A Study on Post-burn Healing: Optimising Scar Outcome Through the Use of a Silicone-based Film-forming Wound Dressing

Fiona Poelchow
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A Study on Post-burn Healing: Optimising Scar Outcome Through the Use of a Silicone-based Film-forming Wound Dressing

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School of Physiotherapy
University of Notre Dame Australia

This thesis is presented for the Degree of
Masters of Science

2022
Thesis Declaration Form

Declaration
To the best of the candidate’s knowledge, this thesis contains no material previously published by another person, except where due acknowledgement has been made. This thesis is the candidate’s own work and contains no material which has been accepted for the award of any other degree or diploma in any institution.

Human Ethics
The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007, updated 2018). The proposed research study received human research ethics approval from the University of Notre Dame Australia Human Research Ethics Committee (HREC) (EC00418), approval number: 018121F, and HREC of Fiona Stanley Hospital (FSH), approval number: RGS0000000027 (Appendix 1).

This trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR). Trial Id: ACTRN12618001227280.

Signature:

Print Name: Fiona Poelchow

Date: 29 November 2022
Abstract

Introduction
The development of scarring is a normal physiological response during burn wound healing for any except the most trivial of injuries. Burn scarring can cause considerable functional and psychological anguish in burn survivors. Prolonged wound healing has been shown to affect scarring outcomes. Superficial cutaneous wound injuries carry a risk of scarring and altered pigmentation after the wound has healed. The primary aim of this study was to explore the effects of topical silicone on the rate of wound healing in superficial wounds. Secondary aims included investigation of scar and pain outcomes.

Methods
This thesis presents two studies which explored the efficacy of topical silicone film-forming dressings (StrataXRT and Stratamed) in comparison to standard care. Two independent double-blinded, single-centre, randomised controlled studies were conducted, one focused on donor sites of split thickness skin grafts (STSG) using StrataXRT, and the other, superficial partial thickness (SPT) face and neck burns using Stratamed. For both studies, time to healing (TTH) was the primary outcome of interest. 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 during dressing changes. In the donor site study, 30 eligible burn patients requiring surgery aged between 18 and 80 years with a donor site wound ≤ 3% total burn surface area (TBSA) were enrolled. The intervention, StrataXRT, was randomly assigned to one half of the donor site or a single donor site where multiple donor passes were required, within the same patient and applied underneath standard care calcium alginate dressings. In the facial burn patient study, 55 patients aged between 18 and 80 years with a non-epithelialised superficial partial thickness face or neck burns were randomised to receive Stratamed or standard care emollient for the topical management of their wounds.
Results
Of the 30 participants enrolled in the donor study, 24 (80%) were male. Median age was 39 years with a range from 20 years to 76 years. Donor site size ranged from 0.1% to 3% TBSA. The median TTH for the intervention group was 10 days (CI 8 - 12) and the control group was 9 days (CI 8 - 10). There was no evidence of a statistical difference observed in time to healing, pain and scar outcomes. Of the 55 participants in the face/neck study, 34 (62%) were male. Median age was 36 years with a range from 25 to 47 years. The median TTH for the intervention group was 9 days (CI 7.6 -10.4) and the control group was 7 days (CI 5.3- 8.7), this result was not significant, p = 0.056. The silicone intervention group exhibited significantly reduced scar pigmentation at six weeks in mVSS scores for the intervention group (Md = 0, IQR = 0) compared to the control group (Md = 0, IQR = 0 - 3), p = 0.043. There was no significant difference in pain between the intervention group (Md = 1.15, IQR 0.3 – 4.5) and the control group (Md = 1.5, IQR 0.6 – 3.8), z = -0.63, p = 0.53. No, adverse events were associated with the topical silicone in either study.

Conclusion
These studies were unable to show any clinically applicable advantage over standard care through the use of topical silicone dressings on donor site wounds and SPT burn wounds of the face and neck. The observation that silicone film-forming dressing systems were associated with a reduction in scar pigmentation and no observed adverse events warrants further studies.
Acknowledgements

I would like to acknowledge the Australian government funding under the Research Education Training Program scheme. Part funding of researcher time to develop research protocol and complete initial stages of data collection was funded by Stratpharma Pharmaceuticals who also provided the products for this trial. Stratpharma were not involved in any part of the research development and implementation including data analysis and thesis development. I am grateful to the Rotary Club of Attadale for supporting the grant award I received from Spinnaker Health Research Foundation and the Fiona Wood Foundation (FWF), both for their significant contribution to research and awarding me a FWF Small Grant.

I must extend a sincere thank you to the following people for helping and supporting me over the last four years. Your time and effort are greatly appreciated and I could not have completed this thesis without your knowledge, guidance and support.

Firstly, Professor Jim Codde, I am truly grateful to you for taking on a total 'rookie' and for your patience in helping me achieve the important objective of learning research. Thank you for assisting with the many thesis iterations. I am so fortunate to have benefitted from your expertise, wisdom and grace.

Associate Professor Dale W. Edgar your role as colleague, teacher and researcher has been invaluable. You lead the way in demonstrating high standards and striving for better outcomes. I appreciate the time you have taken to review and guide me in this thesis.

Professor Fiona Wood, Director of the Burns Service of Western Australia (WA), and a guiding hand at all times throughout this journey. It is funding and support through the Fiona Wood Foundation that made this research possible.
Rosemary Kendell for the inception of this research project and the opportunity for me to experience clinical research. Without you creating and establishing this research project, this would never have happened.

The collection of raw data is crucial in research, and I warmly thank my colleagues of the Statewide Adult Burns Service (SABU) of Western Australia (WA) whom helped me in various aspects of my studies along the way, including identifying suitable patients, completing outcome measures and waiting patiently for the completion of data collection. There was significant 'in kind' contribution of Occupational Therapy clinical time and I thank my colleagues Ashlee Cardey, Tyler Murphy and Laura Halim for the support you provided with data collection in addition to an already busy caseload. My nursing colleagues of SABU including Sharon Rowe, Levineia Egan and Carol Brough who were flexible and patient with me throughout the data collection process. To my allied health colleagues, and fellow research candidates for your camaraderie and support throughout my research journey, namely Tiffany Ryan for your encouraging words, and Helen de Jong, for sharing your knowledge. Thank you to the library staff at Fiona Stanley Hospital (FSH), and University of Notre Dame (UNDA) research office. Max Bulsara and particularly Dana Hince and for your guidance and support as I undertook the steep learning curve of statistical analysis, your expertise has been invaluable.

Last and not least my husband Lutz, and children Nadia and Zoe, whom above all else supported and encouraged me throughout my studies. My husband for his encouragement and support in pursuing higher education, not least, to 'keep going' during the challenging times. My children for demonstrating understanding and endless patience whilst waiting for mum to finish her studies, at long last. I hope I have been an example of hard work, perseverance and resilience to you.

I also extend my thanks and gratitude to the patients and their families that contributed to this research.
Research Output from this Thesis

Scholarship and grant awarded
The candidate received an Early Career Researcher grant presented by the Spinnaker Health Research Foundation and the Rotary Club of Attadale in 2020. This scholarship recognises and supports the candidate’s ability as a future early-career researcher. A research grant was also awarded to this candidate by the Fiona Wood Foundation Small Grants in 2020 (Appendix 2 and 3).

Conference presentations
Statement of Contribution

This thesis originated from the research project that was conceived by Rosemary Kendell at the State Adult Burns Service of Western Australia, Fiona Stanley Hospital. Subsequent research design evolutions were further developed in collaboration with my supervisors.

Concept and protocol development and ethical application were largely completed by Rosemary Kendell and Fiona Wood. I engaged with this research during ethics submission to the Health Research Ethical Committee (HREC) of FSH. From that point, I have led the development and conduct of the research program depicted in this thesis from 2018 including the finalisation of ethical approval from UNDA, further enhancements and concept development, recruitment and management of data collection, data validation, data analysis, and dissemination of research findings (development of manuscripts, posters, and verbal presentations). All co-authors have endorsed and acknowledged my level of contribution. The Statement of Contribution of Others for my publication is presented in Appendix 5.

Signed:

Fiona Poelchow
Candidate

Prof Jim Codde
Primary Supervisor

Date: 2022
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<td>split thickness skin graft</td>
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<td>SPT</td>
<td>superficial partial thickness</td>
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<tr>
<td>TTH</td>
<td>time to healing</td>
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<td>TBSA</td>
<td>total burn surface area</td>
</tr>
<tr>
<td>SABU</td>
<td>State Adult Burn Unit</td>
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<tr>
<td>WA</td>
<td>Western Australia</td>
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<tr>
<td>RD</td>
<td>radiation dermatitis</td>
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<tr>
<td>DPT</td>
<td>deep partial thickness</td>
</tr>
<tr>
<td>FT</td>
<td>full thickness</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
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<td>RISRA</td>
<td>Radiation Induced Skin Reaction Assessment</td>
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<td>mVSS</td>
<td>modified Vancouver Scar Scale</td>
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<tr>
<td>POSAS</td>
<td>Patient Observer Scar Assessment Scale</td>
</tr>
<tr>
<td>PP</td>
<td>per protocol</td>
</tr>
<tr>
<td>ITT</td>
<td>intention to treat</td>
</tr>
<tr>
<td>COD</td>
<td>change of dressing</td>
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**Explanatory Overview**

Each year, about 3367 people are hospitalised in Australia and New Zealand for treatment of burn injuries, of which, the majority (83%) involve less than 10% total body surface area. In 2019/20 approximately 43% of burn injuries were of superficial depth, and a further 1661 cases underwent debridement and skin grafting procedures (Burns Registry of Australia and New Zealand, 2019/20) [https://anzba.org.au/assets/BRANZ_AnnualReport_Jul19-Jun20.pdf](https://anzba.org.au/assets/BRANZ_AnnualReport_Jul19-Jun20.pdf) (1). The Statewide Adult Burn Unit is the only adult burns service for the whole state of Western Australia. Of the 23,450 patients admitted with a burn injury to the SABU of Western Australia between 1983 and 2008 most were for burns less than 10% TBSA (86.3%), of which 17.1% involved the head and neck which is a common burn injury site (2), and a burn location of significance with cosmetic outcome and return to normal participation in life. Out of 227 patients seen for minor burns in the ambulatory care services of SABU in 2004, nearly 40 cases involved the head and neck (3). Current census data shows that the SABU can expect to see up to 100 presentations of face and neck burns within a year. The majority of these are treated in the outpatient ambulatory care facility which between 2015 and 2021, provided 6647 clinic appointments for acute ‘walk-ins’ and a further 24661 dressing appointments for burn injury wounds ([FSH Burns Unit Infographic](#)), see Appendix 6.

While the ultimate goal in wound healing is achieving a flat, imperceptible scar, burn injuries can result in a high incidence of scarring with the type of injury, wound size and depth all playing a role. Similarly, healing time impacts on the quality of scar outcome and so burn care is heavily focused on reducing time to healing time by either conservative or surgical options. While there is evidence that silicone therapy positively impacts the scar outcome there is paucity of evidence regarding the impact of silicone on time to healing, and whether commencing silicone therapy during the wound healing phase will result in an improved scar outcome in burns patients. Prospective controlled studies are needed to test this treatment’s potential.

Burn clinicians and researchers have focused on gaining a better understanding of the scarring and maturation processes and discovering ways to treat burns wounds that improve patient outcomes, whilst also minimising the discomfort, pain and improving cosmetic appearance of scars for the patient. Within this field of innovation, a new
type of silicone has been developed which is suitable for application on unhealed wounds. This presents a new opportunity for an earlier commencement of scar management in healing wounds.

Stratamed and StrataXRT are semi-occlusive, self-drying, transparent, bacteriostatic and inert silicone gels which form a thin wound dressing layer that provides a moist wound healing environment which, in turn, may support faster re-epithelialisation. Both have the same active silicone-based ingredients, and dry to form a semi-permeable film over de-epithelialised skin. Both function in the same way but a minor difference is that StrataXRT dries to form a silicone film that is slightly more viscous.

Currently there is limited evidence whether the early application of film-forming silicone products impact healing times, patient symptoms of pain associated with burns dressings, and scar outcomes. The aim of this research program is to address this knowledge gap.

**Study Objectives**

The hypothesis being tested by this research is that silicone-based dressing products when used in wound care of burn patients can hasten wound healing, reduce pain perceptions, and improve scar outcomes. Both products are developed by the same manufacturer for open wounds and compromised skin, including burn wounds. StrataXRT was primarily developed for the treatment of radiation dermatitis (RD). This condition presents similarly to donor site wounds in regards to pain and discomfort. In the first study, StrataXRT which is a comparatively more viscous silicone than others in the classification, will be applied to donor site wounds underneath a secondary standard care dressing. Stratamed, is a thin transparent topical gel making it ideal to use in visible exposed areas, and was explored in the second study in superficial burns of the face and neck.

This research was conducted within the State Adult Burns Unit of WA, Fiona Stanley Hospital. All participant recruitment and management were carried out or facilitated by the primary researcher Fiona Poelchow (candidate) between December 2018 - December 2020. Researcher contact hours were partly funded through Stratpharma pharmaceuticals and research grants, and the program was completed in a part-time
capacity. Therefore, the timeframes required to complete recruitment and data collection were limited and it was not feasible to carry out a definitive trial within the parameters of this study. Therefore, this project was designed as a pilot study series that addressed the hypotheses and met the requirements of Master of Science degree.

This hypothesis will be tested in two different clinical scenarios in separate studies with the same objectives:

**Aim:** To determine if early application of film-forming silicone products, 1) reduces healing times; 2) positively impacts the scar outcome in non-severe superficial wounds; and, 3) reduces patient pain associated with donor site and burns dressings.

**Study 1:** In skin donor sites of post-surgical burn patients, immediate silicone film therapy, StrataXRT will improve time to donor wound closure, scar and pain outcomes, compared to standard clinical care.

**Objectives:**
1. To assess the impact of StrataXRT on donor site wounds of split skin grafts on:
   a) time to healing
   b) scar outcomes, and
   c) patient's perceived pain

**Study 2:** In patients with burns on their face or neck and do not require surgery, early silicone film therapy with Stratamed will improve time to wound re-epithelialisation, scar and pain quality, compared to standard clinical care.

**Objectives:**
2. To assess the impact of Stratamed on superficial face and neck burn injuries that do not require surgery on:
   a) time to healing,
   b) scar outcomes, and
   c) patient's perceived pain
Thesis Overview

This thesis provides a summary of the work undertaken to address the research objectives. The study program report is presented in four chapters.

Chapter 1: Literature Review
Provides a description of skin anatomy, pathophysiology of burn wound injury and healing, burn wound interventions, and discussion on donor site wounds, superficial face burns and scarring. Lastly, a literature review on silicone in burns scarring, and the case for topical silicone dressing in burn wounds is presented.

Chapter 2: Donor Site Study
This study evaluated the effectiveness of StrataXRT to improve wound healing, reduce pain and improve scar outcome in comparison to standard care. Thirty participants were recruited in this double blinded, randomised controlled trial. Results revealed no evidence of significant differences in wound healing time, scar or pain between intervention and control.

Chapter 3: Face and Neck Study
Explores the effectiveness of Stratamed, in burn wounds of the face and neck in comparison to standard care. Fifty-five participants were recruited in this double blinded, randomised controlled trial. Results revealed no evidence of a difference in wound healing time and pain between intervention and control. Results showed a reduction in scar pigmentation at six weeks.

Chapter 4: Discussion
Presents the final discussion and explores the strengths and limitations of work reported in the thesis and recommended directions for future work in this area informed by the findings of this research program.
Chapter 1:

Literature Review
1.1 Anatomy of the Skin

The skin is the largest organ of the human body and forms the first line of defence against disease and injury (4). Its function is to protect the body’s internal organs and tissues, protect against invasive infectious organisms, and prevent dehydration (4). In some cultures, the skin is regarded as an aesthetic asset which can influence a person’s self-esteem and confidence (5).

The skin is made up of three main layers; the epidermis, dermis and subcutaneous layer (4) (Figure 1). The epidermis is the outermost layer composed of epithelial tissue that is made up of four main types of cells including keratinocytes, melanocytes, Langerhans and Merkel cells. Melanocytes produce pigment while Langerhans and Merkel cells provide functions for immune response and sensation respectively. The epidermis is avascular and depends on the blood supply of the dermis for oxygenation, nutrition and removal of waste. The dermal epidermal junction connects the epidermis to the lower dermis and plays an important role in epithelial repair. (4).

The dermis is the second layer which contains blood vessels, hair follicles, nerve endings, and sweat and sebaceous glands. Contains an upper papillary layer and a deeper reticular layer (4). Cutaneous blood vessels nestled where the dermis and deeper subcutaneous tissue meet supply both the epidermis and structures within the dermis (6).

The subcutaneous layer is the deepest layer composed of fat (adipose) and connective tissue that contains larger blood vessels and nerves. Functions include insulation, and thermoregulation through dilation and vasoconstriction of blood vessels (7).

At a cellular level, epithelial cells make up the epithelium and also form hair follicles, sweat glands and sebaceous glands. Fibroblasts are found in the dermis and are responsible for the formation of collagen which maintains the skin’s tensile strength. Fibroblasts are the main cell type that impact on wound healing and in the formation of hypertrophic scarring. The third main cell population are endothelial cells located in the blood vessels which proliferate during inflammation and increase angiogenesis and account for vascularity seen in healing wounds. Epithelial cells play a significant role in wound healing (8, 9). Understanding the anatomy within these different layers
of the skin provides insight into how burn injuries might impact on wound healing and scarring.

![Figure 1. Cross section of layers of skin and depth of burn injuries](Reproduced with permission from Fiona Wood)

### 1.2 Burn Injuries and Effects on Skin

Worldwide, burns account for more than 300,000 deaths and almost 11 million people a year require burn-related medical attention (10). Of the 3367 burn injury admissions to a New Zealand and Australian burn facility, 43% accounted for superficial depth, 50% mid-dermal depth and 42% for deep dermal depth injuries. The median burn size was 2-3% total body surface area (BRANZ 2019/2020, [https://anzba.org.au/assets/BRANZ_AnnualReport_Jul19-Jun20.pdf](https://anzba.org.au/assets/BRANZ_AnnualReport_Jul19-Jun20.pdf)). Burn injuries are caused by a variety of mechanisms such as thermal, electrical, radiation and chemical agents, and often impair a patient’s emotional well-being and quality of life (11).

When a thermal burn injury is sustained, it causes changes to the skin that can be divided into three zones of injury (Figure 2), as first described by Jackson in 1953 (12). The primary site of the injury refers to the zone of coagulation, where maximum damage has occurred and devitalised tissue is irreversibly destroyed. This is surrounded by the zone of stasis which is marked by decreased tissue perfusion. The most peripheral and deepest zone is the zone of hyperaemia which is characterised by increased inflammatory vasodilation. Tissue within the zone of stasis has the potential to heal if revascularisation is achieved, or can progress to necrosis within the
first 48 hours of injury, which can extend the area and depth of initial burn injury, known as burn wound conversion (13).

![Jackson's burn model](image)

**Figure 2.** Jackson's burn model. Image courtesy of Australian & New Zealand Burn Association (2021) Emergency Management of Severe Burns (EMSB) Course Manual, 19th ed. QLD, Australia (14)

Local and systemic factors including excess oedema, vascular damage, inflammation, infection and pre-existing medical conditions can affect burn wound conversion. Burn wound conversion predominantly affects burns that are initially assessed as superficial or partial thickness but which progress to deep or full thickness in depth. Increased depth of burn injuries can in turn, result in morbidities such as wound infection, sepsis and shock, multiple organ failure, need for surgical skin grafting, prolonged wound healing, hypertrophic scarring and contractures (15).

It is important to understand the pathophysiology of burns and the effect on the skin in both superficial burns and deep burns when a burn injury occurs. In superficial partial thickness burns that involve the epidermis and upper part of the dermis, keratinocyte cells in the epidermis activate an immune response that triggers immune cells such as mast cells and macrophages. Damage to the keratinocytes, mast cells and macrophages will secrete proinflammatory cytokines which cause several immune responses that are characteristic of superficial burns: nociceptor nerve endings within the dermis are stimulated resulting in pain; increased vascular permeability causes fluid to leak out of capillaries creating interstitial oedema; the accumulation of fluid forms blisters on the surface of the skin that rupture giving superficial burns a moist
appearance; and vasodilation of blood vessels causes warmth in the area, erythema and blanching of the skin (13, 15, 16).

Burn injuries that cause damage to the deeper structures of the dermis and subcutaneous tissue trigger several pathologies that result in characteristics associated with deep burns. In deep partial-thickness burn injuries, proinflammatory cytokines increase vascular permeability causing a significant amount of fluid to leak out of blood vessels, resulting in interstitial oedema. In full-thickness burns, damage to blood vessels causes fluid to leak out, this combined with the destruction of blood supply to the area gives injured skin a dry non-blanching appearance. Nociceptors and sensory fibres are also damaged, resulting in loss of sensation. The significant loss of fluids that occurs in major burns (greater than 20% TBSA), can result in hypotension and lead to circulatory shock (13, 15, 16).

The ability for the skin to heal depends on the extent of the injury. Increasing depths of burn wound injuries can result in increased time to heal and increases the likelihood surgical debridement and grafting may be performed if available (13).

1.3 Wound Assessment

Regular assessment of burn injuries throughout the different phases of wound healing informs clinical wound care management (17). Wound assessment is a critical aspect of burn wound care and involves knowing the cause/burn agent, number of days post burn injury, wound size or TBSA, location and depth to guide clinical decision making and optimise treatments for the patient (15, 18).

Total Body Surface Area (TBSA) is a commonly used to estimate the body surface area affected by burns, whereby the ‘rule of nines’ principle assigns percentages to different body areas giving a sum out of a total 100 (Figure 4). For example, the entire head is assigned 9%, with 4.5% each for the anterior and posterior, 18% per lower limb with 9% each for the anterior and posterior. The palmar surface of a patient’s hand accounts for 1% and is commonly used in clinical practice to estimate the size of a burn injury. An altered formula is used for the calculation of TBSA in children (19).
Figure 3. Lund and Browder body chart depicting rule of nines.  

Wound healing is usually determined from visual inspection by clinicians during dressing changes (17). Wounds should be reviewed frequently to monitor the progression of wound healing, and decide on the most clinically appropriate dressing throughout the various stages of wound healing (20, 21). Wound assessment tools should be cost-effective, efficient to use and comfortable for patients (22-24). Subjective assessment of wound healing has been shown to be reliable (22), and studies have shown reliability increases when significant clinician experience is greater than ten years (22, 25). Furthermore, visual inspection avoids contact with the wound bed thus minimising the risk of infection and increasing patient’s experience of pain (22). The regular visual inspection of wounds over time allows clinicians to record the number of days from the point of injury to wound closure, and thus provides ‘time to healing’. Time to healing is a useful outcome tool for monitoring wound healing and the effectiveness of dressing systems, particularly for smaller minor burn injuries (26).

It is the accurate diagnosis of the burn injury depth and size that will determine the best treatment approach for the burn wound (8, 15). The American Burn Association defines a minor burn as burns that involve 15% or less total body surface area (TBSA) (27). Minor burn injuries predominantly involve burns of superficial depth (15), and are
the focus in these two studies, however, there are typically four classifications of burn depth (28) (Figure 3).

i. Epidermal burns affect the epidermis only and are superficial injuries such as sun burn, blistering can occur but is uncommon. These types of burn wounds are painful, but typically heal by spontaneous primary intention within a week and there is negligible risk of scarring.

ii. Superficial Partial Thickness burns affect the epidermis and upper part of the dermis. Nerve endings are exposed and these types of burns are painful, red and raw in appearance, with blistering often present. As this depth of burn injury only involves the superficial portion of the dermis, hair follicles, sweat glands and sebaceous glands are largely preserved, thus providing a supply of epithelial cells that promote spontaneous healing, and therefore do not require skin grafting surgery and are healed through wound dressings. Angiogenesis, the formation of new blood vessels, and fibrogenesis, the proliferation of new fibrous tissue are two key mechanisms in dermal repair. Wound healing occurs between two and three weeks, and may form a scar.

iii. Deep Partial Thickness (DPT) burns affect the epidermis and deepest parts of the dermis. Wounds present with fixed capillary staining, and are painful. Healing occurs between 21–35 days and largely depends on the migration of keratinocytes from surrounding uninjured skin. It is possible to heal this depth of burn wound with dressings, however, it is often associated with scarring. Early excision and skin grafting can expediate wound healing in deep burn injuries and further minimise the development of scarring.

iv. Full Thickness (FT) burns involve the full destruction of the epidermis and dermis, characterised by white waxy, grey or charcoal skin and with an absence of pain due to the total destruction of nerve endings. With the destruction of the dermis, there are no regenerative elements and healing can only heal from the edges of the open wound, therefore surgery is the only option for wound closure.
Treatment of burn wounds can be planned after careful assessment of the injury, (17) which involves estimation of burn depth and extent of the wound (29).

1.4 Wound Healing

Minor burn injuries that involve 15% or less total body surface area (TBSA) predominantly involve superficial burns (15). The superficial layers of the skin, the epidermis and papillary dermis have regenerative capabilities whereby hair follicles, sweat glands and sebaceous glands are largely undamaged thus providing ample supply of epithelial cells that promote spontaneous healing (30). In deeper burn injuries of the skin, wound healing is achieved by fibrosis and scar formation, a process known as wound repair that involves multiple overlapping phases (21):

i. The inflammatory stage increases blood supply to the wound along with neutrophils and monocytes triggering an immune response sustained by macrophages that remove dead tissue and protect from colonisation of microorganisms.

ii. The proliferative stages see growth of blood vessels to the wound accompanied by keratinocyte fibroblasts that produce fibrous infill known as granulation tissue. Collagen and elastin are deposited. Concurrently epithelial cells begin migrating (growing rapidly) from viable skin appendages in the dermis, thus bridging the gap and resulting in wound closure, known as ‘epithelialisation’.
Remodelling is the final stage of wound healing and can last for several months to two years until the scar matures. Collagen and elastin are deposited, remodelled and replaced in this phase. Prolonged action of the fibroblasts in this phase are thought to increase collagen production which results in the formation of a scar.

1.4.1 Complications to Wound Healing

Systemic factors that may affect wound healing include inflammation, oedema, infection and nutrition (31). Patient and injury-related factors can also impact on wound healing including severity of injury and adequacy of first aid applied, age, comorbidities, ethnicity, dressings and surgery (15), those with compromised immunity are more at risk of infection (29, 32).

Oxygenation supports cell metabolism and energy production, and is essential to wound healing processes. The initial hypoxia in burn wounds triggers the wound healing process, and oxygenation is required to maintain tissue repair. If hypoxia is prolonged, then wound healing will be delayed. A burn wound is depleted of oxygen supply due to impaired vascular function. Systemic factors such as older age and diabetes both have reduced vascular flow and therefore reduced tissue oxygenation which will impact on the healing of wounds (31).

Inflammation is a normal part of wound healing and plays an important role in the decontamination of the wound from microorganisms. If decontamination is ineffective, the ongoing presence of bacteria in the wound can prolong and elevate levels of proinflammatory cytokines which can extend the inflammatory phase and further delay wound healing (31).

Patient immune function plays a vital role in the ability of the skin to heal. Immediately after a burn injury a series of biological mediators of inflammation and growth factors are triggered, and healing is dependent upon the integrity of the immune system in response to this process. Complications of burn wound injury include systemic infections such as pneumonia, urinary tract infection, bacteraemia and sepsis. In burns with atleast 15% TBSA, an acute immune response is mounted which leads to systemic inflammation and multi-organ dysfunction, and if bacteria are present, then sepsis and multi-organ failure will result (29).
There is increased risk of infection in burn injured patients due to the loss of skin and removal of the protective barrier. Donor site wounds and SPT burns of the face and neck are two similar wound types that are the focus of this study, both concern superficial partial thickness skin loss and therefore present a risk of wound infection (15). Infection in a burn wound can prolong pain, and prolong the time to healing which increases the risk of scarring (33). Infection is the main cause of mortality and morbidity in burns patients. The surface of burned skin is highly susceptible to contamination and colonisation of pathogens that cause infection, and can slow wound healing (29). Therefore, wound care management and infection control procedures including protective personal equipment (PPE), aseptic dressing technique, sterilised dressing products and hand hygiene are vital in optimising wound healing. Furthermore, burn wound dressings are essential to wound healing and provide important benefits. Dressings provide a barrier to infection and protect wounds from further trauma, provide comfort, pain relief and promote healing (33).

The ability for the skin to heal depends on the extent of the injury. Wound healing needs to be optimised during all stages of wound healing to ensure success (32).

1.5 Interventions for Burn Wounds

Once the depth and area or extent of the burn injury is understood, attention is turned to the management of the burn wound. Systemic interventions are required to optimise wound healing and include fluid management and nutritional support. Increased capillary permeability results in plasma loss and can lead to hypovolaemic shock in burn injuries (13). Adult with burns more than 15% TBSA and paediatric patients with burns more than 10% are at risk of hypovolaemic shock if fluid resuscitation is inadequate (16). Appropriate nutritional supplementation is vital in modulating the hypermetabolic response of severe burns, and high levels of protein and calorie intake are required until burn wounds have healed (16). Optimisation of wound healing is the key focus when selecting wound management interventions. Interventions for burn wound injuries include dressings, or surgical management (17).

1.5.1 Wound Dressings

The aim of dressings is to prevent infection to facilitate and reduce healing times by providing the most ideal healing environment (34). There is an abundance of wound dressing options available and selection will depend on wound depth and the physical
presentation of the wound itself (21). Burn injuries of SPT depth including donor site wounds are typically managed with wound interfacing dressings (21). SPT burn wounds of the face/neck that only involve epidermal and dermal loss are typically managed with topical ointment treatments. The purpose of wound dressings is to provide wound coverage and protection from infection, physical damage, permit gas exchange, and provide a moist environment that promotes wound epithelialisation (21). Dressings should also be sterile, not toxic or allergic to the patient and non-adherent and easy to remove (35).

A by-product of burn wound healing is exudate which is the combination of fluid and leukocytes that move from the circulatory system to the site of injury in response to local tissue damage (36). Blood vessel dilatation results in greater permeability and increased production of exudate (36), therefore dressing selection must also consider and predict the volume of exudate to be managed. Exudate can be described as heavy (dressing soaked), medium (dressing wet), minimal (dressing dry) or non-exudating, and should be treated accordingly with dressings to suit the level of exudate (37). There is a significant range of dressing products available for superficial and partial thickness burns that can be sub-categorised into: films, foams, composites, sprays, gels and traditional gauze dressings (20, 35, 38):

i. Simple wound dressing pads include traditional gauze, bandage and plaster dressings that are dry and primarily used to provide coverage and protection of wounds from contamination, but can become adhered to the wound bed in exudating wounds. Non-adherent examples include knitted viscose dressings, tulle, paraffin gauze and medicated iodine or chlorhexidine infused dressings

ii. Polyurethane films are thin semi-permeable transparent film sheets that adhere directly to the wound, and conform to any shape. Suitable for light exudating epidermal and superficial wounds.

iii. Foam dressings are silicone-based, semi-permeable and non-adhesive, therefore with less risk of causing damage during dressing removal. Used in burn wounds for their highly absorptive properties.

iv. Hydrogels are insoluble hydrophilic material that come in the form of a separate gel or sheets and have a high-water content which provides a moist environment that is beneficial to wound epithelialisation. Suitable for higher levels of exudate.
v. Hydrocolloid dressings are made up of an inner colloidal layer and outer water-impermeable layer. Hydrocolloids are impermeable to bacteria and properties include autolytic debridement and absorption of wound exudates. Used in light exudating wounds such as pressure sores and superficial burn wounds.

vi. Alginites are sodium and calcium-based fibre dressings derived from seaweed, that are absorbent and biodegradable. When in contact with the wound bed the alginate dressing transforms into a hydrophilic gel which in turn limits wound exudate and minimises bacterial contamination whilst maintaining moist wound healing.

vii. Antimicrobials are silver and iodine containing dressings that eliminate many microorganisms and minimise colonisation of wounds.

viii. Biosynthetic skin substitutes such as topical silicone gels and films allow for re-epithelialisation whilst functioning as a replacement for the epidermal layer in de-epithelialised skin. Benefits of these types of film dressings include gas and fluid permeability and bacteriostatic properties. StrataXRT and Stratamed are both topical silicone gels that are explored in the two separate studies of this thesis paper.

In addition to promoting wound healing, the selection of dressings must also address comfort and pain relief for burns patients. Pain management is an essential aspect of wound care management in burns patients.

1.5.2 Pain Management

A burn injury induces a strong inflammatory response where inflammatory mediators sensitise pain nociceptors at the wound site. This causes the wound and surrounding skin to become painful to stimuli such as touch, debridement and application of topical treatments as experienced in wound care. Prolonged peripheral stimulation of nociceptive afferent fibres can eventually cause surrounding unburned skin to become hypersensitive to touch. Furthermore, damage to the nerve endings results in disrupted pain signals where the pain is experienced at much lower threshold parameters. In addition to the physical pain caused by a burn injury, a stress response is triggered, starting with the release of norepinephrine from the sympathetic nervous system, and followed by a gradual release of hormones cortisol, epinephrine and aldosterone (39).
Pain is a subjective experience and responses to burn related pain can widely vary among patients. The size and depth of the burn injury may determine varying amounts of pain (39). Pain is particularly a feature with more superficial injuries because damaged nerve endings are exposed. Deep tissue injuries are less painful initially because the neural end organs are no longer intact (15, 28). In reality, deep burn injuries often have more superficial areas where nerve endings remain undamaged. Therefore, most burns patients experience pain (39).

Assessment of patient pain should be performed in combination with wound assessment and include type of pain, severity, duration, analgesics, and the patient’s subjective experience (40). A patient’s self-reported perception of pain is considered the most valid indicator of pain, assessments include visual analogue scale, numerical rating scale and verbal rating scales (40). Mahar et al. completed a systematic review on pain assessment tools used in burns and found the majority of studies used a numeric rating scale (41). The benefit of using a pain intensity scale within a clinical setting is that it is simple, quick, easy to use and does not overburden the patient, particularly during painful dressing procedures (40).

A burn injury is considered to be one of the most painful types of injury both initially and due to sensitisation through repeated dressing changes (40, 42, 43). The opportunity to reduce the need for changing dressings would optimise patient care. Pain from a burn wound can be debilitating in that it can cause significant psychological distress, and affect the ability to physically move (44, 45). Pain is a complex experience and high levels of acute pain can lead to chronic forms of pain and associated anxiety which can lead to reduced quality of life (43, 44).

Pain is typically present in unhealed wounds due to damage caused to the nerve endings (37). Removal and reapplication of dressings and cleansing of a wound are reported by patients to be the most painful aspects of wound care interventions (40, 42). Good pain management is essential as poorly controlled pain can contribute to anxiety and stress, and can hamper the healing process due to the elevation of stress hormones (33, 40). Furthermore, a single experience of a painful dressing can increase stress levels so that anticipatory pain can increase at the next dressing change (45). Analgesics before commencing dressing procedures can help to reduce pain (37). As wound healing progresses, pain levels typically decline (33).
1.5.3 Surgical Interventions

When burn injuries are deeper in nature, and the epithelial and deep dermal appendages have been destroyed, spontaneous wound healing is not possible (33). Burn injuries of deep partial thickness or full thickness are optimally managed with surgical skin grafting to close the open burn wounds (21, 33). This involves surgery to harvest healthy donor skin, known as skin grafts, that are then transplanted to the burn wounds (33). Skin grafts can be full thickness where both the epidermis and dermis are harvested, or partial thickness involving the epidermis and upper part of the dermis only, known as a split thickness skin graft (STSG) (33). Interventions in this study series will not involve application to skin grafted wounds.

1.5.4 Donor Sites

The harvesting of skin grafts creates a wound that is known as a donor site. Donor site wounds of superficial partial thickness depth heal by epithelialisation (46). Therefore, it is important that donor site dressings create an environment suitable for epithelialisation. Donor site wounds are painful, and can be slow to heal, and also have the potential to result in pigmentation changes, and scarring (33, 47).

Patients frequently report that donor site wounds are more painful than their grafted burn wounds. The widespread nerve endings of the STSG donor site are damaged and exposed, resulting in the sensation of diffuse pain (46). Careful selection of an appropriate wound dressing can have an important effect on pain. It is believed the occlusive nature of a dressing can reduce pain by preventing exposure of these nerve endings to the air (46).

Ideal donor site dressings should maintain a micro-environment of balanced moisture, reduce pain and discomfort, prevent infection, absorb exudates, and also, are easily applicable and economical in cost (46, 48). However, there remains no consensus on a singular optimal choice of dressing (49). Instead, various dressing options exist for donor site wounds (21).

Standard care in the State Adult Burns Unit of WA is that a calcium alginate dressing selected for its effectiveness in wound healing and homeostatic properties in bleeding wounds (48). It has been observed, once post-surgical exudate settles, alginate can become hard and adhered to the wound which can cause pain, particularly at dressing changes, and hamper patient mobility and wound healing (48). It has been reported
the use of moist dressings improve wound healing and pain outcomes (49). Terrill et al observed increased moisture in skin immediately after dressing removal when comparing a polyurethane dressing to alginate, where the skin appeared dry and hard in contrast (50). Donor sites were selected for this study because they are standard depth wounds that enable a more objective measure of the effectiveness of StrataXRT. Furthermore, donor site wounds are painful and impact the functional recovery of the patient, thus presenting a need to explore dressing options that hasten healing.

1.5.5 Face Burns

Burn injuries to the face/neck are considered complex and high risk burn injuries and require a specialised approach to wound care (ANZBA burn centre referral criteria; https://anzba.org.au/care/referral-criteria/). Face/neck burns account for a large portion of outpatient presentations to the State Adult Burn Unit, many of which are SPT in nature. SPT face burns do not require surgical intervention but are not easily managed with dressing systems due to the difficulty with affixing dressings to facial topography, and are typically treated with topical agents (51). The unique blood supply and proficiency for face burn wounds to regenerate makes topical management a highly desirable early treatment option. Antiseptic agents, antimicrobial ointments and silver dressings are frequently used in the treatment of deeper partial thickness burns, with surgical debridement and grafting the gold-standard practice for full thickness burns of the face (9), or those that exceed three weeks of wound healing (52). There is increased risk for scarring following surgery (34), therefore it is paramount to heal facial burns as early as possible.

Topical agents provide a constant moist environment and occlude exposure to the air, thus preventing drying out and minimising wound pain (9, 11). Topical management allows frequent face washing to remove dead tissue and keep the wound clean, which reduces the rate of healing (51, 53). Chlorhexidine is an antiseptic wash that is effective against a wide range of bacteria (54), and was used in the standard care for face burns in the State Adult Burn Unit at the time of this study.

Topical paraffin-based emollient ointment is applied and refreshed repeatedly during the day as the standard care for SPT burns to the face and neck within the study burn facility. Emollients are commercially available creams or ointments that are paraffin or water-based (55). Topical emollients when applied to the skin provide an occlusive
physical barrier that protects the stratum corneum, enhances epidermal barrier function and prevent trans-epidermal water loss thus improving the condition of the skin (56-58).

Potential adverse effect of emollients can include infection from micro abrasions in the skin and contamination from poor product storage (56, 59, 60). Emollients frequently contain lanolin which can cause skin sensitivities (60). Emollients may affect the antimicrobial function of the acid mantle of the skin which can increase the risk of colonisation and infection (60).

Newer topical options include film barrier systems which promote and maintain sufficient hydration levels within injured skin and support greater efficiency in the epithelial recovery (61). Topical film-forming silicone is the intervention treatment explored in this study. Stratamed is a semi-occlusive, self-drying, transparent, bacteriostatic and inert silicone gel that forms an invisible wound dressing layer that promotes a moist wound healing environment which, in turn, promotes faster re-epithelialisation (62). Thus, Stratamed was proposed as the substitute and study comparison for emollient in the head and neck burn study.

Superficial burns involving the epidermis and papillary dermis will typically epithelialise with minimal scarring (9), provided there has been no delay to the healing process. However, all cutaneous injuries carry a risk of scarring and abnormal pigmentation, particularly if normal melanogenesis is disrupted (63). Increased pigmentation can cause an otherwise flat, soft and pale scar to be more obvious and cause distress for patients (63). The distressing experience of scarring on the face is well documented in the literature (63-66). Scarring can have a significant psychological impact on a person, particularly in face burns that are difficult to cover and are often visible in public (5, 67). Deeper burns affecting the more visible areas of the face, neck and chest have the potential for poor aesthetic and psychological outcome (68). It is therefore important for clinicians to seek out treatment options that improve wound healing and therefore optimise scar outcomes for burns patients (69).

1.6 Scarring

Burn scarring and the psychosocial issues faced by people with burn injuries, especially the visible scars, is extensively documented (5, 26, 66, 70, 71). McClean
conducted a qualitative study that involved exploring the ‘lived experience’ of participants during facial burn wound recovery and included those with SPT burns. Emotional trauma and post-traumatic stress resulting from the burn injury experience was a common theme. Other significant themes that emerged during the acute burn injury phase included distress over altered appearance and experiencing uncertainty of cosmetic outcome (5). Gibson (2019) recently completed a study that produced a holistic patient-focused 58-item checklist, The Adult Burns Patient Concerns Inventory, designed to be used in the outpatient setting. During the study the key concerns expressed by participants following burn injury (n = 12) included worry about the development of potential scarring, functional limitations, physical appearance and body image, reduced confidence and low self-esteem, and anxiety associated with societal acceptance (72). Psychosocial difficulties exist with the trauma of a burn, and the immediate trauma phase where people are coming to terms with a burn injury, but with a visible scar, for some, there is no escape. Therefore, optimising the speed of recovery is extremely important to also minimise the psychological impact of a burn and assist in minimising scar development.

Scarring is the final phase of wound healing and can result from any burn injury including those of the face/neck and in donor sites. Scarring can occur if wound healing is delayed with evidence showing that wounds that take longer than 21 days to heal are at increased risk (34, 73, 74). During wound healing the dehydration of the stratum corneum is signalled to the keratinocytes which activate fibroblasts to synthesise and release collagen. Excess collagen production leads to abnormal scarring (75).

Hypertrophic scarring can be unsightly, itchy, and painful and are typically characterised by increased vascularity, thickness, height and pigmentation changes (76). Risk factors that contribute to scarring include dark skin, female gender, burn injury to the face and neck, multiple surgeries and meshed skin grafts, time to healing and burn severity (77). Assessment of scarring is necessary to track progression and apply suitable clinical interventions (78). Assessment of the characteristics of scarring is largely based on subjective evaluation, and whilst objective measures are often included in clinical studies, there is a lack of consensus among burns clinicians on the ideal scar assessment tool (79). Measurement devices such as the laser doppler and colorimeter/spectrophotometer are included as an ‘objective’ measure of scarring but
often only measure a single scar characteristic and can be costly, impractical and time-consuming, and not without observer bias (80). The Vancouver Scar Scale (VSS) is the first validated scar rating tool that was introduced in 1990 (81) and became widely accepted by clinicians, and later resulted in the development of a modified version in 1995 (82). The modified Vancouver Scar Scale (mVSS) is quick and easy to administer in the clinical setting, and the total mVSS score allows a wide range of scars to be assessed on features including pigmentation, vascularity, pliability and height (83-86). A study by Gankande et al assessing ‘best and ‘worst’ areas of scars demonstrated good to excellent inter-rater reliability for total mVSS scores and all individual components for both, however, the individual pigmentation score demonstrated less reliability in the assessment of ‘worst’ scars (86). Whilst the mVSS lacks a subjective patient component, another well-known scar rating scale, the Patient and Observer Scar Scale (POSAS) is one of the few scar evaluation tools that combines clinician and patient-reported assessment. Furthermore, the POSAS rated highly in reliability in a systematic review, and also has the only patient-reported component on scar quality (78). The mVSS and the (POSAS) are scar assessment tools that are most frequently used by burns clinicians to monitor scarring and optimise treatment (80). Thus, both of these tools were employed in this study series.

Treatments including scar massage, pressure garments and silicone have been shown to improve the appearance of scar texture and colour (87-89). Massage and pressure therapy are both presumed to reduce fibroblast activity and therefore minimise the production of collagen (88, 90). Creams and topical lotions aid massage and improve scar hydration (91). Further treatment options for more severe hypertrophic and keloid scars include corticosteroid injections, chemotherapeutic injections, laser treatments, or surgical scar release (8, 88). Silicone products are prescribed broadly after epithelialisation to soften and flatten scars, reduce vascularity, reduce itching and improve comfort for patients (89, 91). Hydration and occlusion are highly regarded as the key functions responsible for the action of silicones in scarring (9, 87, 92).

Many studies have reported on the positive effects of silicone in minimising scarring (89, 93) but traditional silicone products are contraindicated for use in open wounds however, new silicone products are emerging that can now be used in the wound
healing phase. The following section explores currently known potential topical silicone therapy and its benefits in wound healing when used as a dressing.

1.7 Silicone in Burns

The development of hypertrophic scarring is a normal physiological response in deeper burn wound healing and may cause considerable discomfort, functional constraint and psychological anguish to the majority of burn survivors (94, 95). Hypertrophic scarring is characterised by increased vascularity, thickened firm texture, reduced skin elasticity, changes in pigmentation, pain, itch, and displeasing or unacceptable cosmetic outcome. The prevention and/or reduction of this scarring phenomenon is a primary focus of burn centres throughout the world (88, 90).

Silicone therapy (also known as ‘contact media’) has been used in scar management since the early 1980s (90) however, the evidence for its effectiveness at that time was essentially anecdotal. Ahn et al undertook the first controlled clinical trial in 1989 (and again in 1991) that demonstrated clinical improvements on scarring using silicone therapy however the mechanism of action was not determined (96, 97). In 2008, Mustoe discussed the evolution of silicone therapy and specifically discussed the use of silicone gel (formulated in a tube), citing four controlled comparative studies and two large-scale observational studies that showed clinical improvements in scar measured by scar volume, colour, pliability, height, redness, pain and itch (89).

The mechanism of action of silicone therapy remains undetermined however there is growing consensus the hydrating and occlusive properties of silicones which reduce the trans epidermal water loss is critical to their effectiveness in reducing scarring (88, 98). In healing burn wounds, the dehydration of the stratum corneum is signalled to the keratinocytes which activate fibroblasts to synthesise and release collagen (75). Excess collagen production leads to abnormal scarring. However, it is hypothesised that treatment of a re-epithelialised wound or scar with silicone gel restores the barrier function of the stratum corneum, reducing the trans epidermal water loss, turning off the stimulation of keratinocytes, ultimately reducing the production of collagen (99).

Silicone products in the form of gel sheeting and fluid film forming gels are commonly used to prevent and treat hypertrophic scars (88, 100, 101). Silicon gel sheets are usually held in place over scar tissue with tape or fitted underneath compression
garments, and are typically worn for 12 to 24 hours per day. Fluid silicone gel from a tube is applied twice daily and forms a thin transparent flexible film over scarring that is impermeable to fluids. This form of silicone gel is associated with increased patient preference because of ease of application and suitability for use on visible areas such as the face and hands (100). Historically, scar silicone treatments were only applied to re-epithelialised wounds and contraindicated in unhealed burns, or with scarring that is subject to recurrent breakdown (101). However, recently, silicone-based dressing products Stratamed and StrataXRT, also topically applied and film-forming, have been developed for the use in non-epithelialised wounds. Burn clinicians and researchers seek to understand scarring in more depth and discover new ways of effectively treating burns wounds to improve rates of healing and, patient outcomes, whilst also minimising pain and discomfort (88). It is hypothesised that topical silicone film-forming dressings promote rapid moist wound healing and aid epithelial recovery by reducing epidermal and dermal water loss and allowing keratinocytes to migrate over healing surfaces (92, 102). Further, that StrataXRT reduces the inflammatory response in superficial wounds (92).

It is well known that the rate of wound healing can impact on scarring outcomes (34, 73, 103). Finlay et al completed a review of wound healing and scar data from a sample of 295 burns patients and found a link between an increased time to healing within the first 3 weeks of a burn injury with an increase in mVSS score or reduced scar quality (74). Thus, concluding that healing wounds as early as possible is imperative to minimising poor scar outcomes. The focus in burn care is therefore to heal wounds as early as possible and prevent scarring (34, 104).

A review of the literature reveals there is low quality evidence that silicone-based dressings may support faster epithelialisation in non-epithelialised wounds (105-107) and result in a reduction of pain for patients during dressing changes (107, 108). Walker et al presented the case for the use of a silicone sheet to promote gradual wound closure on open fasciotomy wounds (109). The authors reported advantages in the use of this silicone sheet included near painless dressing changes, possible reduced risk of infection and improved cosmetic outcomes. They identified the need for further randomised trials to investigate length of stay and cost savings.

Osuka et al reported benefits in the use of a silicone dressing during tangential excisions in burn surgery included markedly reduced wound bleeding and expedited
homeostasis (110). The authors found the silicone dressing significantly reduced wound oozing and resulted in less coagulation which then resulted in less rebleeding following dressing removal as is commonly the case with gauze dressings. They cited the dressing was practical, easy to use and contributed to shortening procedure time.

Monk et al documented four cases of elderly patients with scalp wounds that presented with significant granulation tissue and a lack of epidermal migration for a period of at least 2 months (106). Stratamed, a topical film-forming silicone-based gel was used in the absence of secondary dressings. In all four cases the results suggest an increase rate of wound healing following the introduction of Stratamed to their treatment, with eventual full wound closure in all. However, the study lacked a control condition and, was limited to four cases, and the authors identified the need for a larger study to ascertain if a silicone-based gel should be standard treatment in these types of scalp wounds.

Sandhofer (2012) reported on observed benefits in Stratamed in promoting faster epithelialisation and improved scar outcomes in 105 patients following various dermatological procedures (111). This was not a randomised controlled trial (RCT), and the authors concede that further rigorous clinical trials with reliable outcome measures are required.

Uva et al (2016) reported on a case where Stratamed was applied to granulating tissue following excision of chronic erosive pustular dermatosis and removal of squamous cell carcinoma in the scalp of an elderly patient (112). The authors reported Stratamed was efficacious in promoting wound healing and cited the anti-inflammatory and bacteriostatic properties as key clinical indications for selecting this product as the treatment in this case. Whilst 98% epithelialisation was achieved after several months, this was only a single case review of one type of wound dressing option, and did not offer a comparison treatment in a RCT. Furthermore, the chronic wound condition is not equivalent to acute burn wounds, therefore this evidence offers little support to the argument for efficacy in burn wound healing. Marini et al (2017) reported on four case studies where topical silicone gel was used in the treatment of severe and unhealing wounds (102). Whilst all wounds resulted in full healing, this was not a RCT and did not use validated scar assessments, and it was not reported whether other scar interventions were implemented.
Topical silicone StrataXRT was used in a study on patients affected by radiation dermatitis and claim the evidence showed a major improvement on patients’ quality of life. The study demonstrated a statistically significant clinical improvement in the Radiation-Induced Skin Reaction Assessment Scale (RISRA) score, an assessment which assesses both investigator items based on wound appearance and a patient assessed component on symptoms including pain, itch, burning sensation and impact on daily activities (92). Priyadarshi reported on a case using StrataXRT in the unhealed burn of an infant which healed without hypertrophic scarring (62).

The focus of research to date has been on silicone gel sheeting and its effects on established scarring, however silicone gel sheeting is typically contraindicated by manufacturers for application to unhealed wounds. There is negligible research on liquid preparations of silicone gels ‘in-a-tube’ (99, 113, 114) or those formulated specifically for application to unhealed areas and therefore with the ability to function concurrently as a wound dressing and a media for scar management (99, 113). There is a need for a greater understanding of silicones that can be used in the acute early stage of wound healing 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 topical silicone.

1.7.1 Summary

Currently there is limited evidence that topical silicones when used as a dressing in superficial wounds are improving the rate of wound healing, and minimising pain and improving scar outcomes. As outlined in the study objectives, the overarching aim of this research is to address this knowledge gap through a number of specific studies investigating time to healing, pain and scar outcomes in donor site wounds and in superficial burns of face and neck, and obtain high quality data through randomised controlled trials, and within-subject and between-subject design. These studies were designed to test the effects of topical silicone in donor site wounds and in the superficial papillary burns of the face and neck.
Chapter 2:

The Effects of StrataXRT on Donor Site Healing

Foreword

The following two chapters are written as draft manuscripts and explore the impact of topical silicone when used as a dressing in superficial depth burn wounds. To date, there is little evidence of the effects of topical silicone when used as a dressing in burn related wounds. The first study investigates topical silicone in donor site wounds of split thickness skin grafts.
2.1 Introduction

Skin grafts are a common surgical procedure where a thin shaving of skin is harvested from the epidermal and dermal tissue and used to cover wounds of many types, such as trauma, ulcers, infection, skin cancer and burns (115).

Despite being a common modality for treating burn wounds, many patients report more pain, pruritus, discomfort at the donor site. Additionally, donor sites are often affected by infection, dyspigmentation, and hypertrophic scarring (116).

As skin graft donor sites are superficial wounds characterised as a standardised depth of injury, extending beyond the epidermis and into the papillary dermis, they are seen as an ideal model for comparing superficial wound healing and scar formation within an experimental clinical study design (117).

Like skin donor sites, radiation dermatitis, is also a superficial skin condition that is associated with a high level of pain at the affected site (118). Radiation dermatitis is a burn arising from radiation therapy for cancer, and characterised by inflamed, painful, peeling, broken skin (92, 114, 119). The silicone product, StrataXRT, has been clinically shown to reduce pain and benefit in healing in radiation dermatitis (114, 119).

Silicone incorporated or coated dressings have been reported to reduce dressing adhesions resulting in improved patient comfort with less pain experienced during removing of dressings (107, 108, 120). StrataXRT is a semi-occlusive, self-drying, transparent, bacteriostatic and inert silicone gel which forms an invisible wound dressing layer that promotes a moist wound healing environment which, in turn, promotes faster re-epithelialisation (62).

Thus, the aim of this study was to compare the effectiveness of a topical film forming silicone dressing (StrataXRT) against standard care treatment on donor site wound healing rates, scar outcomes and pain perception.
2.2 Patients and Methods

2.2.1 Subject Inclusion and Exclusion Criteria
Inclusion criteria were patients aged between 18 and 80 years with a burn injury < 15% TBSA requiring two separate donor sites or a single donor site with a body surface area of ≤ 3% TBSA. Those with pre-existing diagnoses of diabetes, vascular abnormality and dermatological skin conditions, and pregnant women were excluded. Those who failed to complete their treatment and follow-up were removed from the final study analysis. Participants who sustained an adverse event including reaction to the intervention StrataXRT, algisite or fixomull dressings, and required alternative medical treatment were removed from the primary analysis. An adverse event was defined as any skin reaction including redness, infection and wound break-down which indicates a person has had an inflammatory reaction to the product(s).

2.2.2 Study Participants
Demographic information from all study participants was recorded into a password protected excel spreadsheet, and SPSS database by the primary investigator (Fiona Poelchow) using information recorded in the SABU electronic medical record, BIMS (Burns Information Management System). Variables recorded included 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 which is a rating scale used to grade a patient’s skin type based on tendency to tan or burn. Classification includes: i) always burns, never tans; ii) burns easily, tans minimally; iii) sometimes burns, tans slowly to light brown; iv) burns minimally, always tans to moderate brown; v) rarely burns, tans well and vi) never burns, deeply pigmented (121). Date of donor site harvesting surgery was recorded.

TBSA percentage of burns, and injuries requiring surgical intervention were clinically assessed by a medical clinician. Any burn injury that was assessed and deemed to be requiring treatment by dressings other than surgery were excluded.

2.2.3 Recruitment
Patients attending the acute non-scheduled outpatient ‘walk-in’ outpatient clinic and those admitted onto the burns unit were screened to determine if they met the selection criteria. Flyers advertising the research project and containing the contact details of the researcher were placed on the inpatient ward and in clinic so burns staff could
inform the potential participants of the research and subsequently inform the researcher. Patients who consented and met the selection criteria were approached to participate in the study by the primary researcher. Participants were required to sign the written Participant Information/Consent Form prior to enrolment into this study.

2.2.4 Study Design
This study employed a prospective, randomised, single-centre, double-blinded controlled method comparing the efficacy of topical silicone (StrataXRT) with standard clinical care. A within-subjects design investigated both intervention and control within the same participant, and is used to reduce confounding and minimise sample size (122). As shown in Figure 5, the intervention (StrataXRT) was randomised to one of two donor sites, or one half in single donor sites. The study protocol is summarised in Figure 6.

2.2.5 Randomisation and Treatment Allocation
A random allocation sequence was used with permuted block randomisation to generate equal numbers of participants in each of the study groups using the random number generator function in Excel v.14 (Microsoft) by an administration assistant with no involvement in the study.

Allocation of the intervention (StrataXRT) to the lateral or medial donor site, or lateral/medial halves was randomly determined based on the contents of sealed, opaque and serially numbered envelopes compiled by the administration assistant and that were opened in order of enrolment into the study and at the point of surgery by the primary investigator. Surgeons completing the harvesting of donor sites were blinded to randomisation and did not know which donor site was allocated to receive StrataXRT.

2.2.6 Procedure
Standard care in the State Adult Burns Unit of WA for donor site wounds is a calcium based non-woven absorbent alginate and a thin secondary cloth retention tape made of soft stretchable non-woven polyester.

The intervention and control donor sites, within the same patient were selected during theatre. In theatre, the intervention site received StrataXRT which was applied directly to the calcium-alginate dressing before placed on the donor site wound, and the control site was treated with algisite alone, both dressings were then covered by a
cloth retention tape as shown in Figure 5. Intervention and control donor sites were recorded on an anatomical body chart and were only known to the primary investigator.

Figure 5. Image showing how donor sites were divided into halves which supported randomisation of control and intervention. Note day 1 post-operative dressing and wound ooze.

The same dressing protocol was completed at follow-up dressing appointments and StrataXRT was continued in the same intervention site. The participant was blinded to the location of both treatments during application as dressings were prepared away from the participant’s view. Concealment was achieved by masking the dressing preparation for each donor site wound at each dressing change. Participants did not see the application of StrataXRT to the intervention dressing both during preparation of the algisite dressing and subsequent application to the donor site wound. Equally, the preparation and application of the algisite dressing for the control donor site was masked from patient view. Treatment groups were further masked from patient view as both donors were covered by algisite dressings and cloth retention tape once complete. After the first application in surgery, it was decided that StrataXRT would be applied directly to the dressing and not directly to the wound because the application of StrataXRT by smearing directly on to a raw donor site wound would cause additional pain to participants during dressing changes, and potentially impact on pain outcome scores. Analgesics and adverse events were recorded at each visit.
Figure 6. Study protocol

2.2.7 Intervention

Standard care in the State Adult Burns Unit of WA is that donor wound dressings remain intact and are changed at day five post-operatively. Dressings with minor exudate leakage are generally not changed but reinforced without disturbing the wound interface, by applying an absorbent non-stick dressing. If any dressing required complete changing, the researcher was notified so that the allocated treatment protocol was maintained, as recorded. The study protocol plan was to repeat alginate and fixomull dressings at all dressing changes until complete re-epithelialisation.

All participants returned for dressing appointments as per standard care which is usually day 5-7, day 7-10 and day 10-14. Removal of the cloth retention dressing was managed by using a sting-free medical adhesive remover spray that allowed the dressing to be easily peeled off the skin with minimal pain. Wounds were washed by the treating outpatient clinic nurse.

When the independent wound assessment nurse determined wounds were 100% re-epithelialised and no longer requiring dressings, the time to healing was recorded, and standard follow up care with a moisturising lotion was taught.
2.3 Outcome Measures

The primary outcome measure was time to wound healing. Secondary outcome measures included 1) scar assessment at six weeks and three months post-surgery and, 2) pain intensity scale collected at dressing changes (Table 1).

2.3.1 Wound Healing

Time to healing (TTH) is defined as the number of days until 100% wound epithelialisation and requiring no further wound dressing, using similar methods described by Chipp et al and Gravante (83, 123). The number of days since surgery was recorded at this point.

At each dressing appointment one of two independent senior nurses both with more than 20 years of experience, assessed the donor wounds visually and provided a percentage of wound area epithelialised for each donor site. Visual assessment of superficial wound injury is the most common method for diagnosis and determinant of wound healing (124). The percentage of wound healed was recorded at each appointment until fully healed, which was deemed and recorded as the TTH. Both assessors were senior nurse consultants and were blinded to the wound treatment dressing allocation and were not involved in any treatment of the subject’s wounds.

Clinical photography was completed at enrolment and each subsequent dressing appointment for case documentation and to monitor wound healing between appointments (24), using a digital camera and standardised lighting conditions to ensure images were consistent.

2.3.2 Scar Outcomes

Scar outcome measures were completed on both the control and intervention donor sites on the most central point. Donor sites were essentially rectangular as harvesting was completed via the use of an air dermatome. Therefore, two diagonal lines were drawn to locate the most central point. Donor sites were measured and the scar testing site was recorded on the anatomical chart. Measurements and medical photographs were used to relocate the same testing sites for scar assessment at six weeks and three months post-burn injury.
Three scar outcome measures were completed by three experienced Senior Occupational Therapists with an average of three years’ experience in using the mVSS in burns; were not involved in the study; blinded to the treatment allocation group and not involved in data analysis. Clinicians received training from an experienced Senior clinician on the application of and recording objective measurements arising from the Dermalab Combo. Lower scores in all scar assessment tools indicate a better scar outcome.

1. The modified Vancouver Scar Scale (mVSS) (Appendix 7).

2. The Dermalab Combo records measures on vascularity and pigmentation.

3. The Patient and Observer Scar Assessment Scale (POSAS); patient component was provided to participants to complete at their appointments (Appendix 8).

The mVSS is a rating index commonly used by clinicians to subjectively assess and score scarring on four parameters which includes pigmentation, vascularity, pliability and height with a total score out of 15 (83-86). Analysis was completed on the total aggregated mVSS score, and separate pigmentation and vascularity scores.

Hyperpigmentation is commonly associated with superficial burn injury due to the increased activity of melanocytes and deposition of melanin (16, 125). Abnormal colour or dyspigmentation is a common complaint that can have cosmetic and psychosocial implications for those affected by visible scar characteristics such as these (126). It is therefore important to include pigmentation in scar assessment. Whilst the visual assessment of pigmentation is incorporated within many scar scales, it is a subjective evaluation that can result in conflicting opinions and demonstrate the ambiguity of hyper and hypopigmentation because it is affected by skin colour and there is no easy way to measure it (79, 126).

In the pigmentation category of the mVSS, normal skin is denoted with the lowest score (value = 0), and a hyperpigmented scar assessed as a higher score (value = 3). For the purpose of this study hyperpigmentation was defined as a worse outcome because of the predominance of lighter skin people in this sample and as demonstrated historically in the WA burns population. Further, for the purpose of this study a hyperpigmented scar (value = 3) was defined as a poorer outcome than hypopigmentation (value = 1). Although the pigmentation assessment domain is not
Ideal scar assessment should include a combination of subjective and objective tools (79, 126). The Dermalab Combo® (Cortex Technologies, Denmark) is a commercially available testing device that uses a probe held on the skin that provides numerical readings for levels of pigmentation and erythema (vascularity). The dermalab is an objective tool that has successfully been used in burns scar assessment of pigmentation and vascularity previously (130). Lower readings indicate lower amounts of pigmentation and vascularity.

The Patient and Observer Scar Assessment (POSAS) tool was recommended as the preferred scar rating survey by an international scar advisory panel (91, 131). The POSAS has an observer component that is completed by the clinician and a component that is completed by the patient. It is the most commonly used scar assessment for patient-evaluation, and the only patient reported scale that measures scar quality (80). The POSAS patient component is a self-reported severity rating scale that includes six numerical scales from 0-10 upon which the participant rates physical aspects of their scar including pain and itch. The seventh question within this tool asks participants to rate their overall opinion of their scar in comparison to their unaffected skin. A higher score indicates greater dissatisfaction (132, 133). Analysis was completed on patient’s perception of their donor site over time and compared the six week and three month outcomes using the total score and separate scores for colour and overall opinion.

2.3.3 Pain Outcomes

Patient reported pain intensity was recorded using a visual pain intensity scale (0cm to 10cm) with 0 being ‘no pain’ and 10, ‘worst pain imaginable’ (41, 134). Scoring was performed by measuring the length from 0 mm to the respondent's mark. Pain measures were recorded for all participants at the first change of dressing post-operatively for each donor site before and after dressing changes to explore association of the topical silicone with pain after a dressing in situ for several days, and immediately after application. The pain intensity scale was selected because it is
commonly used in the subjective assessment of pain (135, 136) and is simple, quick and easy to apply (40) and is valid and reliable (26).

A separate questionnaire assessing pain was developed for this pilot study and included a series of questions to assess if participants could discern pain between donor site areas allocated to either study condition. Participants were asked a) Does your donor site hurt? b) Does one side hurt more than the other? c) Which side hurts the most? d) Does it all feel the same? Analgesics were recorded at the same time.

Table 1. Schedule of outcome measure application during the study

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Day 2-5</th>
<th>Day 5-7</th>
<th>Day 7-10</th>
<th>Day 10-14</th>
<th>6 weeks</th>
<th>3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Wound healed</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Dermalab</td>
<td></td>
<td>⌂</td>
<td></td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mVSS</td>
<td></td>
<td></td>
<td>√</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POSAS</td>
<td></td>
<td></td>
<td></td>
<td>√</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Pain questionnaire</td>
<td>√</td>
<td>◼</td>
<td>◼</td>
<td>◼</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pain intensity scale</td>
<td>√</td>
<td>◼</td>
<td>◼</td>
<td>◼</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

mVSS, modified Vancouver Scar Scale; POSAS, Patient and Observer Scar Assessment Scale

2.4 Data Storage and Privacy Management

To protect the confidentiality of participant information, the primary investigator provided a numerical identifier for all questionnaires and outcome measures. The master document linking participant names and their numerical identifier was kept on a password protected computer at the State Adult Burns Unit of WA and was not taken off site electronically or manually. Only the primary investigator had the password for the electronic copy.

Hard copies of questionnaires were stored in a locked cabinet in the SABU, FSH. Data is archived at FSH for seven years in a secured area within the Health Institute of Research as required by National Australian guidelines.

Findings will be disseminated to participants via information posted onto the Fiona Wood Foundation Website and through the Fiona Wood Foundation newsletter.

2.4.1 Sample Size Estimation

A preliminary analysis indicated a study of 30 paired donor sites would give 80% power to detect a one-day difference in time to healing if within-subject correlation is high (0.8) or a two-day difference in time to healing if within-subject correlation is low (0.2). Historically, the number of patients requiring surgery at FSH exceeded 100 within a
year, making this proposed study with a sample of 30 donor sites feasible within the planned study funded, and academic program, timeframes.

2.5 Statistics

Descriptive statistics were used to summarise the study data. To explore differences between groups statistical significance was set at \( P<0.05 \). Non-parametric Kaplan Meier survival analysis was completed on TTH as per protocol (PP), and for comparison using intention to treat (ITT) analysis. Wilcoxon signed rank tests were conducted on scar and pain outcomes using IBM SPSS Statistics version 27. Parametric tests were not appropriate as the data was not normally distributed.

Scar analysis was completed on total mVSS scores and separate vascularity and pigmentation scores of mVSS and Dermalab readings at six weeks and three months post-operatively. Pain analysis was completed at the first change of dressing (COD) post-operatively for each donor site, and included scores taken before removal of dressing, and after dressing re-application.

2.6 Results

2.6.1 Patient Demographic and Clinical Data

During the two year study period, 144 patients were screened for eligibility, 9 declined to participate, 105 patients did not meet the inclusion criteria largely because they had burns >15% TBSA and were not requiring surgery. Of the 30 participants recruited to the study, 24 were male and 6 were female. Median age was 39 years with a range from 20 years to 76 years. Donor site size ranged from 0.1% to 3% TBSA. Descriptive data is recorded in Table 2.

The sample analysis had small numbers and survival analysis included both PP and ITT but this did not affect the outcomes. Of the 30 participants, primary analysis was conducted on 14 participants that progressed to 100% healing as PP. In total, 16 participants were not included in the primary analysis due to infection in both intervention and control donor sites \((n = 3)\), shown in Figure 7, lost to follow up \((n = 1)\), and dressing protocol breaches \((n = 12)\). Because the final sample for the primary analysis for per protocol had small numbers, a secondary ITT analysis was completed on all 30 participants based on the group they were randomly assigned to (Figure 9).
A significant number of dressing protocol breaches affected 12 participants where wound care deviated away from the study protocol dressing, algisite. Nurse clinicians selected different dressings based on wound presentation and clinical need. This included the algisite dressing becoming adhered to the wound bed and subsequently being treated with a hydrocolloid dressing so that the algisite could be softened and removed at the next dressing appointment ($n = 4$). Because StrataXRT could not be reapplied to the wound bed, these cases were excluded from PP analysis. In a further eight cases, the algisite dressing was replaced by mepilex ® lite, a soft silicone foam used as a protective dressing in the final stages of wound care. These protocol breaches largely occurred at the third and fourth dressing changes when wounds were $\geq 95\%$ healed, StrataXRT was continued to the intervention site where possible underneath mepilex ® lite, however, as the control wound was contaminated by the use of the silicone-based dressing these cases were not included in the PP analysis. An observation from these eight cases, included a more hydrated intervention site in comparison to the control, as demonstrated in one example shown in Figure 8. This, however, may be associated with variation in the original donor site depth or natural variation in presentation, and further studies would be required to substantiate this observation.
First dressing changes ranged from two to nine days post burn injury, with healing ranging from 0% to 100% of the total donor wound surface area. Percentage of healing in the donor sites of one participant at the first dressing change at day nine showed near complete healing with 97% (intervention) and 100% (control). The majority of participants presented with 0% total wound healing from days two to six. The earliest day to show healing was day five in two cases: first participant (intervention 50%, control 80%), second participant (intervention 90%, control 80%). At the first change of dressing post-operatively (n = 26), there were infections in two participants, one participant was lost to follow-up, and one dressing protocol breach where StrataXRT could not be continued as algisite was adhered to the wound bed. There were no protocol breaches or lost cases at the second change of dressings (n = 26), days ranged from five to ten and the majority of healing ranged from 50% to 100% (one outlier at 15%). Participants that sustained wound infections (n = 3) both intervention and control donor sites were affected in these cases. StrataXRT was ceased and the infections subsequently received treatment as directed after medical review.

Scar outcomes were missing from eight participants lost to follow up at six weeks and nine participants lost to follow up at three months (Figure 9). Due to an administration error, comparative POSAS data was missing, therefore the POSAS results analysis did not involve comparison of the control and intervention donor sites. A single POSAS score was collected at six weeks and three months post-operatively for each participant.
Pain outcomes which included pain intensity scores and the additional exploratory questionnaire for donor pain specific to study allocation were not collected in a number of participants at the first change of dressing resulting in missing data. Pain outcomes were not collected in four participants who were subsequently removed from the study protocol analysis and were those where StrataXRT was ceased (n=4). These included two infections, one lost to follow-up and one dressing protocol breach where algisite was adhered to the wound. Pain intensity scores were not recorded pre-dressing removal in two participants, and post-dressing reapplication in three participants, and one participant was not asked to complete pain scores for both. Overall, pain intensity scores were missing from seven participants ‘before dressing removal’ and eight participants ‘after dressing removal’. Subjective data on donor pain was collected from 20 participants and of these, analgesics was recorded for 15 participants.
**Figure 9.** The CONSORT diagram showing allocation process throughout pilot study.
Table 2. Social and clinical demographics of participants

<table>
<thead>
<tr>
<th></th>
<th>Study Sample</th>
<th>Per Protocol Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of participants</strong></td>
<td>30</td>
<td>14</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>24 (80%)</td>
<td>12 (85.7%)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (20%)</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td><strong>Age, median at time of surgery (IQR)</strong></td>
<td>39 (20-76)</td>
<td>41 (25-50)</td>
</tr>
<tr>
<td><strong>Skin type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type i – always burns, never tans</td>
<td>4 (13.3%)</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>Type ii – burns easily, tans minimally</td>
<td>17 (56.7%)</td>
<td>8 (57.1%)</td>
</tr>
<tr>
<td>Type iii – sometimes burns, tans</td>
<td>6 (20%)</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>slowly to light brown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type iv – burns minimally, always tans</td>
<td>3 (10%)</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>to moderate brown</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type v – rarely burns, tans well</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Type vi – never burns, deeply pigmented</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Mechanism of burn injury</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flame</td>
<td>19 (63.3%)</td>
<td>9 (64.3%)</td>
</tr>
<tr>
<td>Scald</td>
<td>5 (16.7%)</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>Contact</td>
<td>5 (16.7%)</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>Chemical</td>
<td>1 (3.3%)</td>
<td>1 (7.1%)</td>
</tr>
<tr>
<td>Electrical</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>% TBSA of burn injury, median (IQR)</td>
<td>4% (0.2 – 14)</td>
<td>3% (1-6)</td>
</tr>
<tr>
<td>% TBSA of donor site, median (IQR)</td>
<td>0.6% (0.1 – 3)</td>
<td>0.6% (0.2-1.3)</td>
</tr>
<tr>
<td><strong>Location of intervention donor site</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior thigh</td>
<td>7 (23.4%)</td>
<td>4 (28.6%)</td>
</tr>
<tr>
<td>Posterior thigh</td>
<td>11 (36.6%)</td>
<td>5 (35.7%)</td>
</tr>
<tr>
<td>Lateral thigh</td>
<td>10 (33.3%)</td>
<td>4 (28.6%)</td>
</tr>
<tr>
<td>Upper arm</td>
<td>2 (6.7%)</td>
<td>1 (7.1%)</td>
</tr>
<tr>
<td><strong>Location of control donor site</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior thigh</td>
<td>10 (33.3%)</td>
<td>5 (35.7%)</td>
</tr>
<tr>
<td>Posterior thigh</td>
<td>11 (36.6%)</td>
<td>6 (42.8%)</td>
</tr>
<tr>
<td>Lateral thigh</td>
<td>6 (20%)</td>
<td>1 (7.1%)</td>
</tr>
<tr>
<td>Medial thigh</td>
<td>1 (3.3%)</td>
<td>1 (7.1%)</td>
</tr>
<tr>
<td>Upper arm</td>
<td>2 (6.7%)</td>
<td>1 (7.1%)</td>
</tr>
<tr>
<td>Post-op ooze</td>
<td>17 (57%)</td>
<td>5 (36%)</td>
</tr>
</tbody>
</table>

IQR – interquartile range; TBSA – total body surface area
2.6.2 Wound Healing Outcomes

A PP (n = 14) Kaplan-Meier groupwise survival analysis indicated no significant difference in TTH between the two donor sites. The Kaplan-Meier median estimate (and associated 95% confidence interval CI) demonstrated no evidence of statistical difference between treatment groups (log-rank, \( P = 0.93 \)) in TTH. The Kaplan-Meier median TTH for the intervention group was 10 days (95% CI 8 - 12) and the control group was 9 days (95% CI 8 - 10), (Figure 10).

![Kaplan-Meier survival analysis of wound healing](image)

**Figure 10.** Per protocol healing distribution of control and intervention donor site TTH.

Similarly, in the ITT analysis (n = 30), the Kaplan-Meier median TTH in the intervention group was 10 days (95% CI 7.3 – 12.7) and control group 9 days (95% CI 6.3 – 11.7), and there was no evidence of statistical difference in healing time between the two donor site conditions (log-rank, \( P = 0.84 \)).
2.6.3 Scar Outcomes

2.6.3.1 mVSS and Dermalab Outcomes
PP and ITT analysis of the total mVSS scores, and the individual vascularity and pigmentation scores for the mVSS and Dermalab revealed no statistical differences were observed in the intervention and control donor sites at six weeks and three months (Tables 3 and 4). Figure 12 demonstrates the appearance of pigmentation and vascularity in the donor sites of two separate participants at six weeks and three months post-surgery.
Figure 12. Image showing scar outcomes after StrataXRT to left half of single donor site in male (A and B) and female (C and D) participants.
Table 3. Per protocol analysis of mVSS and Dermalab outcomes.

<table>
<thead>
<tr>
<th></th>
<th>6 weeks</th>
<th>3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int Md (IQR)</td>
<td>Ctl Md (IQR)</td>
</tr>
<tr>
<td>Total mVSS</td>
<td>2 (1-3)</td>
<td>2 (1-2)</td>
</tr>
<tr>
<td>mVSS pigmentation</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
</tr>
<tr>
<td>mVSS vascularity</td>
<td>1 (1-2)</td>
<td>1.5 (1-2)</td>
</tr>
<tr>
<td>Dermalab pigmentation</td>
<td>38.5 (35-41)</td>
<td>40 (37-46)</td>
</tr>
<tr>
<td>Dermalab vascularity</td>
<td>17 (16-22)</td>
<td>17 (16-21)</td>
</tr>
</tbody>
</table>

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

Table 4. ITT analysis of mVSS and Dermalab outcomes

<table>
<thead>
<tr>
<th></th>
<th>6 weeks</th>
<th>3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int Md (IQR)</td>
<td>Ctl Md (IQR)</td>
</tr>
<tr>
<td>Total mVSS</td>
<td>2 (1-2)</td>
<td>2 (1-2)</td>
</tr>
<tr>
<td>mVSS pigmentation</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
</tr>
<tr>
<td>mVSS vascularity</td>
<td>1 (1-2)</td>
<td>1.5 (1-2)</td>
</tr>
<tr>
<td>Dermalab pigmentation</td>
<td>40 (37-48)</td>
<td>39 (37-41)</td>
</tr>
<tr>
<td>Dermalab vascularity</td>
<td>20 (16-23)</td>
<td>17 (15-21)</td>
</tr>
</tbody>
</table>

mVSS, modified Vancouver Scar Scale; Int – intervention; Ctl – control; Md – median; IQR – interquartile range; N – number
2.6.3.2 POSAS Outcomes

As seen in Table 5, POSAS analysis was conducted on the overall outcome of both donor sites at six week and three-month timepoints. In routine practice in the SABU, a single POSAS is issued to patients via electronic survey. This resulted in an administration error where patient scores were only collected once and not for each donor site, therefore, POSAS analysis relates to the whole donor site(s). Results indicate that subjects positively rated the overall appearance of their healed donor sites closer to normal skin over time.

PP analysis showed that POSAS question seven (overall opinion) was significantly lower at three months (Md = 1, IQR 1-3, n = 9) than at six weeks (Md = 5, IQR 1.8-6.2, n = 10); z = -2.02, p = 0.043. This result indicates an improvement in the appearance of the whole donor site and that subjects rated the overall appearance of their healed donor sites closer to normal skin over time.

Similarly, ITT analysis showed that POSAS scores were significantly lower at three months (Md = 11, IQR 8.3-12.6, n = 20) than at six weeks (Md = 17.5, IQR 9.6-24.2, n = 18); z = -2.53, p = 0.011).

ITT analysis showed that POSAS question 7 scores were significantly lower at the three months (Md 1, IQR 1-4, n = 17) when compared with six weeks (Md = 5, IQR 2.5-5.5, n = 17); z = -2.57, p = 0.01.

Table 5. Per protocol and ITT analysis of POSAS outcomes

<table>
<thead>
<tr>
<th></th>
<th>6 weeks</th>
<th>3 Months</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>POSAS per protocol</td>
<td>14.5</td>
<td>9.5-22</td>
<td>10</td>
<td>9.5</td>
<td>6.75-12.25</td>
<td>10</td>
<td>-1.37</td>
</tr>
<tr>
<td>POSAS overall opinion</td>
<td>5</td>
<td>1.8-6.2</td>
<td>10</td>
<td>1</td>
<td>1-3</td>
<td>9</td>
<td>-2.02</td>
</tr>
<tr>
<td>POSAS ITT</td>
<td>17.5</td>
<td>9.6-24.2</td>
<td>18</td>
<td>11</td>
<td>8.3-12.6</td>
<td>20</td>
<td>-2.53</td>
</tr>
<tr>
<td>POSAS overall opinion</td>
<td>5</td>
<td>2.5-5.5</td>
<td>17</td>
<td>1</td>
<td>1-4</td>
<td>17</td>
<td>-2.57</td>
</tr>
</tbody>
</table>

Md – median; IQR – interquartile range; N – number; POSAS – Patient and Observer Scar Assessment Scale; ITT – intention to treat.
2.6.4 Pain Outcomes

Pain data for all participants from the first change of dressing (COD) after surgery was analysed. Pain intensity scores were collected for both donor sites and included: 1) before dressings were removed and, 2) after dressings were reapplied. As discussed in the results section above, pain outcomes were missing for a number of the 30 participants at this time point, resulting in a sample of n = 23 for ‘pain before’, and n = 22 for ‘pain after’ for pain intensity scores, and n = 20 for allocation specific data on donor site pain and analgesics, as described further below.

1) Pain intensity scores before:
Per protocol analysis using Wilcoxon signed rank test revealed there was no evidence of statistical difference in pain scores before COD in the intervention (Md = 1.9, n = 23, IQR = 0-4) and control group (Md = 1.5, n = 23, IQR = 0-4), (z = -.45, p = 0.66).

2) Pain intensity scores after:
Analysis of pain after dressing reapplication showed there was no evidence of statistical difference in pain scores between the intervention (Md = 0.95, n = 22, IQR = 0-5.3) and control group (Md = 0.95, n = 22, IQR = 0-5.3), (z = 0, p = 1.0).

Reported pain data demonstrated equivalence in both donor sites as the score for each study allocated donor was the same in most participants. Of the 23 participants analysed, results showed there were 21 ties in pain scores before COD, and 22 ties in pain scores of the 22 participants analysed after COD.

Analysis of whole donor site pain before and after the first COD was completed. A Wilcoxon signed rank test revealed pain scores were higher before (Md = 1.9, n = 21, IQR = 0 - 4), and lower after dressing changes (Md = 0.95, n = 22, IQR = 0 – 5.3), however results were not significant (z = - 0.50, p = .62).

The series of separate subjective questions on donor pain completed prior to dressing removal found that 20 participants (83%) confirmed pain in both their donor sites, whilst four (17%) reported no pain. Similar to the results above, the subjective data showed a large portion of the participants’ reported pain was the same in both donor sites. Of the 20 participants that reported pain, one (5%) reported the intervention ‘hurt more’ and two (10%) reported the control donor site ‘hurt more’, and the
remaining 17 participants (85%) were unable to discern pain differences between their intervention and control donor sites and reported that both donor sites felt the ‘same’ (Figure 13). Of the 20 participants questioned on their donor site pain, 12 were taking analgesics and 3 reported they were not taking analgesics, data was missing from 5 participants.

Figure 13. Image showing intervention and control donor sites halves within the same participant when completing pain outcomes.

2.7 Discussion

Unlike earlier studies that reported improved wound healing rates by the use of silicone-based products compared to standard care treatment (107-109), this was not observed in the current study. Similarly, no differences were observed in scar outcomes or pain perception. That said, the use of the silicone product was not associated with any adverse outcomes and wound infection rates were similar between the two treatment protocols.

One potential explanation for the different outcome in the current study could be that whilst the desired sample size was achieved, the longitudinal repeated measures attrition rate was higher than anticipated. This resulted in almost a 50% reduction in sample analysis, however, when analysed by intention to treat, this also failed to show a difference between the treatment and control. When considering the ITT analysis, the median difference between the two groups in time to healing (intervention = 10 days, control = 9 days), is an interesting outcome from a clinical point of view. This result perhaps challenges the original assumptions made in the calculation of study
sample and future studies applying assumptions of TTH equivalence. A larger sample size, could confirm or deny this result.

A large number of dressing protocol breaches based on clinical care impacted on rates of attrition and confounded the ability to get results. The intervention and control were equally affected in these cases. Given the frequency of changes to the study dressing protocol within this clinical setting, future research may be more suited to a pragmatic randomised control trial which will allow clinical selection of treatment dressing according to clinical practice (137). Interpretation of scar outcomes was impacted by rates of attrition resulting in a small sample for analysis.

StrataXRT is a primary dressing that is designed to go directly on a wound to dry and form a silicone layer. In this study it was used in combination with a secondary calcium alginate dressing. Donor sites were chosen as a standardised wound of SPT wound depth, however, cannot be left exposed and without a physical dressing because they are raw and painful, and can result in significant post-operative exudate and bleeding. Furthermore, donor sites are typically located on the thigh that are highly mobile, high friction areas which may not be conducive to the gel dressing. Therefore, this study involving donor sites could not be completed without a secondary dressing, however, it is possible the addition of the secondary dressing diminished the action of the topical silicone dressing. The routine practice in this clinical setting of leaving the donor dressing intact for 5 or more days may have impacted the efficacy of StrataXRT, particularly if the donor wounds were not treated with a new application of StrataXRT and therefore, the silicone was not refreshed for long periods of time.

Rather than use two discrete groups, this study utilised a within-subject design where each patient was exposed to both intervention and control treatments as it increases the statistical power, and has the advantage of comparing effects of treatment within the same conditions. In practice however, most patients in the study reported they could not differentiate between the pain levels of their two treatment sites, and the intervention and control donor wound pain was reported as being the same, possibly due to neurological innervation and pain on one side potentially overflowing to the other side. While within subject design worked well for wound healing, future studies exploring differences in pain response may be best advised to use a between-subjects design. Within subject design was not an issue with the objective measures of donor
wound healing however. Every person heals differently and within design has the advantage of comparing effects on similar tissues.

Due to this trial being undertaken in an outpatient setting where patients were not seen on weekends, it is possible that the TTH actually occurred prior to the next clinic visit. The timing of assessment was the same for control and intervention donor sites thus limiting confounding introduced by different timeframes between change of dressings. The actual impact of this logistical limitation is not known.

The methodological and logistical challenges experienced in this donor study were reviewed and applied to the face study. Whilst this study used an experimental design with consistent wound characteristics, there were a large number of dressing protocol fails. Learnings have been applied to the face study where the issue of protocol breaks was not a problem because face and neck burn wounds were managed by excluding patients that needed physical dressings.

2.8 Conclusion

In this study, there was no evidence of a difference in time to donor wound healing, scarring and pain outcomes associated with using StrataXRT compared to standard alginate dressing.
Chapter 3:

The Effects of Stratamed in Face and Neck Burns

Foreword

Topical silicone is typically used to treat burn scarring, and has until recently, been contraindicated in unhealed wounds. Silicone treatments are now being developed as wound dressing products, however, there is little evidence of its efficacy in burn wounds. Building on the learnings from the donor study, this second study investigates topical silicone in superficial partial thickness burn wounds of the face and neck.
3.1 Introduction

Cosmetic outcome is potentially particularly important following a burn to the face and neck, as it is highly visible, and plays a crucial role in our identity and means of expressive communication. An altered appearance may cause psychological problems, difficulties with social reintegration and impact on quality of life (138).

From a large, retrospective analysis of Dutch burns data, the incidences per 100,000 for facial burn were 15.1 for emergency department visits, 1.3 for hospital admissions and 1.4 for burn centre admissions. Of those patients with face burns admitted to a Dutch burns centre, the majority were treated topically with only 20.5% receiving primary facial surgery and 5.3% received facial reconstruction in follow-up (139).

Delayed healing is linked to poorer scar outcomes and healing burn wounds as quickly as possible is the focus in burn wound care (34, 74). Burn researchers seek out new ways to improve rates of healing and patient outcomes, whilst also minimising pain and discomfort (88).

Silicone products in varying forms are commonly used to manage hypertrophic scars (90) but until recently, silicone products were not approved for use with unhealed burns, or with scarring that is subject to recurrent breakdown. Research to date has predominantly focussed on silicone gel sheeting and its effects on scarring, however silicone gel sheeting is typically unsuitable for application to unhealed wounds (101).

There is however emerging evidence that silicone-based dressings may support faster epithelialisation (107, 111) and result in a reduction of pain for patients during dressing changes (107, 108). While evidence is limited, there are reports of film-forming silicone (96, 108) being applied to unhealed areas which may improve scar outcomes (99, 113)

Stratamed (Stratpharma AG, Basle, Switzerland) is a semi-occlusive, self-drying, transparent, bacteriostatic and inert silicone gel that forms an invisible wound dressing layer that promotes a moist wound healing environment which, in turn, is promoted to facilitate faster re-epithelialisation (62). It is hypothesised that film barrier dressings
create a microenvironment between total occlusion and air exposure that optimises epithelial recovery (61).

The primary aim of this study was to investigate the impact of the early application of a topical film-forming silicone-based dressing (Stratamed) on the rates of wound healing, and secondary outcomes of pain symptoms and scar outcomes in comparison to standard paraffin-based emollient ointment in burn patients that did not require surgery.

3.2 Patients and Methods

3.2.1 Study Design
This pilot study employed a prospective, randomised, single-centre, double-blinded controlled design comparing the efficacy of Stratamed in the wounds of face and or neck burns with standard clinical care topical emollient. Using a between-subjects design, patients were randomly allocated to receive the intervention (Stratamed) or control (emollient) on their face/neck burns.

3.2.2 Sample Size Estimation
A preliminary analysis indicated that a sample of 30 patients with face/neck burns in each study group would have 80% power to detect a healing time of two days difference in the intervention group. Based on census at Fiona Stanley Hospital we expected more than 100 face and neck burns within a year which makes this study feasible with the conventional sample size of 30 patients in each group (30 control and 30 intervention), 60 people with face and or necks burns in total.

3.2.3 Recruitment
Patients attending the acute non-scheduled outpatient ‘walk-in’ clinic, and those admitted onto the inpatient ward of the State Adult Burns Unit of WA, Fiona Stanley Hospital were screened to determine if they met the selection criteria. Flyers advertising the research project and containing the contact details of the researcher were placed on the inpatient ward and in clinic so burns staff could inform the potential participants of the research and subsequently inform the researcher. Patients who consented and met the selection criteria were approached to participate in the study.
by the primary researcher. Participants were required to sign the written Participant Information/Consent Form prior to enrolment into this study.

3.2.4 Subject Inclusion and Exclusion Criteria
Inclusion criteria were patients aged between 18 and 80 years with non-epitheliised SPT burns to the face and or neck who were identified as not requiring surgical intervention or dressing systems. Assessment of burn depth and the decision to proceed with topical wound care was decided by the medical team. Any face or neck burn that was assessed and deemed to be requiring physical dressing products other than the standard emollient were excluded. Burn wounds to the eyes, ears and mouth were excluded as they mostly require specialised treatment due to important underlying structures (16), and are not treated with emollient in routine clinical practice. Those with of pre-existing diagnoses of diabetes, vascular abnormality and dermatological skin conditions, and pregnant women were excluded. Those unable to return for clinic appointments or with epithelialised wounds including erythema and presentations for burn wounds that were already healed were not considered for the trial. Participants who sustained an adverse event including reaction to the intervention Stratamed, emollient, or chlorhexidine wash, and required alternative medical treatment were excluded from the primary analysis. An adverse event was defined as any skin reaction including redness, infection and wound break-down which indicates a person has had an inflammatory reaction to the product(s).

This trial has been approved by the HRECs of FSH and UNDA, and has been prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR). Trial Id: ACTRN12618001227280. Participants provided written consent for both data collection and photography.

3.2.5 Intervention
Both treatment and control ointments were decanted in to unmarked sample pots outside of participants view to blind participants to group allocation. There is a difference in colour, viscosity and texture of the two products, such that clinicians could not be completely blinded. However, patients were unaware which product they were receiving. Instructions for application to face burns was taught for both groups, emollient to be applied generously and Stratamed a thin application.
Participants were provided with disposable cloths and Chlorhexidine wash and taught face/neck washing three times daily. As per standard care participants were advised to reapply the topical ointment after face washing when awake, and to remain out of the sun. The wounds were evaluated every two to four days starting at the point of first presentation and recruitment into the study. As per standard care, moisturising and sun protection principles are taught at the point of healing. All face burns are reviewed at six weeks post-burn. If requiring scar management, patients are referred to the burn team Occupational Therapist at that timepoint.

3.2.6 Randomisation and Treatment Allocation
A random allocation sequence was used with permuted block randomisation to generate equal numbers of participants in each of the study groups using the random number generator function in Excel v.14 (Microsoft). An administration assistant with no involvement in the study placed small squares of paper printed with 30 x S (to indicate Stratamed) and 30 x C (Control) into opaque envelopes numbered from 1-60 as per the random allocation sequence, these were folded in half and then sealed.

Allocation was concealed from all involved in this research including the primary investigator, assessors, surgeons, nursing staff and statisticians. The numbered envelopes were opened in order of enrolment into the study by the primary investigator.

3.2.7 Study Participants
Demographic information from all study participants was recorded into a password secure excel spreadsheet, and SPSS database by the primary investigator using information recorded in the SABU electronic medical record, BIMS (Burns information management system). Variables recorded included age, gender, TBSA, date and cause of burn, injury site, medications, past history of scarring, scar management interventions and Fitzpatrick skin type which is a rating scale used to grade a patient’s skin type based on tendency to tan or burn. Classification includes; i) always burns, never tans; ii) burns easily, tans minimally; iii) sometimes burns, tans slowly to light brown; iv) burns minimally, always tans to moderate brown; v) rarely burns, tans well and vi) never burns, deeply pigmented (121).
3.3 Outcome Measures

The primary outcome measure was time to wound healing. Secondary outcome measures included 1) scar assessment at six weeks and three months post-surgery and, 2) pain intensity scale collected at dressing changes (Table 6).

3.3.1 Wound Healing

Time to healing (TTH) is defined as the number of days until 100% wound epithelialisation and requiring no further dressing, using similar methods described by Chipp et al and Gravante (83, 123). The number of days since injury was recorded at this point.

At each dressing appointment one of two independent senior nurses both with more than 20 years of experience, assessed the face/neck burn wounds visually and provided a percentage of wound area epithelialised for each donor site. Visual assessment of superficial wound injury is the most common method for diagnosis and determinant of wound healing (124). The percentage of wound healed was recorded at each appointment until fully healed, which was deemed and recorded as the TTH. Both assessors were senior nurse consultants and were blinded to the wound treatment dressing allocation and were not involved in any treatment of the subject’s wounds.

Clinical photography was completed at enrolment and subsequent dressing appointments for case documentation and to monitor wound healing between appointments (24), using a digital camera and the same lighting to ensure images were consistent.

3.3.2 Scar Outcomes

The time it takes for a wound to heal is predictive of scar outcome (34, 85), therefore the site which took the longest to heal was recorded and chosen as the site to monitor for scar progression. The anatomical recording chart in combination with clinical photography was used to relocate the same testing site for scar assessments at six weeks and three months post-burn injury (Figure 14).
Three scar outcome measures were completed by three experienced senior Occupational Therapists each with an average of three years’ experience in using the mVSS in burns; were not involved in the study; blinded to the treatment allocation group and were not involved in data analysis. Clinicians received training from an experienced Senior clinician on the application of the Dermalab Combo. Lower scores in all scar assessment tools indicate a better scar outcome.

1. The modified Vancouver Scar Scale (mVSS) (Appendix 7).

2. The Dermalab Combo records measures on vascularity and pigmentation.

3. The Patient and Observer Scar Assessment Scale (POSAS); patient component was provided to participants to complete at their appointments (Appendix 8).

The mVSS is a rating index commonly used by clinicians to subjectively assess and score scarring on four parameters which includes pigmentation, vascularity, pliability and height with a total score out of 15 (86). Analysis was completed on the aggregated total mVSS score, and separate pigmentation and vascularity scores.

Hyperpigmentation is commonly associated with superficial burn injury due to the increased activity of melanocytes and deposition of melanin (16, 125) (79, 126). Abnormal colour or dyspigmentation is a common complaint that can have cosmetic and psychosocial implications for those affected by visible scar characteristics such as these (126). It is therefore important to include pigmentation in scar assessment. Whilst the visual assessment of pigmentation is incorporated within many scar scales, it is a subjective evaluation that can result in conflicting opinions and demonstrate the ambiguity of hyper and hypopigmentation. Pigmentation is affected by skin colour and there is no easy way to measure it (79, 126).

In the pigmentation category of the mVSS, normal denoted with the lowest score (value = 0), and a hyperpigmented scar assessed as a higher score (value = 3). For the purpose of this study hyperpigmentation was defined as a worse outcome because of the predominance of lighter skin people in this sample and as demonstrated historically in the WA burns population. Further, for the purpose of this study a hyperpigmented scar (value = 3) was defined as a poorer outcome than hypopigmentation (value = 1). Although the pigmentation assessment domain is not
ordinal, defining the assessment of pigmentation as above results in an interpretable and analyzable mVSS aggregated total score, in the context of the WA burn sample in these studies. This approach is in line with the methods used by previous researchers and clinicians where higher total scores indicate a poorer scar outcome (74, 127, 129).

Ideal scar assessment should include a combination of subjective and objective tools (79, 126). The Dermalab Combo® (Cortex Technologies, Denmark) is a commercially available testing device that uses a spectro photometry probe held on the skin to take objective readings for levels of pigmentation and erythema (vascularity). The dermalab is an objective tool that has successfully been used in burns scar assessment of pigmentation and vascularity previously. Lower readings indicate lower amounts of pigmentation and vascularity (140).

The POSAS patient component is a self-reported severity rating scale that includes six numerical scales from 0-10 upon which the participant rates physical aspects of their scar including pain and itch. The separate seventh question asks participants to rate their overall opinion of their scar in comparison to their unaffected skin. A higher score indicates greater dissatisfaction (132, 133). Analysis was completed on the total score and separate scores for colour and overall opinion. The Patient and Observer Scar Assessment (POSAS) tool was recommended as the preferred scar rating survey by an international scar advisory panel (91, 131). The POSAS has an observer component that is completed by the clinician and a component that is completed by the patient. It is the most commonly used scar assessment for patient-evaluation, and the only patient reported scale that measures scar quality (80).

Figure 14. Anatomical face chart
3.3.3 Pain Outcomes

Patient pain symptoms were measured using a visual pain intensity scale (0cm to 10cm) with 0 being ‘no pain’ and 10, ‘worst pain imaginable’ (40, 134). The pain intensity scale is commonly used in the subjective assessment of pain (135, 136) that is simple, quick and easy to apply (40). Pain measures were completed immediately before and after dressing changes at timepoint two, the first follow-up visit after recruitment into the study. Following return to the clinic after commencement of the treatment. Analgesics were recorded at the same time.

Table 6. Schedule for outcome measure collection during the study.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Day 2-5</th>
<th>Day 5-7</th>
<th>Day 7-10</th>
<th>Day 10-14</th>
<th>6 weeks</th>
<th>3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Wound healed</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Dermalab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mVSS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POSAS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain intensity scale</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

mVSS, modified Vancouver Scar Scale; POSAS, Patient and Observer Scar Assessment Scale

3.4 Data storage and Privacy Management

To protect the confidentiality of participant information, the primary investigator provided a numerical identifier for all questionnaires and outcome measures. The master document linking participant names and their numerical identifier was kept on a password protected computer at the State Adult Burns Unit of WA and was not taken off site electronically or manually. Only the primary investigator had the password for the electronic copy.

Hard copies of questionnaires were stored in a locked cabinet in the SABU, FSH. Data is archived at FSH for seven years in a secured area within the Health Institute of Research as req required by National Australian guidelines.

Findings will be disseminated to participants via information posted onto the Fiona Wood Foundation Website and through the Fiona Wood Foundation newsletter.

3.5 Statistical Analysis

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, Kaplan-Meier analysis of TTH, and Mann-Whitney U tests for all scar outcomes, and pain and analgesics were performed in order to compare the two treatment groups, and as per protocol. To investigate potential bias, Chi-square analysis, Mann-Whitney tests and, because the sample size was small, Fisher’s exact test were used to compare characteristics of patients that did not complete the trial, and between the intervention and control groups.

3.6 Results

3.6.1 Patient Demographic and Clinical Data
Between December 2018 - December 2020, 121 patients were admitted to the burns unit with a face burn. Of these, 55 patients were eligible for the study. During screening, 66 patients were excluded from the study: six declined to participate, 11 patients were excluded as their burn had already healed when they first presented, 15 were excluded as their burn did not breach the epithelium (erythema only), 13 had deep burns that required physical dressings, and 21 were unable to return for follow-up appointments including regional patients, overseas patients and those treated with self-management plan. Ambulatory patients were reduced due to COVID19 restrictions and the study was unable to recruit the total sample of 60 participants.

The final sample size consisted of 55 participants, (intervention group, n = 26; control group, n = 29). Individuals who entered the study but were lost to follow up prior to wound healing were censored in the Kaplan-Meier survival analysis. Twelve patients did not complete the trial and were excluded from the final Mann-Whitney U test scar analyses; six participants did not attend follow up appointments (DNA), two received surgical intervention (one control and one intervention), two received physical dressings (one control and one intervention) and two experienced separate adverse events for reactions to the emollient and the chlorhexidine face wash respectively (Figure 15). The reactions were observed during a dressing change immediately following the use of emollient, and chlorhexidine face wash and included red, inflamed and painful skin according to adverse reactions outlined in the inclusion and exclusion criteria. Zero of 26 patients reacted to the silicone product. Statistical analysis of the 12 patients that did not complete the trial, showed a lower proportion of skin types II, III, IV in comparison to those that completed the trial, however this was not significant.
(p = 0.069). There were no differences in age (p = 0.111), gender (p = 0.503), TBSA (p = 0.82) and smoking status (p = 0.703).

Final wound healing analysis included 55 participants (Intervention = 26, Control = 29), pain analysis included 52 participants (Intervention = 24, Control = 28), six week scar analysis included 37 participants (Intervention = 18, Control = 19) and three month scar analysis included 16 participants (Intervention = 6, Control = 10). Analysis of the recruited cohort showed no statistical difference between the intervention and control group in age (p = 0.57), gender (p = 0.78), TBSA (p = 0.87), skin type (p = 0.47) and smoking (p = 0.76) characteristics. The demographics and participant details are reported in Table 7.
Table 7. Social and clinical demographics of participants.

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

IQR – interquartile range; TBSA – total body surface area
**Figure 15.** The CONSORT diagram showing allocation process throughout the study
3.6.2 Wound Healing

The Kaplan-Meier median estimate (and associated 95% confidence interval) demonstrated no significant difference between treatment groups (log-rank, \( P = 0.056 \)) in time to healing. The Kaplan-Meier median time to healing for the intervention group (Stratamed (\( n = 21 \)) participants) was 9 days \((C.I. = 7.6 – 10.4)\) compared to 7 days \((C.I. = 5.3 – 8.7)\) for the control group, (standard care) \(( n = 22 \)) participants, (Figure 16).

![Survival analysis for time to healing.](image)

**Figure 16.** Survival analysis for time to healing.

Time to healing ranged between four and 19 days (Intervention 4-19 days, Control 4-12 days). Figures 17 and 18 show examples of healing from each treatment group.

![Images showing treatment with Stratamed from recruitment to re-epithelialisation](image)

**Figure 17.** Images showing treatment with Stratamed from recruitment to re-epithelialisation
3.6.3 Scar Outcomes

Mann-Whitney U tests revealed a significant difference in favour of the intervention group for the total mVSS scores, and separate mVSS pigmentation scores at six weeks. There were no significant differences for all other scar outcomes including POSAS scores (Table 9).

3.6.3.1 Total mVSS Scores

A Mann-Whitney U test (and associated 95% confidence interval) at six weeks revealed a significantly lower total mVSS score in the intervention group (Md = 1, n = 18, IQR = 0 – 1.3, M = 0.83, CI = 0.37 – 1.29) compared to the control group (Md = 1, n = 18, IQR = 1-3, M = 1.83, CI = 1.1 - 2.6); U = 96.000, z = -2.18, p = 0.029.

3.6.3.2 mVSS Pigmentation

A Mann-Whitney U test (and associated 95% confidence interval) at six weeks revealed a significantly lower score in the mVSS pigmentation scores in the intervention group (n = 18), (Md = 0, IQR = 0, M = 0.22, CI = -0.5 – 0.5) compared to the control group (n = 19), (Md = 0, IQR = 0 - 3, M = 1.2, CI = 0.5 – 1.9); U = 117.500, z = -2.02, p = 0.043. Seven participants in the control group presented with hyperpigmentation compared to zero participants in the intervention group (Table 8).
Table 8. Distribution of mVSS pigmentation scores in participants

<table>
<thead>
<tr>
<th>mVSS pigmentation</th>
<th>6 Week</th>
<th>3 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-normal</td>
<td>Intervention</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>12</td>
</tr>
<tr>
<td>1-hypopigmentation</td>
<td>Intervention</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>1</td>
</tr>
<tr>
<td>2-mixed pigmentation</td>
<td>Intervention</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0</td>
</tr>
<tr>
<td>3-hyperpigmentation</td>
<td>Intervention</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>7</td>
</tr>
</tbody>
</table>

mVSS - modified Vancouver Scar Scale

At 3 months, three participants presented with hyperpigmentation (Intervention n = 1, Fitzpatrick = 5; Control n = 2, Fitzpatrick = 3 both), however, two from each group reported not using sunscreen (Figure 19). Another participant from the control group presented with a blotchy red rash, he reported he had been using epaderm cream®, (an emollient-based ointment) since ceasing the control emollient product at the point of healing. This redness subsequently resolved after he was prescribed a new face care regime that included regular face washing and a water-based sorbolene cream.

Figure 19. Images showing wound healing using Stratamed, and scar outcomes with hyperpigmentation.

3.6.3.3 Dermalab Pigmentation

A Mann-Whitney U test (and associated 95% confidence interval) revealed there was no difference in pigmentation scores at six weeks between the intervention (Md = 37, n = 14, M = 39, CI = 35 - 44) and control group (Md = 43, n = 18, M = 44, CI = 40 - 48), U = 85.000, z = -1.56, p = 0.12.

A Mann-Whitney U test (and associated 95% confidence interval) revealed no difference in Dermalab pigmentation scores at three months between the intervention
(Md = 39, n = 6, M = 41, CI = 35 - 47) and control group (Md = 41, n = 8, M = 39, CI = 32 - 46), U = 21,000, z = -0.59, p = 0.60.

### 3.6.3.4 Dermalab Vascularity

A Mann-Whitney U test (and associated 95% confidence interval) revealed no difference in vascularity scores at six weeks between the intervention (Md = 20, n = 14, M = 21, CI = 19 - 23) and control group (Md = 21, n = 18, M = 22, CI = 21 - 24), U = 95,000, z = -2.1, p = 0.24.

A Mann-Whitney U test (and associated 95% confidence interval) revealed no difference in vascularity scores at three months between the intervention (Md = 19, n = 6, M = 20, CI = 17 - 23) and control group (Md = 20, n = 8, M = 21, CI = 17 - 25), U = 24,000, z = -0.0, p = 1.

Serial images shown in Figures 20 and 21 demonstrate typical examples of intervention versus control outcomes. Not all wound healing and scarring images have been included, however images shown are representative of the healing and scar outcomes. Patient in Figure 21 did not return for three month scar outcomes.

![Figure 20](image)

**Figure 20.** Images showing treatment with Stratamed from recruitment, through wound healing to scar outcomes

80
Figure 21. Images showing treatment with emollient.
Table 9. Mann-Whitney U test of mVSS and Dermalab (weighted average percentiles).

<table>
<thead>
<tr>
<th></th>
<th>6 Week</th>
<th></th>
<th></th>
<th></th>
<th>3 Month</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int Md (IQR)</td>
<td>Ctl Md (IQR)</td>
<td>N Int/Ctl</td>
<td>z</td>
<td>p</td>
<td>Int Md (IQR)</td>
<td>Ctl Md (IQR)</td>
<td>N Int/Ctl</td>
</tr>
<tr>
<td>mVSS total</td>
<td>1 (0-1.3)</td>
<td>1 (1-3)</td>
<td>18, 18</td>
<td>-1.94</td>
<td>0.03</td>
<td>1.50 (0-3)</td>
<td>0 (0-1.5)</td>
<td>6,10</td>
</tr>
<tr>
<td>mVSS vascularity</td>
<td>0.5 (0-1)</td>
<td>1 (0-1)</td>
<td>18, 19</td>
<td>-0.034</td>
<td>0.97</td>
<td>0.5 (0-1.3)</td>
<td>0.0 (0-0.25)</td>
<td>6,10</td>
</tr>
<tr>
<td>mVSS pigmentation</td>
<td>0 (0-0)</td>
<td>0 (0-3)</td>
<td>18, 19</td>
<td>-2.02</td>
<td>0.04</td>
<td>0.0 (0-2.3)</td>
<td>0.0 (0-0.75)</td>
<td>6, 10</td>
</tr>
<tr>
<td>Dermalab vascularity</td>
<td>20 (18-24)</td>
<td>21 (19-25)</td>
<td>14, 18</td>
<td>-1.2</td>
<td>0.24</td>
<td>19 (18-23)</td>
<td>20 (17-24)</td>
<td>6, 8</td>
</tr>
<tr>
<td>Dermalab pigmentation</td>
<td>37 (34-46)</td>
<td>43 (37-47)</td>
<td>14, 18</td>
<td>-1.56</td>
<td>0.12</td>
<td>39 (38-43)</td>
<td>41 (36-45)</td>
<td>6, 8</td>
</tr>
<tr>
<td>POSAS total</td>
<td>8 (6-15)</td>
<td>9 (7-12)</td>
<td>14, 16</td>
<td>-0.2</td>
<td>0.8</td>
<td>8.5 (6-10.3)</td>
<td>9 (6-10)</td>
<td>6, 7</td>
</tr>
<tr>
<td>POSAS colour</td>
<td>2 (1-6)</td>
<td>3 (1-5)</td>
<td>14, 16</td>
<td>-0.166</td>
<td>0.86</td>
<td>2 (1-3.25)</td>
<td>1 (1-4)</td>
<td>6, 7</td>
</tr>
<tr>
<td>POSAS overall opinion</td>
<td>2 (1.8-5.5)</td>
<td>2 (1-2.8)</td>
<td>12, 11</td>
<td>-0.3</td>
<td>0.8</td>
<td>2 (1-2.3)</td>
<td>1.5 (1-5)</td>
<td>6, 7</td>
</tr>
</tbody>
</table>

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.
3.6.4 Pain Outcomes

An analysis of pain experienced by all participants after receiving the first application of treatment at the point of enrolment was completed. A Mann-Whitney U test (and associated 95% confidence interval) revealed there was no significant difference in pain between the intervention group (Md = 1.15, n = 24, IQR 0.3 – 4.5 weighted average, Mn = 2.2, CI = 1.2-3.1) and the control group (Md = 1.5, n = 28, IQR 0.6 – 3.8 weighted average, Mn = 2.4, CI = 1.5-3.3). z = -0.63, p = 0.53.

Twenty-seven (27) participants were taking analgesics at the first application of treatment (Intervention = 12, Control = 15), and 14 participants reported they were not taking analgesics (Intervention = 6, Control = 8). Median pain scores were higher in those taking analgesics than those without, and higher in the intervention group compared to the control group, these results were not statistically different (Figure 22). The type of analgesic was recorded in 18 participants; 12 participants were taking opioid-based medications (intervention n = 6, control n = 6), and six participants were taking common pain killers such as paracetamol (intervention n = 4, control n = 2). A chi-square analysis showed no evidence of statistical difference between the intervention and control groups in their analgesic ingestion behaviours (p = 0.499).

A Mann-Whitney U test revealed no significant difference in pain for those taking analgesics between the intervention group (Md = 3.6, n = 12, IQR = 0.4 – 4.9 weighted average) and control group (Md = 1.8, n = 15, IQR 1 – 5.5 weighted average), z = -0.3, p = .8. Types of analgesics were similarly represented in both groups. There was no significant different in pain for those not taking analgesics between the intervention group (Md = 1.2, n = 6, IQR = .0 – 2.5) and control group (Md = 1.2, n = 8, IQR = 0.5 – 3.8), z = -0.6, p = 0.6.

A second analysis on pain both before and after dressing was completed at timepoint two, the first dressing change appointment subsequent to enrolment (between two and five days after commencing treatment). A Mann-Whitney U test (and associated 95% confidence interval) revealed
there was no significant difference in pain scores before face washing between the intervention (Md = 0.4, n = 13, M = 0.96, CI = 0.03 – 1.92) and the control group (Md = 0.7, n = 10, M = 1.4, CI = 0.11 – 2.8), z = -0.62 p = 0.53. Similarly, there was no significant difference in pain scores after face washing and reapplication between the intervention (Md = 0.6, n = 12, M = 1.2, CI = 0.07 – 2.4) and the control group (Md = 0.3, n = 10, M = 0.96, CI = -0.001 – 1.9), z = -0.6, p = 0.55.

Figure 22. Box graph showing mean pain scores and standard deviation for analgesics at timepoint 1.

3.7 Discussion

This study found no evidence that the topical silicone gel, Stratamed, was associated with faster wound healing compared to routine care (emollient). This outcome is contrary to earlier published reports citing improved wound healing rates (62, 92, 102, 105-107, 111, 141, 142) and improved pain and itch symptoms (92). However, this face and neck burn study did demonstrate a significant reduction in mVSS total score and pigmentation score at six weeks after burn.
Whilst these earlier studies have reported clinical benefits of silicone-based treatments in wound healing, closer examination of their methodology raised some concerns about the findings. Many of the earlier studies did not utilise a RCT design, validated objective tools, and standardised wounds \((102, 106, 111, 112)\), utilised very small sample size or reviewed case studies only \((102, 106, 112)\). One study \((n = 231)\) utilised a RCT design with similar between-subjects design to explore the effects of Stratamed in cutaneous surgical wounds \((141)\). Significant improvements in assessor-rated wound healing properties were demonstrated, however, wound healing was not measured objectively, instead, assessors subjectively rated the quality of wound healing as ‘better’ or ‘worse’. Furthermore, these studies explored silicone treatment in a very different wound context compared to burn wounds. There remains a paucity of evidence in the literature of topical silicone being tested in burn wounds. Recently, Luccatelli et al (2021) used a within subject design \((n = 12)\) to compare Stratamed (with secondary vaseline gauze dressing) with conventional dressings including silver dressings, collagenases and alginites in mid-deep and deep burn wounds \((143)\). Wound washing and dressing changes were completed every 48 hours. Tissue cultures showed no common pathogens. Percentage of epithelialisation showed mean days to 95% re-epithelialisation in Stratamed group were 5.4 days and 12.5 days in the conventional group. Although the case series numbers were small and no other statistical analysis was reported, the comparison of wounds using within-subject design and showing greater rate of healing for Stratamed is promising.

Considering studies that explored scar outcomes also have major design flaws \((144-147)\). To the best of the authors knowledge there are few RCT studies that explore the use of these two silicones in healing burn wounds, however there are studies that have looked at topical silicone in surgically healed wounds \((144-147)\). In this setting, topical silicone was reported to have some improvements in the secondary outcomes of scarring and pigmentation \((144-147)\). Some of these studies use similar tools and design \((144-146, 148)\), so it appears that this study extends the previous findings in scar outcomes in surgical wounds to include burn wounds.
A clinically important finding of this study was a significant reduction in the level of pigmentation in using silicone-based products. This is particularly important in face burns which are visible and have implications in psychological well-being, function, communication and social interactions (66). Possible mechanisms can be contributed to the anti-inflammatory and antimicrobial properties of Stratamed. Cutaneous injury carries a risk of abnormal pigmentation within resulting scars (63). 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 (63). Whilst this study did not demonstrate a significance on wound healing times, the anti-inflammatory and antimicrobial properties of Stratamed may contribute to improved scar outcomes (112, 141). Infection was not an issue for either group, and it is likely that the routine practice protocol of washing face/neck wounds three times daily contributed to this.

There were limitations within the current study including small sample numbers and a lack of validated tools, however visual wound inspection and clinical outcome of TTH with dressing cessation is routinely used and has been shown to be reliable in other studies (26, 83, 90, 123). Similarly, the pain intensity scale (40, 41, 135, 136, 149), POSAS and the mVSS are widely used in burns (83, 84, 86). Whilst results showing reduced pigmentation are promising, the significance was in a subjective evaluation using an objective evaluation tool, to confirm or deny if this clinically relevant result is in line with other studies. For instance, Finlay et al used the aggregated mVSS score in a large sample of 295 burns patients to demonstrate a significant association between TTH and scar outcomes (74). This study utilised three scar assessors to complete the mVSS, and whilst the mVSS has been shown to be unreliable by a single evaluator, Lee et al demonstrated improved reliability when performed by at least three assessors (150). An earlier study by Nedelec et al found the mVSS intrarater reliability was acceptable for normal scars, defined as dermal wounds that healed without needing scar treatment (151), and is similar for the wound types explored in this study. Larger studies are warranted.
3.8 Conclusion

This study did not find evidence of differences in healing times in superficial facial and neck burn wounds between standard care or use of Stratamed. However, film-forming silicone dressings were demonstrated to be associated with a reduction in the level of hyperpigmentation at six weeks after burn and was not associated with any adverse effects.
Chapter 4:

Discussion
4.1 Discussion and Future Directions

The aim of this thesis was to explore the efficacy of topical silicone film-forming dressings in comparison to standard care. Neither of the two separate studies conducted, one in donor site wounds, and the other, in SPT burns of the face and neck observed a difference in the primary study outcome of time to healing.

While the studies undertaken in this thesis did not identify any changes in wound healing rates, it seems to be that silicone films may have prolonged the time to complete healing but there may be a counteracting benefit in decreased inflammation and scar pigment outcomes. The study involving Stratamed on facial burn wounds observed reduced hyperpigmentation at six weeks. This promising observation suggests a possible benefit of topical silicone introduced onto acute wounds, on scar outcomes when used as a wound dressing. However, the significance was in a subjective evaluation in an underpowered study, and there was no observed difference in objective evaluation. This finding warrants further research using a larger sample size with objective evaluation to determine if results can be generalised to a bigger sample and demonstrate clinically meaningful outcomes. 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 (63). The literature reports on how visibility of a pigmented scar can cause significant distress to patients (63). Earlier scar prevention initiated in the wound healing phase has important implications for the outcomes of face and neck burns. Further research testing topical silicone as a wound dressing is needed to bolster the results of this study.

Neither the donor or face/neck burn studies identified any decrease in wound pain during dressing changes using silicone-based products compared to standard practice. While this may have been due to the need to have greater statistical power, it should be noted, that pain levels and infection rates were also not reported as being worse.

To date, there are few RCTs on the effects of topical silicone gel in wound healing, and particularly within the burn wound context. Whilst the present
studies did not demonstrate superiority of topical silicone over standard care in promoting faster wound healing, very recent publications have demonstrated the efficacy of StrataXRT when used as a topical treatment for acute radiation dermatitis (RD) (114, 119). These two recent studies used a between-subjects design to demonstrate differences in skin condition between that of StrataXRT and moisturiser. Similar to donor site wounds and SPT face/neck burn wounds, symptoms of RD include oedema, erythema, hyperpigmentation and most notably pain (119). In a RCT (n = 49) Ahn (2020) demonstrated lower erythema and pigmentation in women with breast cancer and in a larger RCT (n = 197), Chan (2019) reported on reduced severity of symptoms of RD (skin toxicity) in participants with head and neck cancer following radiation (114, 119). A positive comparison with Ahn’s study is the face study also observed reduced pigmentation following the use of topical silicone in wound healing. There is a paucity of research investigating topical silicone in burn wounds, however, Luccatelli et al (2021) recently used a within subject design (n = 12) to compare Stratamed with conventional dressings in mid-deep and deep burn wounds, and observed faster epithelialisation in the wounds treated with Sratamed. Whilst this result was not reported as statistically significant it is a promising outcome (143).

Studies described in this thesis sought to minimise study limitations via robust methodology that included randomisation, double-blinding of assessors and participants, and reliable and validated outcome measures. It is possible, however, that the small sample size made it difficult to detect any improvement in the healing rates between the treatment groups. It is possible the magnitude of response that was assumed in preliminary sample size estimation was optimistic. Despite outcomes from the present thesis studies and findings reported in others (111, 141, 143), design and methodological issues to date mean further studies need to be undertaken to determine whether silicone-based treatments in burn wounds play a beneficial role. In reflecting on the donor study, possible alternative research approaches could include between-subjects design, pragmatic design and adjustment of outcome end-points.
Neither the donor nor face/neck burn studies identified any decrease in wound pain during dressing changes using silicone-based products compared to standard practice. While this may have been due to the need to have greater statistical power, it should be noted, that pain levels and infection rates were also not reported as being worse. While the within-group study designed used for the donor study caused a problem measuring pain, that appears to have been circumvented in studies that utilised a between group study design, (48, 50, 152, 153), it should be noted that this experimental design can also introduce other possible biases due to differences in age, gender and skin type (122).

The high number of dressing protocol breaches impacted on sample size in the donor study. In these cases, algisite was replaced by mepilex ® lite, a soft silicone foam dressing as a protective dressing in the final stages of wound care. It is important to note that these protocol breaches largely occurred at ≥ 95% healed (n = 8). Given the significant amount of clinically appropriate protocol breaches that occurred at this particular timepoint, perhaps using a pragmatic research design with the wound healing endpoint adjusted to 95% healed (26) would reduce the impact on the sample size. Future studies of a pragmatic design may reduce protocol breaches, and improve the final sample analysis size (46).

Although not the focus of this study, other studies have reported on the hydrating benefits of a silicone based mepilex ® dressing in RD and in reducing pain during dressing removal (154-157). Observations from this study include a more hydrated intervention site in comparison to the control (Figure 9). Future studies investigating the combination of Mepilex Lite and StrataXRT may be of benefit.

4.2 Implications of Pigmentation Findings

The result demonstrating reduced pigmentation in patients receiving Stratamed for face burns is a positive outcome for those patients with increased risk of hyperpigmentation. Pigment is a significant issue in exposed skin areas and, therefore, the treatment is worthy of consideration. Larger multi-centre trials using objective pigmentation measures are
needed to bolster this result. Future outcomes may have the following implications for clinical practice:

- Provide early intervention for patients at increased risk of hyperpigmentation, particularly those with Fitzpatrick skin type 3-5.
- Burns clinicians can use best practice for prevention of hyperpigmentation, provide additional information, and confidently counsel and reassure patients with face burns.
- Incorporate in to clinical guidelines best practice for the management of patients with increased risk of hyperpigmentation post burns.
- Findings are applicable to other clinical areas in similar wound types such as plastics, orthopaedics and gynaecology.
- Adds to the body of evidence and points to future research avenues.

4.3 Strengths and Limitations

Burn care and assessment was completed by experts in the field. Findings are applicable to the wider Australian setting.

Another significant strength is the research methodology used a robust design model that included randomisation, standardised wounds (donors), double-blinding, reliable and validated tools. The benefits of this include:

- Observer bias is reduced in both studies with randomisation and double-blinding of participants and assessors. Furthermore, assessors had significant clinical expertise and experience in wound evaluation, and the use of scar assessment tools.
- Assessment of wound healing, pain and scar outcomes was performed using reliable outcome tools that were cost and time efficient to apply, and did not burden the patient. Scarring outcomes were further bolstered with objective measures using the validated Dermalab tool.
- Donor site wounds are a standardised depth of wound that was further strengthened by the within-patient design as wound characteristics and depth were the same for the intervention and control sites.
• Improved reliability of results as observed by repeated scar measures on the same testing site for the six week and three month timepoints.

The study does, however, also have some limitations:

• It was not feasible to complete a definitive trial within the time constraints, therefore this study relied on smaller samples. Analysis indicted a pilot trial was feasible and a sample size of 30 participants in each treatment group for both studies was planned. Future studies with a larger sample size will have more power to detect a difference in treatment.

• The sample population was recruited from a single centre site. Well designed multi-site studies have the potential to provide higher quality evidence.

• Face and neck burn wounds did not use a standardised wound type. Wounds were heterogenous in nature and varied in terms of wound size and shape.

• Whilst subjective assessment of wound healing is widely used in clinical practice, future research could include validated wound measuring tools such as the Visitrak (wound tracing) and photographs with computer software to measure wound surface area.

• StrataXRT was applied underneath a secondary dressing in the donor study, and not as a stand-alone film-forming dressing. It is possible that the secondary algisite dressing may have diminished the impact of StrataXRT in wound healing.

4.4 Future Avenues for Research

Burn researchers and clinicians are focussed on improving methods for wound healing, whilst reducing pain and scarring. Accelerated wound healing can reduce the risk of poor scar outcomes and associated distress for patients. Similarly acute wound pain experienced during dressing changes can also cause distress for patients and impact on wound healing, thus further prolonging treatment and associated costs.
A review of the literature reveals there is paucity of evidence on the efficacy of topical silicone Stratamed in burn wound care, and associated pain and scarring. StrataXRT has been mentioned in the discussion on its benefits in radiation dermatitis, and Stratamed was shown to accelerate donor site healing in a recent study (143). The result of the face study showed differences in pigmentation at six weeks which is promising. Based on the outcomes of this study, further research on these topical silicones and their benefits in burn wound healing is recommended:

- Between-subjects design to explore efficacy of StrataXRT in pain outcomes for donor site wounds.
- Efficacy of Stratamed on vascularity and pigmentation outcomes in skin grafts and burn wounds. One might hypothesise that topical silicone when used during wound healing reduces the risk of hyperpigmentation.
- Exploration study on the benefits of Stratamed dressing when used post-laser treatment.
- Cost benefit and efficacy of donor site wound dressings using topical silicone and mepilex lite using a pragmatic research design.

4.5 Conclusion

These studies did not identify evidence of accelerated wound healing with the use of silicone film-forming dressings or reduction in dressing pain. However, there was improved scar outcomes through the use of silicone-based treatments compared to conventional treatments. While some earlier studies suggested these products may have beneficial effects, closer examination of earlier studies did raise a number of design and methodological concerns about their conclusions. As the current studies undertaken in this thesis also experienced a number of challenges, the lack of observed benefit with silicone products still requires further investigation with larger scale studies. While this may reveal improved wound healing rates, the reduction in skin pigmentation observed in the face and neck burn study of this thesis warrants further investigation.
References

23. Fletcher J. How can I accurately measure a wound and how often should I do it? Nursing times. 2011;107(4):15.
97
62. Priyadarshi A, Marceau J. Aqueous 0.5% Chlorhexidine Induced Chemical Spillage Burns: Use of a Novel Flexible Silicone Dressing Gel2015.
113. Chan KYMRCSE, Lau CLBSP, Adeeb SMMS, Somasundaram SFRCS, Nasir-Zahari MFRCS. A Randomized, Placebo-Controlled, Double-Blind,


Appendix 1: Human Research Ethics Approvals

South Metropolitan Health Service Human Research Ethics Committee
Perkins South Building (Level 3), Fiona Stanley Hospital
11 Robin Warren Drive, Murdoch WA 6150

23 August 2017

Mrs Rosemary Kendall
Level 4, 11 Robin Warren Drive
MURDOCH WA 6150

Dear Mrs Kendall

PRN: RGS0000000027

Project Title: The efficacy of silicone-film forming dressing versus standard care for the treatment of acute burn injuries not requiring surgery, and donor sites

Thank you for submitting the above research project for ethical review. This project was considered by the South Metropolitan Health Service Human Research Ethics Committee at its meeting held on 11 April 2017.

I am pleased to advise you that the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and ethical approval for this research project has been granted by the South Metropolitan Health Service Human Research Ethics Committee.

The nominated participating site in this project is:

- Fiona Stanley Hospital

[Note: If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the Human Research Ethics Committee (HREC). Notification of withdrawn sites should also be provided to the HREC in a timely fashion.]

The approved documents include:

- Participant Information Consent Form 1, version 2.0, dated 16 May 2017
- Participant Information Consent Form 2, version 2.0, dated 16 May 2017
- Strata Protocol, version 2.0, dated 19 May 2017
Ethical approval of this project from South Metropolitan Health Service Human Research Ethics Committee covers use of the data for this project only and is valid from 16 August 2017 to 16 August 2020 subject to compliance with the 'Conditions of Ethics Approval for a Research Project' (Appendix A). If you wish to use the data for other research purposes in the future, this will require a separate ethics application.

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate site authorisation has been obtained from the Chief Executive or Delegate of the site under whose auspices the research will be conducted at that site.

Should you have any queries about the South Metropolitan Health Service Human Research Ethics Committee’s consideration of your project, please contact the Ethics Office at SMHS.HREC@health.wa.gov.au or on 08 6151 1100. The HREC’s Terms of Reference, Standard Operating Procedures and membership are available from the Ethics Office or from http://www.health.wa.gov.au/About-us/South-Metropolitan-Health-Service/About/Human-Research-Ethics-and-Governance.

The SMHS Human Research Ethics Committee wishes you every success in your research.

Yours sincerely

MR RICHARD WOJNAR HORTON
Chairman | South Metropolitan Health Service Human Research Ethics Committee

CC: Fiona Poelchow, Fiona Wood
Q October 2018

Professor Jim Codde & Ms Fiona Poetschow
School of Physiotherapy
The University of Notre Dame Australia
Fremantle Campus

Dear Jim and Fiona,

Reference Number: 018121F

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

Your response to the conditions imposed by the University of Notre Dame Human Research Ethics Committee (HRREC) has been reviewed in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated 2018). I am pleased to advise that ethics approval has been granted for this proposed study.

Other researchers identified as working on this project are:

<table>
<thead>
<tr>
<th>Name</th>
<th>School/Centre</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Dave Edgar</td>
<td>School of Physiotherapy</td>
<td>Co-Supervisor</td>
</tr>
<tr>
<td>Rosemary Kendal</td>
<td>Fiona Stanley Hospital</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Prof Fiona Wood</td>
<td>Fiona Stanley Hospital</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Sharon Rowe</td>
<td>Fiona Stanley Hospital</td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Levinita Egan</td>
<td>Fiona Stanley Hospital</td>
<td>Co-Investigator</td>
</tr>
</tbody>
</table>

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with your study.

Yours sincerely,

[Signature]
Dr Natalie Giles
Research Ethics Officer
Research Office
Appendix 2: 2020 Spinnaker Research Grant

Acceptance of Offer of a 2020 Spinnaker Grant

Research Title: A study of the effects of a silicone-based topical dressing on the rate of wound healing, pain and scarring outcomes in donor site wounds, and in burns to the face in comparison to standard care.

All Chief Investigators: Mrs Fiona Poolschow, Mrs Rosemary Kendall.

Mentors: Prof Jim Cadle & A/Prof Dale Edgar

Certification by Chief Investigator: Mrs Fiona Poolschow

I accept the offer of a Spinnaker Grant of $12,471 for the calendar year 2020.

I agree that:

- I am responsible for lodging my Ethics application/s to the relevant Committee/s by no later than 23 February 2020. Failure to do so will result in the withdrawal of all funds by the Spinnaker Health Research Foundation. The Foundation understands that actual approval might be obtained at a later stage, and the last possible date for Ethics and Governance approval is June 30 2020.
  - Requests for extensions must be submitted prior to the specified milestone dates or the grant will be suspended, subject to appeal. This includes: lodgement of approval, submission of milestone reports, budget acquittal and the raising of scheduled invoices.
  - All requests for extension are subject to completion of the corresponding form available on request from the Foundation and submitted by the Chief Investigator or the delegated authority for the grant.
  - Extensions are granted by the Spinnaker Chief Executive Officer (CEO) and subject to advice from the Chair of the Scientific Advisory Committee (SAC) where deemed necessary by the CEO.
  - Appeals are to be submitted in writing within 2 weeks of notification of a suspended grant and will be considered by the Spinnaker CEO and Chair SAC.
  - All appeal and extension outcomes are considered final.

- I will submit evidence of all relevant Ethics and Governance approvals to the Foundation before any funds can be released.
- I will liaise with the relevant business manager of my organisation as soon as possible to set up the required research fund account and ensure the Foundation is invoiced in two equal instalments including GST within 8 months of each other.
- To obtain the second instalment of the grant, I will provide an interim progress report to the Foundation which will be due on or before the date that is exactly 6 months from the payment of the first instalment.
- The grant funds will be used solely for the approved purposes of this research project and I will ensure appropriate accounting standards are maintained. (Please note: under no circumstances will additional funds be granted by the Foundation to cover cost overruns – this is the responsibility of the Chief Investigator.)

- The research project will be completed by June 30 2021. If extenuating circumstances prevent completion of the project, I will seek written permission for an extension which I understand will need to be approved by the Foundation at its sole discretion.

- I will submit a lay and scientific final report of 250 – 500 words each and project related photographs if possible on completion of the research. I accept for such material being used by the Foundation for its communication and fundraising activities.

- I will provide all information relevant to the Foundation in relation to further funds achieved for the project funded, including extension of the project, as well as all publications and use of research.

- I will make myself available if possible to meet donors and supporters of the Foundation and provide a presentation or similar should such an opportunity emerge. Details of such possible activities are to be discussed and mutually agreed upon.

- I will provide a reconciliation of expenditure on completion of the project. Any unspent funds will be returned to the Foundation.

SPINNAKER HEALTH RESEARCH FOUNDATION
Appendix 3: Fiona Wood Foundation Small Grant

17 March 2020

Mrs Fiona Pooler
Fiona Stanley Hospital

By email Fiona.pooler@health.wa.gov.au

Dear Fiona,

On behalf of the Board of the Fiona Wood Foundation (FWF), I am pleased to inform you that your application for funding has been partially approved.

Your submitted project funding is to “Update & inform re evidence based protocol for management of patients with face burns in relation to silicon based gels with the view of improving patient outcomes & minimising hospital costs”.

The maximum amount to be awarded:

2020 - $8,537

The conditions of the award include:-

1. Provision of evidence of Masters enrolment.
2. Signed acceptance of the Grant Conditions, including:-
   - Submission of an interim report to FWF (against your prescribed timelines/milestones) each year of award;
   - Submission of a final report on completion, including financial acquittal;
   - Requirement to participate in and contribute to FWF events, activities & communications, including presenting at Research Updates to donors/stakeholders; FWF newsletter, website and social media content and other activities of the Foundation.

Congratulations on your award and we look forward to hearing your progress.

Yours sincerely

Diana Liu
Fundraising and Relationships Manager

Fiona Stanley Hospital, CCD/5, Level 6, Burns Unit, 11 Robin Walker Drive, Murdoch WA 6150
P: +61 18 8102 2022 E: info@fionawoodfoundation.com www.fionawoodfoundation.com.au ABN 09 063 192 363
Appendix 4: Poster delivered at the Australian and New Zealand Burns Association Annual Conference 2019

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

**Methodology**

**Data Collection**

- **Site:** Burns Unit, Fiona Stanley Hospital, Perth, Western Australia
- **Participants:** 10 participants
- **Randomisation:** Randomised into 2 groups: Intervention and Control
- **Intervention:** Silicone-based film-forming wound dressing
- **Control:** Standard occlusive dressing

**Intervention Patient**

- **Initial:** Immediately after burn injury
- **3 months:** Post-intervention
- **6 months:** Follow-up

**Conclusion**

The study demonstrated that the silicone-based film-forming wound dressing significantly reduced scar outcome compared to the control group. Further research is needed to confirm these findings.
### Appendix 5: Statement of Contribution of Others

<table>
<thead>
<tr>
<th>Name</th>
<th>Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jim Codde</td>
<td>Primary supervisor for research undertaken by Fiona Poelchow. Development and review of study design, data analysis, statistical analysis, multiple iterations of manuscript.</td>
</tr>
<tr>
<td>Dale Edgar, Fiona Wood and Rosemary Kendell</td>
<td>Co-supervisors for research undertaken by Fiona Poelchow. Review of study design, data analysis, statistical analysis, multiple iterations of manuscript and conference presentation.</td>
</tr>
<tr>
<td>Sharon Rowe, Leviniea Egan</td>
<td>Senior nurse clinicians of the SABU whom completed all blinded wound assessment for this research.</td>
</tr>
<tr>
<td>Ashlee Cardey, Tyler Murphy and Laura Halim</td>
<td>Occupational Therapists of the SABU whom assisted with blinded scar assessments and data collection.</td>
</tr>
</tbody>
</table>
Appendix 6: Fiona Stanley Hospital Burns Unit Infographic

(Reproduced with permission from Fiona Wood, SABU of WA, FSH)
# Appendix 7: Modified Vancouver Scar Scale

![Vancouver Scar Scale Table]

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**PIGMENTATION**
- 0: normal
- 1: hypopigmentation
- 2: mixed pigmentation
- 3: hyperpigmentation

**VASCULARITY**
- 0: normal
- 1: pink
- 2: red
- 3: purple

**PLIABILITY**
- 0: normal
- 1: supple – flexible with minimal resistance
- 2: yielding – giving way to pressure
- 3: firm – inflexible, not easily moved, resistant to manual pressure
- 4: binding - rope-like tissue that blanches with extension of scar
- 5: contracture – permanent shortening of scar producing deformity or distortion

**HEIGHT**
- 0: normal – flat
- 1: > 0 to 1 mm
- 2: > 1 to 2 mm
- 3: > 2 to 4 mm
- 4: > 4 mm
# Appendix 8: POSAS Patient Scale

## POSAS Patient scale

The Patient and Observer Scar Assessment Scale V2.0 / EN

<table>
<thead>
<tr>
<th>Date of examination</th>
<th>Name of patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observer:</td>
<td></td>
</tr>
<tr>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>Research / study:</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of birth</th>
<th>Identification number</th>
</tr>
</thead>
</table>

### Scoring System

- 1 = no, not at all
- 10 = yes, very much

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the scar been painful the past few weeks?</td>
<td></td>
</tr>
<tr>
<td>Has the scar been itching the past few weeks?</td>
<td></td>
</tr>
<tr>
<td>Is the scar color different from the color of your normal skin as present?</td>
<td></td>
</tr>
<tr>
<td>Is the stiffness of the scar different from your normal skin as present?</td>
<td></td>
</tr>
<tr>
<td>Is the thickness of the scar different from your normal skin as present?</td>
<td></td>
</tr>
<tr>
<td>Is the scar more irregular than your normal skin at present?</td>
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</tr>
</tbody>
</table>

### Overall Opinion

<table>
<thead>
<tr>
<th>Your overall opinion of the scar compared to normal skin?</th>
<th>Score</th>
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<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>