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A pragmatic randomised controlled clinical study to evaluate the use of silicone dressings for the treatment of skin tears

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Abstract

One of the most common types of skin breakdown in ageing populations is skin tears. The International Skin Tear Advisory Panel advocates for special attention to be paid to dressing selection related to skin tear management. The panel recommends choosing dressings that will promote the maintenance of moisture balance, suit the local wound environment, protect peri-wound skin, control or manage exudate and infection, and optimise caregiver time. It is paramount that dressings protect the fragile nature of the skin associated with those who at heightened risk for skin tear development. To compare the effectiveness of soft silicone dressings (a contact layer and/or foam) for the healing of skin tears with local practices that do not include soft silicone dressings. The study was a pragmatic randomised controlled prospective study. One hundred and twenty-six individuals from two long-term care facilities in Ontario Canada who presented with skin tears were randomised into the treatment group using either soft silicone dressings (a contact layer and/or foam) or the control group using non-adhesive dressings. The current study demonstrated that 96.9% (n = 63) of skin tears in the treatment group healed over a 3-week period compared with 34.4% (n = 21) in the control group. The proportion of wound healing experienced at week 2 was 89.2% (n = 58) in the treatment group compared with 27.9% (n = 17) in the control group. There was a significantly greater reduction in wound surface area relative to baseline in the treatment group (2.9 cm^2) compared with the control group (0.6 cm^2) ($\chi^2 = 21.792$ $P < .0001$) at week 1. Survival analysis data supported that skin tears healed 50% faster in the treatment group (11 days) compared with the control group (22 days) ($\chi^2 = 59.677$ $P < .0001$). The expected healing trajectory of acute wounds, including skin tears, if proper wound bed preparation is realised and infection is controlled, is 7 to 21 days. Results of this study suggest the use of silicone dressings support wound healing and aid in wound closure within the expected healing

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trajectory, with faster complete wound closure and mean healing times compared with non-silicone dressing for the treatment of STs.

KEYWORDS

randomised control trial, skin tears, soft silicone dressings

1 | INTRODUCTION

Maintaining skin integrity is commonly seen as a benchmark for patient safety and quality of care.[1] One of the most common causes of skin breakdown in ageing population is skin tears (ST). STs are defined as "*a traumatic wound caused by mechanical forces, including removal of adhesives. Severity may vary by depth (not extending through the subcutaneous layer*)."[2]

Skin tears are classified according to the International Skin Tear Advisory Panel (ISTAP) ST Classification System[3]:

- Type 1 ST: No tissue loss (linear or flap tear that can be repositioned to cover the wound bed)
- Type 2 ST: Partial flap loss (partial flap loss that cannot be repositioned to cover the wound bed)
- Type 3 ST: Total flap loss (total flap loss exposing entire wound bed)

Van Tiggelen et al[4] added clarification of a "flap" in relation to STs. "*A flap in skin tears is defined as a portion of the skin (epidermis/dermis) that is unintentionally separated (partially or fully) from its original place due to shear, friction, and/or blunt force. This concept is not to be confused with tissue that is intentionally detached from its place of origin for therapeutic use, for example, surgical skin grafting*."

STs are common across all patient populations but are more prevalent in the extremes of age, the critically ill, and/or those requiring assistance with personal care.[2,5] They are documented as the most prevalent wound aetiology found among long-term care (LTC) populations.[6] Studies conducted in LTC settings report ST prevalence to be between 3.9% and 26.0%.[7-10]

STs are particularly common in the ageing population because of intrinsic changes of the skin, which are frequently seen in those over the age of 65 years. These include but are not limited to: the loss of the extracellular matrix and its major component, hyaluronate (which is responsible for stabilising the intracellular structures with the formation of a viscoelastic network in which collagen and elastin fibres are embedded), and flattening of the epidermal-dermal junction. These changes result in a loss of the skin's mechanical functions because of the loss of the viscoelastic properties.[11] In addition, deterioration of the sweat and sebaceous gland secretions is believed to contribute to skin breakdown and xerosis. Ecchymosis, senile purpura, hematoma, xerosis, stellate spontaneous pseudoscars, and skin atrophy have been previously identified as intrinsic skin changes attributed to ageing.[12]

Key Messages

- silicone dressings are superior with faster complete wound closure and mean healing times compared with non-silicone dressing for the treatment of skin tears
- more studies are required to explore treatment options for STs across the healthcare spectrum

Given the fragility of the skin in those at risk for STs, ISTAP advocates for special attention to be paid to dressing selection related to ST management. The panel recommends choosing dressings that will promote the maintenance of moisture balance, suit the local wound environment, protect peri-wound skin, control or manage exudate and infection, and optimise caregiver time.[13] It is paramount that dressings chosen to protect the fragile nature of the skin associated with those who have been identified as being a risk of ST development.[13]

Skin tears are acute wounds, which should heal in 7 to 21 days.[14] There exists a variety of treatment options for STs including skin closure strips, non-adherent dressings, foam dressings, acrylic dressings, and hydrocolloid dressings.[15] Expert opinion suggests that the use of adhesive strips, film dressings, and hydrocolloids may increase the risk of further skin injury; although more research is needed, case studies and expert opinion suggest that these treatment modalities are no longer a preferred treatment option for STs.[13] Thomas et al[16] conducted a prospective randomised trial of 34 individuals living in a long-term care facility comparing opaque foam dressings with transparent film dressings. Findings included complete wound healing within 21 days in 94% of subjects treated with opaque

foam dressings versus 65% of those treated with transparent film dressings.[16]

While current best practices recommend the use of silicone contact layers and/or silicone foam dressings for the management of STs, there are limited randomised control trials to support these practices.[2] The primary objective of this study was to compare the effectiveness of soft silicone dressings (a contact layer and/or silicone foam) for the healing of STs with local best practices. Local best practice treatments included non-adherent dressing options that were included in the ISTAP best practice recommendations[13] but were not silicone based. Specifically, to determine if there is a difference in the proportion of complete healing (defined as restoration of the complete epithelial cover) between soft silicone dressings and non-soft silicone dressings for treatment of STs.

1.1 | Methodology

The current study was a pragmatic randomised controlled prospective clinical study, which was conducted between June 2019 and October 2019. One hundred and twenty-six individuals from two long-term care facilities in Ontario Canada who presented with STs participated in the study.

1.2 | Participants

The target population included residents residing in LTC who were greater than 18 years of age. A non-probability convenience sampling method was used and participants were selected from the population based on convenience and availability to the researchers. The facility's registered nursing staff initially identified potential participants based on wound aetiology and provided potential participants or their power of attorney (POA) with an information sheet to determine interest in participation and to gather verbal consent to allow the researcher to approach the potential participant or their POA. The researcher provided complete details of the study and obtained informed written consent from either the participant or their POA. Inclusion criteria include: Resident of participating LTC facilities and presence of an ST. Exclusion criteria focused on participant characteristics that will have a negative impact on wound healing beyond which can reasonably be expected[17]:

- medical conditions that in the opinion of the investigator may compromise wound healing above and beyond that which would normally be expected (including but not limited to, malignancies or active untreated infection),
- the participant has received any treatment before the study enrolment that may, in the opinion of the investigator, affect wound healing
- in the opinion of the investigator, the participant is otherwise not suitable for study participation, including but not limited to, extreme illness, demonstrated non-compliance with treatment plans

If an eligible participant had more than one appropriate STs, only one was selected for the purposes of the study.

1.3 | Randomization

Participants were randomised using a computer-based randomization program and blinded to the researcher. Eligible participants were randomised by unit/floor, meaning that each of the 10 units/floors (divided over two facilities) were randomised, using a computer-based block-randomization program, into control or treatment groups. Eligible participants were placed into either the control or treatment group based on which facility unit/floor they resided on. Sealed opaque envelopes were prepared by the sponsor and contained the random assignment of floors. The researcher was informed of the participant assignment after enrolment in the study.

Half of the participants were randomised into the treatment group using soft silicone dressings (Mepitel One and Mepilex Border Flex). Depending on the type of STs and potential exudate produced by the wound, an appropriate form of silicone dressing was used. Specifically, Mepitel One dressing was used for type 1 and type 2 STs where exudate is expected to be minimal and Mepilex Border Flex was used for exudative type 2 and type 3. The other half of the sample were randomly assigned to local best practice excluding the use of soft silicone dressings for the management of all STs. Local best practice included the use of non-adhesive absorbent composite dressings (Alldress or Telfa). As the dressings looked different from one another; it was not feasible to blind the researchers after randomization and during data collection. The researchers were, however, blinded to the two groups during data analysis, as the two groups were coded using a formula concealed from the researchers. Primary endpoint included the proportion of healed STs in 3 weeks (duration of the study). The secondary endpoints involved changes in wound size at week 3. Weekly assessment including measurement of wound sizes and any adverse events.

1.4 | Ethical consideration

Ethical approval was received from the Queen's Health Sciences Research Ethics Board (approval #6024207).

1.5 | Wound dressings

The treatment of silicone dressings included Mepitel One and Mepilex Border Flex (Mölnlycke Health Care). Mepitel One and Mepilex Border Flex both incorporate Safetac silicone adhesion technology. Mepilex Border Flex has the added properties of having multi-layer foam absorption. The control group included Alldress (Mölnlycke Health Care) and Telfa (The Kendall Company Ltd) dressings, which were traditionally used by the facilities to manage STs. Alldress consists of a several layers of absorbent cotton fibres with an adhesive border for minimal to moderately exudation wounds. Telfa consists of a thin layer of absorbent cotton fibres, enclosed in a sleeve of polyethylene terephthalate.[18]

1.6 | Sample size

The primary outcome included the proportion of STs that achieved complete healing over time (3 weeks). Based on a previous study by David et al,[19] comparing soft silicone dressing (Mepitel One) with a non-adherent dressing (Urgotul), in order to detect a clinically relevant difference in proportion healed after 4 weeks between 70% in the study group and 40% in the control group with a two-sided Fisher's exact test, 49 subjects were needed in each group to reach a power of 80% with a significance level of 5%. Anticipating a dropout rate of 5%, the final sample was estimated to be 52 participants in each group or 104 participants in total.

1.7 | Wound healing

Disposable paper rulers were used to obtain the longest wound length and width dimensions that are perpendicular to each other to provide the estimation of wound surface areas. Healing rates, percentage of wound area reduction, were calculated using proportionate changes in mean surface area over the 3-week period. All subjects were evaluated at week 0 (time of enrolment in the study), week 1, and week 3 (ie, at the end of the study). Wound photography was taken during the time of assessment.

1.8 | Data collection tool

The data collection tool was developed based on risk factors identified after a literature search for assessing ST prevalence and associated ST risk factors and the original version of the tool was piloted in an ST prevalence study (n = 114) conducted in LTC[20] and was used in a subsequent prevalence and incidence study (n = 378).[8]

STs were classified according to the ISTAP ST classification system[20] and the anatomical location of each observed ST was recorded. Skin tears were then reassessed to determine the degree of wound healing at week 1 and at week 3. For the purpose of this study, the criteria to determine whether healing has achieved are based on ST types (Table 1):

- Completely healed Type 1 skin tears: When a dry, slightly firm healing ridge or new epithelium has formed along the edge when the flap meets the skin. The development of a healing ridge; described as an area of swelling and hardness under the re-approximated skin edges indicating deposition of new collagen in the wound.

Completely healed type 2 or type 3 skin tears: When the wound edges are bridged by new epithelium including the establishment of a healing ridge.

1.9 | Data collection

Data collection occurred between June 2019 and October 2019, data collection ended when the desired sample size was reached. Posters and flyers were distributed around participating facilities to raise awareness of the study taking place.

Skin tears were assessed and data were collected weekly for a maximum of 3 weeks by the researcher. In keeping with the pragmatic approach, dressing changes were completed by the assigned nursing staff as per facility policy for wound management. Additional dressings were labelled with the patient name and stored in the patient room for use as needed. Prior to the start of the study, assigned nursing staff were provided education on the research study, dressings that were to be used during the study, wound bed preparation, skin tear classification, and dressing application and removal techniques.

1.10 | Data analysis

Data analysis was conducted using the Statistical Package for the Social Science (SPSS) program version 26.

TABLE 1 Skin tear predicted healing times and signs and symptoms of skin tear healing (adapted from: Melling et al[14])

Type 1 Skin tears				
Outcome measure	**Days 1 to 4**	**Days 5 to 9**	**Days 10 to 14 (proliferative healing)**	**Day 15 (remodelling)**
Type 1 ST colour	Red edges approximated	Red, progressing to bright pink (all skin tones)	Bright pink (all skin tones)	Pale pink, progressing to white or silver in light-skinned patients; pale pink, progressing to darker than normal skin colour or may blanch to white in dark-skinned patients
Surrounding tissue inflammation	Swelling, redness or skin discoloration, warmth, pain	None present	None present	None present
Drainage type	Serosanguinous	None present	None present	None present
Drainage amount	Moderate to minimal	None present	None present	None present
Epithelialization	Present by day 14	Present along entire wound	Present	None present
Healing ridge	None Present	Present along entire wound by day 9	Present along entire wound	Present
Type 2 and 3 skin tears				
Outcome measure	Days 1 to 4	Days 5 to 9	Days 10 to 14 (proliferative healing)	Days 15 to years 1-2 (remodelling)
Type 2 and 3 peri-wound ST colour	Red edges not approximated	Peri-wound skin red, progressing to bright pink (all skin tones)	Bright pink (all skin tones)	Pale pink, progressing to white or silver in light-skinned patients; pale pink, progressing to darker than normal skin colour or may blanch to white in dark-skinned patients
Surrounding tissue inflammation	Swelling, redness or skin discoloration, warmth, pain	None present	None present	None present
Drainage type	Serosanguinous	Serosanguinous	Serosanguinous	None present
Drainage amount	Moderate to minimal	Moderate to minimal	Minimal	None present
Epithelialization	None	None	Present	None present
Healing ridge	None Present	None Present	Present along entire wound	Present

Abbreviation: ST, skin tears.

Descriptive statistics was used to summarise demographic and clinical characteristics of the sample. The success of randomization was assessed by comparing the characteristics of the two groups; a Student *t* test was carried out to compare the continuous variables (eg, age) and chi-square tests to compare the categorical data (sex, STs types, etc). Primary statistical analysis compared the proportion of skin tears healed between the two randomised groups with two-sided Fisher's exact test at significance level 0.05 on the ITT population. Repeated measure analysis of variance was used to evaluate the changes in wound size between two groups over time (weekly assessments). *T* tests were used to compare wound size between the treatment and study groups.

2 | RESULTS

One hundred and twenty-six participants, 56 males (44.4%) and 70 females (55.6%) with a mean age of 82.9 (+/− 8) years (45-102 years of age) participated in the study. Fifty-four (43%) of the individuals were randomised to the control group. Seventy-two (57%) of the individuals were randomised to the treatment group (Figure 1).

The majority of participants (n = 100, 79.4%) were treated with either Alldress (n = 45, 35.7%) or Mepilex Border Flex (n = 55, 43.7%). The remaining were treated with Mepitel one (n = 17, 13.5%) or Telfa (n = 9, 7%). STs were classified according to the ISTAP ST classification system. Nursing staff applied the type of dressing based on the randomization of the floor to which the participant resided and clinical judgement. Type 1 STs (n = 16, 12.7%) were treated with non-adherent type dressings (Mepitel One or Telfa, n = 9, 56%) or absorptive dressings (Mepilex Border Flex or Alldress) (n = 7, 44%). Type 2 (n = 55, 43.7%) and 3 STs (n = 55, 43.7%) were treated with absorbent dressings (n = 93, 85%) or non-adhesive dressings (Mepitel One or Telfa, n = 17, 15%) (Table 2). The majority of STs (n = 117, 93%) were reported to be located on the upper and lower extremities (Table 3).

Proportion of healing among the treatment group (Mepitel One or Mepilex Border Flex) was 96.9% compared with 34.4% in the control group (Alldress or Telfa) (Figure 2). There was a significant decrease in the mean surface area reduction in the treatment group compared with the control group ($\chi^2 = 21.792$ $P < .0001$) (Table 4).

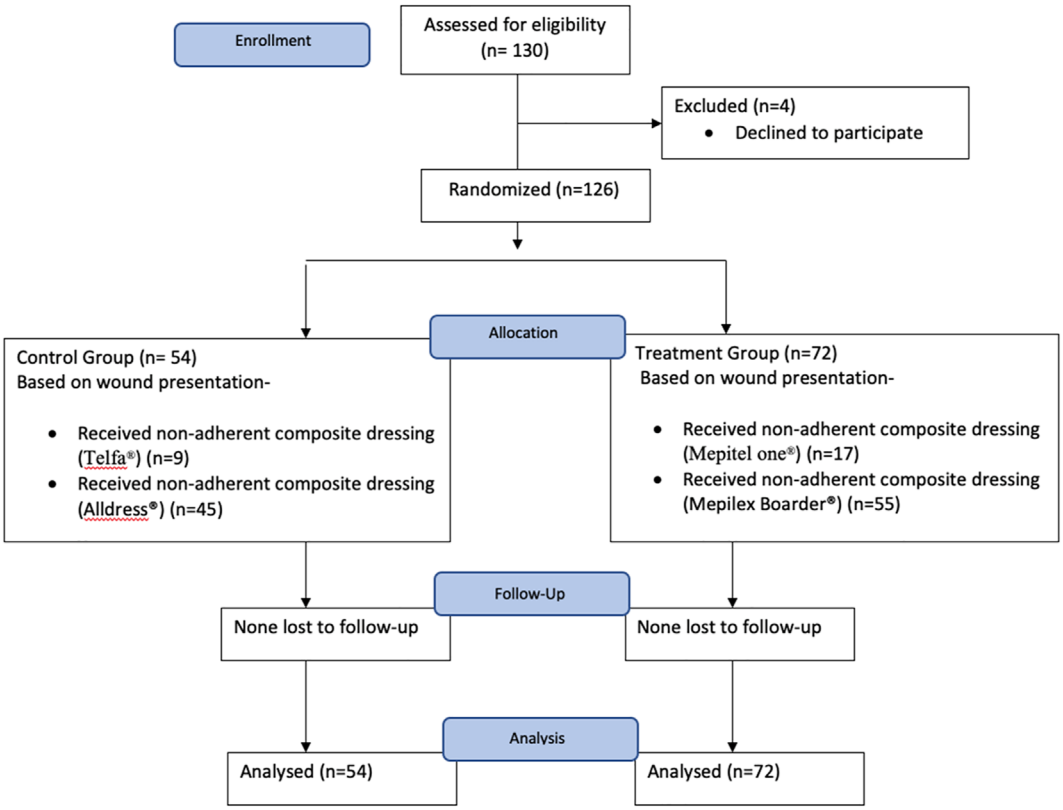

FIGURE 1 Consort flow diagram

TABLE 2 Skin tear types and dressing allocations

Skin tear type	Control (Alldress)	Control non-adherent (Telfa)	Treatment Mepilex (border flex)	Treatment Mepitel one	N	Percent
Type 1	6	1	1	8	16	12.7
Type 2	20	3	26	6	55	43.7
Type 3	19	5	28	3	55	43.7
Total	45	9	55	17	126	100.0

TABLE 3 Skin tear location

Skin tear location	Group assignment		N	Percent
	Control	Treatment		
Arms	21	30	51	40.5
Legs (including ankles)	32	21	53	42.1
Hands	6	5	11	8.7
Back	0	5	5	4.0
Feet	2	0	2	1.6
Head/face	0	2	2	1.6
Buttocks	1	1	2	1.6
Total			126	100

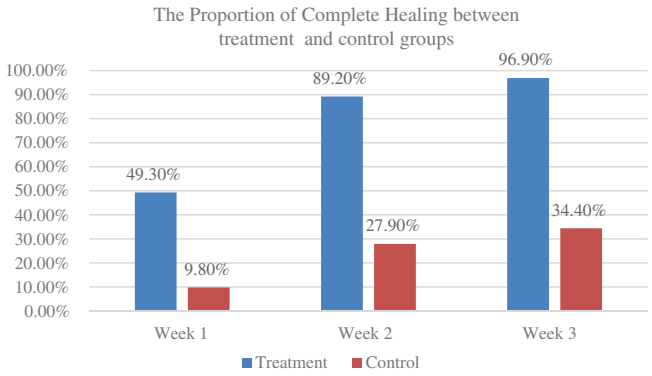

FIGURE 2 The proportion of complete healing between treatment and control groups

Kaplan-Meier survival analysis, based on weekly measurements, demonstrated that STs in the treatment group took, on average, 50% less time to heal (11 days to heal compared with 22 days in the control group) ($\chi^2 = 59.677$ $P < .0001$) (Table 5).

3 | DISCUSSION

There exists limited evidence to support the expected healing trajectory and the management of STs, with the majority of the literature is based on expert opinion.[2,13] However, given that STs are acute wounds, if proper wound bed preparation is realised and infection is controlled, it is expected that these wounds should heal in 7 to 21 days.[14]

In general, wound healing is a dynamic biological process that requires a delicate balance of various host and local wound factors. One of the challenges in wound management is to maintain moisture balance to create an environment that is conducive to healing. While a desiccated wound surface can slow down cellular migration, impairing wound healing, excessive moisture can damage the edges and peri-wound skin.[17]

The concept of moist wound healing has been utilised in practice since the 1960s when ground-breaking research demonstrated that wounds achieve faster healing in moist environment compared with wounds that were allowed to dry.[21,22] This expedited healing is explained by the fact that cells can migrate much more easily and quickly in a moist environment.[17] Best practice is such that dressings should be chosen, which will maintain a moist wound environment, manage exudate, protect the wound bed and peri-wound skin from trauma, and minimise the frequency of dressing changes (Baranoski et al.[23]

Careful selection of dressings with an atraumatic and non-adherent wound contact layer, such as silicone, for ST management has been documented to limit skin damage/trauma with dressing removal and to minimise pain at dressing changes (LeBlanc et al).[24] Silicone coatings consist of chains of hydrophobic polymers with alternate molecules of silicone and oxygen. Compared with other adhesives, the silicone coatings produce a lower surface tension combined with a more extensive contact interface. Silicone-coated dressings adhere to intact dry skin but unlike traditional adhesives, they do not adhere to a moist wound bed. In a comparative study, Matsumara et al,[25] evaluated eight commonly used wound care products with adhesives (soft silicon, hydrocolloid, polyurethane, and acrylic adhesives) and their potential effect on the epidermis in 10 volunteers. It was determined that dressings that incorporated soft silicone technology were less likely to cause skin stripping and removal of stratum corneum than other tested material.

Foam dressings and non-adherent silicone mesh dressings are both considered to be appropriate for the management of STs (LeBlanc et al).[24] Non-adherent silicone mesh dressings act as low-adherence materials when applied to wound surfaces, acting as protective

TABLE 4 Wound surface area reduction (cm^2)

	Group assignment	N	Mean	SD	SEM
Area reduction after 1 week: ST0-ST1	Control	58	0.64	1.56	0.20
	Treatment	64	2.86	5.61	0.70
Area reduction after week 2	Control	47	0.72	1.49	0.22
	Treatment	31	1.29	2.33	0.42
Area reduction after week 3	Control	16	1.05	1.75	0.44
	Treatment	5	1.21	1.33	0.59

Note: $\chi^2 = 21.792$ $P < .0001$.

TABLE 5 Kaplan-Meier survival analysis (weekly)

			Mean	
			95% Confidence interval	
Group assignment	Estimate days	SE	Lower bound	Upper bound
Control	21.73	1.02	19.74	23.72
Treatment	11.06	0.59	9.90	12.22
Overall	16.21	0.75	14.75	17.67

Note: $\chi^2 = 59.677$ $P < .0001$.

interfaces between the wound and secondary dressings. The resulting effect allows for fluid management without compromising wound bed and peri-wound skin health.[23]

The current study has demonstrated that 96.9% (n = 63) of STs treated with either Mepitel One or Mepilex Border Flex healed over a 3-week period compared with only 34.4% (n = 21) of STs treated with Alldress or Telfa. While this difference in healing times is of significance, more impressive is the comparison of the proportion of complete wound healing experienced at week 2, with 89.2% (n = 58) of the treatment group compared with 27.9% (n = 17) of the control group. Mepitel One showed clinical benefits in the treatment of STs type 1 and 2, and Mepilex Border Flex in the treatment of STs type 2 and 3. In relation to reduction of wound surface area, a significantly greater reduction in wound surface area relative to baseline in the treatment group (2.9 cm^2) compared with the control group (0.6 cm^2) ($\chi^2 = 21.792$ $P < .0001$) at week one. Survival analysis data demonstrated that STs healed 50% faster in the treatment group (11 days) compared with the control group (22 days) ($\chi^2 = 59.677$ $P < .0001$). These results demonstrate that the use of Mepitel One or Mepilex Border Flex for the management of STs can have a significant positive impact on wound healing.

These findings support previous case series and pilot studies pertaining to the use of silicone-based wounds dressings for the management of STs. Kennedy-Evans[26] completed a case series using non-adherent mesh silicone for the treatment of STs and demonstrated mean 14-day healing times, absence of dressing-related peri-wound skin trauma, and pain reduction during dressing change.

Meuleneire[27] conducted a 6-month descriptive product trial among 59 hospitalised older adults who sustained a total of 88 Type 1 and Type 2 STs using a silicone mesh dressing. They reported that 88% of STs were closed by day 8, with the remaining 12 STs reported to have delayed wound healing secondary to oedema and/or infection. This finding was supported in the current study wherein the average time to heal among the treatment group was 11 days compared with the treatment group of 22 days. It should be noted that the Meuleneire[27] study was of limited sample size, not randomised, and were limited to type 1 and type 2 ST, as the current study reported the majority of STs to be type 2 and type 3. Further research required to explore treatment options for STs across the health care spectrum to determine if these results can be realised in other populations.

4 | LIMITATIONS

The current study is limited in that wound measurements were only taken at three distinct timepoints (week1, week 2, and week 3) from the time of injury. In addition, as the majority of wounds treated during this study were type 2 or type 3 STs, the findings from this study may not be generalizable to all types of STs. Findings may not be generalizable to other LTC populations, as a convenience

sample of participants was surveyed. Because only participants from only two LTC facilities were surveyed, the findings may not be generalizable to subjects outside of these LTC facilities.

5 | CONCLUSION

The expected healing trajectory of acute wounds, including STs, if proper wound bed preparation is realised and infection is controlled, is 7 to 21 days.[14] The results of this study suggest that silicone dressings are superior with faster complete wound closure and mean healing times compared with non-silicone dressing for the treatment of skin tears. Skin tears healed almost two times faster with soft silicone dressings compared with conventional non-adherent dressings over the course of 3 weeks. In the control group, there were 65% of patients who did not achieve complete healing after 21 days (3 weeks), whereas almost all patients completely healed after 3 weeks in the silicone group. The proportion of healed subjects was almost three times higher in the silicone group compared with the control. The findings from this study provide support to expert opinion that silicone-based dressings should be used in the management of STs in place of traditional dressings.

CONFLICT OF INTEREST

The authors received a research grant from Mölnlycke Health Care to support the study. Both authors are members of the Mölnlycke Health Care speakers bureau and have been paid lecturers for Mölnlycke Health Care.

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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