Optimising scar outcome through the use of a silicone-based film-forming wound dressing: A pilot study on post-burn healing.

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Introduction

Traditionally, silicone has been contra-indicated for application to unhealed wounds, however, in recent years, a new form of silicone has been developed that is suitable for application on non-epithelialised wounds, and claims to minimise patient symptoms. Stratamed and StrataXRT are semi-occlusive, self-drying, transparent, bacteriostatic and inert silicone gels which form an invisible dressing layer that provides a moist wound healing environment which, in turn, may enable faster re-epithelialisation. (Priyadarshi & Marceau, 2015).

Currently there is limited evidence whether the early application of these film-forming silicone products reduces healings times, reduces patient symptoms and pain associated with burns dressings, and positively impacts the scar outcome.

This study aims to compare a topical silicone dressing product with standard care in the treatment of burns to the face/neck and in management of the donor site wound.

Literature Review

- Silicone beneficial to hypertrophic scarring (Mustoe, 2008)
- Delayed healing negatively impacts on scarring outcomes. (Bloemen et al., 2009; Chipp et al., 2017; Finlay et al., 2017; S. Monstrey, Hoeksema, Verbelen, Pirayesh, & Blondeel, 2008)
- Silicone-based dressings hasten epithelialisation (Greenwood, Wagstaff, Mackie, & Mustoe, 2012; Monk, Benedetto, & Benedetto, 2014; Suess-Burghart, Zomer, & Schwanke, 2015)
- Stratamed and StrataXRT are both topical film-forming wound dressing products that come in the form of gel in a tube. (Priyadarshi & Marceau, 2015)
- Stratamed and StrataXRT demonstrate an increased rate of healing (Monk et al, 2014; Priyadarshi & Marceau, 2015; Marini, Odendaal,& Smirnyi, 2017)
- StrataXRT contributed to improved symptoms such as pain and itch (Quilis, Martín, Rodríguez, Sánchez, & Ribes, 2018)
- Applied easily and may produce cost savings (Marini, Odendaal,& Smirnyi, 2017)

There is a need for a greater understanding of silicone gels that can be used in the acute early stage as this early intervention may lead to improved outcomes for patients. This study therefore represents an opportunity to assess a novel approach to scar management through the combination of wound dressing and silicone.

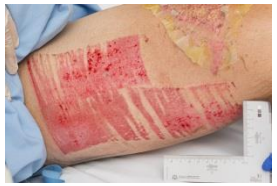
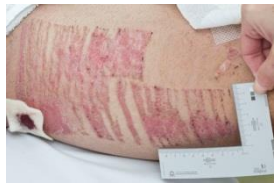
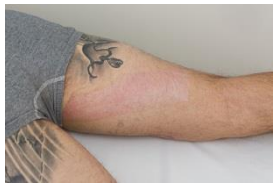
Aim

To study the impact of the early application of silicones in burn wounds on time to healing, pain symptoms and the scar outcome in comparison to standard care.

Hypothesis

The use of a silicone-based product in the treatment of burn wounds can hasten wound healing, reduce pain perceptions and improve scar outcomes.

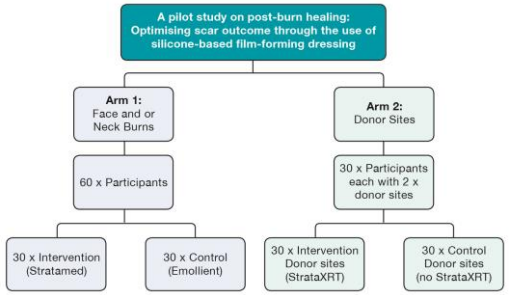
Methodology

This research will employ a prospective, randomised, single-centre, double-blinded controlled method for two different but similar burn wound scenarios.

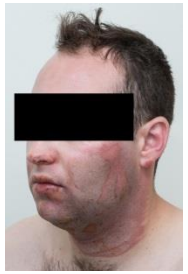
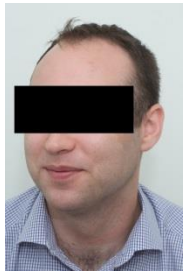
First arm: will study the efficacy of Stratamed on the rate of healing, pain perceptions and scar outcomes in non-operative face and or neck burns compared with standard clinical care.

Second arm: will study the efficacy of StrataXRT on the rate of healing, pain perceptions and scar outcomes in donor sites of burn injuries compared with standard clinical care.



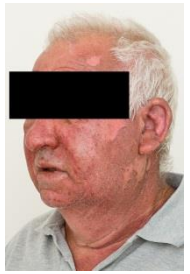
Inclusion Criteria	Exclusion Criteria
• Adults 18 - 65 years of age • First arm: Patients with non-operative face and neck burns • Second Arm: Patient with a burn requiring two skin donor sites >1%	• Aged below 18 years, or older than 65 years • Burn >15% TBSA • Diabetes • Neuropathy • Diagnosis of a vascular abnormality • Pre-existing dermatological condition • Pregnant women • Self-Management Plan (discharged without needing further care)

Intervention Patient

Initial **3 months**

Control Patient




Initial **6 weeks**

Data Collection

Outcome Measure	Day 2-5	Day 5-7	Day 7-10	Day 10-14	6 weeks	3 months
Clinical Photography	√	√	√	√	√	√
% Wound healed	√	√	√	√		
Pain questionnaire	√	√	√	√		
Pain Intensity Scale	√	√	√	√		
Dermalab					√	√
VSS					√	√
POSAS					√	√

Description of outcome measures

Pain Intensity Scale	A rating scale where subjects mark on a 10cm line to indicate their pain symptoms in severity from 0 (no pain) to 10 (worst imaginable pain).
Modified Vancouver Scar Scale (mVSS)	A rating index used by clinicians to assess and score scarring on four parameters which includes pigmentation, vascularity, pliability and height.
Dermalab Combo	The Dermalab Combo is a device with a probe used on healed skin to measure pigmentation and erythema (vascularity).
Patient and Observer Scar Assessment Scale (POSAS), patient response component	A self-reported rating scale for scar severity that includes seven numerical rating scales from 0-10 upon which the participant rates aspects of their scar including pain and itch over the past few weeks, and how they feel about their scar compared to normal skin.

Conclusion

To date, 30 participants have been recruited to the face burn arm and 4 participants have been recruited to the donor site arm. This study is being completed as part of a Masters thesis by publication and will conclude mid 2021.

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