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ORIGINAL RESEARCH

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Healing rate of hospital-acquired skin tears using adhesive silicone foam versus meshed silicone interface dressings: A prospective, randomized, non-inferiority pilot study

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Abstract

Background: A skin tear is a traumatic wound that occurs in up to one in five hospitalized patients. Nursing care includes application of a dressing to create a moist wound healing environment.

Aim: To compare the effectiveness of two standard dressings (adhesive silicone foam vs. meshed silicone interface) to heal hospital-acquired skin tear.

Methods: An intention-to-treat pilot study was designed using a randomized, non-inferiority trial in an Australian tertiary hospital setting. Consenting participants ($n = 52$) had acquired a skin tear within the previous 24 h and had agreed to a 3-week follow-up. Data were collected between 2014 and 2020. The primary outcome measure was wound healing at 21 days.

Results: Baseline characteristics were similar in both arms. Per protocol, 86% of skin tears were fully healed at 3 weeks in the adhesive silicone foam group, compared to 59% in the meshed silicone interface group. Greater healing was observed across all skin tear categories in the adhesive silicone foam dressing group. In the intention-to-treat sample, healing was 69% and 42%, respectively.

Conclusions: Results suggest the adhesive silicone foam dressing may be superior, as it produced clinically significant healing of skin tears at 3 weeks compared to the meshed silicone interface dressing. Accounting for potential loss to follow-up, a sample of at least 103 participants per arm would be required to power a definitive study.

KEYWORDS
acute care; dressing, foam; dressing, silicone; hospital-acquired; nursing; wound, healing; wound, skin tear

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Summary statement

What is already known about this topic?

- A skin tear is a traumatic wound that is commonly acquired during hospitalization that affects older adults in particular. In hospital settings, it may occur in up to one in five patients.
- A variety of skin tear dressings have been used in previous studies, with healing rates ranging from 34% to 97% at 21 days; however, evidence for the most effective dressing type is inconclusive.
- If treated inappropriately, or left untreated, minor skin tears can become chronic or complicated wounds, yet prevalence and treatment of hospital-acquired injuries are under-reported.

What this paper adds?

- Based on our per-protocol results, an adhesive silicone foam dressing may be superior, as it produced clinically significant healing of 86% of skin tears at 3 weeks compared to 59% with the meshed silicone interface dressing.
- Based on the methods and results from this pilot study, a future definitive trial would be feasible but would need to account for a relatively large loss to follow-up rate.

The implications of this paper:

- Using our intention-to-treat results, a future study would need a sample size of 103 per arm to be sufficiently powered, which may be impractical to achieve within a single hospital setting; thus, a multi-site study would be advisable.

1 | INTRODUCTION

Skin tears occur commonly during hospitalization through patient falls, transfers and collisions with furniture and equipment (Miles et al., 2021). These injuries particularly affect older adults, due to age-related skin changes, and reduced cognition and mobility making navigation more difficult (LeBlanc et al., 2018; Rayner et al., 2020; Serra et al., 2017). Although mostly minor, skin tears contribute to unnecessary patient suffering and additional healthcare costs (LeBlanc et al., 2014; Sussman & Golding, 2011). If treated inappropriately, or left untreated, minor skin tears can become chronic or complicated wounds (LeBlanc et al., 2018; Sussman & Golding, 2011). However, skin tear prevalence and thus treatment are under-reported (LeBlanc et al., 2020), and most studies do not distinguish between community- and hospital-acquired injuries (Miles et al., 2021).

In the acute hospital setting, a systematic review of eight studies reported skin tear prevalence of between 3% and 22% (Strazzieri-Pulido et al., 2015), while in other single-site studies, it has been reported between 7% and 11% (Bermark et al., 2018; Chang et al., 2016; Munro et al., 2018), though hospital-acquired skin tears were not clearly differentiated. In a 10-year point-prevalence analysis of skin tears at a single site in Australia, pooled hospital-acquired skin tear prevalence of 5.5% was reported, with 85% of all skin tears occurring in patients aged ≥70 years (Miles et al., 2021).

A skin tear is defined by the International Skin Tear Advisory Panel (ISTAP) as 'a traumatic wound caused by mechanical forces, including removal of adhesives. Severity may vary in depth (not extending through the subcutaneous layer)' (LeBlanc et al., 2018, p. 2). Although it can occur on any part of the body, typically skin tear occurs on the extremities of older adults as a result of shearing and/or friction forces that separate the epidermis from the dermis (partial thickness) or both the epidermis and dermis (full thickness) from the underling structures (LeBlanc et al., 2011). Changes to the skin structure and higher rates of co-morbid disease mean older adults are more susceptible to such injuries. Unlike a classic traumatic laceration, separation of the epidermis and dermis results in flap-like wounds, which require appropriate treatment to prevent further complications (LeBlanc et al., 2014, 2018; Sussman & Golding, 2011). Skin tears vary widely in appearance at the time of injury and during the healing process. In Australia, the Skin Tear Audit Research (STAR) classification system (Carville et al., 2007) has been used to categorize skin tears into three main groups and two subgroups (1A, 1B, 2A, 2B, 3) that describe the skin flap, though international guidelines now recommend use of the International Skin Tear Advisory Panel (ISTAP) classifications (types 1, 2 and 3). STAR categories 1A and 1B, 2A and 2B and 3 are directly equivalent to ISTAP skin tear types 1–3, respectively. However, the STAR system further classifies categories 1 and 2 according to the colour of the skin flap (see Table 1).

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TABLE 1 Skin tear categorization.

	STAR description		ISTAP description
Category 1	Edges can be realigned to their normal anatomical position (without excessive stretching)		Type 1: No skin/flap loss
	2A: Not pale, dusky or darkened	2B: Pale, dusky or darkened	
Category 2	Edges cannot be realigned to their normal anatomical position (without excessive stretching)		Type 2: Partial skin/flap loss
	2A: Not pale, dusky or darkened	2B: Pale, dusky or darkened	
Category 3	Skin flap is completely absent		Type 3: Total skin/flap loss

The prevention and management of skin tear is multidisciplinary; best practice recommendations for aged skin are available via ISTAP (LeBlanc et al., 2018). Consensus treatment recommendations focus on bleeding control, cleansing and debriding, management of infection and inflammation, moisture balance and exudate control and wound closure (LeBlanc et al., 2016, 2018). A variety of dressing types are proposed, depending upon skin tear type and wound exudate (LeBlanc et al., 2016, 2018). Dressings should create a moist wound healing environment while protecting the skin from further injury (LeBlanc et al., 2016), but there is limited evidence to support dressing selection to treat skin tears.

Several studies have investigated different types of dressing previously. In a small pilot study (Edwards et al., 1998), optimal healing rates were achieved by using a non-occlusive dressing, while a small prospective randomized trial in long-term care residents indicated that polyurethane foam occlusive dressings were more effective than transparent film dressings (94% vs. 64% completely healed within 21 days) (Thomas et al., 1999). In a small case series, use of non-adherent meshed silicone dressings provided healing within 14 days with no peri-wound trauma and reduced pain on dressing change (Kennedy-Evans, 2004). In a small pilot study, when an absorbent acrylic polymer dressing (Tegaderm™ Absorbent) was compared to a transparent wound contact layer (Mepitel®) combined with a foam dressing (Mepilex Border®), it was concluded that both had similar healing properties (Gray et al., 2011). More skin tears were healed in the Tegaderm™ group (80%) at the study endpoint compared to the Mepitel®/Mepilex® group (55%), although the follow-up period was unclear.

In a Delphi study, there was international expert consensus agreement (97%) for the use of foam dressings for type 2 and 3 skin tears only (LeBlanc et al., 2016). More recently, soft silicone dressings have become widely used. Described as 'soft and tacky', they are coated with a hydrophobic silicone layer that does not stick to the wound bed but adheres to surrounding skin (Meuleneire & Rucknagel, 2013). A recent pragmatic randomized controlled trial (LeBlanc & Woo, 2022) compared the effectiveness of two soft silicone dressings (Mepitel® One and Mepilex® Border Flex) to usual practice (Alldress® or Telfa™ absorbent cotton fibre dressings). In the intervention group, 97% of skin tears were completely healed at 3 weeks, compared to 34% in the control group, and time to heal was significantly faster in the intervention group (11 vs. 22 days, $p < 0.001$). This study indicates that faster healing rates may be achieved with soft silicone dressings; however, further research is needed to distinguish between dressing types in relation to skin tear types.

2 | METHODS

2.1 | Aim

This was a pilot study to evaluate methods and inform the design of a future larger trial. The aim of this study was to compare the effectiveness of two skin tear dressings, available as standard options in the study setting: an adhesive silicone foam (ASF) dressing (Mepilex® Border) versus a meshed silicone interface (MSI) dressing (Mepitel®), to heal hospital-acquired skin tear. As this was a pilot study, hypothesis testing was not appropriate (Lancaster et al., 2004; Lee et al., 2014; Leon et al., 2011). The results of this study will be used to design and test a hypothesis for a future definitive study.

2.2 | Design

An intention-to-treat (ITT) pilot study was designed using a prospective, randomized, non-inferiority trial to compare the efficacy of two dressings (adhesive silicone foam and meshed silicone interface) on skin tear wound healing. Following recruitment, consenting participants with a hospital-acquired skin tear, on any limb, were randomly allocated (1:1) to receive one of the dressings.

2.3 | Outcomes

The primary outcome measure for this study was wound healing at 21 days. All wounds were photographed by the research assistant at each dressing change, and skin tear type and epithelial healing percentage were validated independently by a wound care nurse practitioner member of the research team. Secondary outcomes of interest, which were recorded by the nurse research assistant applying the dressings, were participant pain associated with dressing change (scale 0–10); dressing functionality: need for early change within last 7 days (yes/no), exudate controlled (yes/no-too wet/no-too dry), dressing conformed to wound (yes/no); nursing satisfaction with dressing: ease of removal (scales 1–5; *very difficult* to *very easy*), ease of application (scale 1–5; *very difficult* to *very easy*), overall satisfaction (scales 1–5; *very poor* to *very satisfied*); and time taken (minutes) to change dressing. These were recorded on a standardized form.

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2.4 | Setting and sample

The setting for this study was a 630-bed tertiary general hospital in south-east Queensland, Australia. All adult patients who had sustained a skin tear on any limb during their hospital admission were eligible to participate. In the study hospital setting, standard nursing care of a skin tear is to control/stop bleeding; cleanse the wound and skin gently with normal saline; dry the surrounding skin; keep the wound bed moist; remove old blood/clot; if a viable skin flap remains, gently re-approximate over the area of the tear (dermis), without stretching; and apply dressing using clinical judgement (two dressings recommended in hospital guideline: adhesive silicone foam or meshed silicone interface).

There are no specific guidelines for pilot study sample size for a dichotomous primary outcome (healed vs. not healed). In general, for a continuous outcome variable, Browne (1995) recommends a 'rule of thumb' sample of at least 30 participants, whereas Whitehead et al. (2016) suggest larger sample sizes based on standardized effect sizes. Following Whitehead et al. (2016), based on a small effect size, we aimed to recruit a sample size of at least 25 per arm. Participants were included if their skin tear was ≤24 h old covering an area of ≤10 cm^2, and they agreed to participate in the 3-week follow-up. Skin tears in all categories were included. Patients were excluded if there was a clot beneath the skin flap, which was unable to be evacuated, or there was uncontrolled bleeding from the wound, or cognitive impairment affected their ability to consent.

2.5 | Recruitment, randomization, allocation and blinding

Potential participants were identified via the hospital's wound and stomal therapy service, daily checking of the incident reporting system and notifications from the wards. Each potential participant was provided with an information letter by a nurse research assistant, explaining the study, and those who agreed to participate provided written consent. A random number generator was used a priori to assign participants (1:1) to the treatment arms, based on enrolment sequence. Following consent, a sealed envelope was opened to reveal dressing allocation. Thereafter, as it was obvious to participants, nursing staff and assessors which dressing was in place, no further blinding was possible. The skin tear was dressed with the randomized dressing upon recruitment and weekly thereafter for 3 weeks, by a nurse research assistant experienced in wound care. Participants who were discharged from hospital during this period were followed up at home.

2.6 | Intervention

Participants were randomized to receive one of the study dressings. Wound management and dressing procedures were applied as per standard care, described above. In the study hospital, at the time of the study, two foam dressings were available to treat skin tears: ASF and MSI. Both dressings are of a type recommended by international consensus guidelines (LeBlanc et al., 2016, 2018) and fall into the generic category of soft silicone foam dressings. Both share the same *Safetac*® soft silicone technology (SSST) (Mölnlycke® Health Care, 2023). The ASF dressing is a five-layer bordered foam self-adhesive waterproof dressing that absorbs exudate and evaporates excess exudate through the top of the dressing via moisture vapour permeability. The dressing contact layer contains the SSST, which, when placed onto a skin tear, anchors the skin flap preventing movement. The absorptive pad absorbs exudate, preventing maceration of the flap and peri-wound area. The MSI dressing has a soft silicone contact layer on one side, combined with a transparent, flexible and thin perforated polyurethane film. The wound contact layer is not unlike traditional tulle gras in appearance and is wholly constructed with the SSST. The dressing is placed on a skin tear and the surrounding skin; the SSST anchors the skin flap to the surrounding skin and allows exudate to pass through it. However, the dressing requires a secondary covering to absorb the exudate, for example, a combine pad (super-absorbent three-layer dressing) and then a fixation device (e.g. bandage) to hold the dressing in place.

2.7 | Data collection

Data were collected between November 2013 and March 2020 until the required sample size was met. The lengthy recruitment time was due to several issues, which are noted in the limitations below. Demographic and baseline data (see Table 2) were collected at recruitment. Follow-up data (primary and secondary outcome measures) were collected at 1, 2 and 3 weeks. In this study, skin tears were classified by the research nurse and validated by a wound care nurse practitioner team member using the STAR system (Carville et al., 2007), as it is used as standard practice in Australia.

2.8 | Data analysis

Data were entered into a Microsoft Excel spreadsheet, cleaned, coded and then imported into Statistical Package for the Social Sciences (SPSS version 28; IBM Corporation) for analysis. Variables are described using means with standard deviation (SD) and counts with percentages. Differences in categorical and scale baseline and secondary outcome variables were analysed using chi square and *t*-tests, respectively. Yates' continuity correction was applied for 2 × 2 tables. The primary outcome variable (21-day wound healing) is described using proportions (%) with 95% confidence intervals (CI). Between-groups differences in event (wound healed) proportions and dressing characteristics were analysed using Fisher's exact test, and mean scores across the 3 weeks for secondary outcome measures such as pain or satisfaction were analysed with *t*-tests. Significance was set at $p < 0.05$.

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TABLE 2 Baseline characteristics ($n = 52$).

		Meshed silicone interface $n = 26$		Adhesive silicone foam $n = 26$		Significance p
Mean age, years (SD)		85.1 (9.2)		83.0 (8.6)		0.389
Gender n (%)	Male	13 (50.0)		18 (69.2)		0.258
	Female	13 (50.0)		8 (30.8)		
[a]Hospital-acquired skin tear n (%)		18/24 (75.0)		24/26 (92.3)		0.132
Injury caused by fall n (%)	Yes	9 (34.6)		7 (26.9)		0.506
	No	7 (26.9)		11 (42.3)		
	Unknown	10 (38.5)		8 (30.8)		
Skin tear category n	1A	1	11	0	9	0.702
	1B	10		9		
	2A	1	10	4	13	
	2B	9		9		
	3	5	5	4	4	

[a]Missing $n = 2$.

2.9 | Ethical considerations

The study is registered via the Australian New Zealand Clinical Trials Registry (ref: ACTRN12623000294651) and received ethical approval from the hospital's Human Research Ethics Committee (ref: HREC/13/QPCH/69). The study conformed to the provisions of the Declaration of Helsinki in 1995 and revised in Edinburgh 2000. The CONSORT checklist for reporting a pilot trial was followed (Eldridge et al., 2016).

3 | RESULTS

3.1 | Baseline characteristics

Fifty-two participants were initially recruited and randomized to the study. There were no statistically significant differences in baseline characteristics between the two groups (see Table 2). Due to the relatively small samples sizes, for the purpose of analysis of differences between skin tear categories, the five STAR categories were re-categorized within the three ISTAP categories.

3.2 | Loss to follow-up

There was an overall loss to follow-up of 27%. Following randomization, a total of 14 participants (MSI $n = 9$, 34.6%; ASF $n = 5$, 19.2%) did not complete the study as per protocol for various reasons (see Figure 1), Two participants were withdrawn shortly after recruitment: One participant's skin tear was found to be >72 h old, and a dressing could not be applied to the other due to the presence of a compression garment. In the ASF group, one participant died within the first week. In the MSI group, one participant's dressing was changed to an ASF dressing before follow-up at Week 1 by a ward nurse (reason unknown); however, this participant was followed up until Week 3, when complete wound healing had occurred.

3.3 | Wound healing

Across both groups, seven skin tears were fully healed at Week 1, with a further 11 at Week 2 and another 11 at Week 3 (see Figure 1).

3.3.1 | ITT

At study completion, a total of 11 and 18 skin tears had healed in the MSI and ASF groups, respectively, giving an ITT incidence of skin tear healing of 42.3% (95% CI 23.4%–63.1%) in the MSI group and 69.2% (95% CI 48.2%–85.7%) in the ASF group ($p = 0.093$). At week 1 follow-up, ITT incidence of wound healing was 7.7% (2/26) in the MSI group and 19.2% (5/26) in the ASF group ($p = 0.419$). By week 2, it was 30.8% (8/26) in the MSI group and 38.5% (10/26) in the ASF group ($p = 0.771$). Using an online calculator (Kohn & Senyak, 2021) to estimate the sample size for a future definitive trial based on our 21-day healing rate results (ASF–MSI risk ratio 1.63), a sample size of 154 (77 per arm) would be required to power the study (two-tailed $\alpha = 0.05$, $1 - \beta = 0.9$).

3.3.2 | Per protocol

Thirty-eight participants completed the trial per protocol. At the conclusion of the trial, 10/17 (58.8%) skin tears had healed in the MSI group compared to 18/21 (85.7%) in the ASF group ($p = 0.078$). At week 1 follow-up, per-protocol incidence of wound healing was

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11.8% (2/17) in the MSI group and 23.8% (5/21) in the ASF group ($p = 0.423$). By week 2, it was 47.1% (8/17) in the MSI and 47.6% (10/21) in the ASF group ($p = 1$). With regard to skin tear types, the healing rates at week 3 are shown in Table 3.

Of the unhealed skin tears, in the MSI group ($n = 7$), the estimated epithelial healing percentage at 3 weeks was 0% ($n = 2$), 10%, 20%, 70%, 90% and 95%, whereas in the ASF group ($n = 3$), epithelial healing was 0% ($n = 2$) and 80%.

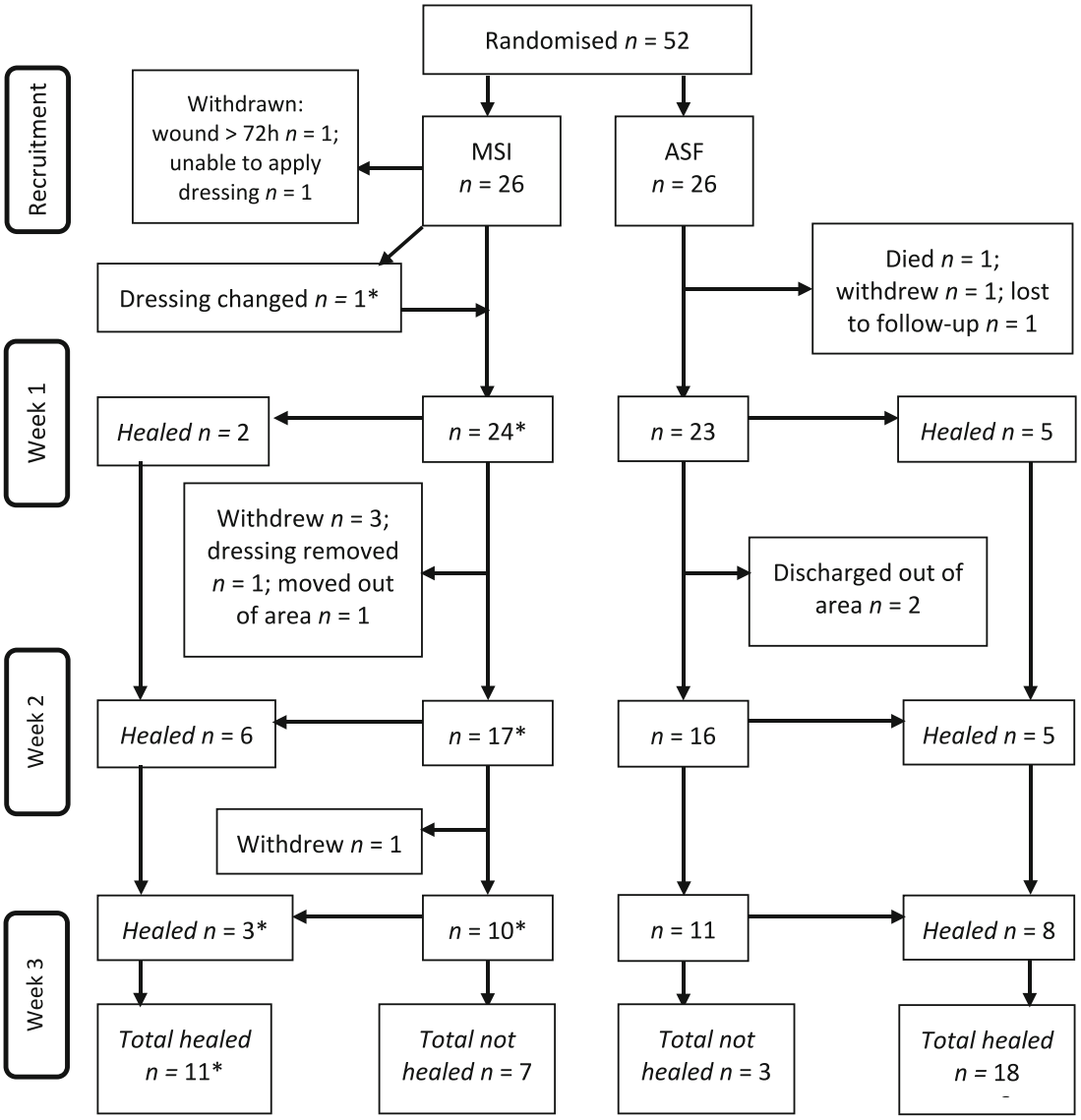


FIGURE 1 Flow diagram. *Per-protocol violation: one participant had a meshed silicone interface (MSI) dressing changed to an adhesive silicone foam (ASF) dressing prior to week 1 follow-up; wound was healed at week 3.

TABLE 3 Healing at 3 weeks, by skin tear category and dressing type.

		STAR skin tear category					
Dressing	**Outcome at 3 weeks**	**1A**	**1B**	**2A**	**2B**	**3**	**Total**
Meshed silicone interface	Healed *n* (%)	0 (0)	4 (67)	–	3 (50)	3 (75)	10 (59)
	Not healed *n* (%)	1 (100)	2 (33)	–	3 (50)	1 (25)	7 (41)
	Total *n*	1	6	–	6	4	17
Adhesive silicone foam	Healed *n* (%)	–	7 (100)	2 (50)	5 (83)	4 (100)	18 (86)
	Not healed *n* (%)	–	0 (0)	2 (50)	1 (17)	0 (0)	3 (14)
	Total *n*	–	7	4	6	4	21

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3.4 | Secondary outcomes

Secondary outcomes are described in Table 4. Where participants were scored on more than one occasion, average scores were calculated. Frequencies were calculated for the total number of events reported for early dressing change, exudate not controlled and dressing wound conformity.

Pain associated with the wound/dressing was low at all times for both dressings, and both dressings were found to be similarly easy to remove and apply, although the MSI dressing conformity was less ($p = 0.032$) and overall satisfaction with the ASF dressing was greater ($p < 0.001$). In both groups, an early dressing change was required on only a few occasions, and wound exudate was controlled. The MSI dressing change took slightly longer than the ASF dressing but the time difference was not significant.

4 | DISCUSSION

The results of this study are clinically significant as there was an 80% greater total healing rate at 3 weeks in the ASF group compared to the MSI group. While the sample size was small and drawn from a single site, one dressing resulted in a faster healing rate than the other, which was evident across all three ISTAP skin tear grades. However, further research with a larger sample size would be required to demonstrate statistical significance. Based on the 21-day healing proportions found in our study, a definitive trial would need a sample size of at least 154 participants. However, a large proportion was lost to follow-up for various reasons, most of which were beyond control of the study. Therefore, a 25% adjustment to account for this would increase the sample size for a future study to 206. The length of time required to recruit a sample of this size may be impractical within a single hospital setting, especially given our experience of recruitment problems, and a multi-site study would be advisable.

The secondary outcomes in our study suggest that the functional characteristics of the two dressings are similar, and although there was a small time–cost associated with the ASF dressing, the time difference to perform dressing changes between the two dressings was not clinically significant.

Our results concur with those of a randomized prospective study of adults ($n = 34$) with type 2 or 3 skin tear living in a long-term care facility (Edwards et al., 1998), with 71% of skin tears (12/17) completely healed at 14 days when treated with one of three opaque foam dressings (Duoderm, Lyofoam and Opsite). However, 100% (13/13) were healed within 14 days in those treated with non-occlusive dressings (Steristrip/Melolite), though protocol violations and premature participant withdrawal by staff may have biased these results (Edwards et al., 1998). In a pragmatic randomized controlled trial (LeBlanc & Woo, 2022) in which Mepitel® One and Mepilex® Border Flex were applied in the treatment group, nearly all (97%) skin tears were healed at 3 weeks. Seventeen participants received Mepitel® One, of whom most had type 1 ($n = 8$) or type 2 ($n = 6$) skin tears, and 55 participants received Mepilex® Border Flex, of whom most had type 2 ($n = 26$) or type 3 ($n = 28$) skin tears. However, the healing rates for the individual dressings were not reported. By comparison, in our study, of the seven participants with type 1 skin tears and six participants with type 2 skin tears that received the ASF dressing, 57% and 50%, respectively, were healed at 3 weeks, giving an overall healing rate of 54%. And, of the 10 participants with type 2 skin tears and four participants with type 3 skin tears that received a MSI dressing, 70% and 100%, respectively, were healed at 3 weeks, giving an overall healing rate of 79%.

With regard to baseline characteristics, our sample is similar to that reported in a 10-year skin tear prevalence study (Miles et al., 2021) and an earlier 6-year prevalence study associating malnutrition with skin tears (Munro et al., 2018). The mean age of 80 and slightly higher proportion of males (55%) reported by Miles et al. is similar to the sample in this and other studies (Bermark et al., 2018; Lopez et al., 2011; Munro et al., 2018). These characteristics align with risk factors noted in a skin tear predictor model developed by Rayner et al. (2020). In this study, the proportion of hospital-acquired skin tears (84%) was somewhat higher than that reported by Miles

TABLE 4 Secondary outcomes.

Secondary outcome		Meshed silicone interface (*n*)	Adhesive silicone foam (*n*)	Significance *p*
Mean dressing-associated pain score (scales 0–10)	Before dressing removal	<0.1 (23)	0.1 (25)	0.700
	On dressing removal	0.3 (17)	0.3 (9)	1
	During dressing application	0.3 (24)	<0.1 (25)	0.122
Mean dressing satisfaction score (scales 1–5)	Ease of application	4.0 (19)	4.8 (13)	0.014
	Ease of removal	4.2 (21)	4.3 (12)	0.772
	Overall satisfaction	3.9 (24)	4.7 (25)	<0.001
Dressing conformed to wound (yes/no)		56/62	50/50	0.032
Dressing changed early (yes/no)		9/47	5/25	1
Dressing controlled exudate (yes/no)		40/44	25/25	0.289
Mean dressing time (minutes)		11.6 (20)	8.4 (17)	0.168

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et al. (61%) although the proportions caused by falls were similar (31% and 28%, respectively). Notably, the proportions of severe skin tears (STAR categories 2B and 3) were similar in both studies (69% and 70%, respectively). These data suggest that the small sample in our study is relatively representative of the population. High rates of severe skin tears in acute settings have been reported previously (Bermark et al., 2018; Chang et al., 2016) and may relate to patients moving about in an unfamiliar and potentially cluttered environment. Skin tear prevention should be linked to falls prevention and focused on maintaining an uncluttered, well-lit environment as free from equipment as possible (Miles et al., 2021), while hourly rounding can promote safe toileting and within reach possessions (Mitchell et al., 2014).

4.1 | Limitations

As this was a single-site pilot study, with a relatively small sample, results should not be generalized. A larger sample size would be required for a definitive study. Recruitment took much longer than anticipated. The main reason for this was that many potential participants with skin tears were cognitively impaired and unable to provide consent. Although *person responsible* consent was considered as an option, it was not deemed to be viable as dressing compliance could not be assured for this group. Another reason that patients declined to participate was that they did not want to take part in follow-up assessments following hospital discharge. Furthermore, many potential participants were not alerted to the research team in a timely manner; thus, they were not able to be recruited within the 24-h time frame of initial injury. There was a large loss to follow-up that may have led to some bias in the results. This would need to be accounted for in a future study. Secondary outcome assessments were made by an experienced wound care nurse/research assistant and may not be representative of bedside nurses' opinions. Furthermore, pain scores did not take account of healing and dressing removal, which would need to be accounted for in a definitive study. A future study would benefit from further investigation of the patient experience.

5 | CONCLUSION

Although healing rates were not statistically significant, the results are clinically relevant and provide important insight into dressing choice for skin tear treatment and healing rates. Skin tear dressing choice is an important topic for further research, especially in association with healing rates of different skin tear types, using a rigorous multi-site randomized controlled trial design. The findings contribute some evidence to international skin tear management and dressing selection in relation to evidence-based procedures and policymaking. In terms of education, participation in studies such as this would offer nurses' opportunities for skills development for skin tear classification as well as research methods.

AUTHORSHIP STATEMENT

All listed authors meet the authorship criteria and are in agreement with the content of the manuscript. Paul Fulbrook, Damian M. Williams, Sandra J. Miles designed the study; Damian M. Williams, Sandra J. Miles and Paul Fulbrook collected and supervised collection of the data; Paul Fulbrook, Sandra J. Miles and Damian M. Williams analysed the data; Paul Fulbrook, Sandra J. Miles and Damian M. Williams prepared and revised the manuscript. All authors approved the final version for submission.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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REFERENCES

Bermark, S., Wahlers, B., Gerber, A. L., Philipsen, P. A., & Skiveren, J. (2018). Prevalence of skin tears in the extremities in inpatients at a hospital in Denmark. *International Wound Journal*, *15*, 212–217. https://doi.org/10.1111/iwj.12847

Browne, R. H. (1995). On the use of a pilot sample for sample size determination. *Statistics in Medicine*, *14*(17), 1933–1940. https://doi.org/10.1002/sim.4780141709

Carville, K., Lewin, G., Newall, N., Haslehurst, P., Michael, R., Santamaria, N., & Roberts, P. (2007). STAR: A consensus for skin tear classification. *Primary Intention*, *15*(1), 18–21, 24-28.

Chang, Y., Carville, K., & Tay, A. (2016). The prevalence of skin tears in the acute care setting in Singapore. *International Wound Journal*, *13*(5), 977–983. https://doi.org/10.1111/iwj.12572

Edwards, H., Gaskill, D., & Nash, R. (1998). Treating skin tears in nursing home residents: A pilot study comparing four types of dressings. *International Journal of Nursing Practice*, *4*(1), 25–32. https://doi.org/10.1111/j.1440-172X.1998.00066.x

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., Lancaster, G. A., & PAFS consensus group. (2016). CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ*, *24*(355), i5239. https://doi.org/10.1136/bmj.i5239

Gray, D., Stringfellow, S., Cooper, P., Russell, F., Johnson, S., Leak, K., Ridsdale, D., Spruce, P., & Clark, M. (2011). Pilot RCT of two dressing regimens for the management of skin tears. *Wounds*, *7*(2), 26–31.

Kennedy-Evans, K. (2004). An innovative solution for skin tears: A case study. *Ostomy/Wound Management*, *50*(2), 9–10.

Kohn, M. A., & Senyak, J. (2021). Sample size calculators [website]. UCSF CTSI. Retrieved December 20, 2021, from https://www.sample-size.net

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice*, *10*(2), 307–312. https://doi.org/10.1111/j..2002.384.doc.x

1440172x, 2024, 3, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jjn.13229 by South African Medical Research, Wiley Online Library on [16/07/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

LeBlanc, K., Baranoski, S., Christensen, D., Langemo, D., Edwards, K., Holloway, S., Gloeckner, M., Williams, A., Campbell, K., Alam, T., & Woo, K. Y. (2016). The art of dressing selection: A consensus statement on skin tears and best practice. *Advances in Skin & Wound Care*, *29*(1), 32–46. https://doi.org/10.1097/01.ASW.0000475308.06130.df

LeBlanc, K., Baranoski, S., Holloway, S., Langemo, D., & Regan, M. (2014). A descriptive cross-sectional international study to explore current practices in the assessment, prevention and treatment of skin tears. *International Wound Journal*, *11*, 424–430. https://doi.org/10.1111/iwj.12203

LeBlanc, K., Baranoski, S., & Skin Tear Consensus Panel Members. (2011). Skin tears: State of the science: Consensus statements for the prevention, prediction, assessment, and treatment of skin tears. *Advances in Skin & Wound Care*, *24*(9 Suppl), 2–15. https://doi.org/10.1097/01.ASW.0000405316.99011.95

LeBlanc, K., Campbell, K., & Expert Working Group. (2018). ISTAP best practice recommendations for the prevention and management of skin tears in aged skin. *Wounds International 2018*. https://woundsinternational.com/best-practice-statements/istap-best-practice-recommendations-prevention-and-management-skin-tears-aged-skin/

LeBlanc, K., & Woo, K. (2022). A pragmatic randomised controlled clinical study to evaluate the use of silicone dressings for the treatment of skin tears. *International Wound Journal*, *19*(1), 125–134. https://doi.org/10.1111/iwj.13604

LeBlanc, K., Woo, K. Y., VanDenKerkhof, E., & Woodbury, M. G. (2020). Skin tear prevalence and incidence in the long-term care population: A prospective study. *Journal of Wound Care*, *29*(7), S16–S22. https://doi.org/10.12968/jowc.2020.29.Sup7.S16

Lee, E. C., Whitehead, A. L., Jacques, R. M., & Julious, S. A. (2014). The statistical interpretation of pilot trials: Should significance thresholds be reconsidered? *BMC Medical Research Methodology*, *20*(14), 41. https://doi.org/10.1186/1471-2288-14-41

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, *45*(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008

Lopez, V., Dunk, A. M., Cubit, K., Parke, J., Larkin, D., Trudinger, M., Stuart, M., & Joanna Briggs Institute. (2011). Skin tear prevention and management among patients in the acute aged care and rehabilitation units in the Australian Capital Territory: A best practice implementation project. *International Journal of Evidence-Based Healthcare*, *9*, 429–434. https://doi.org/10.1111/j.1744-1609.2011.00234.x

Meuleneire, F., & Rucknagel, H. (2013). Soft silicone dressings made easy. *Wounds International*. http://www.woundsinternational.com/pdf/content_10804.pdf

Miles, S. J., Fulbrook, P., & Williams, D. M. (2021). Skin tear prevalence in an Australian acute care hospital: A 10-year analysis. *International Wound Journal*, *19*(6), 1418–1427. https://doi.org/10.1111/iwj.13735

Mitchell, M. D., Lavenberg, J. G., Trotta, R. L., & Umscheid, C. A. (2014). Hourly rounding to improve nursing responsiveness: A systematic review. *Journal of Nursing Administration*, *44*(9), 462–472. https://doi.org/10.1097/NNA.0000000000000101

Mölnlycke® Health Care. (2023). Dressings with Safetac: Proven choice for better outcomes. https://www.molnlycke.com.au/our-knowledge/safetac-technology/

Munro, E. L., Hickling, D., Williams, D. M., & Bell, J. J. (2018). Malnutrition is independently associated with skin tears in hospital inpatient setting—Findings of a 6-year point prevalence audit. *International Wound Journal*, *15*(4), 527–533. https://doi.org/10.1111/iwj.12893

Rayner, R., Carville, K., Leslie, G., & Dhaliwal, S. S. (2020). Models for predicting skin tears: A comparison. *International Wound Journal*, *17*(3), 823–830. https://doi.org/10.1111/iwj.13340

Serra, R., Ielapi, N., Barbetta, A., & de Franciscis, S. (2017). Skin tears and risk factors assessment: A systematic review on evidence-based medicine. *International Wound Journal*, *15*(1), 38–42. https://doi.org/10.1111/iwj.12815

Strazzieri-Pulido, K. C., Peres, G. R., Campanili, T. C., & Santos, V. L. (2015). Skin tear prevalence and associated factors: A systematic review. *Revista da Escola de Enfermagem*, *49*(4), 668–674. https://doi.org/10.1590/S0080-623420150000400019

Sussman, G., & Golding, M. (2011). Skin tears: Should the emphasis be only their management? *Wound Practice & Research*, *19*(2), 66–71. https://doi.org/10.3316/informit.127929276082687

Thomas, D. R., Goode, P. S., LaMaster, K., Tennyson, T., & Parnell, L. K. (1999). A comparison of an opaque foam dressing versus a transparent film dressing in the management of skin tears in institutionalized subjects. *Ostomy Wound Manage*, *45*(6), 22–28.

Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, *25*(3), 1057–1073. https://doi.org/10.1177/0962280215588241

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