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ORIGINAL ARTICLE

A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial

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Pressure injuries are prevalent in highly dependent aged care residents. This study investigated the clinical effectiveness of the application of the Mepilex Border Sacrum and Mepilex Heel dressings to prevent the development of facility-acquired pressure injuries. A total of 288 recently admitted residents were enrolled from 40 Australian nursing homes into a randomised controlled trial. Residents randomised to standard care ($n = 150$) received pressure injury prevention as recommended by international guidelines. Residents randomised to the intervention ($n = 138$) received standard pressure injury prevention care and had dressings applied to their sacrum and heels. Participants were comparable on demographic and physiological parameters. More residents in the control group developed pressure injuries than in the intervention group (16 vs 3, $P = 0.004$), and they developed more pressure injuries in total than residents in the intervention group. The results represent a relative risk reduction of 80% for residents treated with the dressings and for every 12 patients that we treated we prevented one pressure injury. Based on our findings, we conclude that the use of the Mölnlycke Mepilex Border Sacrum and Mepilex Heel dressings confers a significant additional protective benefit to nursing home residents with a high risk of developing a facility-acquired pressure injury.

KEYWORDS
aged care, pressure injury, prevention, prophylactic dressings

1 | INTRODUCTION

Pressure injuries are prevalent among highly dependent aged care residents and are associated with increased morbidity and mortality.[1,2] Residents are at particularly high risk of developing pressure injuries (PIs) due to factors such as ageing,[3,4] age-related skin changes,[5] chronic conditions that reduce peripheral blood supply and decreased tissue tolerance to pressure,[3] malnutrition,[6,7] immobility,[3] incontinence,[3,4,8] cognitive impairment,[1] and complex comorbidities.[1,2,9] Literature suggests that a strong relationship exists between aged care facility placement and PI development.[10]

Internationally reported PI prevalence rates for aged care facilities range from 4.3%[11] to 35.1%,[8] and reported PI incidence rates range from 2.5%[12] to 25.16%.[2] Anatomically, the sacrum[12] and heels[3] are the 2 most frequently reported sites for PI development in residents of aged care facilities. The financial burden of PIs to the health care system has been estimated at AU$13000000 annually, spent on the treatment of PIs in aged care.[13]

The prophylactic use of multi-layer silicone foam dressings to reduce PI incidence has received increased attention internationally over the past 7 years in the acute hospital setting. In the US, Brindle[14] used a soft silicone multi-layered foam dressing (Mepilex Border Sacrum, Mölnlycke Healthcare AB Sweden) to protect the sacrum from PIs in 41 Intensive Care Unit (ICU) patients. In the 3-month study period, none of the patients developed PIs while a sacral

dressing was used. In an Australian emergency department (ED) setting, the use of a soft silicone multi-layered foam dressing (Mepilex Border Sacrum, Mölnlycke Healthcare) in reducing the incidence of sacral PIs was tested by Cubit et al,[15] who noted an 8.4% difference in incidence of PIs between the dressing group and the non-dressing group (1.9% vs 10.3%) over a 61-day study period. While encouraging, these studies[14,15] were limited due to a lack of randomisation. More recently, Santamaria et al[16] conducted a large randomised controlled trial (RCT) to examine the effectiveness of multi-layered foam dressings (Mepilex Border Sacrum & Mepilex Heel, Mölnlycke Healthcare AB) in the prevention of sacral and heel PIs among critically ill Emergency Department (ED)/ICU patients and reported a reduction of 10% in the PI incidence rate ($P = 0.001$) and a significant reduction in both sacral ($P = 0.05$) and heel ($P = 0.002$) PIs in patients treated prophylactically with the dressing. Additionally, Santamaria et al[17] reported significant wound care cost reductions in patients treated with the dressings due to the reduced incidence of PIs. Kalowes et al[18] reported virtually identical reductions in ICU-acquired PIs in an RCT conducted in a US hospital but with larger cost savings, in part, due to differences between the US and Australian health care system funding models. A systematic review examining the use of prophylactic dressings in the prevention of PIs[19] suggested that the aforementioned high-quality RCT, as well as a number of smaller RCTs, cohort studies, and case series, provide evidence that prophylactic dressings may reduce PI incidence in intensive care patients; however, evidence in other patient groups is lacking. At the organisational level, Santamaria et al[20] reported hospital-wide PI prevalence reductions of the order of 60% following the introduction of the use of these dressings for all high-risk patients on admission to hospital.

The actual mechanisms through which these dressings impart an additional protective function in preventing PI have not been well understood until recently. For decades, the mechanism of injury in PI was believed to be primarily an ischaemic process where pressure exerted over a bony prominence such as the sacrum caused the compression and occlusion of capillaries supplying the soft tissues and, consequently, resulting in tissue ischaemia and the accumulation of metabolic waste products locally. The ultimate endpoint of the sustained exposure of pressure to these tissues was localised tissue necrosis and the creation of a wound of variable depth.[21,22] More recently, the application of sophisticated imaging and computer modelling of anatomical structures has revealed that pressure and shear forces at the cellular level of tissues exposed to compression between a surface and an underlying bone result in direct cellular destruction through a process of cellular cytoskeleton disruption. This process has been clearly modelled in the work of Levy and colleagues[23] who demonstrated, through finite element analysis of tissues, that sufficient force is exerted in tissues exposed to prolonged pressure to disrupt cellular function and ultimately cellular survival. The use of prophylactic dressings to reduce these destructive levels of tissue distortion has also recently been modelled, and it has been demonstrated that significant reductions in cellular deformation can be achieved with the application of the Molnlycke Border Sacrum and Heel 5-layer soft silicone dressings applied over bony prominences.[24] These results have revealed a potential new approach to the prevention of PIs using multi-layer silicone foam dressings; however, caution is required because not all multi-layer silicone foam dressings work in a similar manner due to the formulation of the foam and the construction of the multiple layers.[25]

Key Messages

- highly dependent aged care residents are at high risk of developing facility-acquired pressure injuries; this is the first Randomised Controlled Trial (RCT) that has investigated the clinical effectiveness of prophylactic multi-layer silicone foam dressings to prevent these injuries in this population
- the pressure injury incidence rate reductions that resulted from the use these multi-layer silicone foam dressings in aged care are similar to those reported in the acute setting; however, the anatomical distribution is different
- the multi-layer silicone foam dressings investigated in this trial provide an important additional protective effect when used in addition to international guideline-driven pressure injury prevention practice
- the results from this trial on the effectiveness of these multi-layer silicone foam dressings in preventing pressure injuries cannot be generalised to other dressings in this class due to important differences in the materials and construction of other dressings

Although there is emerging international evidence suggesting that prophylactic dressings can reduce the incidence of sacral and heel PIs among hospital patients, data on using advanced dressings for PI prevention in aged care residents are scant, apart from a study conducted by Torre I Bou et al,[26] which included both aged care residents and home care patients.

The aim of the current study was to examine the clinical effectiveness of Mepilex Border Sacrum and Mepilex Heel dressings used in addition to usual care to prevent the development of sacral and heel PIs among aged care residents compared with usual care only.

2 | METHODS

2.1 | Study design

This study was designed as an RCT where aged care facilities were randomly allocated to 1 of 2 groups. Residents

with a high risk of developing PIs at nursing homes allocated to the intervention group ($n = 138$) received a Mepilex Border Sacrum (Mölnlycke Healthcare AB) dressing applied to their sacrum and Mepilex Border Heel (Mölnlycke Healthcare AB) dressings, retained with Tubifast, applied to each heel plus usual care for PI prevention. Residents in nursing homes allocated to the control group ($n = 150$) received usual care for PI prevention only.

An RCT design with randomisation of study sites was selected for administrative and logistic convenience in the implementation of the intervention and to minimise the risk of contamination between the 2 groups.[27] Our intention was to enhance the application of evidence by the whole aged care facility; therefore, the unit of randomisation was the aged care facility rather than the individual resident.

2.2 | Aim

The aim of this study was to determine the clinical effectiveness of multi-layer soft silicone foam dressings in preventing sacral and heel PI development in high-risk residential aged care patients.

2.3 | Hypothesis

Residents in aged care facilities randomised into the intervention group using the Mölnlycke Mepilex Border Sacrum and Mepilex Heel dressings will have a lower incidence rate of sacral and heel PI development than residents in facilities randomised to the control group.

2.4 | Study outcomes

The primary outcome measure was the incidence of PIs expressed as the total number of PIs developed in both the intervention and control group during the study period.

2.5 | Study setting and population

This study was conducted in 40 residential aged care facilities in Australia. The total resident population was 3823, and data were collected from February 2016 to August 2017. The research team provided training to staff at each participating facility, which included an overview of the study (recruitment, monitoring, and data collection) and instruction and practice on how to stage pressure injuries and the application and removal of the dressings for facilities that were randomised to the intervention.

The study was approved by the Melbourne Health Human Research Ethics Committee (2014.107), the University of Melbourne Human Research Ethics Committee, and registered as a clinical trial with the Australian Therapeutic Goods Administration Clinical Trial Notification Scheme.

2.6 | Eligibility criteria

Residents were eligible to participate if they:

- Had been recently admitted to the facility
- Were bed-bound
- Had a Braden Scale score of ≤12
- Had an expected length of stay in the facility of more than 4 weeks.

Residents were not eligible to participate if they:

- Had a pre-existing sacral and/or heel PIs.
- Had a life expectancy of less than 4 weeks
- Were classed as palliative care or end of life.

2.7 | Randomisation

Facilities were randomised by a member of the research team, who was blinded to the identity of the facilities using a computer programme to generate a series of random numbers. These random numbers were then used to allocate each facility to either the intervention (dressings) or control group (standard PI prevention). Following the randomisation, centre managers of the facilities were informed by the chief investigator whether their facility was an intervention or control group facility.

2.8 | Recruitment

Potentially eligible residents were identified soon after admission by senior nurses at the participating facilities with support from the researchers. All eligible residents (or the "person responsible" if the resident did not have capacity to provide consent) were provided with information about the study. Written consent to participate was obtained.

2.9 | All participants

All participants (intervention and control group) were cared for as usual during the study period. This care included pressure risk screening, skin inspection, skin care, and pressure area care such as 2-hourly repositioning and the use of alternating air mattresses. All care was provided by the registered nurses and personal care workers who were usually employed by the facilities.

2.10 | Intervention group

Intervention group participants received a Mepilex Border Sacrum dressing applied to their sacrum and a Mepilex Heel dressing, retained with Tubifast, applied to each heel. The interval between dressing changes was 3 days or as required if the dressing became soiled or dislodged. The sacrum and heels were observed every day by partially peeling off the dressings so that the skin could be visualised and assessed for the development of PIs. Any observed PIs were staged according to the National Pressure Ulcer Advisory Panel,

European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance guidelines.[28]

Mepilex Border Sacrum is a 5-layered soft silicone bordered foam dressing, and it is specifically shaped to fit the sacrum. The absorbent core of the dressing consists of 3 components, a thin sheet of polyurethane foam, a piece of non-woven fabric, and a layer of superabsorbent polyacrylate fibres. The core is located centrally on a larger piece of polyurethane film and is held in place by the perforated silicone adhesive layer that extends to the outer margins of the dressing.

2.11 | Measurement and data collection

All participants were followed for a total of 4 weeks from enrolment to the trial or less if a PI developed or the participant died or was discharged. The period of 4 weeks was chosen because most PIs develop within 4 to 8 weeks in aged care facilities.[2,26,29]

Baseline data collected for both study groups included age, gender, Charlson Comorbidity Index,[30] and pressure injury risk score according to the Braden Scale.[31] The condition of the skin, continence status, use of continence aids, body mass index, mobility status, and use and type of pressure-redistributing equipment was also recorded.

Data were collected daily for both study groups and included assessment of the skin on the sacrum and both heels for PI development. Any PI that developed during the study was staged according to international guidelines.[28] For the intervention group, additional daily data were collected on whether the sacrum or heel dressings were changed and the reason for the change (either a routine dressing change or a dressing change due to soiling or dislodgement).

2.12 | Sample size

The sample size was calculated based on an expected effect size of an 8% reduction in PI incidence for individuals in the intervention group compared with those in the control group. Power was set at 80% with an alpha of 0.05. Under these assumptions, a total of 260 residents (130 residents per group) were required.

2.13 | Analysis

Statistical analyses were based on "intention to treat"[32] where all participants randomised to the intervention group were analysed regardless of protocol violations. The primary outcome of PI incidence rates of the 2 groups was compared to assess the effect of intervention. The difference in incidence rates between the intervention and control group during the study period was analysed using a random effects Poisson regression analysis.

3 | RESULTS

Participant enrolment, group allocation, follow up, and inclusion in the analysis is displayed in Figure 1. The demographic characteristics of the groups were generally comparable on all parameters (Table 1). Of note was the large numbers of incontinent residents in both groups.

Table 2 reveals a large, statistically significant difference between the groups on the incidence of PI developed during the 4-week intervention/observation period for each

TABLE 1 Demographic characteristics of the sample ($n = 288$)

	Intervention ($n = 138$)			Control ($n = 150$)		
	Mean (SD)[a]	Median (IQR)[b]	*n*	Mean (SD)	Median (IQR)	*n*
Age (years)	84 (9)	85 (79-92)	82 (12)	86 (75-90)		
Gender						
Male			48			38
Female			90			112
BMI	22.5 (4.8)	22.3 (19.1-24.8)		24.1 (6.8)	22.4 (20.0-26.9)	
CCI Total	6 (1)	5 (5-6)		6 (2)	5 (5-6)	
Braden Scale total	11 (2)	11 (10-12)		11 (2)	12 (10-12)	
Immobility			138			150
Continent of urine						
Yes/No			26/112			21/127
Continent of faeces						
Yes/No			28/109			25/123
Alternating air mattress use			138			150

[a] Standard deviation.

[b] Interquartile range.

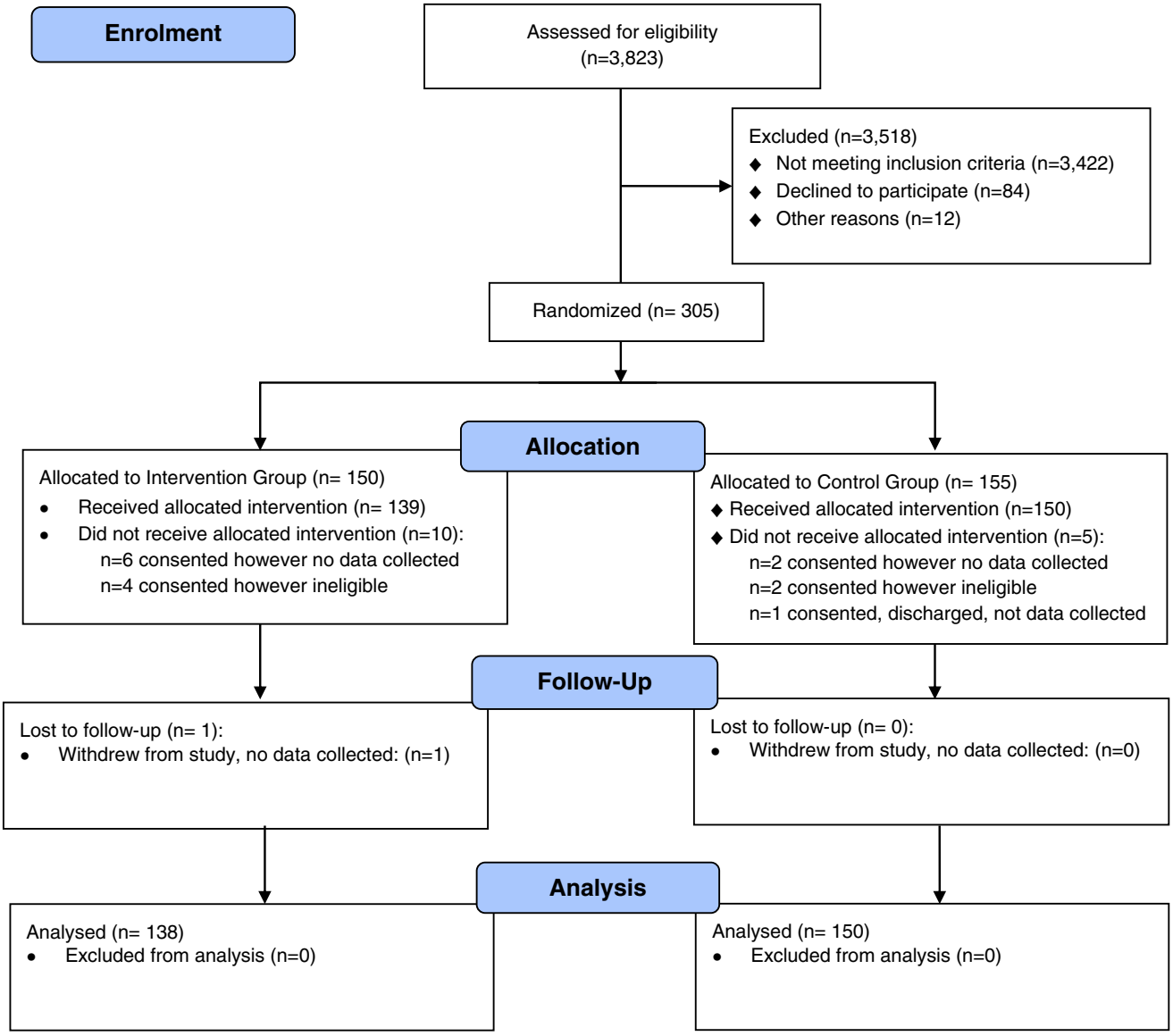

FIGURE 1 CONSORT diagram of participant enrolment, group allocation, follow up, and inclusion in the analysis

resident. The absolute risk reduction (ARR) between the intervention and control group was 8.5%, and the relative risk reduction (RRR) was 80%, which yielded a number needed to treat (NNT) of 12 (11.8) to prevent the development of 1 PI in residents using the dressings.

The distribution and severity of the PIs between the groups were different (Table 3). Control group residents developed more sacral PIs, and those wounds were of greater severity than residents in the intervention group. The difference in the severity of heel PIs between the groups was not as great but was still numerically greater in the control group.

Figure 2 presents the survival analysis of the intervention and control groups and demonstrates that the control group PI incidence begins to diverge from that of the intervention group at approximately day 5, and residents in the control group developed PIs at an increasing rate up to day 28 of the study.

TABLE 2 Pressure injury incidence

	Intervention (n = 138)	Control (n = 150)	P
Developed PI (n)	3	16	0.004
Incidence (%)	2.1	10.6	
Sacrum (n)	2	13	0.007
Left heel (n)	1	2	n.s.
Right heel (n)	2	3	n.s

4 | DISCUSSION

The prevention of facility-acquired pressure injuries remains a significant challenge to clinicians in the aged care nursing home sector. Previous research has highlighted the high prevalence and incidence rates of PIs in elderly nursing home residents.[2,8,11,12]

TABLE 3 Pressure injury distribution and severity

	Intervention (n = 138)	Control (n = 150)
Sacrum (n)	**2**	**13**
Stage 1	1	5
Stage II	1	6
Stage III	—	—
Stage IV	—	2
Unstageable	—	—
Deep Tissue Injury	—	—
Heel (n)	**3**	**5**
Stage 1	2	4
Stage II	1	1
Stage III	—	—
Stage IV	—	—
Unstageable	—	—
Deep Tissue Injury	—	—
Total	**5**	18

Research in the acute care and ICU setting[14–16,18] has clearly demonstrated the clinical and cost effectiveness of using the Mepilex Border Sacrum and Mepilex Heel (Mölnlycke Health Care AB Sweden) dressings to prevent the development of hospital-acquired PIs in ICU. Of importance in these studies was the application of the dressings to the sacrum and heels as soon as the patient was admitted to the ED to maximise the protective effects of the dressings in minimising shear and pressure experienced by the patients during their stay in hospital.

The aim of this trial was to investigate the clinical efficacy of the Mepilex Border Sacrum and Mepilex Heel (Mölnlycke Health Care AB Sweden) to prevent facility-acquired PIs in high-risk aged care residents of nursing homes. To our knowledge, this is the first time that the application of these dressings has been used in high-risk nursing home residents in a randomised controlled trial.

The demography and physiological parameters of the 2 groups (Table 1) was very similar, and as such, we believe that the risk profile of residents in the 2 groups gives us confidence in the validity of comparing the clinical outcomes of the intervention. All residents who were enrolled in the trial were recently admitted to the nursing homes, and this is an important aspect of the trial because, as in our previous research, in the acute hospital setting, we believe that it is important to commence the application of the prophylactic dressings as soon as possible. Additionally, research[21–23] has clearly demonstrated the close relationship between exposure time to pressure and shear forces and tissue tolerance in the development of a PI. All participants in the trial had PI prevention protocols in place that included risk assessment, the use of alternating air mattresses, repositioning per NPUAP guidelines, skin care, and daily skin assessment. Intervention group residents had the addition of the sacral and heel dressings. The skin under the dressings was examined daily by partially peeling back the dressings to visualise the skin. The dressings were replaced every 3 days or if they became soiled or dislodged. This timeframe was chosen because we have used this time interval for dressing changes previously, so it would allow us to compare our current results with previous work in the acute hospital setting. There was a concern that, given the high

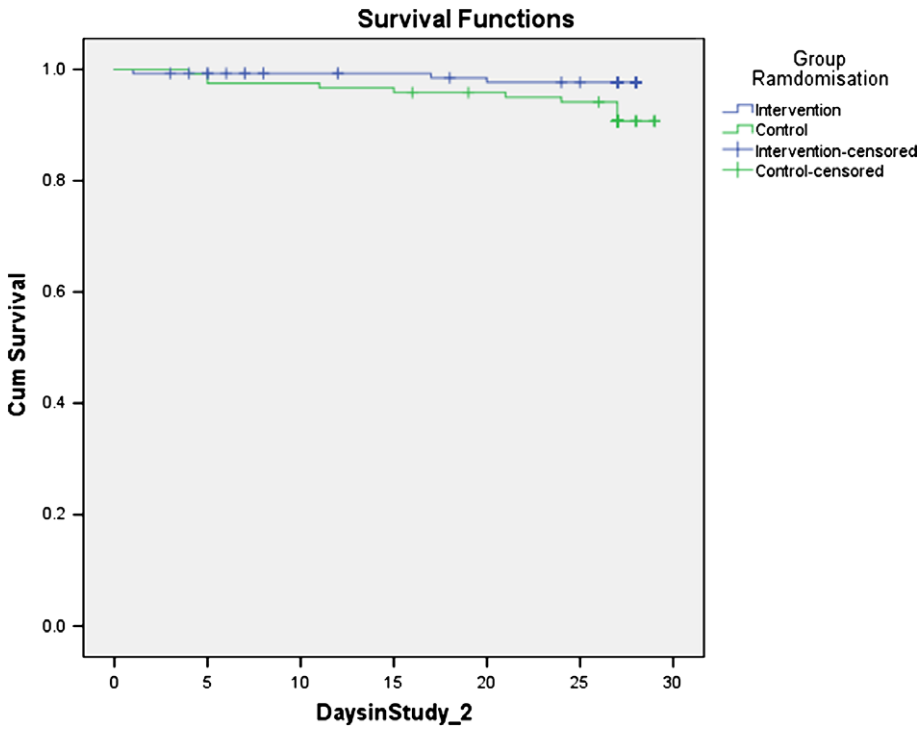

FIGURE 2 Kaplan–Meier survival analysis

rates of urinary and faecal incontinence in subjects, there would be a high need to replace sacral dressings. We conducted an initial pilot study prior to the main study reported here to determine if this was a risk. We found that with adequate education of staff to accurately position the dressing and to ensure that the skin was clean, dry, and free of emollients prior to application of the dressings, we did not need to replace dressings due to soiling at any greater rate than in the acute hospital environment.

The statistically significant difference in PI incidence rates detected between the intervention and control groups (Table 2) was comparable with that described for this intervention in the ICU setting.[14,16,18] The absolute risk reduction of 8.5% between the groups and the consequent NNT of 12 is once again similar to the risk reductions detected for the use of these dressings in the ICU.

The anatomical distribution and severity of PIs in the study was different to those previously reported in ICU[14,16,18]; the greater number of sacral PIs in controls was particularly different to previous studies that found a higher rate of heel PIs and fewer sacral injuries. A specific explanation for this difference is unknown; however, it could be surmised that the finding may be associated with ageing-related and/or diabetes-related tissue changes at the sacral region,[21,24] which may make these soft tissues more prone to injury than in younger (and non-diabetic) individuals.

In the above context, the biomechanics of sacral PIs needs to be discussed. In a supine patient, the forces originating from the weight of the trunk are transferred through the nearly rigid triangular-shaped sacral bone into a relatively thin and deformable layer of skeletal muscle (if not atrophied), subcutaneous fat, and skin. Bodyweight forces continuously distort and deform this delicate layered tissue structure and the living cells within. Moreover, as the sacrum is a highly curved and perhaps the sharpest bony element in the body, it tends to heavily distort the inferior soft tissues in a supine position so that cells embedded in these tissues are simultaneously compressed, stretched, and sheared.[33] Patients who had the head of their bed elevated, for example, to ease respiration efforts or as part of a mechanical ventilation intervention (which is common in elderly care), tend to slide downwards as they are pulled by gravity. Their instinctive reaction is to then anchor themselves in the mattress, which considerably adds to the distorting forces that are deforming cells and tissues near the bone-soft tissue interfaces, including under the sacrum.[34] Another principal biomechanical reason for the sacral region to be particularly susceptible to PIs during supine lying is the direct interface between the rigid sacral bone and substantially more compliant muscle, fat, and skin tissues at this anatomical site. The tissue stiffness gradient adds to the forceful internal cell and tissue distortions, especially causing shearing. In the elderly, capillary density is generally reduced, and so, the fewer capillaries are more susceptible to the effect of shear, which thus have a more pronounced impact on perfusion quality.[35] Additionally, the overall mass of soft tissues surrounding the sacrum may be diminished in older individuals, and the anchoring between the skin layers (specifically the interlocking at the epidermal–dermal junctions) is typically compromised.[36] These factors, taken together, make the sacral region of the elderly more vulnerable to PIs.

The internal shearing deformations near the weight-bearing sacrum occur as the soft tissue layers attempt to slide on each other and over the sacrum but cannot as they are constrained by connective tissue fibres at the interfaces. These internal mechanical constraints cause the tissues themselves and the cells within to severely distort and change shape. Over time, these shape changes in tissues and cells cause tissue breakdown. The first event in the onset of the tissue damage occurs at the microscale: death of the first individual cells leading to multiple necrotic and apoptotic cell death events. As growing masses of cells are dying, the injury progresses macroscopically to the tissue scale and becomes detectable, first by medical imaging examinations if such are conducted (eg, ultrasound or MRI) and eventually through visual skin assessment. Up-to-date aetiological research points to sustained tissue deformations as the primary cause of PIs, both at the skin and in deeper tissues.[37,38] The sustained exposure to tissue deformations has a multifactorial influence on tissue health and cell viability, including direct damage to the distorted cells through failure of cytoskeletal structures and pore formation in plasma membranes of cells,[37–39] compromised perfusion, and lymphatic function.[35] Multiple model systems, including MRI of human subjects, animal models, tissue-engineered constructs, and cell culture models, have highlighted the role of direct deformation damage to cells.[40] Moreover, these model systems altogether identified the short time frames at which damage to cells is inflicted, which is in the order of tens of minutes, much faster than previously assumed for ischaemic damage, which takes several hours to build up.[34,40]

At the microscopic scale, the chronic distortion of cells causes disruption of the cytoskeleton, which, especially in lack of available energy, gradually loses its capacity of structurally supporting the plasma membrane.[37–39] This leads to the formation of nanometre-wide openings (pores), which form at the plasma membranes. The mechanically (and sometimes biochemically) stressed cells are typically unable to repair the poration. Hence, fluxes of biomolecules penetrate the cell bodies and/or escape cells uncontrollably, eventually causing loss of homeostasis (biological equilibrium) in the cells and resulting in apoptotic cell death in growing cell numbers.[37–39]

The above-described cell-scale destructive processes are strongly affected by the mechanical state of tissues, 1 important specific factor being tissue stiffness. Connective tissues, specifically skin, tend to stiffen with old age, and likewise with type-2 diabetes, due to localised fusion of collagen fibres and pathologically increased fibre thickness, which

reinforces the skin and makes it less able to relieve mechanical stress.[21,24] These age-related and/or diabetes-related changes exacerbate the mechanical state in tissues subjected to bodyweight forces, particularly around the sacrum, and may contribute to the susceptibility to sacral PIs in older individuals. These changes may explain the relatively high number of sacral PIs identified in controls in this study.

4.1 | Limitations

The study is limited by our inability to blind both the subject and the assessor to the presence or absence of the intervention. This is not an uncommon limitation found in wound care trials investigating a specific product or device.[41] As such, it should be regarded as a pragmatic trial of the clinical effectiveness of the dressings to prevent the development of a PI in high-risk aged care residents.

A potential further limitation of this research was the difficulty in obtaining consent due to the high numbers of individuals with impaired cognitive function that precluded them from giving informed consent to participate. In instances where an individual was unable to provide consent, we approached their guardian/next of kin to seek consent. The consequence of this process was that recruitment was very low in this group of residents and may have introduced a potentially unknown bias to the study.

4.2 | Summary

This is the first study that we are aware of that has attempted to investigate the clinical effectiveness of multilayer soft silicone dressings to prevent PI development in high-risk aged care nursing home residents. Our results suggest that the dressings are clinically effective when used as soon as the resident is admitted to the facility. The results are generally consistent with those found when using the dressings as PI prophylaxis in the acute hospital setting. However, there are some important differences between aged care residents and acute hospital patients. These differences relate to comorbidity profile and to continence status. We found the anatomical distribution of PIs to be different in the aged individual compared with the acute patient. Specifically, aged care residents developed more sacral PIs, and acute care patients developed more heel PIs. We believe that this finding may be related to ageing-related tissue changes; however, further research is required to elucidate the reasons underlying this finding.

The finding in our ITT risk analysis that for every 12 residents treated with the dressings we prevented the development of 1 PI is important from a prevention perspective and should encourage nursing homes to consider the use of prophylactic dressings for residents at high risk of developing a PI even when all current preventative measures are in place.

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