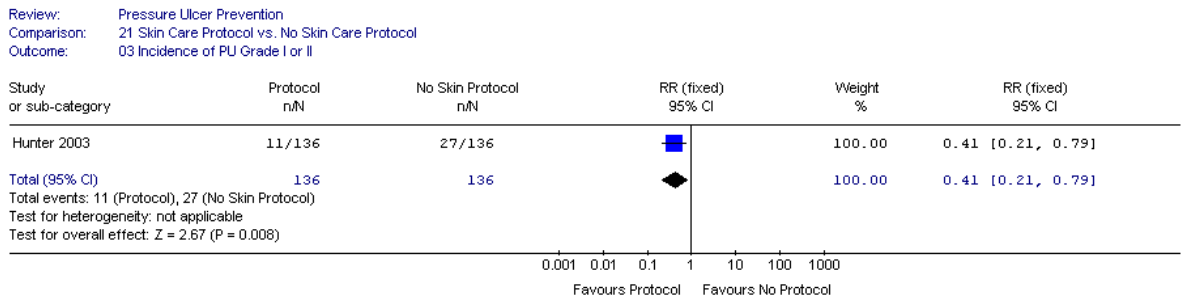
Of note, the investigators state that the only change in the care was the addition of the specific body wash and the skin protector. However, the treatment group (postphase group) also received structured education sessions, and specific components of the skin care protocol were stipulated as well as a skin care regimen (checking patient every 2 hours and apply skin protector at least every 8 hours). Indeed, the authors acknowledge that the education provided to the nursing staff may have influenced the study outcome by either enhancing the knowledge base of the caregivers and/or increasing the caregivers' vigilance for skin assessment. The authors further state that it is difficult to determine whether the decrease in the incidence of pressure ulcers was due to the study treatment (skin care protocol) or an increased staff vigilance for pressure ulcer assessment.

Table 65: Quality Assessment of Included Studies – Skin Protocols Versus Standard Care

Study	Inclusion/ Exclusion Criteria Stated	Consecutive Sampling Used	Are Baseline Characteristics In Groups Are Similar	Is Treatment Valid and Reliable	Is a Reliable and Valid Outcome Measure Used	Is Outcome Measure Done Independently of Exposure Status	Is Duration of Follow-Up Adequate	Loss to Follow-Up (%)
Hunter et al., 2003	✓	X Convenience sample. All residents other than 2 in the facility participated.	Unclear 105 (77%) of the residents in the before phase participated in the after phase. Characteristics of the study sample by phase were not reported.	✓	✓	X Caregivers were the data collectors.	✓ 3-month duration for each phase	✓ 13 persons died and 17 were discharged. The full study sample (n = 136) was used to calculate incidence of pressure ulcers.

Results

There was a significant difference in the total number of persons with stage 1 or 2 new pressure ulcers between phase 1 and phase 2 (19.8% vs. 8.1%, *P* = .000) and therefore a statistically significant RRR of developing a pressure ulcer in persons treated with the skin care protocol compared with the control group (RR, 0.41; 95% CI, 0.21–0.70) (Figure 23). We chose to express the estimate of effect as a RR. However, given that the baseline risk is less than 30%, the odds ratio may be the preferred estimate of effect. (52) The odds ratio is 0.36 (fixed effects model, 95% CI, 0.17–0.75).



CI indicates confidence interval; PU, pressure ulcers; RR, relative risk.

Figure 23: Skin Care Protocol Versus No Skin Care Protocol

Grade of Evidence

Table 66 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of a structured skin care protocol compared with standard care in persons with urinary and fecal incontinence. The quality of evidence is very low for the outcome incidence of pressure ulcers grade 1 or 2.

Table 66: GRADE Evidence Profile – Structured Skin Care Protocol Versus Standard Care Outcome: Incidence of Pressure Ulcers Grade 1 or 2*

Studies	Design	Quality	Consistency	Directness	Other Modifying Factors	No. of Patients		RR(95% CI)	
						Pre	Post	Incidence of pressure ulcers grade 1 or 2	Quality/ Importance
Hunter et al., 2003	Observa-tional	Some serious limitations†	N/A‡	No uncertainty about directness	Sparse data§	136	136	0.41 (0.21–0.79)	**Very Low/** Critical
	LOW	**VERY LOW**	**VERY LOW**	**VERY LOW**	**VERY LOW**				

*RR indicates relative risk; CI, confidence interval; N/A, not applicable.
†Lacks blinded outcome assessment (−1)
‡Only 1 study
§One study n = 136

Summary of Results

There is very low quality evidence supporting the benefit of a structured skin care protocol to reduce the incidence of grade 1 or 2 pressure ulcers.

Comparison 2: pH-Balanced Cleanser Versus Soap and Water

Characteristics of Included Studies

Table 67 reports the characteristics of 1 study (53) comparing the effectiveness of a pH-balanced cleanser with that of soap and water. The treatment group was slightly older than the control group on average. The median number of incontinent episodes per 24 hours was comparable in both groups (4 in the control group and 5 in the treatment group). The treatment group had a longer median length of stay in the nursing home or hospital (1.72 years) compared with the control group (0.38 years). The study used the Stirling pressure sore classification system, which graded pressure sores as either grade 0 (healthy), grade 1 (erythema), or grade 2 (broken skin) (Table 68).

Table 67: Characteristics of Included Studies – ph-Balanced Cleanser Versus Soap and Water*

Study	Population	Treatment	Control	Follow-Up	Outcome
Cooper and Gray, 2001 RCT N = 93	Long-term care residents for elderly or dependent patients in the United Kingdom Any persons with incontinence including i) urinary ii) fecal iii) urofecal, iv) catheterized but fecally incontinent catheterized but bypassing urine and/or fecally incontinent. Mean age: Treatment: 85 y Control: 79 y	Clinisan pH-balanced foam cleanser. pH of 5.5 combined with an emollient, water-repellent deodorant and a water-repellent barrier.	Soap and water Standard hospital soap with pH of 9.5–10.5.	14 days	Incidence of pressure ulcers Stirling Pressure Sore Severity Scale

*RCT indicates randomized controlled trial.

Table 68: Pressure Ulcer Classification System – Study of pH-Balanced Cleanser Versus Soap and Water*

Study	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Cooper and Gray, 2001	Health skin, normal appearance, intact skin with no alteration in the colour	Erythema Discoloration of intact skin, abnormal redness	Broken skin Partial thickness skin loss or damage involving epidermis or dermis	N/A	N/A

*N/A indicates not applicable.

Quality Assessment of Included Studies

The individual study quality assessment is presented in Table 69. The study by Cooper and Gray (53) used an RCT design. Initially, the first 11 subjects were randomized using unmarked envelopes which contained the treatment allocation (soap and water or Clinisan). However, because patients changed hospital rooms frequently, it was difficult to keep treatment assignment organized. Therefore, the investigators switched to a cluster randomization scheme and randomized a unit (ward) to either treatment or control. It is unknown if allocation concealment was maintained for the cluster randomization. The authors do not report completing a sample size calculation. Photographs were taken of the skin (pressure ulcer) and all slides were assessed in a blinded fashion. Loss to follow-up was minimal. An ITT analysis was not completed, but rates of pressure ulcer incidence were calculated on the per-protocol sample.

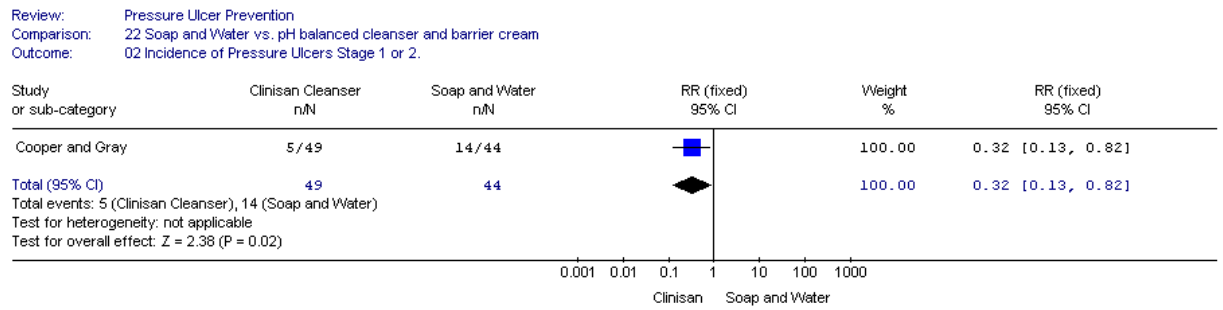
Table 69: Quality Assessment of Included Studies – pH-Balanced Cleanser Versus Soap and Water*

Study	RCT	Concealment	Sample Size Calculation	Blinded Assessment	Loss to Follow-Up	ITT Analysis
Cooper and Gray, 2001	✓	unknown	x	✓	7%	x

*ITT indicates intention-to-treat; RCT, randomized controlled trial.

Results

The incidence of pressure ulcer development grade 1 or 2 was 5/41 (12%) in the treatment group and 14/46 (30%) in the control group (per-protocol analysis). Figure 24 reports an ITT analysis. There is a statistically significant decrease in the incidence of pressure ulcers stage 1 or 2 in the group that received treatment with the pH-balanced cleanser compared with those using soap and water (RR, 0.32 [95% CI, 0.13–0.82]). We chose to present the estimate of effect as an RR because the baseline risk in the control group (soap and water) is 31%. (52)



CI indicates confidence interval; RR, relative risk.

Figure 24: Soap and Water Versus pH-Balanced Cleanser and Barrier Cream

Grade of Evidence

Table 70 reports the GRADE evidence profile for the body of evidence evaluating the effectiveness of a pH-balanced skin cleanser compared with soap and water in persons with urinary and fecal incontinence. The quality of evidence is low for the outcome incidence of pressure ulcers grade 1 or 2.

Table 70: GRADE Evidence Profile – pH-Balanced Skin Cleanser Versus Soap and Water Outcome: Incidence of Pressure Ulcers Grade 1 or 2*

Studies	Design	Quality	Consist-ency	Direct-ness	Other Modifying Factors	No. of Patients			
						pH-Balanced cleanser	Soap and Water	RR (95% CI)	Quality/ Importance
Cooper and Gray, 2001	RCT	Some serious limitations†	N/A‡	No uncertainty about directness	Sparse data§	49	44	0.32 (0.13–0.82)	**Low/** Critical
	HIGH	**MOD**	**MOD**	**MOD**	**LOW**				

*RR indicates relative risk; CI, confidence interval; N/A, not applicable; RCT, randomized controlled trial.
†Concealment status unknown, changed from individual randomization to cluster randomization. Sample size not completed for cluster randomization methods. (−1)
‡ Only 1 study.
§One study n = 93 (−1).

Summary of Results

There is low quality evidence supporting the benefit of a pH-balanced cleanser compared with soap and water to reduce the incidence of grade 1 or 2 pressure ulcers in persons with urinary and fecal incontinence.

Summary of Results

Table 71 consolidates the effect estimates for the comparisons presented in this review. Moderate quality evidence is available to support the use of an alternative foam mattress to reduce the incidence of pressure ulcers compared with a standard foam mattress for patients in acute care.

Moderate quality evidence also exists for 2 other comparisons including:

- alternating pressure mattress versus alternating pressure overlay
- Australian sheepskin versus standard treatment

There is a statistically nonsignificant difference in the incidence of pressure ulcers in persons using an alternating pressure mattress compared with an alternating pressure overlay.

There is a statistically significant difference in the incidence of pressure ulcers in persons using an Australian sheepskin compared with standard care. However, clinical experts indicate this intervention is not feasible given that the sheepskins move about in the bed and may contribute to wound infection.

Table 71: Summary of Systematic Review Results*

Comparison	Evidence	Model	Results RR (95% CI)	Quality of Evidence
Risk assessment scale vs. none or clinical judgment	Bale, 1995	FE	0.11 (0.03–0.46)	Very Low
Alternative foam mattress vs. standard mattress	Gray and Campbell, 1994 Hofman et al., 1994 Santy et al., 1994 Collier, 1996	RE	0.31 (0.21–0.46)	Moderate
Alternative foam mattress vs. alternative foam mattress	Kemp et al., 1993 Vyhlidal et al., 1997 Gray and Smith, 2000	FE FE FE	0.66 (0.37–1.16) 0.42 (0.18–0.96) 1.00 (0.15–6.82)	Very Low
Alternating pressure mattress or overlay vs. standard foam mattress	Andersen et al., 1982 Sanada et al., 2003	FE FE	0.32 (0.14–0.74) 0.29 (0.12–0.73)	Very Low
Alternating pressure mattress vs. alternating pressure overlay	Nixon et al., 2006	FE	0.96 (0.74–1.24)	Moderate
Sheepskin vs. standard treatment	McGowan et al., 2000 Jolley et al., 2004	RE	0.42 (0.22–0.81)	Moderate
Alternating pressure mattress (Micropulse System) vs. standard care in perioperative setting	Aronovitch et al., 1999 Russell and Lichtenstein, 2000	RE	0.21 (0.06–0.70)	Very Low
Vesico-elastic polymer (gel pad) on operating table vs. standard operating table foam mattress	Nixon et al., 1998	FE	0.53 (0.33–0.85)	Low
Air suspension bed vs. standard ICU bed	Inman et al., 1993	FE	0.24 (0.11–0.53)	Low
Alternating pressure mattress vs. alternate foam mattress	Whitney et al., 1984 Stapleton, 1986	RE	0.89 (0.54–1.47)	Very Low
Nutritional supplementation pulse standard diet hospital diet vs. standard hospital diet alone	Delmi et al., 1990 Ek et al., 1991 Bourdel-Marchasson, 2000 Houwing et al., 2003	RE	0.85 (0.73–0.99)	Very Low
Repositioning every 4 hours on an alternative foam mattress vs. every 2 hours on a standard foam mattress	Defloor et al., 2005	FE	0.21 (0.05–0.94)	Low

Structured skin care protocol vs. standard care	Hunter et al., 2003	FE	0.41 (0.21–0.79)	Very Low
pH-balanced cleanser vs. soap and water.	Cooper and Gray, 2001	FE	0.32 (0.13–0.82)	Low

*FE indicates fixed-effects; RE , random-effects; RR, relative risk; CI, confidence interval.

In 2005, the Registered Nurses Association of Ontario (RNAO) systematically reviewed similar preventive interventions for pressure ulcers. (50;54) Table 72 reports the levels of evidence for the interventions assessed in this review at the time of the RNAO review. Our systematic review has improved the level of evidence for risk assessment (from level 5 to level 3a) and skin care (use of a pH-balanced skin cleanser, level 5 to level 2); however, the quality of the evidence is still very low and low, respectively. Overall there remains a paucity of moderate or higher quality evidence in the literature to support many of the preventive interventions. Until better quality of evidence is available, pressure ulcer prevention must be guided by expert opinion for those interventions where low or very low quality evidence supports the effectiveness of such interventions.

Table 72: Registered Nurses Association of Ontario Guidelines 2005

Intervention	Recommendation	Level of Evidence RNAO Guidelines 2005†	Level of Evidence 2008†	Quality of Evidence 2008
Risk assessment	Complete risk assessment	5	3a	Very Low
surfaces	Use high density (alternative) foam mattress	1	1 (SR)	Moderate
	Consider pressure redistribution surfaces intraoperateively for high risk persons.	1	1 (Large RCT)	Low
Turning and positioning	Turn at least every 2 hours on standard foam.	5	5	
	Turn 4-hourly on pressure redistribution mattress.	N/A	2	Low
Skin care	Use protective barriers and pH-balanced skin cleanser.	5	2	Low
	Skin care protocol	N/A	3a	Very Low
Nutrition	Supplement critically ill older clients	1 (large RCT)	1 (SR)	Very Low
Education	Structured, organized and comprehensive educational programs	5	Not Reviewed	N/A
Delivery of care	Interdisciplinary approach	5	Not Reviewed	N/A

RCT indicates randomized controlled trial; SR, systematic review; N/A, not applicable.
†Levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (11) See Table 1 in this report for more detail.
Level 1 = SR or large RCT
Level 2 = Small RCT
Level 3a = Controlled clinical trial.
Level 5 = Expert Opinion

Appendices

Appendix 1: Search Strategy for Risk Assessment

Search date: February 26, 2008
Databases searched: MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library, INHTA/CRD

Database: Ovid MEDLINE(R) <1950 to February Week 2 2008>
Search Strategy:

1	exp Pressure Ulcer/ (7358)
2	(((pressure or bed or decubitus) adj2 (sore$ or ulcer$)) or bedsore$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (8686)
3	1 or 2 (8686)
4	exp Risk Assessment/ (87361)
5	exp "Severity of Illness Index"/ (90294)
6	exp "Reproducibility of Results"/ (150807)
7	exp Risk Management/ (104932)
8	exp "Predictive Value of Tests"/ (80491)
9	exp Nursing Assessment/ or exp "Weights and Measures"/ or exp Validation Studies/ (211803)
10	((Norton or Waterlow or Braden or Care Dependency) adj4 (Scale$ or instrument$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (218)
11	(risk adj4 (assess$ or calculat$ or score$ or predict$ or scale$ or instrument$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (125336)
12	or/4-11 (599506)
13	3 and 12 (1627)
14	limit 13 to (english language and humans and yr="1997 - 2008") (1056)
15	limit 14 to (controlled clinical trial or meta analysis or randomized controlled trial) (77)
16	exp Technology Assessment, Biomedical/ or exp Evidence-based Medicine/ (34655)
17	(meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (67764)
18	exp Random Allocation/ or random$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (522495)
19	exp Double-Blind Method/ (94618)
20	exp Control Groups/ (822)
21	exp Placebos/ (26618)
22	RCT.mp. (2558)
23	or/15-22 (624606)
24	14 and 23 (196)

Database: EMBASE <1980 to 2008 Week 08>
Search Strategy:

1	exp DECUBITUS/ (3867)

2 ((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (3146)
3 bedsore$.mp. (154)
4 or/1-3 (4758)
5 exp Validation Process/ or exp Risk Assessment/ or exp Scoring System/ (289704)
6 exp Reproducibility/ (32728)
7 exp Risk Management/ (9906)
8 exp "Prediction and Forecasting"/ (278725)
9 exp Nursing Assessment/ (40)
10 exp "NAMED INVENTORIES, QUESTIONNAIRES AND RATING SCALES"/ (33227)
11 exp Validation Study/ (4404)
12 ((Norton or Waterlow or Braden or Care Dependency) adj4 (Scale$ or instrument$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (70)
13 (risk adj4 (assess$ or calculat$ or score$ or predict$ or scale$ or instrument$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (188794)
14 exp rating scale/ (49508)
15 or/5-14 (643661)
16 4 and 15 (633)
17 limit 16 to (human and english language and yr="1997 - 2008") (421)
18 Randomized Controlled Trial/ (154703)
19 exp Randomization/ (25108)
20 exp RANDOM SAMPLE/ (981)
21 exp Biomedical Technology Assessment/ or exp Evidence Based Medicine/ (279621)
22 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab. (56340)
23 Double Blind Procedure/ (68338)
24 exp Triple Blind Procedure/ (8)
25 exp Control Group/ (1437)
26 exp PLACEBO/ (110247)
27 (random$ or RCT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (400713)
28 or/18-27 (609634)
29 17 and 28 (100)

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to February Week 3 2008>
Search Strategy:

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1 exp Pressure Ulcer/ (5067)
2 (((pressure or bed or decubitus) adj2 (sore$ or ulcer$)) or bedsore$).mp. [mp=title, subject heading word, abstract, instrumentation] (5741)
3 1 or 2 (5741)
4 exp Risk Assessment/ (11570)
5 exp "Severity of Illness Indices"/ (7071)
6 exp "Reproducibility of Results"/ (4649)
7 exp Risk Management/ (5441)

8 exp "Predictive Value of Tests"/ (6607)
9 exp Nursing Assessment/ (10283)
10 exp Scales/ or exp Clinical Assessment Tools/ or exp Braden Scale for Predicting Pressure Sore Risk/ (66516)
11 exp Instrument Validation/ (9215)
12 exp Validation Studies/ (8444)
13 exp Wound Assessment/ (1587)
14 ((Norton or Waterlow or Braden or Care Dependency) adj4 (Scale$ or instrument$)).mp. [mp=title, subject heading word, abstract, instrumentation] (558)
15 (risk adj4 (assess$ or calculat$ or score$ or predict$ or scale$ or instrument$)).mp. [mp=title, subject heading word, abstract, instrumentation] (23282)
16 or/4-15 (110645)
17 3 and 16 (1860)
18 limit 17 to (english and yr="1997 - 2008") (1341)
19 random$.mp. or exp RANDOM ASSIGNMENT/ or exp RANDOM SAMPLE/ (65135)
20 RCT.mp. (810)
21 exp Meta Analysis/ (6067)
22 exp "Systematic Review"/ (3491)
23 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$) or published studies or medline or embase or data synthesis or data extraction or cochrane).mp. (21587)
24 exp double-blind studies/ or exp single-blind studies/ or exp triple-blind studies/ (12702)
25 exp PLACEBOS/ (4008)
26 or/19-25 (85090)
27 18 and 26 (148)

Appendix 2: Search Strategy for Pressure Redistribution Devices

Search date: October 24, 2007
Databases searched: Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, Embase, Cochrane Library, INAHTA/CRD

Database: Ovid MEDLINE(R) <1996 to October Week 3 2007>
Search Strategy:

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1 exp Beds/ (1214)
2 (bed or beds or bedding).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (31944)
3 (mattress$ or cushion$ or foam$ or transfoam$ or overlay$ or pad or pads or gel).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (123324)
4 (pressure adj1 (relie$ or reduc$ or device$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (2660)
5 (positioning or reposition$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (15147)
6 (elevation adj1 device$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1)
7 ((low adj pressure) and (support$ or device$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (842)
8 (constant adj1 pressure).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (671)
9 (alternat$ adj1 pressure).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (75)
10 ((air or water) adj1 suspension).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (67)
11 (static adj1 air).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25)
12 (therarest or clinifloat or vaperm or maxifloat or hammock$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (100)
13 (foot adj1 waffle).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3)
14 (silicore or pegasus).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (48)
15 (cairwave adj1 therapy).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4)
16 (turning adj1 table$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1)
17 (kinetic adj1 (table$ or therap$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (42)
18 (air adj bag).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (156)
19 or/1-18 (172565)
20 exp Pressure Ulcer/ (3354)

21 ((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4099)
22 20 or 21 (4099)
23 19 and 22 (1118)
24 limit 23 to (humans and english language and yr="2004 - 2007") (293)
25 limit 24 to (controlled clinical trial or meta analysis or randomized controlled trial) (35)
26 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (55568)
27 exp Random Allocation/ or random$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (329544)
28 exp Double-Blind Method/ (48416)
29 exp Control Groups/ (498)
30 exp Placebos/ (8441)
31 RCT.mp. (2048)
32 or/25-31 (371081)
33 24 and 32 (61)

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to October Week 3 2007>
Search Strategy:

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1 exp "bedding and linens"/ or exp "beds and mattresses"/ (2148)
2 (bed or beds or bedding).mp. [mp=title, subject heading word, abstract, instrumentation] (8804)
3 (mattress$ or cushion$ or foam$ or transfoam$ or overlay$ or pad or pads or gel).mp. [mp=title, subject heading word, abstract, instrumentation] (5222)
4 (mattress$ or cushion$ or foam$ or transfoam$ or overlay$ or pad or pads or gel).mp. [mp=title, subject heading word, abstract, instrumentation] (5222)
5 exp Patient Positioning/ (3989)
6 (positioning or reposition$).mp. [mp=title, subject heading word, abstract, instrumentation] (4577)
7 ((low adj pressure) and (support$ or device$)).mp. [mp=title, subject heading word, abstract, instrumentation] (57)
8 (constant adj1 pressure).mp. [mp=title, subject heading word, abstract, instrumentation] (45)
9 (alternat$ adj1 pressure).mp. [mp=title, subject heading word, abstract, instrumentation] (153)
10 ((air or water) adj1 suspension).mp. [mp=title, subject heading word, abstract, instrumentation] (8)
11 (therarest or clinifloat or vaperm or maxifloat or hammock$).mp. [mp=title, subject heading word, abstract, instrumentation] (15)
12 (foot adj1 waffle).mp. [mp=title, subject heading word, abstract, instrumentation] (3)
13 (silicore or pegasus).mp. [mp=title, subject heading word, abstract, instrumentation] (17)
14 (cairwave adj1 therapy).mp. [mp=title, subject heading word, abstract, instrumentation] (2)
15 (turning adj1 table$).mp. [mp=title, subject heading word, abstract, instrumentation] (2)
16 (kinetic adj1 (table$ or therap$)).mp. [mp=title, subject heading word, abstract, instrumentation] (77)
17 (air adj bag).mp. [mp=title, subject heading word, abstract, instrumentation] (54)
18 (elevation adj1 device$).mp. [mp=title, subject heading word, abstract, instrumentation] (1)
19 (static adj1 air).mp. [mp=title, subject heading word, abstract, instrumentation] (8)
20 or/1-19 (17521)
21 exp Pressure Ulcer/ (4966)

22 ((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, subject heading word, abstract, instrumentation] (5583)
23 21 or 22 (5583)
24 20 and 23 (1430)
25 random$.mp. or exp RANDOM ASSIGNMENT/ or exp RANDOM SAMPLE/ (61139)
26 RCT.mp. (741)
27 exp Meta Analysis/ (5741)
28 exp "Systematic Review"/ (3348)
29 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$) or published studies or medline or embase or data synthesis or data extraction or cochrane).mp. (20170)
30 exp double-blind studies/ or exp single-blind studies/ or exp triple-blind studies/ (11627)
31 exp PLACEBOS/ (3830)
32 or/25-31 (79660)
33 24 and 32 (164)
34 limit 33 to (english and yr="2004 - 2007") (51)

Database: EMBASE <1980 to 2007 Week 42>
Search Strategy:

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1 exp Bed/ (2465)
2 (bed or beds or bedding).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (50844)
3 (mattress$ or cushion$ or foam$ or transfoam$ or overlay$ or pad or pads or gel).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (205228)
4 (pressure adj1 (relie$ or reduc$ or device$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (5470)
5 (positioning or reposition$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (24928)
6 exp Patient Positioning/ (6783)
7 (elevation adj1 device$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (1)
8 ((low adj pressure) and (support$ or device$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (443)
9 (constant adj1 pressure).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (1508)
10 (alternat$ adj1 pressure).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (71)
11 ((air or water) adj1 suspension).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (530)
12 (static adj1 air).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (71)
13 (therarest or clinifloat or vaperm or maxifloat or hammock$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (155)
14 (foot adj1 waffle).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (0)
15 (silicore or pegasus).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (42)

16 (cairwave adj1 therapy).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (0)
17 (turning adj1 table$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (1)
18 (kinetic adj1 (table$ or therap$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (64)
19 (air adj1 bag).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (174)
20 or/1-19 (286534)
21 exp Decubitus/ (3736)
22 ((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (3053)
23 21 or 22 (4571)
24 20 and 23 (968)
25 limit 24 to (human and english language and yr="2004 - 2007") (182)
26 Randomized Controlled Trial/ (150225)
27 exp Randomization/ (24211)
28 exp RANDOM SAMPLE/ (823)
29 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).ti,mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (77407)
30 Double Blind Procedure/ (66927)
31 exp Triple Blind Procedure/ (8)
32 exp Control Group/ (1062)
33 exp PLACEBO/ (105480)
34 (random$ or RCT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (389019)
35 or/26-34 (514868)
36 25 and 35 (35)

Textwords searched in INAHTA/CRD: (bed or bedding or cushion or pillow or pressure relief or pressure relieving or pressure reduction or mattress or positioning or repositioning or therarest or clinifloat or vaperm or maxifloat or hammock or silicore or pegasus or cairwave) and (pressure sore or pressure ulcer or decubitus or bedsore)

Appendix 3: Search Strategy for Nutritional Supplementation

Search date: October 26, 2007
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, Embase, Cochrane Library, INAHTA/CRD

Database: Ovid MEDLINE(R) <1996 to October Week 3 2007>
Search Strategy:

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1 exp Pressure Ulcer/ (3354)
2 ((bed or pressure or decubit$ or isch?emic) adj2 (sore$ or ulcer$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4369)
3 bedsore$.mp. (93)
4 or/1-3 (4411)
5 exp Nutrition Therapy/ (21903)
6 exp Diet/ (54480)
7 exp Food/ (293634)
8 (nutri$ or diet$ or food$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (293881)
9 (enteral or parenteral or protein$ or vitamin$ or mineral$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1339881)
10 exp "amino acids, peptides, and proteins"/ (1912805)
11 exp Dietary Supplements/ or exp Antioxidants/ (137725)
12 growth substances/ or exp vitamins/ (76725)
13 exp "enzymes and coenzymes"/ (819718)
14 exp Enzyme Inhibitors/ (341584)
15 exp Minerals/ (31108)
16 exp Lipids/ (271328)
17 exp Antilipemic Agents/ (28150)
18 or/5-17 (2657807)
19 4 and 18 (760)
20 limit 19 to (humans and english language and yr="2003 - 2007") (271)
21 limit 20 to (controlled clinical trial or meta analysis or randomized controlled trial) (29)
22 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (55568)
23 exp Random Allocation/ or random$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (329544)
24 exp Double-Blind Method/ (48416)
25 exp Control Groups/ (498)
26 exp Placebos/ (8441)
27 RCT.mp. (2048)
28 or/21-27 (371080)
29 20 and 28 (49)

Database: EMBASE <1980 to 2007 Week 43>

Search Strategy:

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1 exp Decubitus/ (3741)
2 ((bed or pressure or decubit$ or isch?emic) adj2 (sore$ or ulcer$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (3659)
3 bedsore$.mp. (146)
4 or/1-3 (5151)
5 exp nutrition/ or exp diet therapy/ (798997)
6 exp DIET/ (65465)
7 exp FOOD/ (209307)
8 (nutri$ or diet$ or food$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (496473)
9 (enteral or parenteral or protein$ or vitamin$ or mineral$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (1894831)
10 exp Amino Acid/ (508877)
11 exp "Peptides and Proteins"/ (3414934)
12 exp Diet Supplementation/ (26443)
13 exp Antioxidant/ (39357)
14 exp Growth Promotor/ (865)
15 exp Vitamin/ (211037)
16 exp Enzyme/ (1265606)
17 exp coenzyme/ (947)
18 exp Enzyme Inhibitor/ (842490)
19 exp Mineral/ (6830)
20 exp Lipid/ (507543)
21 exp Antilipemic Agent/ (85172)
22 or/5-21 (4763456)
23 4 and 22 (1451)
24 limit 23 to (human and english language and yr="2003 - 2008") (444)
25 Randomized Controlled Trial/ (150503)
26 exp Randomization/ (24258)
27 exp RANDOM SAMPLE/ (826)
28 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).ti,mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (77576)
29 Double Blind Procedure/ (67017)
30 exp Triple Blind Procedure/ (8)
31 exp Control Group/ (1076)
32 exp PLACEBO/ (105770)
33 (random$ or RCT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (389627)
34 or/25-33 (515753)
35 24 and 34 (77)

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to October Week 3 2007>
Search Strategy:

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1 exp Pressure Ulcer/ (4966)
2 ((bed or pressure or decubit$ or isch?emic) adj2 (sore$ or ulcer$)).mp. [mp=title, subject heading word, abstract, instrumentation] (5618)
3 bedsore$.mp. (70)
4 or/1-3 (5632)
5 exp NUTRITION/ (32637)
6 exp Diet Therapy/ (6433)
7 exp FOOD/ (26691)
8 (nutri$ or diet$ or food$).mp. [mp=title, subject heading word, abstract, instrumentation] (78659)
9 (enteral or parenteral or protein$ or vitamin$ or mineral$).mp. [mp=title, subject heading word, abstract, instrumentation] (31657)
10 exp Amino Acids/ (4396)
11 exp Peptides/ (11963)
12 exp DIETARY PROTEINS/ or exp PROTEINS/ (32219)
13 exp Dietary Supplements/ (1903)
14 exp ANTIOXIDANTS/ (2750)
15 exp Growth Substances/ (5659)
16 exp VITAMINS/ (9680)
17 exp Enzymes/ (7839)
18 exp COENZYMES/ (374)
19 exp Enzyme Inhibitors/ (11330)
20 exp MINERALS/ (1674)
21 exp LIPIDS/ (17434)
22 exp Antilipemic Agents/ (3902)
23 or/5-22 (149452)
24 4 and 23 (678)
25 limit 24 to (english and yr="2003 - 2007") (250)
26 random$.mp. or exp RANDOM ASSIGNMENT/ or exp RANDOM SAMPLE/ (61139)
27 RCT.mp. (741)
28 exp Meta Analysis/ (5741)
29 exp "Systematic Review"/ (3348)
30 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$) or published studies or medline or embase or data synthesis or data extraction or cochrane).mp. (20170)
31 exp double-blind studies/ or exp single-blind studies/ or exp triple-blind studies/ (11627)
32 exp PLACEBOS/ (3830)
33 or/26-32 (79660)
34 25 and 33 (31)

Appendix 4: Search Strategy for Repositioning

Search date: April 18, 2008
Databases searched: MDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library, INAHTA/CRD

Database: Ovid MEDLINE(R) <1996 to April Week 2 2008>
Search Strategy:

1	exp Pressure Ulcer/ (3534)
2	((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4336)
3	1 or 2 (4336)
4	(reposition$ or re-position$ or position$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (160069)
5	(mobiliz$ or mobilis$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (24127)
6	exp Posture/ (19236)
7	exp Prone Position/ (1470)
8	exp Supine Position/ (2456)
9	(turn$ adj3 (patient$ or schedul$ or interval$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1630)
10	or/4-9 (194918)
11	3 and 10 (412)
12	limit 11 to (english language and humans and yr="2000 - 2008") (259)
13	limit 12 to (case reports or comment or editorial or letter) (30)
14	12 not 13 (229)

Database: EMBASE <1980 to 2008 Week 15>
Search Strategy:

1	exp Decubitus/ (3909)
2	((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (3181)
3	1 or 2 (4770)
4	(reposition$ or re-position$ or position$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (243757)
5	(mobiliz$ or mobilis$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (45414)
6	(turn$ adj3 (patient$ or schedul$ or interval$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (2735)
7	exp Patient Positioning/ (7098)
8	exp Body Posture/ (15566)
9	or/4-8 (300588)
10	3 and 9 (542)

11 limit 10 to (human and english language and yr="2000 - 2008") (226)
12 limit 11 to (editorial or letter or note) (36)
13 Case Report/ (985499)
14 11 not (12 or 13) (170)

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to April Week 2 2008>
Search Strategy:

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1 exp Pressure Ulcer/ (5186)
2 ((decubitus or bed or pressure) adj1 (ulcer$ or sore$)).mp. [mp=title, subject heading word, abstract, instrumentation] (5871)
3 1 or 2 (5871)
4 (reposition$ or re-position$ or position$).mp. [mp=title, subject heading word, abstract, instrumentation] (22332)
5 (mobiliz$ or mobilis$).mp. [mp=title, subject heading word, abstract, instrumentation] (2522)
6 (turn$ adj3 (patient$ or schedul$ or interval$)).mp. [mp=title, subject heading word, abstract, instrumentation] (678)
7 exp Patient Positioning/ (4230)
8 exp Posture/ (6653)
9 or/4-8 (29902)
10 3 and 9 (521)
11 limit 10 to (english and yr="2000 - 2008") (289)

Appendix 5: Search Strategy for Incontinence Management

Search date: April 25, 2008
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library, CINAHL, and INAHTA/CRD

Database: Ovid MEDLINE(R) <1996 to April Week 3 2008>
Search Strategy:

1	exp Pressure Ulcer/ (3538)
2	exp Skin Ulcer/ (12680)
3	exp Wound Healing/ or exp Wound Infection/ (34511)
4	((pressure or bed or skin or decubitus) adj2 (ulcer$ or sore$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (7005)
5	(bedsore$ or (chronic adj2 wound$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1445)
6	or/1-5 (45985)
7	exp Incontinence Pads/ or exp Fecal Incontinence/ or exp Urinary Incontinence/ or exp Feces/ or exp Urine/ (36994)
8	(incontinen$ or continen$ or diaper$ or toilet$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (61681)
9	exp Diaper Rash/ (146)
10	or/7-9 (85691)
11	6 and 10 (555)
12	limit 11 to (english language and humans and yr="2000 - 2008") (377)
13	*Diabetic Foot/ (2601)
14	*Burns/ (7358)
15	*Venous Ulcer/ (1089)
16	*Ischemia/ (8464)
17	*Postoperative Complication/ or *Surgical Wound/ or *Surgical Infection/ (37790)
18	or/13-17 (56875)
19	12 not 18 (346)
20	limit 19 to (case reports or comment or editorial or letter) (37)
21	19 not 20 (309)
22	limit 21 to medline records [Limit not valid in: Ovid MEDLINE(R); records were retained] (309)

Database: EMBASE <1980 to 2008 Week 17>
Search Strategy:

1	exp Decubitus/ (3919)
2	exp Skin Ulcer/ (18030)
3	exp Chronic Wound/ (244)
4	exp Wound Healing/ or exp Wound Infection/ (51059)
5	((pressure or bed or skin or decubitus) adj2 (ulcer$ or sore$)).mp. [mp=title, abstract, subject

headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (9510)
6 bedsore$.mp. (158)
7 or/1-6 (67664)
8 exp Incontinence/ or exp Urine/ or exp Feces/ (52601)
9 exp diaper/ or exp diaper dermatitis/ (699)
10 (incontinen$ or continen$ or diaper$ or toilet$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (43062)
11 or/8-10 (69761)
12 7 and 11 (941)
13 limit 12 to (human and english language and yr="2000 - 2008") (574)
14 limit 13 to (editorial or letter or note) (34)
15 Case Report/ (987264)
16 13 not (14 or 15) (498)
17 *Burns/ (12467)
18 *Varicosis/ (3652)
19 *MICROVASCULAR ISCHEMIA/ (47)
20 *Diabetic Foot/ (1990)
21 *Postoperative Complication/ or *Surgical Wound/ or *Surgical Infection/ (10663)
22 or/17-21 (28794)
23 16 not 22 (487)

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to April Week 3 2008>
Search Strategy:
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1 exp Pressure Ulcer/ (5204)
2 exp Skin Ulcer/ (10309)
3 exp Wound Healing/ or exp Wound Infection/ (9655)
4 exp Wounds, Chronic/ (848)
5 ((pressure or bed or skin or decubitus) adj2 (ulcer$ or sore$)).mp. [mp=title, subject heading word, abstract, instrumentation] (6621)
6 bedsore$.mp. (76)
7 or/1-6 (18545)
8 exp Incontinence/ or exp Urine/ or exp Feces/ (6728)
9 exp Diapers/ or exp Diaper Rash/ (270)
10 exp Incontinence Aids/ (605)
11 (incontinen$ or diaper$ or toilet$ or continen$).mp. [mp=title, subject heading word, abstract, instrumentation] (9065)
12 or/8-11 (10718)
13 7 and 12 (518)
14 limit 13 to (english and yr="2000 - 2008") (368)
15 limit 14 to (brief item or commentary or editorial or letter) (21)

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