



Prospective randomized-controlled comparison between silicone plus herbal extract gel versus *Aloe vera* gel for burn scar prophylaxis



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ARTICLE INFO

Article history:

Received 21 January 2015
Received in revised form 19 April 2015
Accepted 20 April 2015
Available online 24 April 2015

Keywords:

Herbal extract
Silicone
Burn
Hypertrophic scar
Aloe vera

ABSTRACT

This study was to determine the effects of topical silicone plus herbal extract gel in comparison with *Aloe vera* gel in preventing scar formation after dermal burn. 70 patients were included in this study had dermal burns which are able to heal without skin grafts. The patients were randomized into two treatment groups: topical silicone plus herbal extract gel group (study group) and *A. vera* gel group (control group). Two (2) physicians, who do not know which treatment method was used, examined all subjects for 24 weeks from the date of wound healed. Post-burn scar was graded using the Modified Vancouver scar scale (MVSS – with the following parameters: pigmentation, vascularity, height, pliability, itching and pain) and the results from both groups were compared using *T*-test. Total MVSS were different in the two treatment groups and was statistically significant from week 12 ($p < 0.05$). The pigmentation and vascularity scores in the study group were significantly lower than control group at week 16 ($p < 0.05$). There were no statistical differences in pain and height between both groups ($p > 0.05$). In conclusion, the silicone plus herbal extract gel appears to be superior to *A. vera* gel in prevention of hypertrophic scars formation.

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1. Background

Hypertrophic scars, resulting from alterations in the normal processes of cutaneous wound healing, are characterized by proliferation of dermal tissue with excessive deposition of fibroblast-derived extracellular matrix proteins, especially collagen, over long periods, and by persistent inflammation and fibrosis [1]. A significant problem following thermal, postsurgical and traumatic injuries is the development of hypertrophic scarring. Postsurgical, traumatic and burn scars can be painful, pruritic, erythematous, raised, and also cosmetically unacceptable [2].

There is no universal treatment protocol for hypertrophic scar treatment even though there are many modalities that have been proposed for the management of keloids and hypertrophic scars such as, surgical removal, laser surgery, radiotherapy, compressive therapy, silicone gel sheeting, intralesional corticosteroid injection and external agents. The prevention of keloid and hypertrophic scars before they appear remains the best strategy [3]. In this

study, we are interested in external agent because it is a non-invasive treatment and easy to use.

At the present, post spontaneous healing of dermal burn treatment has no universal treatment protocol yet. Some physicians recommend patients to keep the skin moist with topical agents and *Aloe vera* is used widely by wound care specialists on these patients. However, sometimes, even though the dermal burn can heal by epithelialization, the chance of scar formation might occur. We are interested to prevent scar development as early as possible after dermal burn healing using the silicone plus herbal extract gel, which might be more effective than *A. vera* gel.

A. vera is a tropical plant, which has claims in both animal and clinical studies that its constituents can promote wound healing by induce appropriate moisturizing environment for wound epithelialization, so it is used as a wound-healing agent. The early wound closure will decrease chance of hypertrophic scar formation. Because it has antimicrobial effect, moisturizing effect and anti-inflammatory effect [4–8]. Therefore it has been widely used by some physicians to relief pain, itching symptoms and to promote skin moisturizing effect after wound healing which might decrease chance of hypertrophic scar formation [7–9].

The silicone plus herbal extract gel (Cybele® Scagel, Bangkok Botanica, Thailand) is a topical agent consisting of silicone gel derivative and herbal extracts. The active herb ingredients of

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Cybele® Scagel are *Allium cepa* (12%), *Tamarindus indica* (1%), *Centella asiatica* (1%) and *A. vera* (1%). It is believed that these compounds in the gel preparation will help to improve scars [10–12].

In this double-blinded, randomized, prospective, controlled trial, we compared the efficacy, safety, and tolerability of the silicone plus herbal extract gel against *A. vera* gel (87.4% Aloegel®, GPO, Bangkok, Thailand) in the prevention of hypertrophic scars and keloids formation.

2. Study design and methods

This study design was a prospective double-blinded randomized control trial model. A total of 70 out patients at the burn unit, Siriraj hospital, were recruited for the study. This study was approved by the ethic committee of the hospital. Consent forms, which conformed to the ethical guidelines of the 1975 Declaration of Helsinki, were accepted and signed by each patient. The inclusion criteria for this study were patient age of 18–60 years with spontaneously healed dermal burn including superficial second degree (grade 2a) to deep second degree (grade 2b) burn wounds at extremities. The exclusion criteria were patients with second degree burn wounds who underwent surgical treatment, patients younger than 18 years old, family history of keloid or hypertrophic scar.

The patients were divided into either a study group or a control group by a random number table. The study group of 35 patients was treated with topical herbal extract plus silicone gel and a control group of 35 patients was treated with *A. vera* Gel. The topical treatment started on the first day of complete wound epithelialization. In both groups, patients were instructed to apply the topical agent 2 times daily by gently rubbing it into the wound and to continue with the application for 6 months.

Two experienced burn physicians, who do not know which treatment type were given to each subject, conducted the clinical evaluations. The age and sex of the patient, the scar type, location, and etiology of the scar or keloid were documented and a routine medical history was recorded.

Clinical evaluation of the scar was done after burn wound at 0, 1, 2, 4, 6, 8, 12, 16, 20 and 24 weeks after the dermal burn wounds had spontaneously healed. Clinical evaluation and grading of the lesions was done at each visit using the Modified Vancouver Scar Scale (MVSS), which include the following parameters: pigmentation, vascularity, height, pliability, itching and pain. The patients were interviewed during each visit to discuss any side effects. The results from both groups were compared using *T*-test. Results with a value of less than 0.05 are considered to be of significant value

3. Results

3.1. Demographic data

A total of 70 subjects were successfully recruited (39 men and 31 women) with a mean age of 36.89 ± 9.9 years and 36.57 ± 13.5 years in the study and control group respectively. Most of the burn wounds, 67.14% of the total number of cases, were caused by flame burns. 22.86% was caused by scald burns and 10% by chemical burns. The duration of treatment was 6 months. The demographic data was as shown in Table 1.

3.2. Modified Vancouver scar score (modified VSS) evaluation

The score of MVSS slightly increased at the beginning and there were not difference between each group until the 12th week (Fig. 1). The efficacy of scar prevention in study group was seen after week 12. The pigmentation, vascularity scores from the study

Table 1
The demographic data.

	Study group	Control group
Patient (n)	35	35
Gender: Male (n)	20 (57.14%)	19 (54.29%)
Age (years)	36.89 ± 9.90	36.57 ± 13.50
Cause of burn		
Flame (n)	22 (62.85%)	25 (71.43%)
Scald (n)	9 (25.71%)	7 (20.00%)
Chemical (n)	4 (11.43%)	3 (8.57%)

group were significantly lower than those from the control group at weeks 16, 20 and 24 (pigmentation – $p = 0.035, 0.002, 0.022$ and vascularity – $p = 0.005, 0.003, 0.002$, respectively). The itching score in the study group was also significantly better than the control group at 12, 20 and 24 weeks ($p = 0.025, 0.047$ and 0.026 , respectively). The study group demonstrated a trend of reduced pliability score compared to *A. vera* gel treatment group from the 12th week ($p > 0.05$). There were no differences in height and pain scores between both groups.

The study group demonstrated significant decreasing total Vancouver scar scale compared to the control group at 12, 16, 20 and 24 weeks ($p = 0.044, 0.002, 0.0009$ and 0.0003 , respectively, Fig. 2).

4. Discussion

Keloid and hypertrophic scarring develop as a result of excessive proliferation of dermal tissue after skin injuries. These proliferative scars are characterized by increased collagen and glycosaminoglycan content as well as an increased in collagen turnover [13,14]. There are many ways to prevent these conditions, with different responses.

A. vera has an anti-inflammatory activity by inhibiting the arachidonic acid pathway (7). Previous studies (7–9) demonstrated that *A. vera* provide a moist environment that enhances epithelialization in the wound healing process. The early wound closure by epithelialization might decrease the chance of hypertrophic scar formation. It contains salicylate compound, which can decrease pain and itch [12]. Although it has an effect on vascularity, itch and pain parameters, there are other compounds in silicone plus herbal extract gel in study group, which can improve the effect on itch, pain and hypervascular conditions. These compounds were reported in studies on the prevention of hypertrophic scar formation [10–12]. Nano Hydroxypropylsilane CN or silicone gel derivative generates static electricity and can help in the alignment of collagen fibers. It also trapped moisture by restoring the barrier function of the stratum corneum, which helps to reduce fibroblast stimulation [15–17]. *A. cepa* or onion extract has Quecertin, which is the active compound in the extract. It can inhibit inflammation and excessive fibroblast proliferation. It may also play a role in reducing the vascularity condition [18,19]. *C. asiatica* promotes balanced collagen production by increasing the production of type I collagen and decreasing myofibroblast production. It also helps to rearrange the collagen fiber [20–22]. Paper Mulberry extract contains and active ingredient – Kazinol F. It can inhibit the activity of tyrosinase synthesis and that lead to reduced melanin formation [23,24]. The scar treated with gel containing paper mulberry will have less pigmentation than *A. vera* gel.

In this study, the treatment with topical silicone plus herbal extract gel might create a risk of allergic and toxic side effects on the skin in the study group, however there were no allergic or any toxic side effects on skin demonstrated in this study. This result proved that this herbal extract formula is clinically safely to use for prevention of scar formation.

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