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ORIGINAL ARTICLE
Hand/Peripheral Nerve

Efficacy of Silicone Gel versus Silicone Gel Sheet in Hypertrophic Scar Prevention of Deep Hand Burn Patients with Skin Graft: A Prospective Randomized Controlled Trial and Systematic Review

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Background: Burn injuries are burdensome to the public health system. Hypertrophic scars are the most common undesirable sequelae associated with burn scar contracture, resulting in reduced hand function. This study compared 2 different forms of silicone combined with pressure garment (PG) to determine the efficacy in hypertrophic scar prevention in hand burns.
Methods: A systematic review was also performed, including only randomized control trials with silicone materials in burned patients. A prospective intraindividual randomized controlled trial was conducted to compare the efficacy of 3 treatment groups: silicone gel and silicone gel sheet combined with PG versus PG alone.
Results: There were no significant differences in all Vancouver Scar Scale parameters. Three of 6 Patient and Observer Scar Assessment Score parameters showed significant differences among the 3 groups ($P < 0.05$). Scar stiffness improved at 8- and 12-weeks follow-up in both silicone gel and silicone gel sheet combined with PG; however, there was no significant difference between silicone groups. Scar thickness significantly improved at 2, 4, and 8 weeks in the silicone gel group compared with PG. Scar irregularity significantly improved at 2, 4, 8, 16, and 20 weeks in both silicone combined PG groups compared with PG alone.
Conclusions: Silicone gel and silicone gel sheet combined with PG were more effective than PG alone in some aspects of the Patient and Observer Scar Assessment Score. However, there was no significant difference between the silicone gel and silicone gel sheet on the Vancouver Scar Scale. *(Plast Reconstr Surg Glob Open 2020;8:e3190; doi: 10.1097/GOX.0000000000003190; Published online 4 November 2020.)*

INTRODUCTION

Burn injuries are burdensome to the public health system. Every day, worldwide, over 30,000 people suffer new burns that are severe enough to warrant medical attention, equating to an estimated 11 million new burns each year globally (about 500,000 cases in the United States).[1–3] In addition, approximately 180,000 burn-related deaths are reported globally every year. Of note, 39% of these injuries affect upper extremities and hands, as observed in previous studies.[2] The socioeconomic burden of burn injuries mostly aggravate low- and middle-income countries.[4,5] Moreover, nonfatal burn injuries are a leading cause of morbidity, long-term complication, and chronic sequelae.[6,7]

Although the surface area of the hand is only 3% of the whole-body surface area,[8,9] the hand is highly susceptible to injury, both due to its proximity to the thermal source but also because it is commonly used as a shield to protect other parts of the body. Deep second- and third-degree hand burns may diminish hand function; improper treatment and rehabilitation lead to functional deficits, poor cosmetic outcomes, and psychosocial problems.[10] Patients may not recover well enough to perform basic daily activities. For deep, second- and third-degree burns, patients need tangential debridement and skin graft resurfacing. Hypertrophic scars are the most common undesirable sequelae associated with burn scar contracture and cause reduced hand function.[11,12] A hypertrophic scar is reported in 31%–90% of cases after the healing process and typically occurs within 1 year.[13–15]

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Many nonsurgical treatment methods are used to prevent hypertrophic scars, for example, pressure garment (PG), silicone materials, corticosteroids, laser, and cryotherapy.[11,16–18] However, to date, there is no gold standard treatment protocol. The use of PG for hypertrophic and contracture scar prevention is recommended for patients with burn wounds.[11,19] Silicone materials reportedly aid hypertrophic scar prevention. Silicone materials for medical use are divided into 2 types: gel and gel sheet. The efficacies of both types are supported by previous studies[20,21]; however, there has been no prior randomized controlled trial (RCT) comparing the use of both types of silicone in hand burns. According to the inconclusiveness of the gold standard in the treatment of postburn hypertrophic scar, we hypothesize that combined methods would offer a better clinical outcome. We, therefore, measured the quality of scar by Vancouver Scar Scale (VSS) and Patient and Observer Scar Assessment Score (POSAS) assessment to determine the hypertrophic scar formation process and its effects.

This study aimed to compare 2 different forms of silicone, gel, and gel sheet combined with PG, to determine the efficacy in hypertrophic scar prevention in hand burns. We focus on both the patient and physician views by using the VSS and POSAS. A systematic review and a double-blind RCT were conducted. Our primary objective was to demonstrate the superiority of combined treatments compared with the use of PG only, whereas our secondary objective was to compare the results of our study with those in the existing literature.

PATIENTS AND METHODS

Part I

Systematic Review

We searched the electronic databases MEDLINE, EMBASE, and Google Scholar (up to January 2019), using search terms related to silicone gel or silicone gel sheet, and the incidence of burn wounds. The inclusion criteria were full-length articles and sufficient data. The exclusion criteria were incomplete or interim data, abstract-only studies, non-English language articles, and non-RCT. Two authors screened the titles and abstracts of the retrieved articles. Reference lists were imported to Endnote software version 9 (Thompson Reuters, CA), and duplicate reports were removed.

We included only clinical trials of silicone gel or silicone gel sheet for a deep second- to third-degree burns published in English. Articles published between 1990 and 2018 were evaluated by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist. Two authors independently assessed the eligibility of all studies identified using the predetermined selection criteria.

Part II

Prospective Study

The study was approved by the ethics committee and institutional review board of the Phramongkutklao Hospital (IRBRTA486/2559) and followed the Helsinki declaration. This prospective, randomized, intraindividual placebo-controlled clinical trial was conducted from August 2015 to October 2016. There were 16 consecutive hand burns with second- and third-degree burns requiring a skin graft and secondary intention for the superficial burn. All patients provided written consent before enrollment (Fig. 1). Demographic data were recorded. Exclusion criteria were pregnancy, breastfeeding, immunocompromised patients, and associated vascular, nerve, tendon, and bone injury. Once burn wounds were completely healed, all patients were randomly assigned to a PG treatment protocol (Fig. 2) combined either with silicone gel or silicone gel sheet, continuously for at least 23 h/d, except during bath/shower.

Randomization

The dorsum of the hand was divided into 3 areas: radial, central, and ulnar, by a vertical line drawing along the second and third webspace. Ulnar and radial areas were used as the treatment area, and the central area was used as the border between groups (Fig. 3). For each hand burn, both treatment areas were randomly treated with 4 block randomization methods by a plastic surgeon, by applying silicone gel on the one side and silicone gel sheet on the other side (Fig. 4). The scar prevention protocol was performed in healed hand burn wounds; within 1 month, the hypertrophic scar was evaluated by the VSS and POSAS. Each hand was photographed before and after treatment for up to 12 months, using an Olympus EM-10 camera (Olympus Inc., Japan), and following standard photography guidelines.

Silicone Gel and Silicone Gel Sheet Combined with PG

The silicone gel (A. Menarini Asia-Pacific PTE LTD, Singapore) was self-applied to one side on the dorsum of the hand. Next, 0.25 ml of the gel was applied to 5 cm^2 of scar surface area and then left to dry before applying a customized PG glove. A silicone gel sheet (Smith & Nephew, UK) was cut and fit for the burned wound lesion, not extending beyond the knuckle, and self-applied to the other side of healed hand burn in a randomized sequence.

Vancouver Scar Scale

According to the VSS[22,23] evaluation method, 2 experienced plastic surgeons who were blinded to the treatment group assessed the scar. The patient removed the PG for 30 min before grading the score to avoid pressure effect on the skin. The VSS has 4 parameters: pigmentation, pliability, vascularity, and height. The total score was ranked from 0 to 15. The scar assessments were performed at 2, 4, 8, 12, 16, and 20 weeks and at 1-year follow-up.

Patient and Observer Scar Assessment Score

For patient evaluation, POSAS[24,25] was conducted in this study. The patients provided a score rating for each area on the dorsum of the hand. The parameters consisted of pain, itching, color, thickness, stiffness, and irregularity. The total score ranged from 6 to 60. The scar assessments were performed at 2, 4, 8, 12, 16, and 20 weeks and at 1-year follow-up.

Statistical Analysis

Data were analyzed using SPSS version 18 to evaluate the differences between 2 groups, the repeated measure

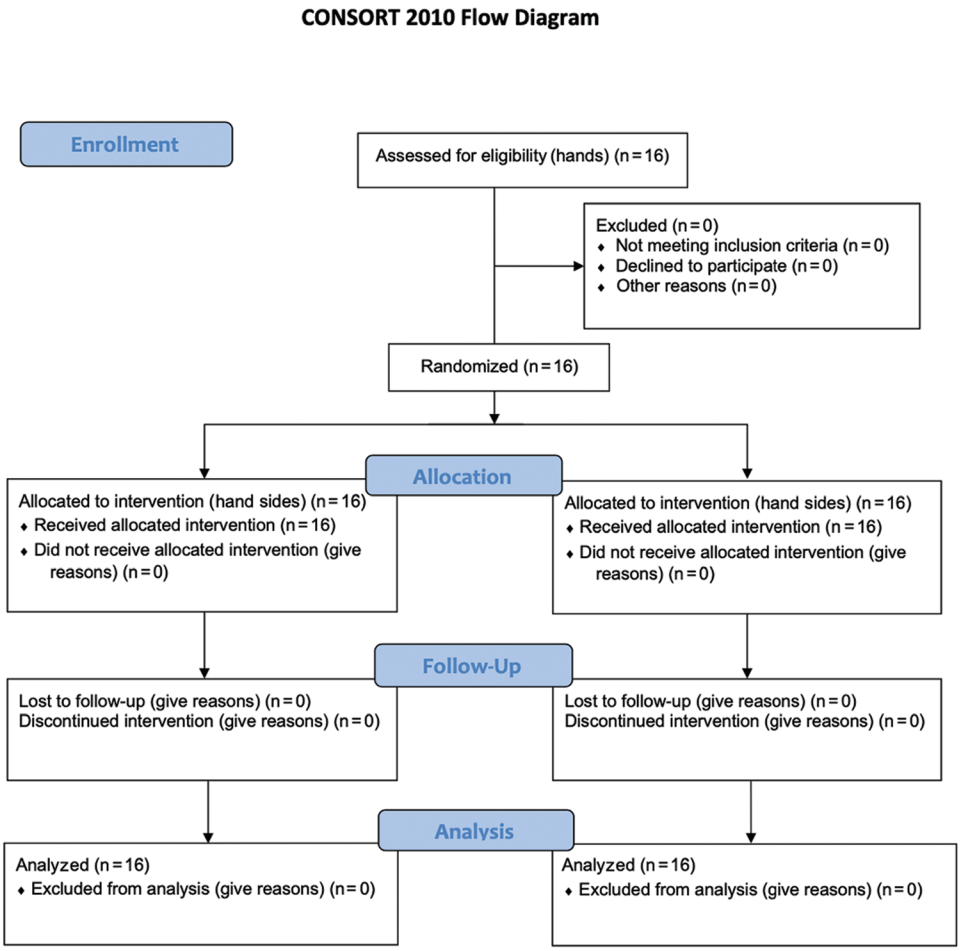

Fig. 1. Consort 2010 flow diagram.

ANOVA was applied. Results were reported as means ± SD. Values of $P < 0.05$ were considered statistically significant in all analyses.

RESULTS

Part I

Systematic Review

Seven articles met the inclusion criteria (Fig. 5). All study topics were relevant to burn wounds, hypertrophic scars, and prevention of keloids (Table 1). In total, 3 articles used PG combined with silicone material,[26–28] 6 articles investigated silicone gel sheet,[26–31] 2 articles tested silicone gel,[30,32] and 4 articles were RCTs with intraindividual or within-subject comparative[27,29,31,32] studies.[30,32]

Carney et al[29] conducted an intraindividual RCT to compare the efficacy of silastic gel sheet, and silicone gel sheet using Cica care. Forty study subjects were included; the results showed that both study groups did significantly better than the control, but there was no difference between study groups (Group 1 at 2 months: extensibility, $P < 0.001$; color, $P = 0.005$; texture, $P = 0.001$; Group 2 at 6 months: extensibility, $P < 0.03$; texture, $P = 0.012$; Group 2 at 2 months: extensibility, $P < 0.001$; color, $P = 0.007$; texture, $P = 0.001$; Group 2 at 6 months: extensibility, $P < 0.04$; color, $P = 007$; texture, $P = 0.02$).

Esther et al[32] studied 23 subjects in the Netherlands by conducting an RCT within-subject comparative study between silicone gel and placebo. The results showed improved scar surface roughness ($P = 0.14$) and less itching ($P = 0.18$) in the silicone gel group.

Harte et al[26] studied 22 patients in Northern Ireland, by conducting an RCT to compare silicone gel sheet (Mepiform) combined with PG versus PG alone. Results showed no clinically significant difference between both groups.

Karagoz et al[30] conducted an RCT in 32 subjects to compare the efficacy of 2 groups, including silicone gel (Scarfade) and silicone gel sheet (Epi-Derm), with control using onion extract (Contractubex). The results showed that both study groups were more effective than the control, but no clinical difference between groups (group 1 versus placebo and group 2 versus placebo, $P < 0.05$)

Lars Steinstraesser et al[27] studied 38 patients in Germany, by conducting an RCT within-subject comparative study to compare silicone spray combined with PG versus silicone sheet combined with PG versus PG alone. The

Fig. 2. Pressure garment therapy was used for all patients.

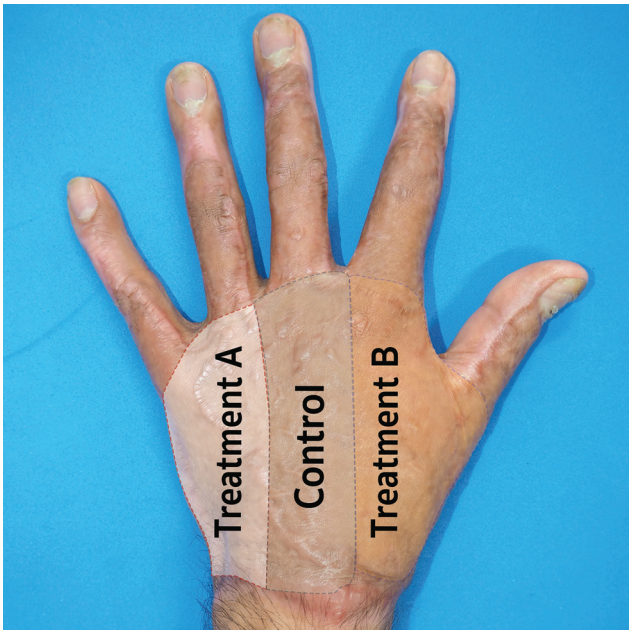

Fig. 3. The dorsum of the hand was divided into three areas: radial, central, and ulnar, by an imaginary line drawn along the second and third web space.

results showed that multimodal therapy with silicone and PG failed to prevent hypertrophic scars when compared with PG alone.

Fig. 4. Silicone gel sheet applied to the radial side of the right hand.

Li-Tsang et al[28] conducted an RCT in 104 patients in China, with 3 treatment groups: PG, silicone gel sheet, and a combination of PG and silicone gel sheet. The result showed that the improvement in scar thickness was most significant in the combined therapy group ($P < 0.001$).

Part II

Prospective Study

Twelve patients with 16 hand burns were included in the study (Fig. 1). The demographic data showed that the mean age was 27 years; all patients were men (Table 2). Fourteen hands (87.5%) were healed by split-thickness skin graft; the other 2 hands (12.5%) healed with secondary intervention.

Each parameter of VSS was compared among three groups, that is, control, silicone gel combined with PG, and silicone gel sheet combined with PG. There was no significant difference in all parameters and the total score of VSS at the time of evaluation (Fig. 6).

Three of 6 parameters of POSAS (stiffness, thickness, and irregularity) showed significant differences among the 3 groups ($P < 0.05$). In the study groups, both silicone gel and silicone gel sheet combined with PG improved the stiffness outcome at 8- and 12-weeks follow-up; however, there was no significant difference between the 2 material silicone groups. The thickness had significantly improved when the silicone gel group was compared with the control group at 2, 4, and 8 weeks follow-up. The scar irregularity showed significant improvement at 2, 4, 8, 16, and

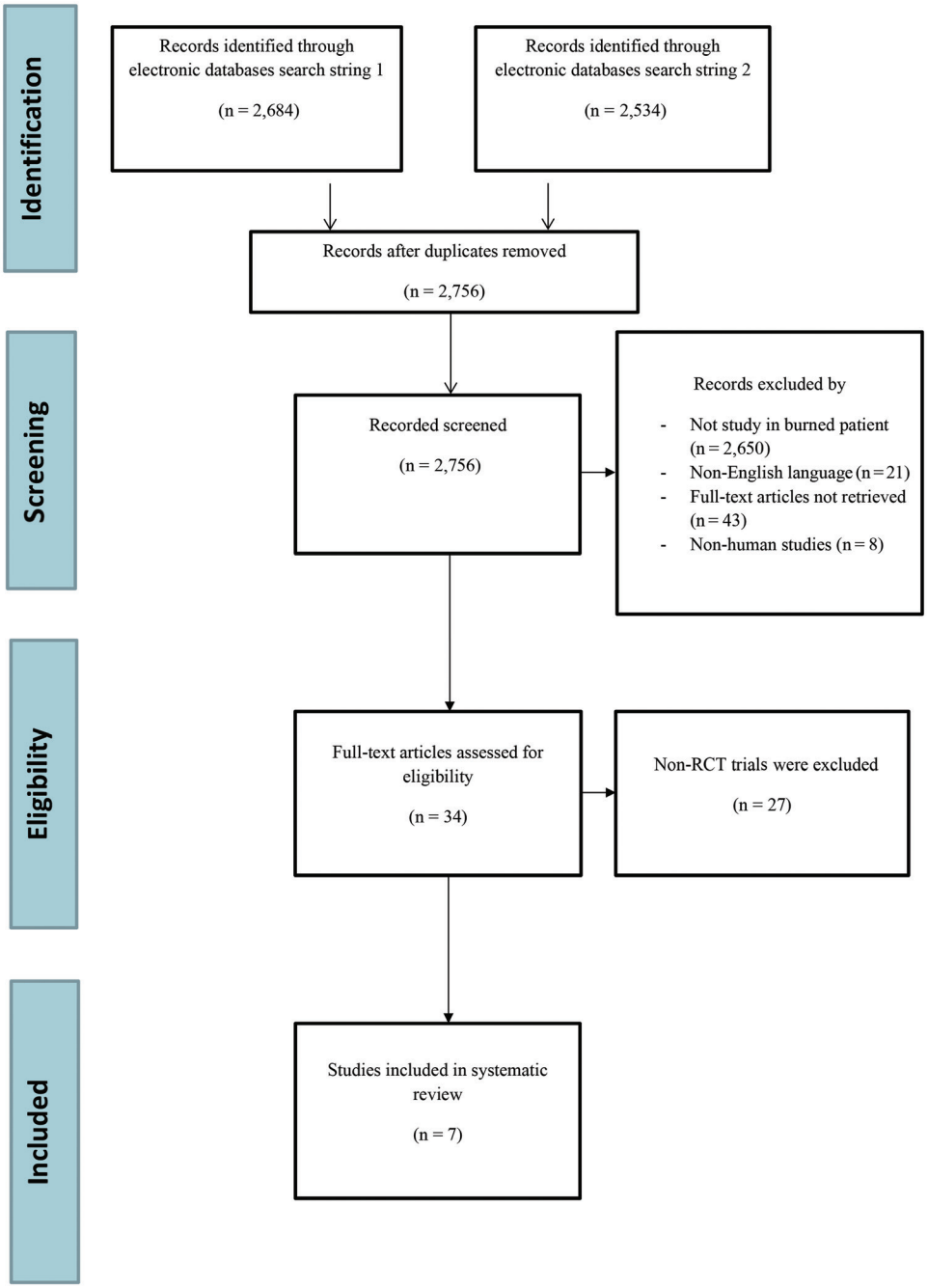

Fig. 5. Flow diagram depicting the screening and selection of the studies included in the systematic review.

20 weeks in both silicone material combined PG groups when compared with PG alone. Nevertheless, no statistical difference between both study groups when observed at the 1-year follow-up (Fig. 7–9).

DISCUSSION

The latest practice guideline for scar management advocates silicone therapy as a noninvasive first-line prophylactic and treatment option for both hypertrophic scars and keloids.[33,34] Silicone is thought to influence collagen remodeling via multiple mechanisms, including hydration, increasing local temperature, scar tissue polarization, local chemical effects, elevated local oxygen tension, and increasing local mast cell population.[35]

This study demonstrated the efficacy of silicone material in scar management. Our study used silicone gel and silicone gel sheets, which have been used in many previous reports with good results. PG was used as a control because, since the 1970s, PG therapy has been generally accepted as the gold standard procedure for preventing hypertrophic scarring after severe burns, especially in hands and other functional areas. Theoretically, the

Table 1. Results of the Systematic Literature Review

Reference	Study Site	No. Subjects	Study Design	Silicone Form	Comparison	Application	Result
Carney et al[29]	United Kingdom	42	RCT intraindividual	Group 1: Silastic gel sheet; Group 2: Cica care	Placebo	Apply all day	Both study groups did better than control; no difference between study groups
Esther et al[32]	Netherlands	23	RCT within-subject comparative	Silicone gel (Dermatrix)	Placebo	Twice a day	Improved surface roughness, less itching
Harte et al[26]	Northern Ireland	22	RCT	Silicone gel sheet (Mepiform) + PG	PG alone	23 h/d, replace every 7 d	No difference between study groups
Karagoz et al[30]	Turkey	32	RCT	Group 1: Silicone gel (Scarfade); Group 2: Silicone gel sheet (Epi-Derm)	Onion extract (Contractubex)	24 h/d for gel sheet; Twice a day for gel	Both groups did better than control; no difference between study groups
Lars Steinstraesser et al[27]	Germany	38	RCT within-subject comparative	Silicone spray (Dermatrix), Silicone sheet (Mepiform)	PG	Twice a day	Silicone failed to improve scar compared with PG
Li-Tsang et al[28]	China	104	RCT	Group 1: PG Group 2: SGS Group 3: PG + SGS	Placebo	24 h/d except for hygiene purposes	Thickness: improved in all study groups compared to control, but no difference between study groups; Pliability: group 3 had more significant improvement than control; Pigmentation: all groups were lighter and more yellow; Pain: group 2 and 3 had more pain reduction pain than control; Itch: reduced itching in all groups
Momeni et al[31]	Iran	38	RCT intraindividual	SGS (Cica care)	Placebo (placebo comprised of self-adhesive propylene glycol and hydroxyethyl cellulose sheet)	24 h/d	Gel sheet group was better than control in all parameters

SGS, silicone gel sheet.

Table 2. Demographic Data

Variable	PGT Alone	Silicone Gel and PGT	Silicone Gel Sheet and PGT	*P*
Number of hands	16	16	16	
Age (mean ± SD)	26.75 ± 5.26	26.75 ± 5.26	26.75 ± 5.26	1
Sex (male/female)	16/0	16/0	16/0	
Healing process				
STSG	14 (87.5%)	14 (87.5%)	14 (87.5%)	1
Secondary intervention	2 (12.5%)	2 (12.5%)	2 (12.5%)	1
Site of treatment radial:ulnar (hands)	N/A	8:8	8:8	1
History of keloid/hypertrophic scar	2	2	2	1

PGT, pressure garment therapy; STSG, split-thickness skin graft.

pressure effect may involve the reduction of oxygen tension in the wound through occlusion of small blood vessels, resulting in decreased myofibroblast proliferation and collagen synthesis.[36] This study is the first intraindividual RCT study that enrolled only hand burn patients. This is important because the hand is a highly functional body part whose functional recovery is more important than cosmetic concerns. Hypertrophic scars can lead to contracture scar and limit hand function.

Our study has several advantages: first, we used a 2-way assessment with surgeons using the VSS and patients using the POSAS and compared the results with 7 RCT studies from our systematic review. Second, we did a long-term follow-up, up to 1 year, in which we observed the complete remodeling phase of wound healing, whereas many study follow-up periods last up to 6 months or less. In this study, VSS showed no significant difference between both silicone groups with PG versus PG alone; in agreement with

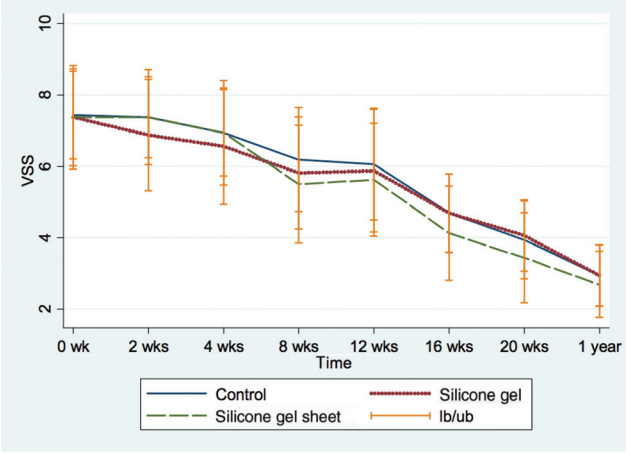

Fig. 6. VSS showed no difference among the three groups at the time of follow-up.

previous studies by Lars Steinstraesser et al[27] and Harte et al.[26] However, most previous studies that compared silicone material and placebo (without PG) showed superior results in silicone arms; therefore, it may be postulated that combining silicone material with PG to the burned hand area does not improve clinical outcomes when evaluated by the VSS. Besides, it cannot be ruled out that the protective effects of PG alone may equal those of silicone alone.

Our POSAS assessment showed significantly improved scar quality in terms of stiffness and thickness, up to the 12 weeks follow-up, whereas scar irregularity showed significant improvement up to the 20 weeks follow-up. When compared with previous studies, results are in agreement. From the data collected by interviewing patients using the POSAS assessment, some patients had compliance issues after the 6-months follow-up due to hygienic issues. In Thailand and other tropical countries, the weather and humidity affect compliance with applying PG gloves. The main complaints were regarding daytime sweating and moisture inside the PG. In the authors' opinion, the patient assessment (POSAS) is more important in identifying patient concerns and their satisfaction with using the PG. Perhaps, if the study was done in a colder climate, patients may have had better compliance, less sweating, and itching, and long-term results may be better.

Based on our results, our recommendation to patients with hand burns is to apply any type of silicone material combined with PG for at least 6 months, which expectedly beneficial. If a patient can tolerate the PG and comply with the treatment guidelines, the clinical outcome may be improved. In our country, the estimated cost of the treatment per month (including both types of silicone materials) is around 70 USD.

Of the 7 reviewed studies, 5 from Europe[26,27,29,30,32] and 2 from Asia[28,31] (China and Iran), 4 studies compared silicone gel and/or silicone gel sheet with control; of these, 3 studies compared with placebo,[29,31,32] and the other study compared with onion extract.[30] All studies demonstrated that both silicone gel and silicone gel sheets were better than placebo in all parameters for hypertrophic

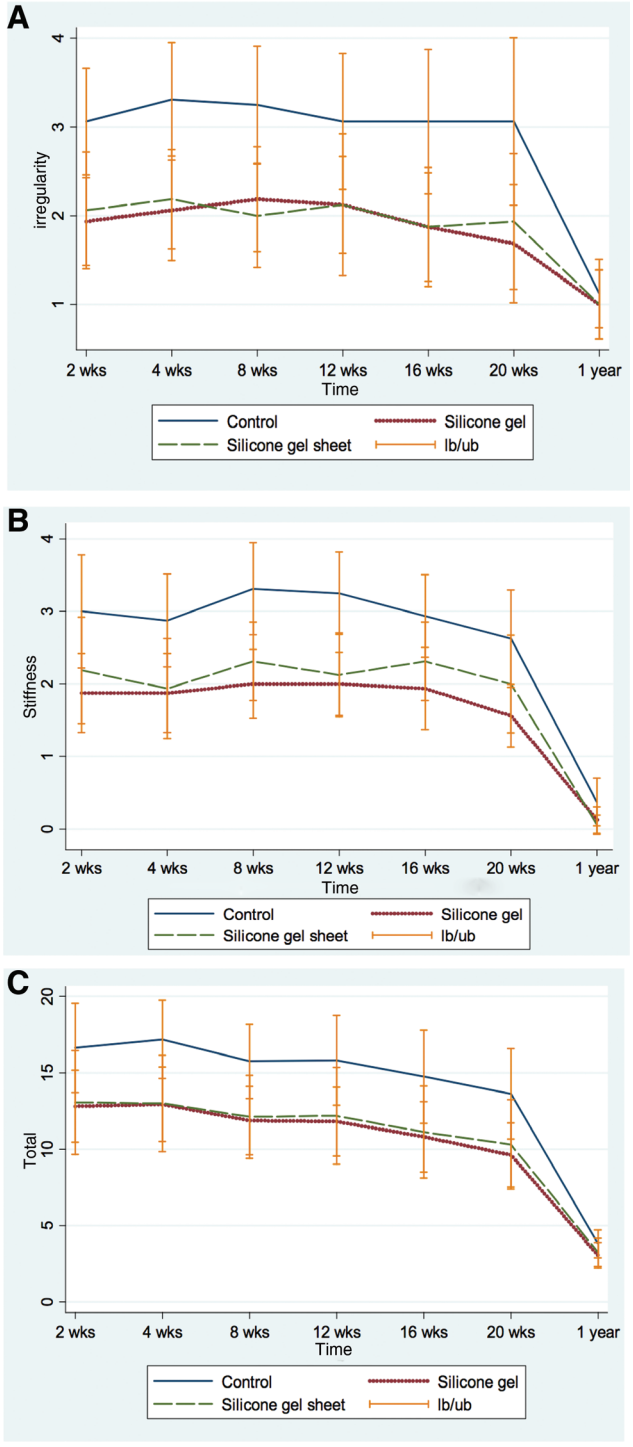

Fig. 7. Parameters of irregularity (A), stiffness (B), and the total score (C) were were statistically significant when the silicone groups were compared with the control, but no difference was seen between silicone gel and silicone gel sheet groups in all parameters and total scores.

scars. Only 2 studies compared silicone gel with silicone gel sheet[29,30] and revealed no statistically significant difference between both forms of silicone. The PG, combined with silicone, was used in 3 studies.[26–28] All showed that silicone combined PG failed to improve scar compared

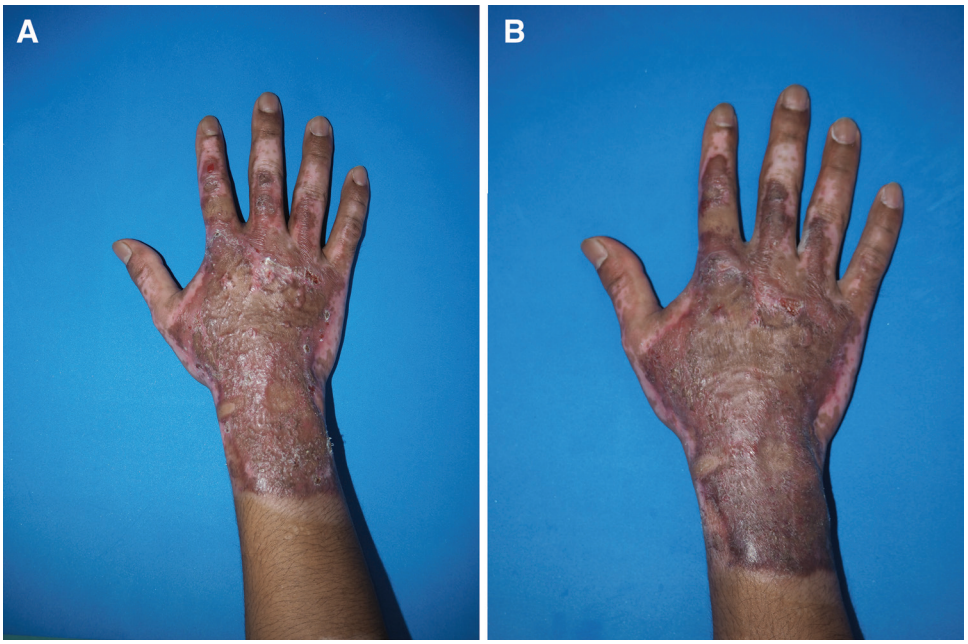

Fig. 8. Case sample 1. A, at the start of treatment (Wk 0) (silicone gel sheet on radial site, silicone gel on ulnar site). B, At treatment Week 20 (silicone gel sheet on radial site, silicone gel on ulnar site).

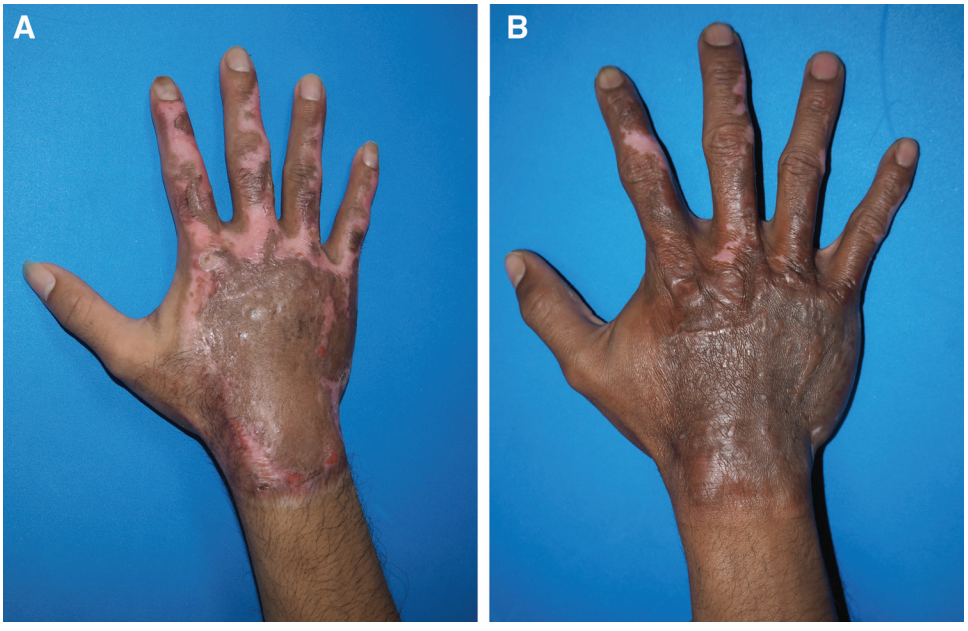

Fig. 9. Case sample 2. A, at the start of treatment (Wk 0) (silicone gel sheet on ulnar site, silicone gel on radial site). B, at treatment Week 20 (silicone gel sheet on ulnar site, silicone gel on radial site).

with PG alone. However, Lars Steinstraesser et al[27] reported that silicone gel combined with PG improved pigmentation better than PG alone and combined with silicone gel sheet. The result of our study is similar to that of Steinstraesser et al,[27] which showed that silicone material combined with PG could improve scar outcome when compared with PG alone.

The disadvantages of our study are the small sample size and uneven depth of the burn. Further studies with a larger sample size may be of benefit. Other outcomes, such as hand function and quality of life, may complement our evaluation.

CONCLUSIONS

The efficacy of silicone gel and silicone gel sheet combined with PG was better than that of PG alone in some aspects using the POSAS assessment. Statistically significant differences were found in terms of scar thickness and

irregularity after combined methods relative to PG alone. However, no significant difference was found when silicone gel was compared with the silicone gel sheet. Further study with greater sample size and other parts of the body should be considered.

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