

NON-HEALING BURN WOUND TREATMENT WITH A STERILE SILICONE GEL

TRAITEMENT DES BRÛLURES TRAÎNANTES PAR GEL DE SILICONE STÉRILE

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SUMMARY. Treatment of burn wounds can be complicated due to fluid and electrolyte loss and the increased chance of infectious complications. Silicone-based products have become increasingly used for non-healing wound treatment, but no study has specifically addressed its potential on burn patients. The purpose of this study was to compare the use of sterile silicone gel with conventional medication in improving the healing of burn wounds. Between November 2019 and March 2020, 12 patients with mid-deep and deep burn wounds were included in the present study (average TBSA approximately 29%, range 13-51%). Patient average age was 49 years (range 29-67 years), 7 were male. In each patient two clinically similar areas were identified and treated every 48 hours with topical application of silicone gel in the form of Stratamed® (Group 1) and conventional medication (Group 2). All the cases healed without requiring skin grafting. No secondary wound infection nor allergic reactions were found. The mean days from commencing the treatment to 95% re-epithelialization in Groups 1 and 2 were 5.4 and 12.5, respectively. Culture samples were negative for common pathogens. Silicone gel has shown to be particularly effective in speeding up the re-epithelialization process. The protective film formed by the silicone helps to reduce possible infectious complications. Finally, silicone gel is easy to apply and associated with greater pain control during medication.

Keywords: silicone, non-healing, burns, dressing, secondary intention

RÉSUMÉ. La cicatrisation des brûlures peut être obérée par les pertes hydro- électrolytiques et les infections. Les produits à base de silicone sont de plus en plus utilisés dans le traitement des brûlures d'évolution torpide mais n'ont pas été évalués. Cette étude compare un gel de silicone stérile à un traitement conventionnel dans cette indication. Douze patients avec des brûlures intermédiaires et profondes ont été inclus dans cette étude, qui s'est déroulée entre novembre 2019 et mars 2020. Ils étaient brûlés sur 29% SCT (13 à 51%), avaient 49 ans et 7 étaient des hommes. Deux zones comparables étaient traitées l'une par silicone (Statamed®, groupe 1), l'autre par traitement conventionnel (groupe 2), changées toutes les 48 h. Une cicatrisation spontanée a été obtenue chez tous les patients, il n'a été observé ni infection (clinique comme bactériologique) ni allergie. Cette cicatrisation sur 95% de la surface traitée était observée à J5,4 dans le groupe 1 et J12,5 dans le groupe 2. La silicone semble être particulièrement efficace pour accélérer l'épithélialisation et le film formé permet de prévenir les infections. Il est facile à mettre en place et permet une meilleure analgésie.

Mots-clés: silicone, brûlure, absence de cicatrisation, pansement secondaire

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Introduction

Healing burn wounds depends on many factors, such as degree of burn (superficial partial-thickness burns – SPTB, or deep partial-thickness burns – DPTB), quality and cause (for instance, chemical or thermal), general condition of the patient (acidosis, lethargic, immunosuppressive) and associated comorbidities.^{1,2} Various mechanisms, such as coagulation, inflammation, matrix synthesis and deposition, angiogenesis, fibroplasias, epithelialization, contraction and remodeling occur during the healing of burn injuries.^{3,4} Growth factors control cellular migration, attachment, proliferation, differentiation, maturation and matrix synthesis and exert a powerful influence on the process of wound repair.⁵

In recent years, silicone-based products have become increasingly used for non-healing wound treatment. Such products act as a barrier by reducing mechanical friction⁶ and transepidermal water loss (TEWL),⁷ which have been shown to be associated with the severity of a subsequent infection. In vitro studies have suggested that silicone has a regulatory effect on inflammatory growth factors responsible for fibrosis and acute wound healing.^{8,9} The key factors involved in this process are also inflammatory markers involved in acute inflammation, including IL-1, IL-6, TNF- α and TGF- β .

Recently, a sterile silicone-based film forming gel dressing (Stratamed® GP Dermal Solution, Piacenza, Italy) has become available with the aim of accelerating the healing process for difficult wounds. Silicone products have already been reported to have waterproof properties, and can be used on areas with facial hair.¹⁰ Although various aspects of these products on wound healing have been validated, it appears that no study has specifically addressed their potential on the burn wound healing process.

The purpose of this study was to compare the use of sterile silicone gel with conventional medications in improving the healing of burn wounds.

Patients and methods

This study was carried out between November 2019 and March 2020 and involved 12 patients

with mid-deep and deep burn wounds (average TBSA approximately 29%, range 13-51%). Patient average age was 49 years (range 29-67 years), 7 were male. The study was performed in accordance with the Declaration of Helsinki and consent was obtained from all participants. The presence of delayed re-epithelialization in burn wounds, skin graft donor-sites or small areas of graft failure were the criteria for the topical use of silicone gel. Exclusion criteria were the presence of tissue necrosis, local infection and/or sepsis, severe renal or hepatic failure, positive history of myocardial infarction, ischemic or hemorrhagic stroke, coagulation, dysmetabolic, immunological or psychological disorders.

Patients were also excluded if they had known allergic or other systemic skin disease, any known allergic reactions towards any ingredient of Stratamed®, or failed the patch test.

In each patient, two dimensionally-similar areas were identified: after careful removal of all epidermal debris and wound irrigation with saline solution, tissue cultures were obtained every 48 hours and percentage of re-epithelialization was measured.

The areas were then irrigated with sodium hypochlorite and treated as listed below:

Group 1: topical application of 1mm silicone gel in the form of Stratamed® and coverage with vaseline gauze.

Group 2: conventional medication (e.g. silver dressings, collagenases, alginates).

Results

Patient data are summarized in *Table I*. The average treated surface was 160cm² (range 50-300cm²). All the cases achieved 95% re-epithelialization without requiring skin grafting (*Fig. 1*). No secondary wound infection nor allergic reactions were found. The mean days from commencing the treatment to 95% re-epithelialization in Groups 1 and 2 were 5.4 and 12.5, respectively (*Fig. 2*). Culture samples were negative for common pathogens, e.g. *Pseudomonas aeruginosa* or *Staphylococcus aureus*.

Table I - Demographic characteristics of the 24 burned children who received off-label prescribing medications

n°	Age	Sex	TBSA (%)	Treated surface (cm ²)	Start of Stratamed dressing to 95% healing (days)	Start of conventional medication to 95% healing (days)
1	35	F	34	70	6	13
2	67	M	23	130	5	11
3	50	M	36	250	7	18
4	43	F	51	50	4	9
5	62	M	21	300	8	11
6	46	M	20	60	3	12
7	29	F	13	120	6	11
8	56	M	43	210	7	14
9	57	M	27	170	4	7
10	28	F	22	90	3	17
11	61	F	34	200	5	12
12	58	M	24	280	7	16

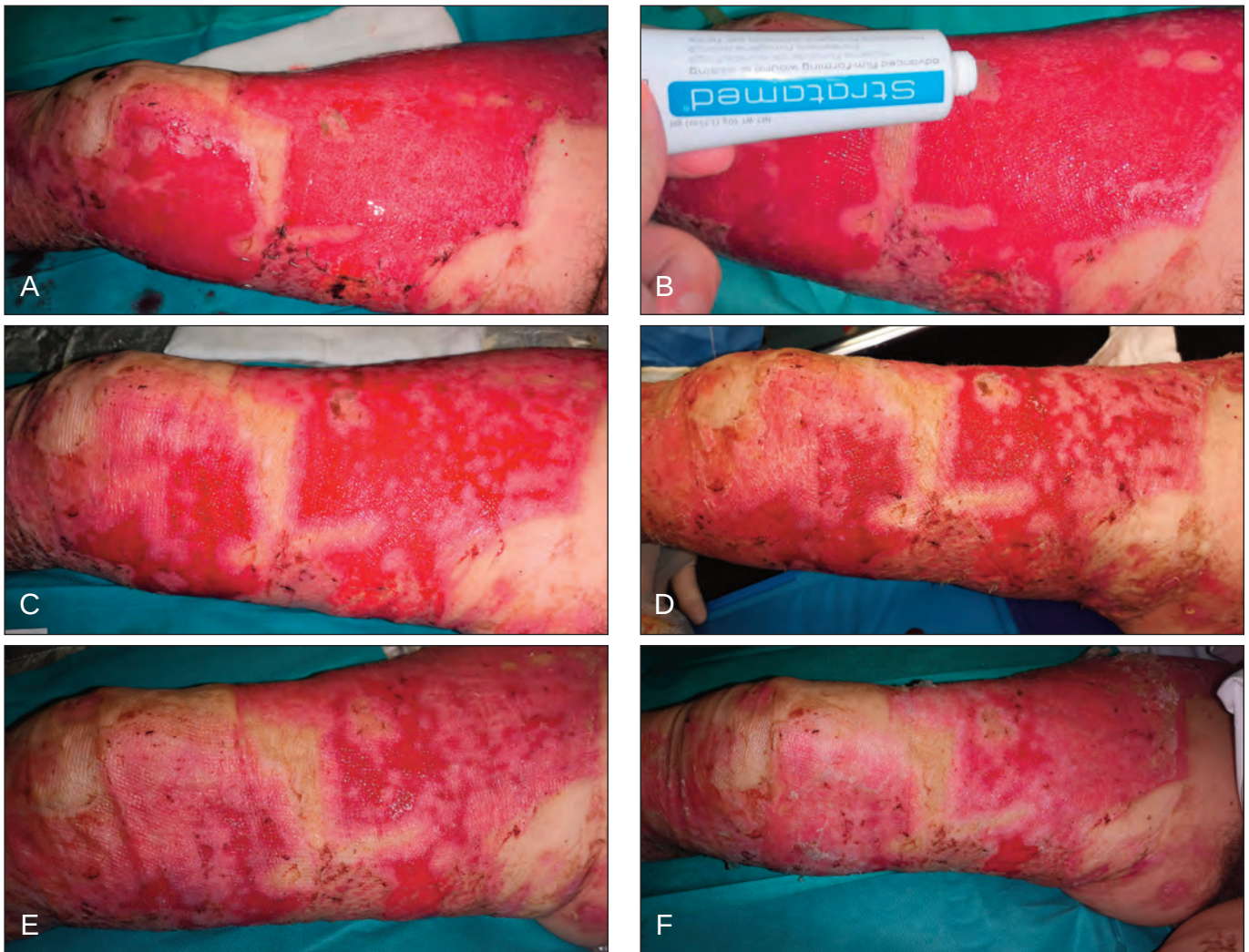


Fig. 1 - A) Skin graft donor site in a burn patient showed delayed re-epithelialization; B) Stratamed® silicone gel applied on the wound two days after initial treatment; C) Four days after silicone gel application; D) Five days after silicone gel application; E) Six days after silicone gel application; F) Six days after silicone gel application the wound was completely healed.

Discussion

Compared to acute traumatic or surgical wounds, treatment of burn wounds is complicated due to fluid and electrolyte loss, the wound edges becoming compromised and/or necrotized, and the increased chance of infection. In SPTB, healing occurs rapidly and becomes completely epithelialized by migration of the epithelial cells from the deeper portions, such as sweat and sebaceous glands, to the wound site.

The results of this study suggest that silicone gel can influence the healing process. A faster wound closure was observed in Group 1 compared to Group 2, as shown in Fig. 2. Moreover,

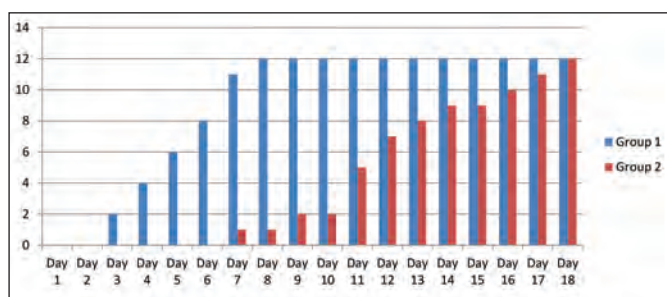


Fig. 2 - A faster wound re-epithelialization was observed in Group 1 compared to Group 2.

there was a lower incidence of both pain and pruritus in the treatment vs. control group. Topical silicone has been used for over 30 years as a treatment to improve the overall appearance of scars, and more recently to improve wound healing of difficult wounds or post-surgical and cosmetic procedures.¹¹ It has been shown to soften, flatten and improve the overall pigment of scars as well as reduce associated pruritus, erythema and pain.^{8,12} In addition, it dries to form a bacteriostatic film, which may decrease exposure to bacteria, antigens and irritation, inhibiting inflammation and, in turn, angiogenesis. Non-healing wounds are characterized by poor epidermal migration. Silicone-based dressings favorably influence a wound's electrical charge, with a positive effect on epidermal migration. Since silicone is hydrophobic, it does not adhere to granulation, allowing unimpeded epidermal migration and more rapid re-epithelialization.¹³ Additionally, a

recent study on cultured fibroblasts has shown that these gels are able to influence the expression of growth factors, specifically fibroblast growth factors, a key cytokine in the scar formation process. Thus silicone gels seem to act in several ways, influencing scar formation both by inducing physical modification and by modifying cytokine levels, with the fibroblasts as the ultimate target of its actions.¹⁴

Stratamed® is a silicone-based film-forming, self-drying, semi-occlusive, non-resorbable topical gel preparation. Moreover, as silicone products have also been reported to reduce the risk of developing keloid/hypertrophic scars, early post-operative use of silicone gel dressing over defects at keloid-prone sites could also be beneficial. It was also worth noting that there were no adverse nor allergic events due to products in this study. This can be also due to the exclusion of any known allergy to the study products at enrolment.

Some factors might cause bias and limitations in the authors' study. The case number was small, and the study did not evaluate a score for long-term scarring. However, we believe that our results are valuable and warrant debate, because this is the first study to compare clinical evidence of wound healing between silicone gel and conventional medications in burn patients. This is only a preliminary report and further studies will be necessary to confirm our findings.

Conclusions

Usually, after deep burn surgical treatment, the healing process of skin graft donor sites or skin graft failure areas can be slow and difficult. Silicone gel application has proved to be particularly effective in speeding up re-epithelialization thanks to its ability to physically and biologically interact with injured tissue. The protective film formed by the silicone due to sufficient gas permeability helps to reduce possible infectious complications. Finally, silicone gel is easy to apply and associated with greater pain control during medication compared with conventional dressings, making it ideal for non-healing wound management in burn patients.

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