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# A randomised investigation of film-forming silicone gel in superficial partial thickness face and neck burn patients: Indication of improved early scar pigmentation outcomes

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ABSTRACT

*Introduction:* Burns to the face and neck are a source of considerable distress and a challenge to manage with dressings. Further, these often superficial injuries pose a risk of scarring and altered pigmentation. Silicone gels have emerged as a potential solution to the challenges of conservative management for face and neck burn injuries. The aims of this study were to explore the effect of topical silicone compared to routine treatment of conservatively managed burns to the face and neck.

*Methods:* This single-blind, randomised, controlled trial compared topical silicone film-forming dressing to standard of care for superficial partial thickness burns to the face and neck. Time to healing was the primary outcome and secondary outcomes included: 1) scar assessments (modified Vancouver Scar Scale, Dermalab Combo and Patient and Observer Scar Assessment Scale) at six weeks and three months; and 2) pain intensity scale at wound review appointments.

*Results:* Of the 55 participants in the face/neck study, 34 were male and 21 were female. Median age was 36 years (range from 25 to 47 years). The median time to healing for the silicone group was 9 days (CI 7.6 –10.4) and the control group was 7 days (CI 5.3- 8.7), p = 0.056. Analysis demonstrated significantly reduced pigmentation at six weeks in mVSS scores for the silicone group (Md = 0, IQR = 0) compared to the control group (Md = 0, IQR =

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0 – 3), p = 0.043. We found no evidence of differences in reported pain between the groups (Silicone - Md = 1.15, IQR 0.3 – 4.5 vs control group - Md = 1.5, IQR 0.6 – 3.8, z = –0.63, p = 0.53). No other differences were observed, and no adverse events were associated with the topical silicone in the study whereas an infection and a reaction were experienced in the control group.

*Conclusion:* Film-forming silicone gel had comparable effects to standard of care emollient on wound healing of superficial partial thickness burns of the face and neck. Silicone treated wounds were associated with a significant improvement in scar pigmentation outcome at six weeks post-burn.



## 1. Introduction

Millions of people worldwide suffer from burn injuries, which constitutes a significant global public health concern and can cause variable degrees of scarring [1,2]. Scarring is a challenging complication following burns as it can be stigmatizing, thereby causing psychological distress and negatively impacting patients' quality of life [2–4]. Facial scars in particular, have been associated with increased levels of self-consciousness and anxiety [3], as they can be highly visible. An altered appearance may evoke mental health issues and result in difficulties with social reintegration and impact quality of life [5]. In addition, skin pigmentation changes resulting from burn injuries can increase the risk of photoaging [1,5]. Previous studies identified severe scar pigmentation and prolonged wound healing [6] as the primary contributors to poorer scar outcomes. Therefore, regulating these two factors and expediting the healing process is crucial in mitigating functional and psychological distress in burn survivors.

For more than 40 years, topical silicone has been used to manage hypertrophic scars [7], with research to date predominantly focusing on silicone gel sheeting. However, whilst silicone gel sheeting is a promising treatment for scarring, it is not approved for the application on open wounds such as burn injuries. Recently, emerging evidence confirmed that film-forming silicone gels have similar scar treatment characteristics to silicone gel sheets. This has led to the development of a new generation of gels that are suitable for use as primary dressings on open wounds [8,9]. Due to their ability to support faster epithelialisation, reduce the inflammatory response, normalize hypergranulation and improve associated symptoms, film-forming silicone gels present as an enhanced dressing for conservatively managed, superficial burn injuries [10–12].

Film-forming silicone gel products (such as Stratamed, Stratpharma AG, Switzerland) are semi-occlusive, self-drying, transparent and bacteriostatic. They form an invisible wound dressing layer and promote a moist wound healing environment, which in turn promotes faster re-epithelialisation [13–15]. It is hypothesised that these film barrier dressings create a microenvironment between the semipermeable membrane and the air exposure that optimises epithelial recovery [15,16]. Although various aspects of silicone gel products on wound healing and scar outcomes were validated individually, research is negligible investigating the effects of film-forming silicone to function as a combined wound dressing and scar treatment [17,18].

This study was designed to investigate the efficacy of topical silicone in the treatment of superficial partial thickness burn wounds of the face and neck. Therefore, the aim of this study was to assess the impact of the early application of a topical film-forming silicone gel dressing compared to standard paraffin-based emollient ointment on wound healing rate, pain symptoms and scar outcomes in burn patients that did not undergo surgery.

## 2. Materials and methods

This independent single-blinded, single-center, prospective, randomised controlled study was conducted to investigate the use of topical silicone gel on superficial partial thickness face and neck burns. This trial was approved by the HRECs of Fiona Stanley Hospital and the University of Notre Dame, and was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR). Trial Id: ACTRN12618001227280.

### 2.1. Enrolment

Eligible patients were aged between 18 and 80 years with non-epithelialised superficial partial thickness burns to the face and or neck, with no plan for surgical intervention or affixed dressing systems. Any face or neck burn treated with physical dressing products other than the standard emollient, such as burn wounds to the eyes, ears, and mouth, were excluded [19]. Patients with a pre-existing diagnosis of diabetes, vascular abnormality and dermatological skin conditions were excluded, as were pregnant women, patients unable to return for clinic appointments and those with delayed presentation and, or with partially or fully epithelialised wounds.

After giving their informed consent, all participants were randomly allocated 1:1 to receive either topical silicone gel ('intervention'; Stratamed, Stratpharma AG, Switzerland) or standard of care emollient ('control'; Pharmacy Select Liquid Paraffin 50% w/w & White Soft Paraffin 50% w/w ointment, Petrus Pharmaceuticals, Australia) for the topical management of their wounds [20].

Treatment allocation was concealed from all parties involved in this research, including the participants, principal investigator, outcome assessors, surgeons, nursing staff and

statisticians. However, due to the difference in colour, viscosity, and texture of the two products, investigators could not be completely blinded.

### 2.2. Intervention

Participants were told to perform face/neck washing three times daily using disposable cloths and Chlorhexidine wash. As per standard of care, participants were advised to reapply the topical product after each wash, and to remain out of the sun. At the point of healing, participants were taught the moisturising and sun protection principles. All face burns were reviewed at six weeks post-burn. From time to healing until the 6-weeks review assessment, no dressings or other scar management was applied. If scar management was undertaken afterwards, patients were referred to the burn team Senior Occupational Therapist.

### 2.3. Outcome measures

Demographic information from all study participants was recorded, including age, gender, total body surface area (TBSA), date and cause of burn, injury site, medications, past history of scarring, scar management interventions and Fitzpatrick skin type[21].

The primary outcome measure was time to wound healing which was defined as the number of days until the wound is 100% epithelialized and no further dressings or applications [19,20]. The wounds were evaluated during wound review appointments every two to four days from first presentation and recruitment into the study. At each review, a visual assessment of the wound was performed [22], and the percentage of wound area healed was recorded. Assessments continued until the wound was fully healed, and the number of days since injury was recorded as the end point of the study. In addition, clinical photography using a digital camera and standardised lighting was performed at enrolment and each subsequent dressing change appointment to aid the case documentation, to monitor wound healing and scar outcomes [23].

Secondary outcome measures included 1) pain intensity and 2) sub-acute scar assessment. Pain intensity was assessed immediately before and after wound check-up appointments, using a 10-point visual pain intensity scale, 0 representing 'no pain' and 10 indicating the 'worst pain imaginable' [24,25]. Modified Vancouver Scar Scale (mVSS), Dermalab Combo and Patient and Observer Scar Assessment Scale (POSAS) were used to measure scar outcomes at six weeks and at three months post-surgery. In WA where sun exposure is a concern after burn injury, the six-week scar assessment in practice is key to predicting long term scar quality and colour outcomes [4,26]. Historically, patients with superficial, conservatively healed burn injuries rarely return to follow up beyond six weeks after their burn. Thus, as an added safeguard in this study, a second scar assessment was planned to provide a robust prediction of the long term scar quality and increased surety that the use of the novel silicone intervention did not alter the expected recovery of these common burn injuries. An anatomical recording chart in combination with clinical photography was used to locate the wound area that took the longest to heal. The identified site was then used for scar assessments at both follow-up timepoints.

### 2.4. Statistics

All statistical analyses were performed using IBM SPSS Statistics version 27. Values for $p < 0.05$ were considered statistically significant. As data was not normally distributed, descriptive statistics are presented as median (Md) and inter quartile range (IQR); and, Kaplan-Meier analysis of time to healing, and Mann-Whitney U tests for all scar outcomes, and pain and analgesics were performed to compare the two treatment groups. Individuals who entered the study but were lost to follow up prior to wound healing were censored in the Kaplan-Meier time to healing analysis. To investigate potential bias', Chi-square analysis, Mann-Whitney tests and, due to the small sample size, Fisher's exact test were used to compare characteristics of patients that did not complete the trial, and to compare the intervention and control group.

## 3. Results

### 3.1. Patient demographic and clinical data

Between December 2018 and December 2020, 121 patients were admitted to the burn center with a face and, or neck burn. Of these, 55 patients were eligible and consented to join the study (intervention = 26; control = 29). Twelve patients did not complete the trial and were excluded from the primary outcome final analyses; five participants did not attend follow up appointments, two received surgical intervention, two received physical dressings and three experienced unrelated adverse events (Fig. 1).

Analysis of the recruited cohort showed no statistical difference between the intervention and control group in age, gender, TBSA, skin type or smoking status. The demographics and participant details are reported in Table 1.

### 3.2. Time to wound healing

Confirmed wound healing times were available from 43 participants (intervention = 21, control = 22). The Kaplan-Meier median estimate (and associated 95% confidence interval) demonstrated no evidence of statistical difference between treatment groups (log-rank, $p = 0.056$) (Intervention: Md = 9 days, CI = 7.6 – 10.4; Control: Md = 7 days, CI = 5.3 – 8.7), with the overall time to healing ranging between 4 – 19 days (Fig. 2).

#### 3.2.1. Pain intensity

Pain analysis included 52 participants (intervention = 24, control = 28). A Mann-Whitney U test revealed no significant difference in pain between the intervention and the control group at the timepoint after first application of treatment at enrolment (intervention: Md = 1.15, n = 24, IQR 0.3 – 4.5; control: Md = 1.5, n = 28, IQR 0.6 – 3.8; $z = 0.63$, $p = 0.53$). Similarly, no statistically significant difference was found at the first wound check-up appointment after

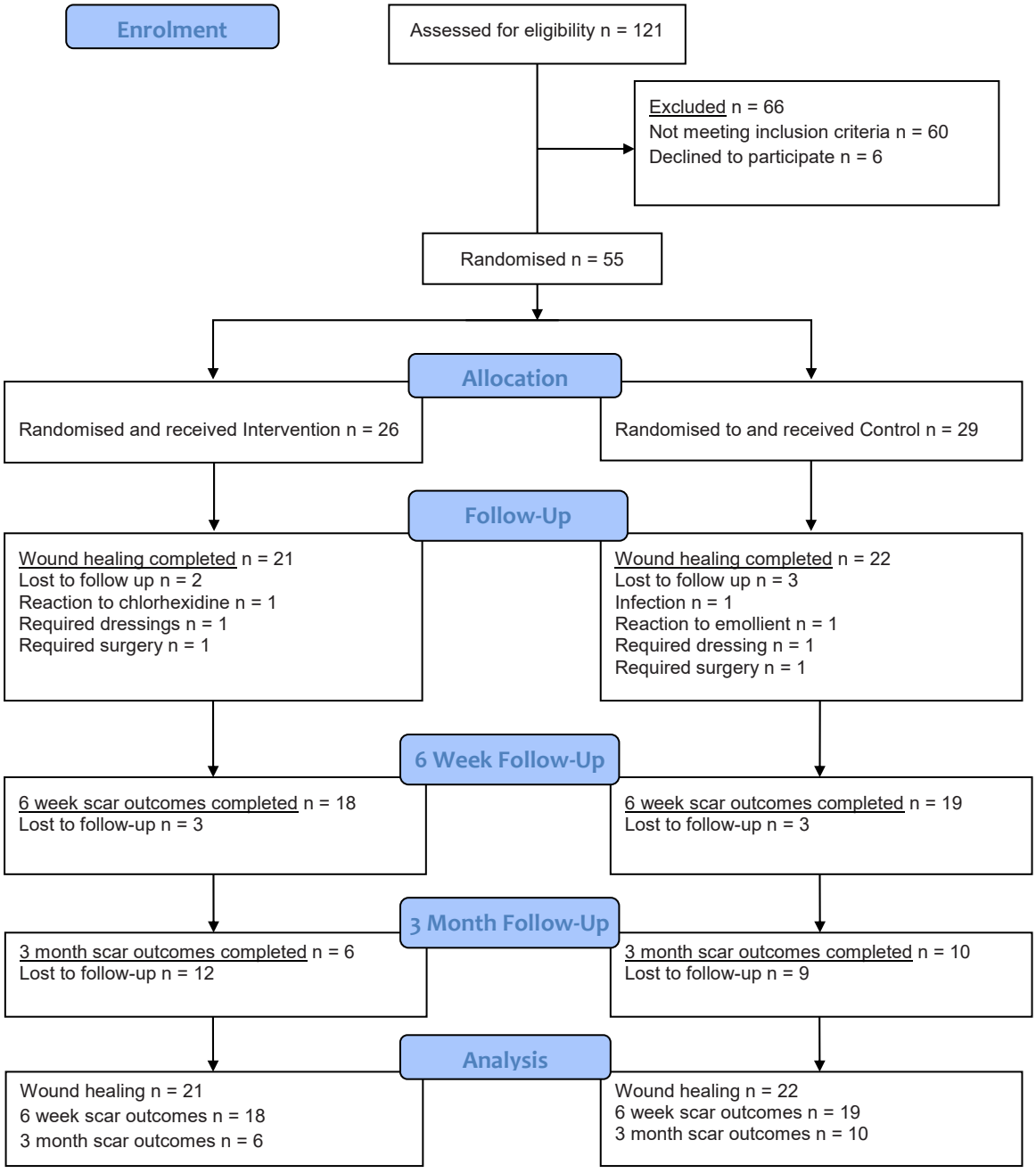


**Fig. 1 – CONSORT diagram showing allocation process throughout the study.**

2–5 days post-burn for pain scores before the dressing change (intervention: Md = 0.4, n = 13; control group: Md = 0.7, n = 10; z = 0.62 p = 0.53) or after face washing and re-application of the products (intervention: Md = 0.6, n = 12; control: Md = 0.3, n = 10; z = 0.6, p = 0.55). Twenty-seven participants reported the use of analgesics during the study period (intervention = 12, control = 15), with no statistically significant difference in pain between patients receiving the intervention (Md = 3.6, n = 12, IQR = 0.4 – 4.9) vs. the control (Md = 1.8, n = 15, IQR = 1.0 – 5.5) (z = –0.3, p = 0.8), and similarly represented types of analgesics in both groups.

#### 3.2.2. *Scar outcomes*

The 6-weeks scar analysis included 38 participants (intervention = 18, control = 20) and the 3-months scar analysis included 16 participants (intervention = 6, control = 10). Mann-Whitney U tests revealed a significant difference in favour of the intervention group for the total mVSS scores (intervention: Md =1, n = 18, IQR = 0 – 1.3; Control: Md= 1, n = 18, IQR = 1 – 3; z = –2.18, p = 0.029), based on reduced mVSS pigmentation scores at six weeks post-burn (intervention: Md =0, n = 18, IQR = 0; control: Md= 1, n = 19, IQR = 0 – 3; z = –2.02, p = 0.043). Seven participants in the control group presented with hyperpigmentation during the 6-weeks

**Table 1 – Social and clinical demographics of recruited participants.**

| | Intervention | Control | Total Sample |
|---|---|---|---|
| **Number of participants** | 26 (47%) | 29 (53%) | 55 |
| **Gender** – Male | 17 (65%) | 17 (59%) | 34 (62%) |
| – Female | 9 (35%) | 12 (41%) | 21 (38%) |
| **Age**, median (IQR) | 32 (25, 47) | 36 (29, 50) | 36 (25, 47) |
| **Smoker** - Yes | 8 (32%) | 7 (27%) | 15 (29%) |
| – No | 17 (68%) | 19 (73%) | 36 (71%) |
| – Missing | 1 | 3 | 4 |
| % TBSA of burn injury, Median (IQR), | 0.3% (0.09, 0.9) | 0.25% (0.1, 0.63) | 0.28% (0.1,0.76) |
| Missing | 1 | 0 | 0 |
| **Skin type** | | | |
| Type i – always burns, never tans | 2 (8%) | 4 (14%) | 6 (11%) |
| Type ii – burns easily, tans minimally | 9 (35%) | 12 (44%) | 21 (72%) |
| Type iii – sometimes burns, tans slowly to light brown | 8 (31%) | 6 (21%) | 14 (25%) |
| Type iv – burns minimally, always tans to moderate brown | 4 (15%) | 1 (3%) | 5 (9%) |
| Type v – rarely burns, tans well | 3 (12%) | 4 (14%) | 7 (13%) |
| Type vi – never burns, deeply pigmented | 0 (0%) | 2 (7%) | 2 (4%) |
| **Mechanism of burn injury** | | | |
| Flame | 16 (62%) | 16 (55%) | 32 (58%) |
| Scald | 7 (27%) | 8 (28%) | 5 (27%) |
| Contact | 0 (0%) | 3 (10%) | 3 (5%) |
| Chemical | 2 (8%) | 1 (3%) | 3 (5%) |
| Radiant | 1 (4) | 1 (3%) | 2 (4%) |
| **Site of burn** | | | |
| Whole face | 13 (50%) | 12 (41%) | 25 (45%) |
| Neck | 1 (4%) | 1 (4%) | 2 (4%) |
| Forehead | 1 (4%) | 1 (4%) | 2 (4%) |
| Right forehead | 0 (0%) | 2 (8%) | 2 (4%) |
| Nose | 1 (4%) | 0 (0%) | 1 (2%) |
| Left cheek | 1 (4%) | 1 (4%) | 2 (4%) |
| Right cheek | 1 (4%) | 1 (4%) | 2 (4%) |
| Central face | 0 (0%) | 1 (4%) | 1 (2%) |
| Right side of face | 1 (4%) | 0 (0%) | 1 (2%) |
| Multiple scattered spots | 7 (27%) | 10 (34%) | 17 (31%) |

IQR – interquartile range; TBSA – total body surface area

assessment, compared to zero participants in the intervention group (Table 2).

At 3 months, three participants presented with hyperpigmentation (intervention n = 1, Fitzpatrick = 5; control n = 2, Fitzpatrick = 3 (both)), however, two from each allocated study group reported not using sunscreen. We found no evidence of differences for all other scar outcomes including POSAS scores (Table 3).

#### 3.2.3. *Safety*

Three patient experienced adverse events during the study and were consequently excluded from further participation. Of these adverse events, two occurred in the control group, namely one reaction to the emollient and one wound infection. The adverse event in the intervention group was a reaction to the chlorhexidine face wash (Fig. 1).

## 4. Discussion

This single-blinded randomized controlled trial found no evidence of differences in wound healing rate or pain perception between the treatment with silicone gel and standard of care. However, the silicone gel was associated with significantly reduced scar pigmentation of facial burn wounds after 6 weeks. These results underpinned an improvement in the total modified Vancouver Scar Scale scores in the silicone intervention group compared to controls.

These findings differ from the results of previous studies that report silicone products aid in wound healing and decrease pain by facilitating epithelialisation and reducing the inflammatory response [9,15]. The lack of a significant difference in pain perception between interventions could be attributed to the fact that the neck or face wound of participants were occluded with either the silicone gel or emollient, which potentially led to participants reporting similar pain experiences due to limited exposure of the wound to air. Silicone gels are known to facilitate these improvements by reducing trans-epidermal water loss (TEWL) and maintaining hydration through their semi-occlusive nature [27,28]. Lucatelli et al. [12] conducted a study using a topical film-forming silicone gel product in combination with a secondary Vaseline gauze dressing versus conventional dressings including silver dressings, collagenases, and alginates on mid-deep and deep burn wounds. Results of this within-subject design showed that the mean days to 95% re-epithelialisation in the silicone gel group was 5.4 days vs. 12.5 days in the conventional group, indicating a reduction of time to healing by more than 50%. Although the sample size was small and, no other statistical analysis was reported, the comparison of

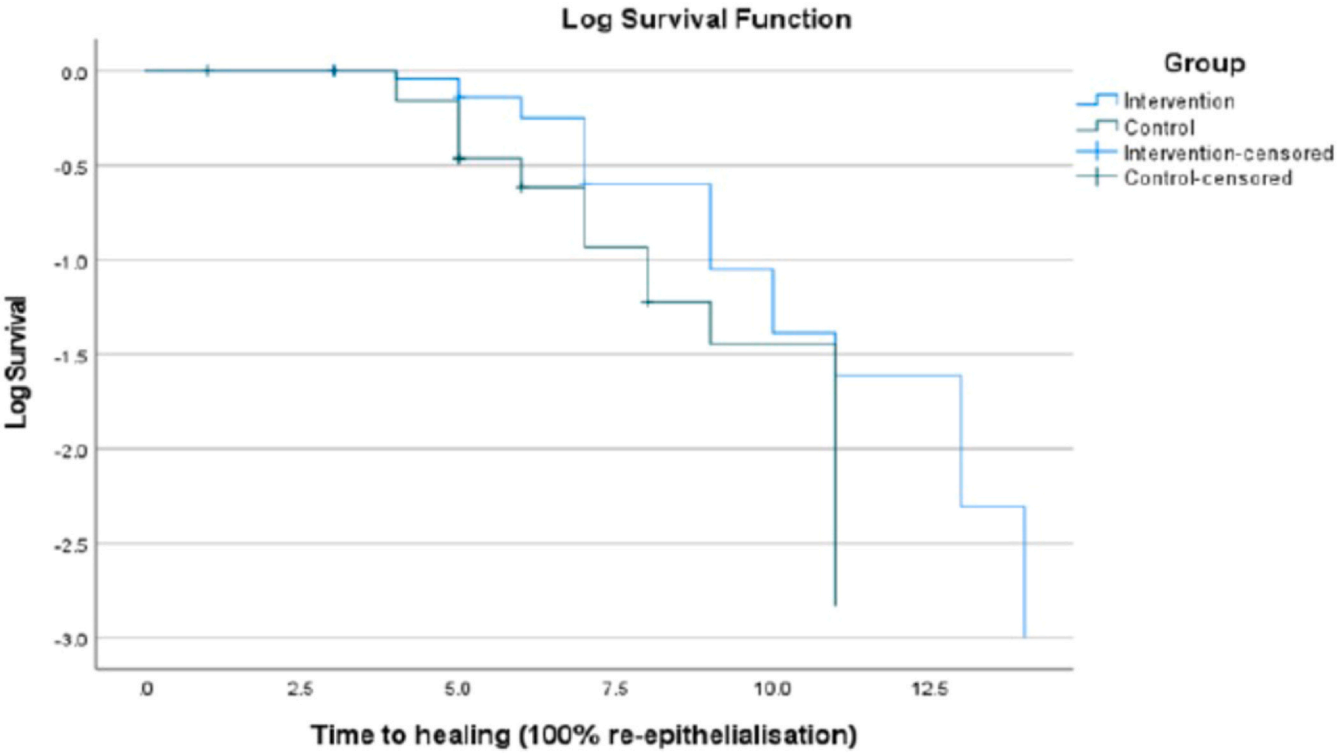


**Fig. 2 – Time to healing (100% re-epithelialisation).**

**Table 2 – Distribution of mVSS pigmentation scores in participants.**

| | 6 Week | | 3 Month | |
|---|---|---|---|---|
| mVSS pigmentation | Intervention | Control | Intervention | Control |
| 0 - normal | 15 | 12 | 4 | 8 |
| 1 - hypopigmentation | 2 | 1 | 0 | 0 |
| 2 - mixed pigmentation | 1 | 0 | 1 | 0 |
| 3 - hyperpigmentation | 0 | 7 | 1 | 2 |

mVSS - modified Vancouver Scar Scale

**Table 3 – Mann-Whitney U test of mVSS and Dermalab (weighted average percentiles).**

| | 6 Week | | | | 3 Month | | | |
|---|---|---|---|---|---|---|---|---|
| | Intervention Median (IQR) | Control Median (IQR) | z | p | Intervention Median (IQR) | Control Median (IQR) | z | p |
| mVSS total | 1 (0 –1.3) [n = 18] | 1 (1-3) [n = 19] | -1.94 | 0.03 | 1.50 (0-3) [n = 6] | 0 (0-1.5) [n = 10] | -1.10 | 0.29 |
| mVSS vascularity | 0.5 (0-1) | 1 (0-1) | -0.03 | 0.97 | 0.5 (0-1.3) | 0.0 (0-0.3) | -1.33 | 0.18 |
| mVSS pigmentation | 0 (0-0) | 0 (0-3) | -2.02 | 0.04 | 0.0 (0-2.3) | 0.0 (0-0.8) | -0.43 | 0.67 |
| Dermalab vascularity | 20 (18-24) [n = 14] | 21 (19-25) [n = 18] | -1.20 | 0.24 | 19 (18-23) [n = 6] | 20 (17-24) [n = 8] | 0.00 | 1.00 |
| Dermalab pigmentation | 37 (34-46) | 43 (37-47) | -1.56 | 0.12 | 39 (38-43) | 41 (36-45) | -0.52 | 0.60 |
| POSAS total | 8 (6-15) [n = 14] | 9 (7-12) [n = 16] | -0.20 | 0.80 | 8.5 (6-10.3) [n = 6] | 9 (6-10) [n = 7] | -0.20 | 0.80 |
| POSAS colour | 2 (1-6) | 3 (1-5) | -0.17 | 0.86 | 2 (1-3.25) | 1 (1-4) | -0.08 | 0.82 |
| POSAS overall opinion of scar | 2 (1.8-5.5) | 2 (1-2.8) | -0.30 | 0.80 | 2 (1-2.3) | 1.5 (1-5) | -0.23 | 0.82 |

mVSS, modified Vancouver Scar Scale; POSAS, Patient and Observer Scar Assessment Scale; Int – intervention; Ctl – control; Md – median; IQR – interquartile range. Dermalab scores - lower readings indicate lower amounts of pigmentation and vascularity

wounds using a within-subject design that revealed a faster rate of healing for topical silicone gel is promising.

Cutaneous injuries carry a risk of abnormal pigmentation within resulting scars, particularly if exposed to sunlight during early recovery [29]. Silicone gel treatment led to a significant reduction in mVSS pigmentation at six weeks post-burn. Consequently, total mVSS, the widely used measure of scar severity within a clinical setting [6,30], demonstrated similar results. The positive effects of topical silicone gel on scars have been attributed to its ability to restore the barrier function of the stratum corneum, reduce TEWL, and regulate the production of keratinocytes and fibroblasts in the dermis, subsequently normalising the production of collagen and improving scar outcomes [14,31].

Although the reduction in the level of hyperpigmentation was not confirmed by the outcome of the Dermalab pigmentation score, a similar trend in results occurred at six weeks post-burn, where the silicone gel treatment resulted in lower Dermalab pigmentation scores compared to those in the standard of care group. Several studies have reported the beneficial effects of topical silicone gel on measures of scar hyperpigmentation [32,33], which is particularly important in face burns as they are visible and have implications in psychological well-being, function, communication, and social interactions [34,35]. Hyperpigmentation has been linked to the inflammatory response, therefore efforts to promote rapid wound healing and minimise the inflammatory response may assist in preventing abnormal pigmentation of scars [29]. Whilst this study did not demonstrate significant differences in wound healing times, the anti-inflammatory and antimicrobial properties of the silicone gel may contribute to improved scar outcomes, including a reduction in scar pigmentation [27,36].

Overall, both treatments were found to be safe to use. One infection and one reaction to the emollient occurred in the control group, whereas no adverse events were associated with the use of silicone gel. This result is in line with other studies reporting that the use of topical silicone gel preparations is well-tolerated [15,32]. The silicone gel used for this study does not contain parabens, fragrances or alcohol and therefore is approved for use on children, pregnant or breastfeeding mothers as well as on sensitive skin [37]. Once dry, silicone gel can be used in combination with sunscreen [32], thereby protecting the scar from the sun exposure and reducing the risk of post-inflammatory hyperpigmentation [38]. Such pigment changes presents as dark patches or a flat distinct, discolouration of the skin and can be of particular concern since it can take several months or even years to diminish even with treatment. As such, changes in pigment are often visible and can have a significant psychological impact on patients, and several studies have associated it with a decreased quality of life [38].

Limitations within the current study include a small sample size and a lack of validated tools for assessing time to healing and area of wounds. To mitigate the latter issue, visual wound inspection by senior, independent clinicians and dressing cessation was used as these clinical outcomes have been shown to be reliable in other studies [19,20,39]. Similarly, the pain intensity scale [24,40,41] and the mVSS are widely used in burn assessments [20,30,42]. Unfortunately, discomfort or resting pain between clinic attendances was not investigated. In future, exploring participant experiences between treatments may assist to determine any relative benefits of occlusive ointments as used in this study. Finally, we acknowledge that the study may have benefitted from scar assessments beyond three months post-burn. However, it was not considered feasible to add these assessments based on past experiences with similar patients to those eligible for the study. The return to follow up observed in the study, confirmed the validity of those observations and assumptions made during the design of the study.

## 5. Conclusion

While this study found no evidence of difference in wound healing time or pain perception between silicone gel and standard of care treatment in facial burns, it showed that silicone gel was associated with significantly reduced scar hyperpigmentation and overall scar outcomes scores, after six weeks.

## Credit Author Statement

All authors meet the criteria for authorship as stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. All authors have made substantial contributions to all the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

Specifically, DE, RK and FW primarily designed the study and led the drafting and editing of the manuscript. FP, JC completed the statistical analysis (with advice from MB and DH – acknowledged) and drafted and edited statistical methods sections. FP, RK collated and cleaned the dataset and FP primarily responsible for data collection in the SABU. DE, FW, JC were supervisors of the project and post-graduate studies and provided quality control. DE, JP led the responses to reviewers. All authors assisted with the interpretation of results and editing of the final approved manuscript.

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## Declaration of Competing Interest

All authors warrant that they have no competing interests to declare with respect to this study and the findings stated herein with integrity. Ms Poelchow's involvement in the study was funded at arm's length by Stratpharma AG and was in partial fulfilment of requirements for her Masters of Philosophy award (conferred 2023, The University of Notre Dame Australia). Stratpharma AG scientific advisors and representatives were consulted during the design of the study;

were not involved in the conduct of the study or collection of data and outcomes; and, did not have access to raw data. Stratpharma AG representatives and advisors were given opportunity to review the manuscript and provide their feedback on the wording of the report text only after independent interpretation. The interpretation of raw data and results was conducted solely by the clinicians and academic supervisors.

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