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Research Article

Comparison of the Efficacy Between the Combination of Herbal Extracts and Silicone Derivative VS the Combination of Herbal Extracts, Silicone Derivative and Sunscreen in Reducing Scar Development at Donor Site of the Split Thickness Skin Graft

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Abstract

Background: To compare the efficacy between the combination of herbal extracts and silicone derivative VS the combination of herbal extracts, silicone derivative and sunscreen in reducing scar development at the split-thickness skin graft donor site and also the different between the two treatment groups and placebo.

Methods: A prospective randomized double-blind control study to compare efficacy between the combination of herbal extracts and silicone derivative (Group I) VS the combination of herbal extracts, silicone derivative and sunscreen (Group II) VS placebo (Group III) in reducing scar development at the split-thickness skin graft donor site within 1 month after complete epithelialization. Scar assessments using the Vancouver Scar Scale (VSS) and Cutometer® (The Multiprobe Adapter System Cutometer Dual MPA580) were taken 4, 8, 16 and 24 weeks postoperatively.

Results: Of the 12 patients, 8 were enrolled, total 18 split-thickness skin graft donor sites were evaluated in this study. There was statistically significant lower in itching parameter of VSS between treatment groups compared to the placebo group after 8 weeks of treatment; Group I VS Group III ($p = 0.003$, 0.002, 0.002 at 8, 16, 24 weeks, respectively), Group II VS Group III ($p = 0.003$, 0.002, 0.002 at 8, 16, 24 weeks, respectively). After 24 weeks of treatment, there was statistically significant lower erythema index in Group II when compare to Group III (359.09 VS 378.40, $p = 0.004$). There was statistically significant lower melanin index in both treatment groups when comparerd to placebo group; Group I VS Group III (317.80 VS 341.600, $p = 0.013$)) and Group II VS Group III (316.19 VS 341.60, $p = 0.028$). There was no statistically significant different in pliability index between groups.

Conclusion: The results from this study confirmed that the combination of herbal extracts and silicone derivative with or without sunscreen could reduce scar itching and these combinations might improve scar pigmentation and tend to reduce scar erythema.

Keywords: Herbal Extracts Gel; Onion Extract; Silicone Delivertive; Sunscreen; Split-Thickness Skin Graft; Donor Site

Introduction

Skin grafting is a very common procedure in plastic surgery. Split-thick ness graft donor site is usually expected to heal like any abrasions, unnoticible scar. However, donor site problems such as hypertrophic, keloid, hyperpigment or hypopigment scar are not uncommon. Dark- skinned individuals have higher susceptibility to develop hypertrophic and keloid scar, with an incidence of 3 to 5 times higher in Asians compared to Caucasians [1,2]. The risk of hyperpigmented scar in Asians is also common especially in Fitzpatrick skin types III to VI [3]. For the donor site of split-thickness skin graft, the incidence of hypertrophic scar

in Indian patient was reported as high as 94% after 2 months follow up4 and another study in South eastern Nigeria patient reported the incidence of 4% of hypertrophic scar 96% of hyperpigmented scar and 4% of hypertrophic scar in split-thickness skin graft donor site after 6 months follow up [4,5]. Recent reports have introduced the use of herbal extracts, Quercetin from onion extract, in scar prevention. The combination of herbal extracts and silicone derivative in gel preparation may also have synergistic effects in scar improvement [6-9].

However, scar hyperpigmentation is still the major problem in Asian. Sun protection factor 30 has ultraviolet B prevention effect, which can reduce melanogenesis. Therefore, we conduct a prospec- tive, randomized, double-blinded study to compare the efficacy between the combination of herbal extracts and silicone derivative and the combination of herbal extracts, silicone derivative and sunscreen in reducing scar development at the split-thickness skin graft donor site.

Materials and Methods

The study was conducted at the outpatient unit, Division of Plastic surgery, Department of Surgery, Siriraj Hospital, Mahidol University, Thailand, with the approval from of the university Institutional Review Board (IRB). The research protocol conformed to the guidelines of the Helsinki Declaration and informed consent was obtained from subjects prior to enrollment. Patients who underwent split-thickness skin graft procedures at Siriraj Hospital, Mahidol University between May - September 2016 were included in this study. All skin graft procedures were performed by plastic surgeons. Inclusion criteriors were: patient's age ≥18 years old, donor site of STSG area ≥ 25 cm^2. Exclusion criteriors were: patient in intensive care unit, patient who has a history of allergy to the substance in the study and patient who lost follow up or poor compliance (apply products < 5 days in a week). The studied groups were Group I (the combination of herbal extracts, silicone derivative), Group II (the combination of herbal extracts, silicone derivative and SPF 30) and Group III (placebo). These tropical treatments and placebo were prepared as gel paste the in the same type of containers, then the containers were labled as gel paste No.1, No.2, No. 3 by randomized method. Within 1 month after donor site was complete epitheliali-zation, it was devided into 3 parts equally by plastic template and labelled as area No.1, No.2 and No. 3 to applied gel paste No.1, No.2 and No.3 (Fig. 1). The patients were advised to apply all gels with the plastic template on twice daily. No another treatments or skin care were applied on the wound.

The scars were assessed with the Vancouver Scar Scale by blinded OPD surgeons (Table 1). Using Cutometer® MPA 580(The Multiprobe Adapter System Cutometer Dual MPA580) for erythematous index, pigmentation index and pliability index evaluations by one blinded experienced nures at 4, 8, 16 and 24 weeks (Fig. 2). All statistical analyses were performed using SPSS statistical software v18.0 (SPSS, Inc., Chicago, IL, USA). Each variable of VSS was analyzed with Friedman's test. Melanin index, erythema index and pliability index were analyzed with repeated measure ANOVA. The p-value was adjusted by the Bonferroni method, p-value < 0.05 was considered statistically significant.

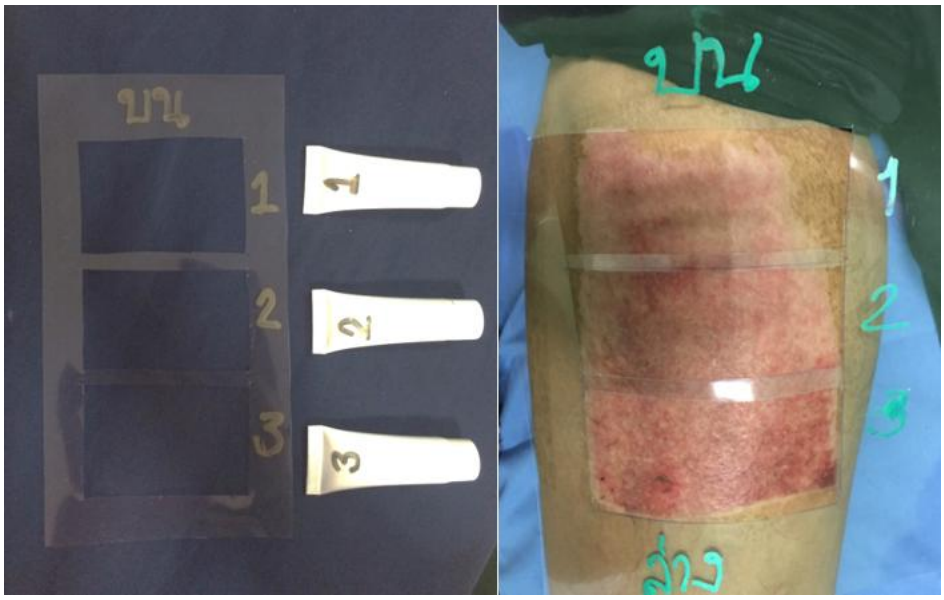

Figure 1: Plastic template for gel application.

Pigmentation	0 = normal, 1 = hypopigmented, 2 = mixed, 3 = hyperpigmented.
Vascularity	0 = normal, 1 = pink, 2 = red, 3 = purple.
Pliability	0 = normal, 1 = supple/ flexible, 2 = yielding to pressure, 3 = firm/ inflexible, 4 = bandina/rope like, 5 = contracture.
Height	0 = flat, 1 = > 2 mm, 2 = 2-5 mm, 3 = > 5 mm
Pain	0 = none, 1 = occasional, 2 = require medication.
Itching	0 = none, 1 = occasional, 2 = require medication.

Table 1: The Vancouver Scar Scale (VSS).

Results

Of the 12 patients, 8 were enrolled, total 18 split-thickness skin graft donor sites were evaluated in this study. Mean age was 31 years old. Fitzpatrick's skin type III was 25% (2/8) and type IV was 75% (6/8). All patients regulary applied the studies gel pastes. There was statistically lower in itching parameter of VSS between treatment groups compared to the placebo group after 8 weeks of treatment; Group I VS Group III ($p = 0.003, 0.002, 0.002$ at 8, 16, 24 weeks, respectively), Group II VS Group III ($p = 0.003, 0.002, 0.002$ at 8, 16, 24 weeks, respectively) but there was no significantly different between Group I and Group II. There was no statistically significant different between groups in other parameters of VSS. After 24 weeks of treatment, there was statistically significant lower erythema index in Group II when compare to Group III (359.09 VS 378.40, $p = 0.004$), but no different between Group I VS Group II (367.15 VS 359.09, $p = 0.386$) and Gr.I VS Gr.III (367.15 VS 378.40, $p = 0.079$) (Fig. 3). There was statistically significant lower melanin index in both treatment groups when comparerd to placebo group; Group I VS Group III (317.80 VS 341.600, $p = 0.013$)) and Group II VS Group III (316.19 VS 341.60, $p = 0.028$) but no different between Group I and Group II (317.80 VS 316.19, $p = 0.868$) (Fig. 4). There was no statistically significant different in pliability index between groups(Fig. 5). No adverse effects from gel pastes have been reported.

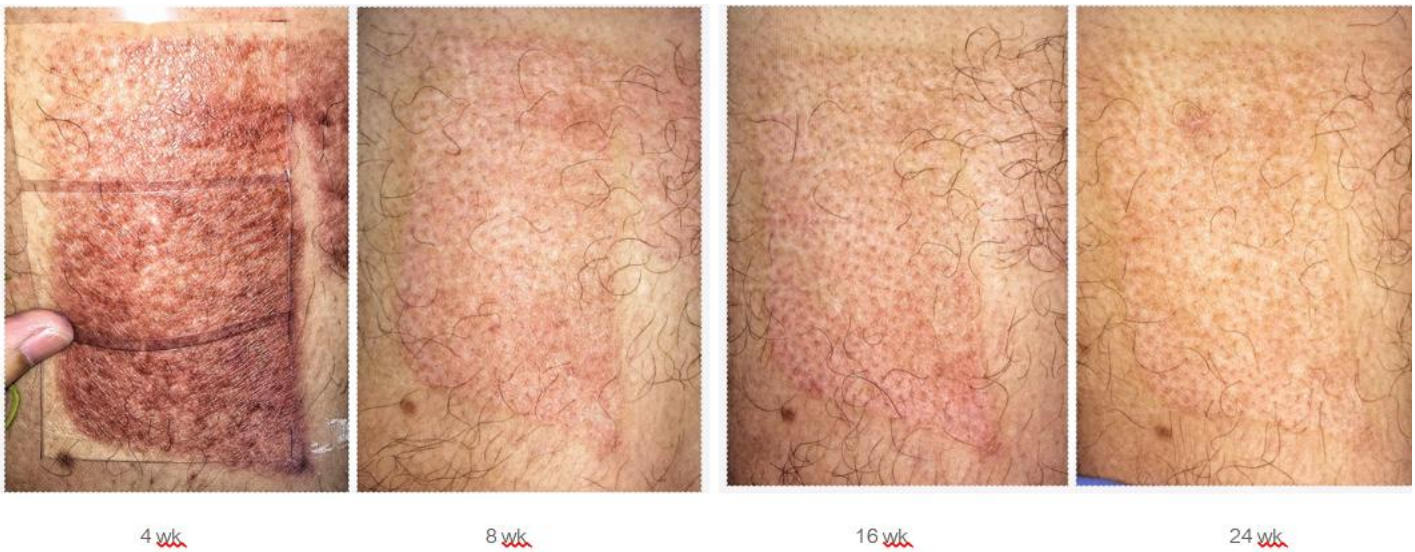

Figure 2: The healed donor site was devided equally into 3 areas with plastic template. Upper: Placebo (Gr. III), Middle: the combined herbal extracts and silicone derivative (Gr. I), Lower: the combined herbal extracts and silicone derivative +SPF 30(Gr. II). Pictures show wound at different time of follow up.

Discussion

Many literature reviews showed that silicone gel-based therapy is one of the effective methods and it is recommended for prevention of hypertrophic and keloid scar formation in high-risk patients [10,11]. The risk ratio of silicone sheet in reducing hypertrophic scar formation in Asians is 0.46 [12]. The silicone gel is the other form of silicone that have equal effectiveness as silicone gel sheet. Previous studies showed benefit of the combined herbal extracts and silicone derivative in reducing pain and itching of the scar [3-6].

Quercetin (Allium cepa extract) is also known as onion extract. It has been proven for antiinflammatory, antihistamine, antibacterial and collagen rearrange-ment [13-15]. Asiaticoside (Centella asiatica) Using a rabbit ear model, Ju-Lin, et al., reported that asiaticoside could alleviate scarring by decreasing transform growth factor beta-1 expression and regulation of collagen synthesis [16]. *In-vitro* study, Asiaticoside also inhibit keloid fibroblast proliferation [17,18]. Aloe vera (Aloe vera barbadensis) has been used for many indications for long time. There are many study reports it promotes wound healing by enhancing epithelialization, enhance blood flow in dermis an anti-inflammatory effect [19-22]. Aloe vera has a moisturizing effect and reduce pain and itching during scar formation. Kanzinol F (Broussonetia papyrifera) is one of the active agents from paper mulberry It has been proven for antioxidants effect and Tyrosinase inhibitory effect which result in reduction of hyperpigmentation [23,24]. Xyloglucan (Tamarindus indica) enhance epithelilization and remodelling in wound healing and anti-antiinflammatory effect [25]. Allantoin (Symohytum officinale) provides properties for stimulating epithelization, collagen rearrangement and moisturizing effect [26]. Cybele®scagel (Bangkok Botanica, Bangkok, Thailand) is a gel preparetion product compose of 12% allium cepa, 1% allantoin, asiaticoside, aloe vera extract, kazino F, tamarind extract and Silanols which is a silicone derivertives and has a moisturizing effect, decrease skin vapourization and inhibitory of collagen over-production [27-29]. The results from this study confirm that the combined herbal extracts and silicone derivative could reduce itching score. The effect of antimelanogenesis of SPF 30 in this study show no diffent between two treatment groups may be because the area of donor site was concealed in sun protection area. The limitation of this study was small number of sample size.

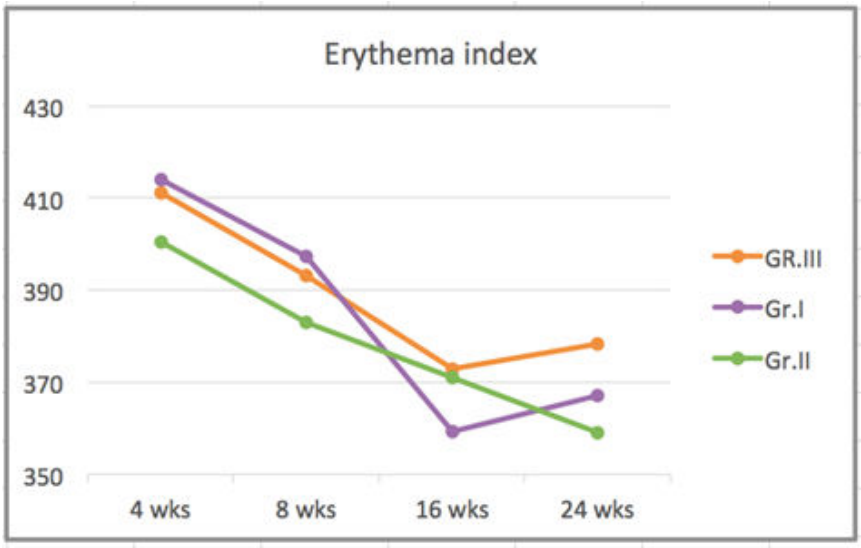

Figure 3: Erythematous index.

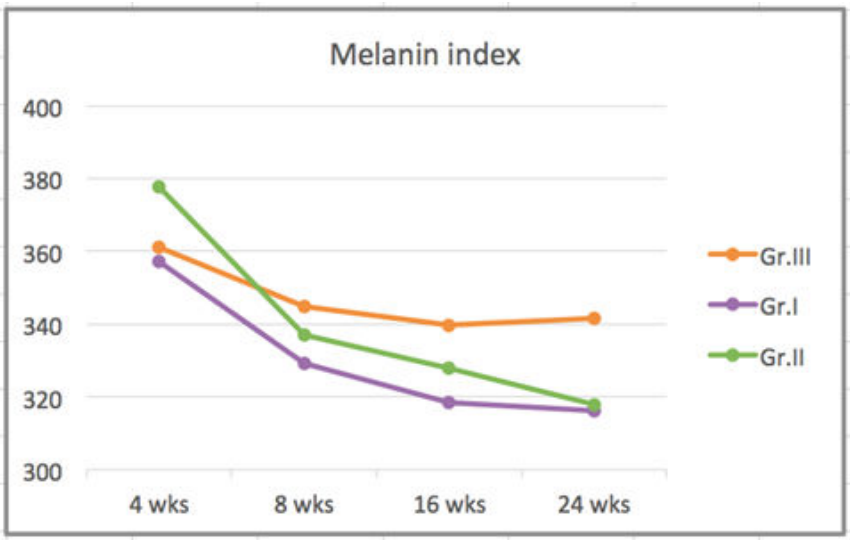

Figure 4: Melanin index.

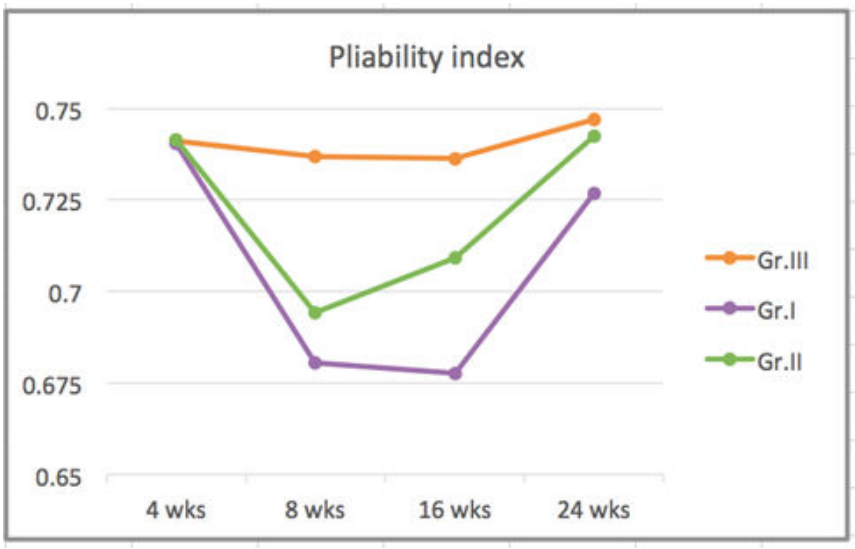

Figure 5: Pliability index.

Conclusion

The results from this study confirmed that the combination of herbal extracts and silicone derivative with or without sunscreen can reduce scar itching and proved that this combination may improve scar pigmentation and tend to reduce scar erythema.

Conflicts of Interest

The authors declare no conflict of interest in this paper.

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