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스카클리닉-씬™과 스카클리닉™의 반흔 개선효과 및 편리성 비교 -예비보고-

이상균 · 한승규 · 김우경

고려대학교 의과대학 성형외과학교실

Comparison of Scarclinic-thin™ and Scarclinic™ in Terms of Scar Improvement - A pilot study -

Sang Kyun Lee, M.D., Seung-Kyu Han, M.D., Woo-Kyung Kim, M.D.

Department of Plastic Surgery, Korea University College of Medicine, Seoul, Korea

Silicone gel sheets are widely used to treat keloids and hypertrophic scars. Scarclinic™ is a type of silicone gel sheet developed in Korea, and has been shown to improve the appearance of scars. However, Scarclinic™ has demerits that include weak adhesiveness, a color that differs from skin, and too great a thickness. Scarclinic-thin™ was recently developed with these disadvantages in mind. The purpose of this pilot study was to compare the effects of Scarclinic-thin™ and Scarclinic™ on scar appearance and wearer's comfort. From April 2010 to May 2010, Scarclinic-thin™ and Scarclinic™ were applied to treat a single scar in each of 8 patients. One half of each scar was treated with Scarclinic-thin™ and the other with Scarclinic™. After 3 months, scar quality and wearer's comfort were evaluated using the Vancouver Scar Scale (VSS) and an objective self-assessment scale (OSAS). Mean Vancouver Scar Scale scores for Scarclinic™ and Scarclinic-thin™ at 3 months were 3.4 ± 1.3 and 3.3 ± 2.0, respectively, and mean objective self-assessment scale scores were 21.7 ± 4.5 and 22.3 ± 2.9, respectively. No statistically significant difference was observed between Scarclinic™ and Scarclinic-thin™ in terms of Vancouver Scar Scale or objective self-assessment scale scores (p=0.83 and 0.70, respectively). Scarclinic-thin™ and Scarclinic™ are similar in terms of their scar improving effects and wearer's comfort. (*Archives of Aesthetic Plastic Surgery* 18: 51, 2012)

Key Words: Scar, Silicones, Silicone gels

I. INTRODUCTION

Hypertrophic scars and keloids cause cosmetic problems or uncomfortable symptoms such as color change, itchiness, and pain. However, no treatment modalities have been established to ameliorate these symptoms. The treatment modalities currently used include surgical resection, steroid injection, radiotherapy, compression therapy, laser therapy, cryotherapy, and silicone gel sheet therapy.[1-3]

As compared with the above modalities, silicone gel sheet therapy, which was first subjected to a controlled trial in 1989 by Ahn et al.,[4] has the advantages of non-worrisome systemic side effects, cost-effectiveness, and safety as compared with surgery or laser therapy. In addition, because it causes no pain, it can be easily applied to children. Silicone gel sheets were first used by Perkins in 1982 to treat burn patients.[5] Since then it has frequently been used to treat hypertrophic scars or keloids caused by burns, trauma, or surgical resection.[6] Furthermore, the treatment effects of silicone gel sheets have been well established.[7]

Scarclinic™ (Ildong Pharm. Co., Seoul) was developed in Korea and it has been reported to have favorable treatment effects.[8] However, despite its efficacy, the use of Scarclinic™ is restricted by its thickness (1.5 mm) by the discomfort

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Address Correspondence : Seung-Kyu Han, M.D., Department of Plastic Surgery, Korea University Guro Hospital, 97 Guro-dong, Guro-gu, Seoul 152-703, Korea. Tel: 82-2-2626-3333, Fax: 82-2-868-6698, E-mail: pshan@kumc.or.kr

caused at scar sites. Furthermore, the silicone gel sheet should be washed at least 3 times a day and then re-attached. In addition, while it is being used, it frequently detaches due to its poor adhesiveness, and it is also quite noticeable because its color is quite different from skin color. In order to overcome these disadvantages, Scarclinic-thin™ (Ildong Pharm. Co., Seoul), which as its name implies is thinner (0.45 mm) than Scarclinic™, has been developed. In addition, it also has improved adhesiveness and a color that better matches that of skin. However the scar improving effect and wearer's comfort of Scarclinic- thin™ have yet to be established.

Given the above background, we conducted this pilot study to compare the scar improvement effects and wearer's comforts of Scarclinic-thin™ and Scarclinic™.

II. PATIENTS AND METHODS

This clinical trial was approved by the Institutional Review Board (IRB) at the authors' institution (IRB No. MD0920). During the period from April 2010 to May 2010, Scarclinic™ and Scarclinic-thin™ were applied a scar on each of 8 patients. All patients were followed up for 3 months. Scars were caused by a split thickness skin graft at donor sites. However, 1 of the patients withdrew written informed consent, and thus, the analysis was performed on 7 patients (5 men and 2 women).

The major inclusion criterion of the current clinical study was scars formed within 3 months of wound healing. The major exclusion criteria were an unhealed wound, a scab or another foreign material at the scar site, and the possibilities of infection at the wound site, a dermatologic disease, or a psychiatric disease.

One scar on each of the 7 study subjects was divided equally into two parts. One half was treated with Scarclinic™ and other with Scarclinic-thin™. Both products were applied so as to adhere to scars. For physically active patients, medical paper or cotton tapes were used to fix the products. Patients were advised not to use ointment, cosmetics, or any other skin care product during the 3-month study period.

After 1 week, 1 month, and 3 months of treatment, patients were asked to visit our outpatient clinic. At each visit, patients were evaluated to determine the presence of pruritis or other adverse effects. After 3 months of treatment, the Vancouver Scar Scale (VSS) was applied by a chief resident in the plastic surgery department unaware of patient history or sites of application (Table I). In addition, patients were asked provide an assessment of each product using the objective self- assessment scale (OSAS), which includes assesses product effect, and convenience and overall patient satisfaction using 10-point scales (10 points represented the best result).

VSS and OSAS scores were analyzed using the paired t-test, and p values of < 0.05 were considered statistically significant.

Table I. Vancouver Scar Scale

Vascularity	Nomal	0
	Pink	1
	Red	2
	Purple	3
Pigmentation	Normal	0
	Hypo-pigmentation	1
	Mixed-pigmentation	2
	Hyper-pigmentation	3
Pliability (Elasticity)	Normal	0
	Supple (flexibile with minimal resistance)	1
	Yielding (giving way to pressure)	2
	Firm (inflexible, not easily moved, resistant to manual pressure)	3
	Banding (rope-like tissue that blanches with extension of the scar)	4
	Contracture (permanent shortening of scar, producing deformity or distortion)	5
Height	Flat	0
	< 2 mm	1
	2~5 mm	2
	> 5 mm	3
Pain	None	0
	Occasional	1
	Requires medication	2
Itchiness	None	0
	Occasional	1
	Requires medication	2

III. RESULTS

Mean VSS scores were 3.4 ± 1.3 points for Scarclinic™ and 3.3 ± 2.0 points for Scarclinic-thin™, which were not significantly different (p=0.83). In more detail, no significant difference in vascularity was observed in 7 patients (100%). In terms of pigmentation, no significant difference was observed in 3 patients (42.9%). In 2 patients (28.6%), skin color faded under Scarclinic™, whereas in another 2 patients (28.6%), the skin color faded under Scarclinic-thin™. In terms of scar tissue pliability, no stiffness was observed in 7 patients (100%), and for scar height, 6 patients (85.7%) showed no protuberance, and in the other 1 patients (14.3%), Scarclinic- thin™ sides were elevated more than Scarclinic™ sides. Pain analysis revealed that 6 patients (85.7%) had no scar pain, but 1 patient (9.1%) complained of intermittent pain on the Scarclinic™ side. In terms of the itchness, 5 patients (71.4%) did not complain of pruritis, but mild severity pruritis was observed

on the Scarclinic™ side in 1 patient (14.3%) and on Scarclinic-thin™ sides in 1 patients (14.3%) (Table II). The examples of cases are shown in the Figs. 1, 2, and 3 (Fig. 1-3).

Table II. Results of Vancouver Scar Scale

Mean ± SD	Scarclinic™	Scarclinic-thin™
Vascularity	1.3 ± 0.7	1.3 ± 0.7
Pigmentation	1.9 ± 0.8	1.7 ± 1.2
Pliability	0	0
Height	0	0.1 ± 0.3
Pain	0.1 ± 0.3	0
Itchness	0.2 ± 0.3	0.1 ± 0.3
Total	3.4 ± 1.3	3.3 ± 2.0

Mean OSAS scores were 21.7 ± 4.5 for Scarclinic™ sides and 22.3 ± 2.9 for Scarclinic-thin™ sides, which was not a significant difference (p=0.70). In more detail, 5 patients (71.4%) found no significant difference between the two products in terms of effects. 2 patients (28.6%) found that Scarclinic-thin™ had a better effect. In terms of convenience, 4 patients (57.1%) favored Scarclinic™, and 2 patients (28.6%) favored Scarclinic-thin™, and 1 patients (14.3%) scored the products equally. In terms of overall degree of satisfaction, 1 patient (14.3%) favored Scarclinic™, 3 patients(42.9%) favored Scarclinic-thin™, and 3 patients (42.9%) scored them equally.

The above results indicate no significant differences between the two products in terms of scar improvement effect and wearer's comfort based on VSS and OSAS scores (Table III).

Table III. Overall results of Vancouver Scar Scale (VSS) and Objective Self-assessment Scale (OSAS)

No.	VSS		OSAS	
	Scarclinic™	Scarclinic-thin™	Scarclinic™	Scarclinic-thin™
1	4	3	22	22
2	3	3	13	18
3	5	7	23	22
4	1	1	23	22
5	3	1	28	28
6*	-	-	-	-
7	5	3	25	20
8	3	5	18	24
Mean±SD	3.4±1.3	3.3±2.0	21.7±4.5	22.3±2.9
p value	0.83		0.70	

* : the patient withdrew written informed consent
VSS : 0 ~ 18 points. A lower point represents a better result.
OSAS : 0 ~ 30 points. A higher point represents a better result.

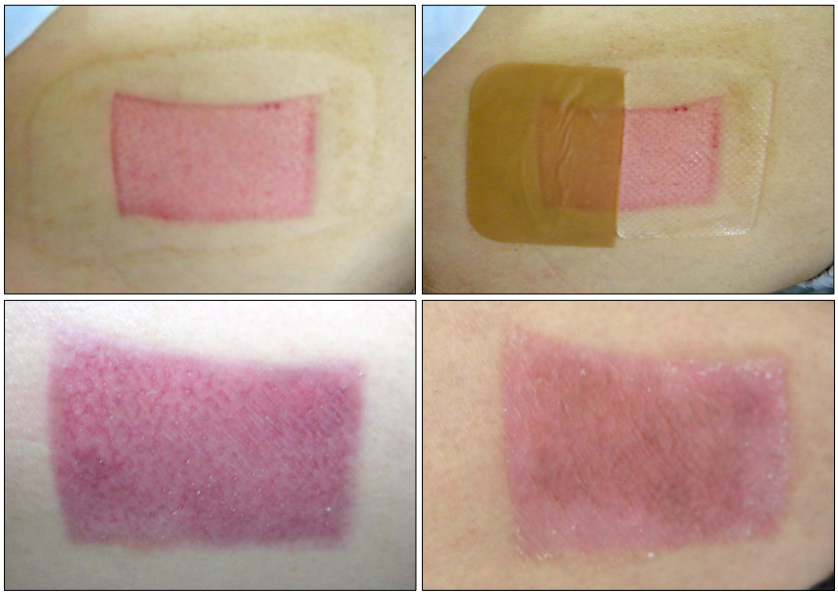

Fig. 1. Case 1. patient No. 2 (Above, left) Donor site of split thickness skin graft. (Above, right) Left half of scar was treated with yellowish Scarclinic-thin™ and right half with transparent Scarclinic™. (Below, left) After one month and (Below, right) after three months. The sites where Scarclinic-thin™ and Scarclinic™ were applied produced same VSS results.

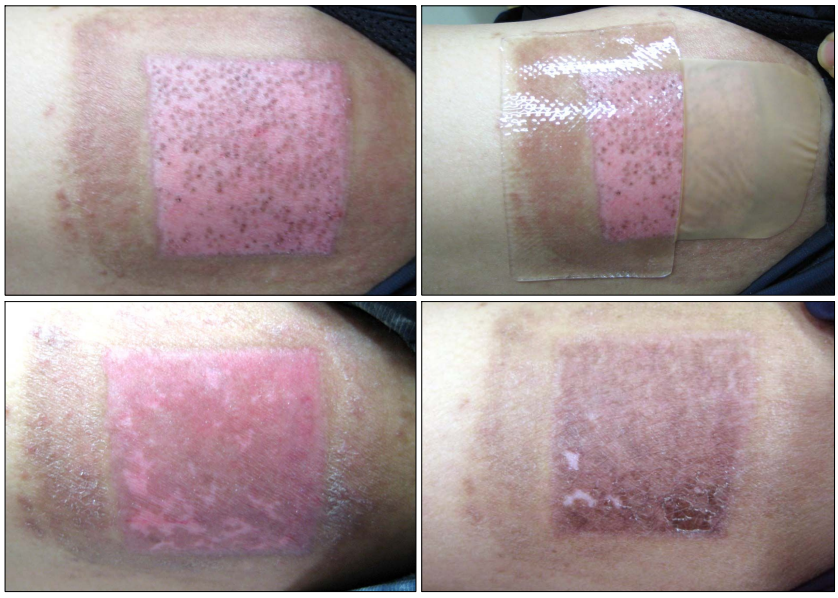

Fig. 2. Case 2. patient No. 3 (Above, left) Donor site of split thickness skin graft. (Above, right) Left half of scar was treated with transparent Scarclinic™ and right half with yellowish Scarclinic-thin™. (Below, left) After one month. (Below, right) After 3 months. The site where Scarclinic™ was applied produced the better VSS result.

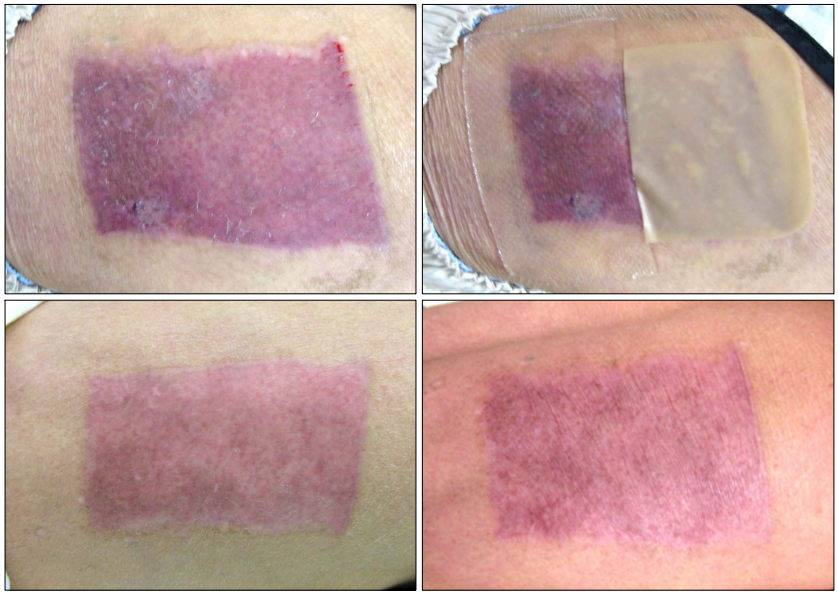

Fig. 3. Case 3. patient No. 5 (Above, left) Donor site of split thickness skin graft. (Above, right) Left half of scar was treated with transparent Scarclinic™ and right half with yellowish Scarclinic-thin™. (Below, left) After one month. (Below, right) After 3 months. The site where Scarclinic-thin™ was applied produced the better VSS result.

IV. DISCUSSION

The treatment modalities of hypertrophic scars and keloids currently include steroid injection, surgical resection, laser therapy, radiotherapy, compression therapy, cryotherapy, and silicone gel sheet therapy.[1-3] The efficacy of steroid injections has been demonstrated, and they have been reported to soften and flatten scars and to be effective at alleviating symptoms, but they can also cause side effects such as atrophy of adjacent skin, hypopigmentation and telangiectasia.[9] On the other hand, surgical resection is disadvantaged by its side effects and the high recurrences of hypertrophic scars and keloids. Lasers are frequently used to treat patients with a hypertrophic scar or keloid. Alster reported that hypertrophic scars improved clinically after treatment with a 585 nm flashlamp-pumped pulsed dye laser.[10] Wittenberg conducted a prospective, single-blind, randomized, controlled study, and found no significant difference in the efficacies of a 585 nm flashlamp-pumped pulsed dye laser and a silicone gel sheet.[11] Radiotherapy alone does not produce good treatment outcomes, but it is effective when used as a postoperative adjuvant therapy.[3] Compression therapy requires that patients wear a compression garment or bandage for a considerable time, and is restrictive in terms of suitable sites. Furthermore, patients and medical staff find it inconvenient. On the other hand, cryotherapy causes severe pain and may also produce irreversible depigmentation.[3]

Therefore, silicone gel sheets are beneficial for scar improvement, because they cause very few serious side effects and

can be used as an alternative to invasive treatment regimens. As described above, surgical resection, intralesional steroid injection, radiotherapy, compression therapy, laser therapy, and cryotherapy have well-defined demerits.[3,9,10] Accordingly, silicone gel sheets are commonly used to prevent and treat hypertrophic scars or keloids.

Little is known about the exact mechanisms responsible for the beneficial effects of silicone gel sheet therapy, though several hypotheses have been proposed. In 1987, Quinn noted that the water vapor transmission rate through a silicone gel sheet was approximately half that of normal skin tissue. Accordingly, it was hypothesized that silicone gel sheets produce a water content rich environment, whereas other factors, such as pressure, the partial pressure of oxygen, and temperature change have no effects on scar improvements.[12,13] At the 7th International Society for Burn Injuries held in 1986, Davey reported that the non-permeability of silicone gel contributed to the maintenance of homeostasis and reduced congestion and fibrosis in the keratin layer, and thus suppressed scar tissue formation. On the other hand, Hirshowitz et al., proposed that the electrical field by silicone gel sheets acts to suppress hypertrophic scar and keloid formation.[14] According to Borgognoni, who conducted a histopathological, and immunological analysis of hypertrophic scar and keloid tissues, the application of a silicone gel sheet reduces spindle-shaped cells numbers and markedly increases the numbers of lymphocytes expressing CD11a/CD18 and thus reduces hypertrophic scar and keloid formation.[15] In summary, the presumptive functions of a silicone gel sheet might include the following: water retention,[13] the maintenance of homeostasis due to the non-permeability of a silicone gel sheet, the electrical field with a certain degree of magnitude being the impedance signal against the formation of hypertrophic scar and keloid,[14] and the functions decreasing spindle-shaped cells and increasing lymphocytes expressing CD11a/CD18 to a strong extent.[15]

Furthermore, it has been reported that silicone gel sheets are effective when continuously applied for 12 hours a day for at least 2 to 3 months. And the treatment should be started at 2 to 3 weeks after trauma, when the deposition of collagen tissue becomes completed following the onset of trauma.[12]

As mentioned above, the two silicone gel sheets examined in this study are different in thickness. Furthermore, the adhesiveness of Scarclinic-thin™ is greater than that of Scarclinic™. In addition, Scarclinic™ and Scarclinic-thin™ are transparent and skin colored, respectively. However, according to our results, the VAS scores of the two products were similar, which suggest that thinner Scarclinic-thin™ also reduces scar tissue formation as like Scarclinic™. From the perspective of wearer's comfort, the authors considered at the onset that Scarclinic-thin™ would have the advantage, but it was found that their OSAS scores were similar (Scarclinic™ 21.7 ± 4.5 and Scarclinic- thin™ 22.3 ± 2.9; p=0.70).

In addition, Scarclinic-thin™ and Scarclinic™ are different only in terms of thickness, adhesiveness and color. Moreover, those products are manufactured by the same company in a same process. Therefore, the bias of this study was able to be minimized, and the study design became more systematic.

We suggest that it might be desirable to select a product based on considerations of scar sites and environments. In flat body areas with limited movement and in regions where rinsing the gel is likely to performed frequently, for example, due to greater perspiration, Scarclinic™ might be appropriate, whereas Scarclinic-thin™ might be more appropriate in body areas with greater movement, where a UV block is mandatory due to exposure to sunlight (e.g., face or neck), or it regions where the skin is folded. Bearing in mind that the effects of these product types are largely dictated by continuous application times, the above considerations might increase patient compliance and contribute to treatment outcomes.

The present clinical study has several limitations, as it was a pilot study, conducted on only 7 patients, with a treatment duration of 3 months. The 3-month follow-up was chosen due to concerns of bias due to other factors had the study been prolonged and because it is generally recommended that silicone gel sheets be applied for 3 months. In addition a previous study on the effects of Scarclinic™ on scar improvements was also conducted over 3 months.[8] However, further studies are required in a larger cohort with a longer follow-up, particularly to determine the effect that sheet thickness has on scar tissue formation.

V. CONCLUSION

In this pilot study, we compared the scar improvement effect and wearer's comfort of Scarclinic-thin™ and Scarclinic™. From the perspective of the scar improvement effect, it suggested that thinner Scarclinic-thin™ also reduced scar tissue formation as like Scarclinic™. From the perspective of the wearer's comfort, the authors considered at the onset that Scarclinic-thin™ would have the advantage because of thickness, adhesiveness, and color, but it was found that their wearer's comforts were similar. Therefore, we suggest that it might be desirable to select a product based on considerations of scar sites and environments.

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