Clinical investigation of the performance and safety of a soft silicone wound contact layer containing silver in the treatment of skin grafts and a soft silicone transfer dressing containing silver in the treatment of donor sites in surgical burn patients

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Background

It has been estimated that, annually, 486,000 people in the United States suffer burn injuries that require medical treatment (American Burn Association, 2016). Burns that are more superficial are typically treated conservatively with topical medication, or with some type of dressing or covering that promotes the natural course of healing. For deep dermal burns, a combination of excision and grafting is generally preferred (Orgill, 2009). Patients with deep dermal burns often suffer from pain and anxiety, hence optimal dressing selection for both graft and donor sites is key.

Aims

The aims of this investigation were to evaluate the use of a non-adherent soft silicone wound contact layer containing silver (SSWCL-Ag*) in the management of split-thickness skin grafts (study Part A), and the use of a soft silicone transfer dressing containing silver (SSTD-Ag**) in the management of skin graft donor sites (study Part B) in surgical burn patients (**Figure 1**).

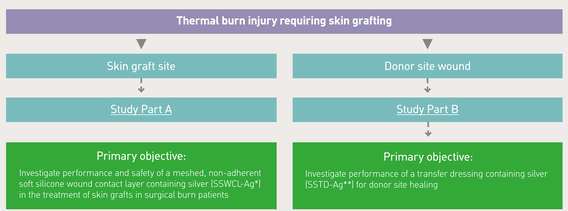

Figure 1 Study objectives.

*Mepitel® Ag (Mölnlycke Health Care, Sweden); **Mepilex® Transfer Ag (Mölnlycke Health Care, Sweden)

Methods

This was an open, non-controlled, multi-centre clinical investigation. Patients presenting with a thermal burn injury that required skin grafting and resulted in a donor site (overall % total body surface area burned not exceeding 30%), from 3 clinical investigation sites were included in the study (according to inclusion and exclusion criteria). Treatment lasted for a maximum of 14 days.

A total of 25 patients were included in the intention-to-treat (ITT) analysis in study Part A (19 males; 6 females, mean age 28.6 years) and 19 of these patients were included in the ITT analysis in study Part B (15 males; 4 females, mean age 26.9 years). A subject who did not fulfill the criteria for study Part B still had the option to participate in study Part A.

Part A

The primary outcome measure for Part A was adequate skin graft take (defined as 95% adherent and healed) at post-operative days 7–14. Secondary objectives relating to in-use dressing characteristics, clinical outcomes and safety included: fixation of dressing over skin graft; passage of exudate to secondary dressing; peri-wound skin condition; pain (prior to, during and after dressing change); antimicrobial protection of dressing; safety (related to silver exposure); clinician assessment (handling and general use of dressing); and patient assessment (comfort, overall satisfaction).

Procedures and assessments conducted for Part A are outlined in **Table 1**.

Visit	Procedure(s)	Assessment(s)
Visit 1	Patients evaluated for inclusion and exclusion criteria; demographics/ burn history/medical and surgical history/vital signs/concomitant medication recorded; physical examination conducted; debridement/ cleansing as required; photograph of burn wound taken	Burn wound assessment
Visit 2 (same day as visit 1 or later)	Burn wound prepared for grafting (temporary skin substitutes were allowed to be used until the burn was ready for autograft); debridement/ cleansing as required; photograph of burn wound taken; skin grafts applied, anchored with staples; SSWCL-Ag* applied directly in contact with skin graft; then covered by an absorbent layer (dressing remained in place until post-op day 2); dressing log completed; concomitant medication recorded	Peri-wound status assessment; investigator/nurse evaluation; adverse events (AEs)
Visit 3 (post-operative day 2)	All outer layers removed; photograph of burn wound taken; dressing log completed; concomitant medication recorded; all dressing layers replaced	Assessment made for any slippage of the study product; pain evaluation (100mm visual analog scale (VAS)/Wong-Baker FACES Pain Rating Scale***); peri-wound status assessment; investigator/ nurse evaluation; patient evaluation; AEs
Visit 4 (post-operative day 7)	All outer layers and study product removed; photograph of burn wound taken; dressing log completed; concomitant medication recorded; all dressing layers replaced	As above (visit 3); first graft take assessment; dressing removal assessment *(if graft take was ≥95%, day 14 assessment not completed)*
Visit 5 (post-operative days 8–13 (unscheduled visit))	As above *(where unscheduled visits occurred)*	Subsequent graft take assessments occurred anytime between post-op days 8-13 *(where unscheduled visits occurred)*; patient considered completed with the study once the graft had taken
Visit 6 (post-operative day 14)	As above End of study; patient considered completed with the study once the graft had taken	As above (visit 4)

Table 1: Procedures and assessments for study Part A.
(all procedures and assessments made according to product instructions for use and standard clinical protocol).

***Wong-Baker FACES Pain Rating Scale completed for subjects 3–<13 years old

Part B

The primary outcome measure for Part B was percentage donor site healing at post-operative days 10-14 (defined as >95% epithelialization). Secondary objectives relating to in-use dressing characteristics, clinical outcomes and safety included: presence of abnormal bleed issues after hemostasis achieved; pain; adherence of dressing to donor site without slippage.

Procedures and assessments conducted for Part B are outlined in **Table 2**.

Visit	Procedure(s)	Assessment(s)
Visit 1	As Part A	As Part A
Visit 2	Selected donor site designated as 'study site' in each eligible patient; treatment initiated in the operating room following debridement and split thickness grafting of wounds; photograph taken prior to donor skin harvesting; donor skin harvested (0.010–0.012 inches thickness) and hemostasis achieved according to normal clinical routine; once adequate hemostasis achieved; photograph taken after donor skin harvesting and hemostasis achieved; SSTD-Ag** applied directly to study site with an overlap of 5cm followed by an absorbent layer (secondary dressing included an Ace bandage to prevent study dressing from slipping)	Peri-wound assessment
Visit 3 (post-operative day 2)	Bleeding assessment – drainage; outer Ace wrap removed and photograph taken; assessment of drainage present on Ace wrap; absorbent dressing removed and SSTD-Ag** assessed for adequate coverage of donor site; any slippage of study product addressed as appropriate	Bleeding and drainage assessments; peri-wound assessment; pain evaluation (100mm visual analog scale (VAS)/Wong-Baker FACES Pain Rating Scale***) prior to, during, after dressing removal and 30 minutes after dressing removal; clinician assessment; subject evaluation
Visit 4 (post-operative day 7, +/- 2 days)	All procedures repeated as visit 3; special care made to keep original SSTD-Ag** in place until the donor site showed adequate signs of healing	All assessments repeated as visit 3 If study product completely dislodged due to full healing of donor site, additional assessment performed to capture donor site healing and product removal assessment; photograph taken of donor site
Visit 5 (post-operative day 10–14 +/- 2 days)	All procedures repeated as visit 3; if adequate donor site healing achieved, SSTD-Ag** gently removed from donor site; donor site photographed	All assessments repeated as visit 3; product removal assessment; quantitative photograph analysis performed using PictZar® software; clinician assessment of healing documented in terms of percentage healed (clinician assessment compared to photographic analysis)
Visit 6 (Unscheduled visits, from post-operative day 10)	All procedures repeated as visit 5; if a patient was discharged from hospital and their study site had not healed, that patient continued to be followed as part of their regularly scheduled clinic follow-up appointments	All assessments repeated as visit 5

Table 2: Procedures and assessments for study Part B.
(all procedures and assessments made according to product instructions for use and standard clinical protocol).

***Wong-Baker FACES Pain Rating Scale completed for subjects 3–<13 years old

Results

No adverse events related to the two dressings were reported during the investigation.

Study Part A

The SSWCL-Ag* performed well on skin graft sites; adequate skin graft take (defined as at least 95% graft take) was recorded in 87.5% and 91.7% of participants at days 7 and 14, respectively (ITT population, n=24) (**Figure 2**). Peri-wound skin was effectively managed, pain levels experienced by the patients were considered to be acceptable, and results suggested that SSWCL-Ag* exerted adequate antimicrobial protection.

The dressing demonstrated satisfactory fixation over the skin graft and allowed adequate passage of exudate to the secondary dressing. In terms of product handling and general use, the dressing demonstrated, in general, conformability to the graft site, ease of application and ease of removal. Overall, the dressing was well appreciated by both the clinicians and the patients.

Given that no adverse device effects (ADEs) were reported, it was concluded that the SSWCL-Ag* exhibited an acceptable safety profile related to silver exposure.

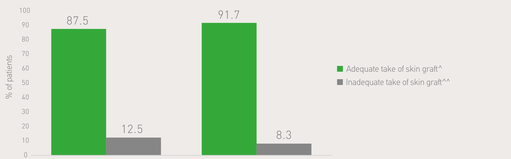

Figure 2: Percentage of patients with adequate take of skin graft at day 7 and day 14 (ITT population, n=24).

*Defined as at least 95% adherent and healed as assessed by clinical investigator ^^Defined as less than 95% adherent and healed as assessed by clinical investigator

Study Part B

Based on healing data, the SSTD-Ag** performed well. Whilst abnormal bleeding was somewhat higher than expected at day 7, this may be explained due to premature lifting of the dressing. Pain levels experienced by the patients were considered to be acceptable for these types of wounds. The dressing efficiently managed the peri-wound status, was conformable and adhered adequately to the donor sites, without slippage or sticking during removal. In terms of product handling and general use, the dressing demonstrated, in general, ease of application and removal, flexibility and comfort. Overall, the dressing was well appreciated by both the clinicians and the patients.

Conclusions

The results indicate that the SSWCL-Ag* and the SSTD-Ag** dressings are suitable for the management of split-thickness skin grafts and donor sites in surgical burn patients, respectively.

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