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# The role of sheepskins in preventing pressure ulcers in elderly orthopaedic patients

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## Summary

A randomised controlled trial was undertaken in the orthopaedic ward at two hospitals to estimate the efficacy of a newly developed Australian Medical Sheepskin overlay to prevent hospital acquired pressure ulcers relative to a standard hospital mattress or other low technological constant pressure supports. A total of 297 patients aged 60 years and above were randomised to receive the sheepskin overlay (experimental group) or the standard hospital mattress, with or without other low technological constant pressure supports (control group). At risk status for developing an ulcer was assessed daily using the Braden Scale. Patients were assessed for evidence of a pressure ulcer on a daily basis. The risk ratio for development of at least one pressure ulcer for the 155 patients in the experimental group and 142 control group was 0.30 (95% confidence interval 0.17 to 0.52). The hazard ratio for time to development of first pressure ulcer in the experimental group relative to control group was 0.31 (0.17 to 0.58). These results provide evidence that the Australian Medical Sheepskin is effective in preventing pressure ulcers in elderly orthopaedic patients. A more comprehensive investigation, concentrating particularly on the effect of the sheepskin on duration of stay in hospital, is indicated.

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## Introduction

Managing patients' pressure areas is an important part of nursing care. Despite the provision of nursing care aimed at prevention, hospital acquired pressure ulcers occur frequently and are responsible for untold suffering for patients. It has been estimated that hospital acquired pressure ulcers cost the Australian taxpayer up to \$350 million per annum and they reduce access to scarce bed space through unnecessary and increased stays in hospital<sup>1</sup>. Point prevalence studies undertaken at Fremantle Hospital, a 400 bed teaching hospital in Western Australia, have shown rates for hospital acquired pressure ulcers as high as 12 patients per 100 (1994) and as low as 6.9 patients per 100 patients (1996)<sup>2,3</sup>.

Opportunity costs associated with pressure ulcers are immense and it has been calculated that for each full thickness sacral pressure ulcer that is prevented, it is possible to undertake 16 total hip replacements<sup>4</sup>. Estimates of the cost of treating a full-thickness pressure ulcer in Australia have been reported as being about \$61,000<sup>5</sup>. Litigation regarding the development of hospital acquired pressure ulcers is common in both the USA and the UK and a precedent has already been set in NSW where a damages claim for \$632,500 has been reported<sup>6</sup>.

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In recent years, there has been a substantial increase in the variety and cost of equipment available for nurses to choose from to assist in the prevention and treatment of pressure ulcers. Most of this equipment, however, has not been reliably evaluated and nurses often have to rely upon information provided by manufacturers as to the therapeutic value of their product<sup>7</sup>.

Constant low pressure supports in the form of high-specification foam or fibre filled mattresses are generally 'first choice' for prevention because of their relatively low cost, particularly when compared with the more expensive alternating pressure mattresses. These low pressure supports all have a common aim to reduce the point pressure by dispersing pressure over a greater body surface area. Evidence from a few randomised controlled trials is sufficient to suggest that high specification foam is superior to the standard hospital mattress in preventing pressure ulcers<sup>8</sup>.

Many hospitals, however, cannot afford to replace the cheaper standard hospital mattress with low-pressure alternatives, particularly since their durability is often unknown. The durability and pressure relieving qualities of the overlay mattresses are generally dependent upon their usage. Most hospitals have limited supplies of alternative mattresses for use with patients assessed at low or medium risk of developing pressure ulcers and therefore they are in constant use. Overlay mattresses require regular inspection and testing to ensure that the fibre or foam has not deteriorated, collapsed or 'bottomed out' thus eliminating the pressure relieving qualities. Few hospitals have mattress inspection protocols and busy nurses rarely have time to unzip covers to check the condition of the mattress.

Sheepskins are claimed to be of value in the prevention of pressure ulcers<sup>9</sup>. Their therapeutic value is believed to be due to the pressure reducing and distributing properties of the high density, soft, springy but resilient wool fibres. In a simulated comparison<sup>10</sup>, objective measurement of peak pressure beneath an electropneumatic sensor placed either directly on a hospital mattress or onto an Australian Medical Sheepskin on the same mattress, indicates that medical sheepskins reduce peak pressure from 95 mm Hg on the mattress to 27 mm Hg on the sheepskin (CSIRO, unpublished work). The fibres have a low friction coefficient that reduces the strain on skin and alleviates shearing forces on the underlying tissues. Wool can also absorb up to 33 per cent of its dry weight in moisture without feeling

damp and can rapidly dissipate moisture<sup>11</sup> (a contributing factor to pressure ulcer development) away from pressure points.

Few studies have, however, been conducted to evaluate the merit of sheepskins in preventing or assisting in the treatment of pressure ulcers. Two small studies conducted in the 1960s to evaluate sheepskin overlays and boots were not well designed and the results were generally inconclusive<sup>12, 13</sup>. Other early research into the effectiveness of sheepskins used patients as their own controls and reported that sheepskins were advantageous in the prevention of pressure ulcers in bedridden patients<sup>14</sup>. Limitations of this study include a very small sample size and non-randomisation of patients. Another study conducted in 1990 evaluated the effectiveness of sheepskins with two patients using a single case design<sup>15</sup>. Results did not lend support to the theory that sheepskins reduce pressure ulcers.

A further study in 1993 compared the use of a genuine sheepskin with a synthetic pile product<sup>16</sup>. The study group was comprised of 64 residents of a long-term institution who were randomly placed on a genuine sheepskin. A control group was selected by conducting a retrospective audit of the medical records of 44 long-term care residents placed on the synthetic product. At the end of a 2 month period, results for the study group showed 63 per cent of residents maintained skin integrity compared with 41 per cent in the control group. The authors concluded that the genuine sheepskin is more effective in the prevention and treatment of pressure ulcers than the synthetic product. To date, there are limited studies undertaken with sheepskins. Those that have been conducted lack rigour and the outcomes are inconclusive.

Until recently, there has been no reliable standard regarding the quality of sheepskins used in hospitals for pressure relief. Cheap substandard sheepskins or synthetic products are often purchased in an effort to reduce health costs and inappropriate laundering results in rendering the leather backing hard, making them unsafe for patient use. The CSIRO Leather Research Centre addressed these problems by facilitating the development of an Australian Standard for Medical Sheepskins, AS 4480.1-1998. The standard defines the high performance requirements by specifying leather quality, wool type and length as well as laundry procedure to ensure its capacity to be washed with selected chemicals through commercial laundries at a temperature of 80°C for high level thermal disinfection. To confirm compliance with

the Australian Standard, a permanent label must be bonded to the leather side of the sheepskin. Laboratory testing has shown that these skins retain their characteristics after at least 50 wash cycles. The Mercy Private Hospital laundry in Victoria has successfully washed the skins up to 65 times with no deterioration of the leather or wool.

## Objective

The objective of this investigation was to estimate the relative incidence of hospital acquired pressure ulcers among elderly orthopaedic patients nursed on a standard hospital mattress plus an Australian Medical Sheepskin overlay, compared to those nursed on either a standard mattress alone or a standard mattress with other low technology constant pressure supports.

## Hypothesis

The null hypothesis addressed by this study was that patients nursed on a standard hospital mattress plus an Australian Medical Sheepskin overlay have the same incidence of hospital acquired pressure ulcers as patients nursed with standard hospital care. This may or may not include other low technological constant pressure supports.

## Study design

The study design was a two arm parallel group, open label randomised controlled trial. Blinded outcome assessments were not possible because the support surfaces could not be disguised and patients could not be moved off the bed for assessment of their pressure areas.

## Study setting

The study was conducted in two Western Australian hospitals; Fremantle Hospital, a 400 bed teaching hospital and Hollywood Hospital, a 360 bed private hospital. Over a 13 week period, patients (emergency and elective) admitted to two orthopaedic wards (62 beds) at Fremantle Hospital and two orthopaedic wards (61 beds) at Hollywood Private Hospital were assessed within 24 hours of admission for suitability for inclusion in the trial.

Two registered nurses were employed as research nurses to obtain patient consent, undertake randomisation and to complete daily assessments of the patients' skin condition and their risk status for developing pressure ulcers.

## Sample size

Based on data obtained from this casemix of patients during annual point prevalence studies at Fremantle Hospital, a prevalence rate of 20 per cent was estimated. Assuming an average duration of 5 days, the approximate background incidence rate of pressure ulcers is thus about 40 per 1000 person-days. The number of events required in the control group to detect a rate ratio of  $RR=0.5$  at the 5 per cent level with 90 per cent power is 63<sup>17</sup>. The target number of person-days exposure in the control group was therefore 1575. From casemix data from these hospitals, the average length of stay of elderly orthopaedic patients is about 10 days and so the number of patients required in each group was about 150.

## Inclusion criteria

Patients who met the following criteria were enrolled in the study:

- age 60 years or greater;
- admitted with an orthopaedic diagnosis;
- assessed at low or moderate risk of developing a pressure ulcer based on the Braden Pressure Ulcer Risk Assessment Scale<sup>18</sup>;
- patient or significant other (relative or legal guardian) able to give informed consent.

## Exclusion criteria

Patients were excluded from the study if one of the following was present:

### Sheepskin in use.



- patients assessed as no risk (requiring no intervention) or high risk (requiring more complex interventions) for developing pressure ulcers;
- patients with a pre-existing pressure ulcer;
- non-English speaking patients (unless an interpreter was available);
- patients with an anticipated stay of less than 48 hours;
- coloured skin patients where stage 1 ulcer detection is difficult.

Approval to conduct the study was obtained from the participating hospitals' Ethics Committees. Subject to the inclusion and exclusion criteria and following consent, patients were randomly allocated (using sealed envelopes) by research nurses to receive one of two interventions:

- Standard hospital mattress and sheet with or without other low technological constant pressure relieving devices as determined by ward nursing staff (control group).
- Standard hospital mattress and sheet plus an Australian Medical Sheepskin overlay. Sheepskin heel and elbow protectors were also provided by the research nurses where the clinical condition indicated these were required (experimental group).

## Procedure

Baseline data regarding demographics, surgical procedure, medications or treatments that could increase the risk of developing pressure ulcers (for example epidural local anaesthetic post-operatively<sup>19</sup>) were collected.

Patients admitted on the day of surgery, considered likely to be at risk of developing pressure ulcers post-operatively because of the planned procedure, were enrolled in a pre-admission clinic. Consent was obtained at this time and randomisation usually occurred on the day of surgery. This enabled the sheepskins to be placed on beds (for experimental patients) prior to the patient's return from the operating theatre. At risk status was re-confirmed once the patient had returned from surgery.

Patients randomised to the experimental group were provided with Australian medical sheepskins on top of the standard hospital mattress for the duration of their hospital stay. Patients randomised to the control group were nursed on a standard hospital mattress and received other pressure relieving equipment based on availability and as determined by the ward nursing staff. At risk status for developing a pressure ulcer was assessed on a daily basis for patients in both groups by research nurses using the Braden Pressure Ulcer Risk Scale. Total scores on six sub-scales reflecting critical determinants of pressure range from 6 to 23,

with lower scores indicating greater risk. Good reliability of the tool ( $r=0.99$ ) has been reported when used by registered nurses<sup>18</sup>.

Training in the identification of pressure ulcers and in the use of the Braden Scale was provided for the research nurses. Patients were assessed daily by these nurses, using operational definitions recommended by the Agency for Health Care Policy and Research<sup>20</sup> for evidence of pressure ulcers (Figure 1).

One of the investigators undertook regular inter-rater comparisons (Intraclass correlation coefficient 0.93). Where a Stage 2 pressure ulcer (broken skin) occurred in either group, nursing staff on the ward were informed and determined what treatment was required. All patients who were able to comprehend English and had normal cognitive function were asked prior to discharge to rate the comfort of the bed surface on a 10 point scale where 1 indicated 'very uncomfortable' and 10 'very comfortable'. Patient's comments regarding satisfaction with the support surfaces were also noted.

Education sessions were held on each ward to inform nursing staff of the purpose of the trial. To reduce the occurrence of control

**Figure 1. Classification of stage of pressure ulcers.**

### Stage 1

Non-blanching erythema or erythema not resolving within thirty (30) minutes of pressure relief. Epidermis remains intact. Reversible with intervention.

### Stage 2

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.

### Stage 3

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. If wound involves necrotic tissue, staging cannot be confirmed, therefore classified as Stage 4.

### Stage 4

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.

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patients being given the experimental sheepskin (a problem at commencement of the trial) posters were developed and displayed where the sheepskins were stored to remind staff that sheepskins were allocated to patients by the research nurses. Additional notices were placed in the experimental patients' nursing notes asking staff to provide patients with a clean sheepskin when wet or dirty sheepskins were removed. The research nurses were responsible for checking sheepskins daily and changing them when the wool pile required rejuvenation, generally every 3-4 days.

### Study end point

The end point of the trial was discharge from hospital or transfer to a rehabilitation ward. Clinical response to preventive interventions was based upon the presence or absence of a pressure ulcer. Incidence and severity of pressure ulcers were recorded during the period of hospitalisation. The day of risk that the ulcer first occurred, the site of the ulcer, subsequent severity and the type of preventive intervention *in situ* were recorded. Patients whose clinical condition resulted in at risk status increasing to high continued in the trial if their at risk status reverted to moderate or low after 48 hours. Data collection ceased for any patient still identified as high risk after 48 hours. Data prior to and including the 48 hours at high risk are included in the analysis.

### Analysis

Cumulative incidence of pressure ulcers was computed in each group and compared using a standard risk ratio with 95 per cent confidence intervals. Incidence density was computed using person-time of exposure and rate ratios were formed with confidence intervals.

## Results

A total of 297 patients were enrolled in the trial. Of these, 142 (48 per cent) were randomised to the control group and 155 (52 per cent) to the experimental group. Table 1 compares the baseline characteristics of both groups. There were more males in the experimental group and more patients in this group were admitted for total knee replacement, compared to the control group. The mean Braden Score and assessed risk status on admission or post-operatively were almost identical in the two groups. The average ages of the control and experimental groups were 74 and 73.6 years, respectively.

Of the 297 patients enrolled in the trial, two patients (one in each group) withdrew prior to data collection. Six patients in the experimental group withdrew before completion of data collection because the sheepskin caused an irritation, was too hot or uncomfortable. An additional seven patients in the control group and three in the experimental group were also withdrawn due to protocol violations (sheepskins given to control group by mistake, sheepskins not replaced for >12 hours and additional pressure relieving equipment provided in experimental group). Data collected for patients up until the time of withdrawal has been included in the analysis with the exception of five controls and two patients from the experimental group for whom study participation time was not available.

A total of 43 (30.3 per cent) of the 142 patients in the control group developed a pressure ulcer compared with 14 (9 per cent) of the 155 patients in the experimental group. The cumulative incidence risk ratio was 0.30 (95 per cent confidence interval: 0.17 to 0.52). The 40 control patients with valid data developed a total of 67 pressure ulcers (rate= 46.9 per 1000 patient-days) whilst the 14 patients in the experimental group

with valid data developed a total of 21 pressure ulcers (13.1 per 1000 patient-days). The rate ratio for sheepskins relative to standard treatment was 0.28 (95 per cent confidence interval: 0.16. to 0.46).

Figure 2 displays Kaplan-Meier survival curves for the ulcer-free experience of the experimental group compared to the control group. A log-rank test of the 40 patients with ulcers observed in the control group and the 14 seen in the experimental group was statistically significant ( $\chi^2 = 15.75$  on 1 df,  $P < 0.0001$ ).

Twenty five (58.1 per cent) of the 43 patients in the control group had one pressure ulcer, seven (16.3 per cent) had two and 11 patients (25.6 per cent) developed three pressure ulcers. In four of the patients, the pressure ulcers progressed to Stage 2 (broken skin) and one patient developed Stage 4 pressure ulcers on both heels. This compared with seven (50 per cent) of the 14 patients in the experimental group who had one pressure ulcer and seven (50 per cent) who developed two pressure ulcers. No patient in the experimental group had a pressure

ulcer that progressed beyond Stage 1. The most common sites for pressure ulcers in the control group were the sacrum and elbows and for the experimental group the elbows (Table 2).

A total of 268 patients (124 control and 144 experimental) were able to complete the rating scale on the level of comfort of the bed surface. Patients in the experimental group rated comfort significantly higher than the control group (Mann-Whitney U,  $Z=-7.74$ ,  $P<0.0001$ ). No significant differences in comfort levels were observed between control patients nursed on the standard hospital mattress or patients nursed on a foam or Spenco overlay mattress.

Sixteen patients (11.4 per cent) in the experimental group and seven (5.5 per cent) in the control group provided additional responses regarding the bed surface. Patients in the experimental group commented that the sheepskins were hot, curled up when in bed, the full length sheepskin provided comfort for feet, should be larger to cover the length of the bed and was very comfortable particularly on first day. Comments from patients in the control group all related to the hardness of the beds.

**Table 1. Baseline characteristics of control and experimental groups.**

	Control		Experimental			Control		Experimental	
<b>Age (years)</b>					• Hip arthrotoomy	1	0.7%	1	0.6%
• Mean	74		73.6		• Total ankle replacement	1	0.7%	0	0%
• Median	74		74		• Bone graft lower leg	1	0.7%	0	0%
• Min.	60		60		<b>Braden Score on admission or post-operatively</b>				
• Max.	96		97		• Mean	14.01		13.9	
• Std Dev	7.65		8.08		• Median	14		14	
<b>Gender</b>					• Min.	12		12	
• Male	55	39%	72	46%	• Max.	18		17	
• Female	87	61%	83	54%	• Std Dev	1.4		1.08	
<b>Admission type</b>					<b>Assessed risk status at admission or post-operatively</b>				
• Emergency	31	22%	32	21%	• Low (scores 15-18)	32	23%	27	17%
• Elective	111	78%	123	79%	• Moderate (scores 13-14)	99	70%	120	77%
<b>Admission diagnosis</b>					• High (score 12 or less)	9	6%	6	4%
• Total knee replacement	64	45%	78	50%	• Missing	2	1%	2	1%
• Total hip replacement	41	29%	35	23%	<b>Low scores on admission or post-operatively (=1 or 2)</b>				
• # femur (neck & shaft)	21	15%	22	14%	• Sensory	2	1%	4	3%
• # lower leg/patella	5	3.5%	4	3%	• Moisture	2	1%	1	1%
• Shoulder/arm surgery	4	3%	1	0.6%	• Activity	137	96%	153	99%
• Laminectomy	0	0%	5	3%	• Mobility	134	94%	152	98%
• # pelvis	0	0%	3	2%	• Nutrition	105	74%	107	69%
• Wound infection hip/leg	1	0.7%	1	0.6%	• Friction	140	99%	152	98%
• Tibial osteotomy	0	0%	2	1%	<b>At risk status high for &gt;48 hrs</b>	5	3.5%	4	2.6%
• Hip/knee pain	2	1%	2	1%	<b>Epidural post-operative</b>	50	35%	56	36%
• Dislocated THR	1	0.7%	0	0%					
• Removal of screws ankle	0	0%	1	0.6%					

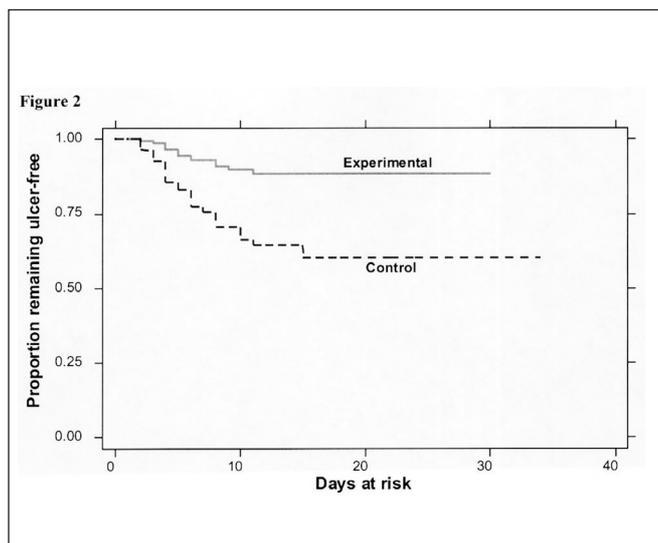
At commencement, at 6 weeks and on completion of the trial, thermal disinfection of the sheepskins was confirmed by measuring median colony counts on three of the sheepskins. Satisfactory results were obtained on all three occasions.

## Discussion

Findings from this study show that patients nursed on the Australian Medical Sheepskin had fewer pressure ulcers. The results also show that the number of days free from pressure ulcers was significantly higher for patients nursed on the sheepskin. Where pressure ulcers did develop, they were less severe. Of the 142 patients in the control group, 43 (30.3 per cent) developed a pressure ulcer, compared with 14 (9 per cent) of the 155 patients in the experimental group. Patients in the control group developed a total of 72 ulcers, with 28 (39 per cent) of the ulcers occurring on the heels. In comparison, patients in the experimental group developed 21 pressure ulcers with 15 (71 per cent) of the ulcers occurring on the elbows.

The sheepskin booties and elbow protectors were of limited value with this group of patients because they were difficult to keep in place, particularly once the patient started to mobilise. Pressure ulcers on the heels occur because of pressure applied to a bony prominence over a prolonged period of time or friction and shearing as a result of patients attempting to move around in bed. Where booties could not be kept in place, a second sheepskin was placed on the bottom of the bed to minimise friction and shearing forces on the heels and thus the development of pressure ulcers.

**Figure 2. Kaplan-Meier survival curve comparing ulcer-free survival of experimental to control groups.**



The sheepskins were not wide enough to provide protection for the elbows and none of the experimental patients with pressure ulcers on their elbows had elbow protectors *in situ* at the time of ulcer development. Only when a pressure ulcer developed were some patients in the experimental group prepared to persevere with the elbow protectors because of the relief from pain that they provided. Of the 15 pressure ulcers on the elbows, three patients (20 per cent) tried the elbow protectors and their pressure ulcers resolved prior to discharge.

Comfort is an important factor for patients and when asked to rate the level of comfort of the bed surface, patients nursed on the Australian Medical Sheepskin indicated a significantly higher level of comfort than those nursed on the hospital mattress alone. There is no definition of what constitutes a standard hospital mattress and little information was available on the age or the composition of the standard foam hospital mattress used in this study. It is likely that, depending upon the age of the bed, mattresses of different foam composition are in use throughout the hospital. The pressure reducing foam overlay mattresses used were 4" Dunlop high density flexifoam. The condition of the foam overlay mattresses at the time of the trial was unknown and, since mattress longevity is also not known, foam collapse cannot be ruled out in many of them.

## Limitations

There are several limitations to this study. First, the study was conducted with elderly orthopaedic patients which limits the generalisability of the results to a similar population. Further research is required to investigate the efficacy of the sheepskins with at risk patients of other ages and with other medical conditions.

Second, patients were only followed for the acute period of their hospital stay. It is possible that those patients who were transferred to a rehabilitation ward may have developed pressure ulcers after transfer.

Third, although nurses appeared impressed with the new sheepskins, it is possible that they provided more regular turning and re-positioning for patients in the experimental group. Blinded outcome assessments were not possible, so a

**Table 2. Site of pressure ulcers.**

Site	Control Group	Experimental Group
• Sacrum	22 (30.5%)	4 (19%)
• Heels	28 (39%)	2 (10%)
• Elbows	22 (30.5%)	15 (71%)
• Total	72 (100%)	21 (100%)

bias cannot be excluded. Standardisation of the management of pressure areas is not possible because of nursing workloads and the peaks and troughs of activity in acute care areas. A more comprehensive study to address some of the above issues is planned.

## Conclusion

Pressure ulcer prevention is generally recognised as a nursing responsibility. Despite an increased knowledge about the aetiology of pressure ulcers and the development of guidelines for preventing and treating pressure ulcers, they still remain a major problem. The use of appropriate assessment tools to identify patients at risk and the implementation of prevention strategies all assist in reducing the development of pressure ulcers.

Prevention strategies over the years have included skin care of incontinent patients and second hourly turning regimes to relieve pressure. Labour intensive turning strategies are not, however, practical today and current resource levels generally make it impossible to implement them. Alternatives such as low technological constant pressure support surfaces are therefore required. These surfaces need to be chosen based upon reliable information about the therapeutic value of the product and how often turning and re-positioning regimes can be implemented on a 24 hour basis. The Australian Medical Sheepskin overlay is a simple, low cost, easy to use product that, unlike other supports surfaces (e.g. foam or fibre filled mattresses) can be used on beds, chairs and trolleys for patients at risk of developing hospital acquired pressure ulcers. The sheepskin does not impede patient care, has a demonstrated longevity of at least 50 washes and it is easy to identify any deterioration.

Whilst pressure relieving equipment can never replace skilled nursing care, it is a useful adjunct in the prevention of hospital acquired pressure ulcers. Results from this study showed that for elderly orthopaedic patients assessed at low or moderate risk of developing pressure ulcers, the Australian Medical Sheepskin significantly reduced the number of hospital acquired pressure ulcers.

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