

Self-adhesive Silicone Gel Sheet : A Treatment for Hypertrophic Scars and Keloids

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Abstract

An open clinical trial was conducted to assess the effect of self-adhesive silicone gel sheet (SASGS) for the treatment of hypertrophic scars and keloids in Thai people. Patients were instructed to apply the SASGS to the scars as long as possible, but not less than 12 hours per day for at least 8 weeks. The subjective results of the treatment were evaluated by the patients. The scars were evaluated for color, height, weight before and after treatment at 4 and 8 weeks.

Eighteen patients with 18 hypertrophic scars or keloids were recruited into the study. Their ages ranged from 6 to 33 years (mean 21 years). The average duration of the scars was 5.7 years. Twelve patients (66.67%) stated good results. All of the 18 patients wanted to continue the treatment with SASGS. Heights of the scars were reduced in 12 lesions (66.67%) after treatment for 8 weeks ($P=0.058$). Weights of the lesions were decreased in 10 lesions (55.55%) but were not statistically different ($P=0.090$). Seven lesions (36.84%) were improved in color. Two patients (11.11%) developed erythematous rash around the lesions which subsided after withdrawal of the treatment. The long term follow-up for the recurrence and the mechanism of action of this treatment should be studied further.

Key word : Keloid, Silicone Gel Sheet

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Hypertrophic scars and keloids are common problems but the ideal treatment for them still remains undiscovered. Many measures have been

used with limited success(1). Corticosteroid intra-lesional injection, pressure garment, radiation, and laser(2) are the popular modalities in the treatment

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of hypertrophic scars and keloids. Corticosteroid injection causes pain, so it is not suitable for children. Pressure garments are uncomfortable especially in hot weather as in Thailand. Silicone gel sheeting has been reported as one of the effective treatments of hypertrophic scar and keloid for the past few years⁽³⁻⁷⁾. Such reports have not been carried out in a hot, humid region like Thailand.

In this report we studied the efficacy of self adhesive silicone gel sheet (SASGS) as a treatment of hypertrophic scars and keloids in Thai people, using prospective protocols.

PATIENTS AND METHOD

Silicone gel sheets are soft, self-adhesive, semi-occlusive sheets made from medical graded silicone reinforced with silicone membrane backing.

The patients with hypertrophic scars or keloids of more than 3 months were recruited into the study. The details of the study including complications were explained to the patients before the consent forms were signed. Silicone gel sheets were applied to 18 keloids and hypertrophic scars for 8 consecutive weeks. The gel sheets were self - adhesive, however some skin tapes might be applied to the edge of the sheets for keeping them in place. The gel sheet should be applied for at least 12 hours a day during the therapy. It was possible that the

application be applied for 24 hours, allowing for a washing period. The symptoms before and after treatment were recorded. The results of the treatment were classified by the patients as poor, fair or good. The scars were photographed, measured and printed with dental molds prior to treatment, then 4 and 8 weeks after treatment. Scar weight measurements were performed to determine whether they could indicate quantitative measures of the results of the treatment or not. Vinyl poly-siloxane was used for making impressions on the scars. These were filled with sand. Weight of the sand would represent mass of each scar over its skin surface. All scars were photographed using a 100 mm macro lens with the same background. A color control chart was included in the field. The lens aperture, exposure time and subject distance were kept constant.

RESULTS

There were 18 patients whose ages ranged from 6 to 33 years (mean 21 years) enrolled in the study. The causes of the scars are listed in Table 1. The duration of the scars was 3 months to 20 years (average 5.7 years). Twelve patients (66.67%) gave good results. All of the 18 patients wanted to continue the treatment with the silicone gel sheeting. For the objective evaluation, the heights of the lesions were decreased in 12 lesions (66.67%) (Fig.

Table 1. Details of the patients.

Patient	Age (yrs)	Sex	Cause	Duration of scar (yrs)	Site	Previous Treatment
1	32	Female	Abscess	9	Rt. breast	No
2	20	Female	Unknown	20	Sternum	Steroid
3	26	Female	Trauma	1	Rt. shin	No
4	32	Female	Vaccination	15	Lt. shoulder	No
5	15	Male	Abscess	5	Lt. shoulder	No
6	23	Female	Vaccination	20	Lt. shoulder	No
7	13	Female	Vaccination	2	Lt. shoulder	No
8	15	Female	Excision	15	Lt. shoulder	No
9	14	Female	Vaccination	15/12	Lt. shoulder	Excision
10	28	Female	Acne	5	Sternum	No
11	20	Female	Jelly	4/12	Lt. shoulder	Steroid
12	26	Female	Accident	5/12	Lt. foot, dorsum	No
13	19	Male	Accident	6/12	Lt. elbow	No
14	14	Male	Vaccination	7	Bilateral shoulders	No
15	26	Male	Laser	2	Re. forearm	No
16	21	Male	Trauma	5	Back	No
17	6	Male	Burn	3	Lt. forearm	No
18	18	Female	Excision	2	Lt. shoulder	No

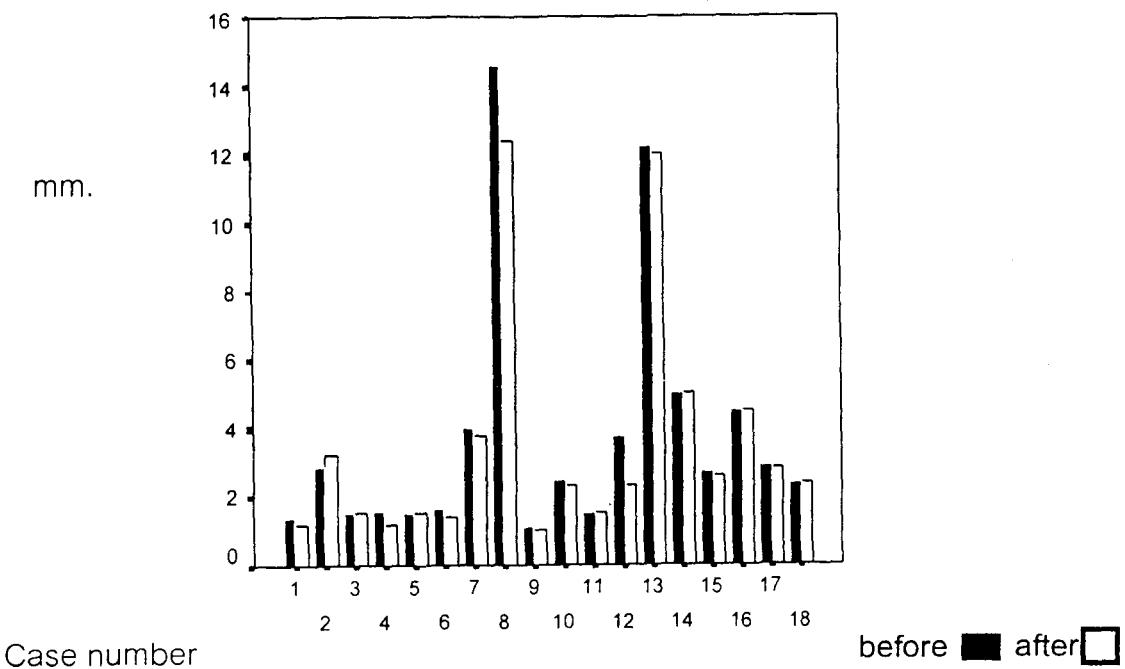


Fig. 1. Height of the scars before and after treatment.

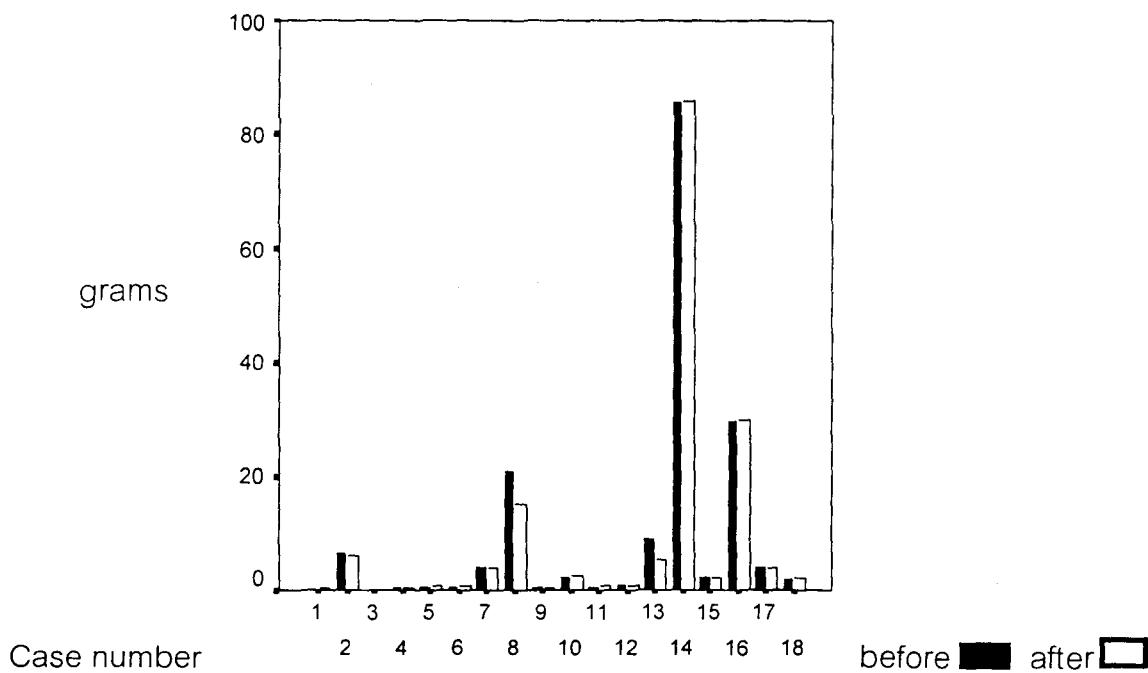


Fig. 2. Weight of the scars before and after treatment.

1). Means of the lesions's heights before and after treatment were 3.76 mm and 3.47 mm, respectively. By using paired *t*-test analysis, there was no significant improvement of the lesions after treatment ($p=0.058$). Ten lesions (55.55%) were reduced in weight (Fig. 2). Means of the lesions' masses before and after treatment were 9.6183 g and 9.1211 g, respectively. The reduction in weight of the lesions was not significant by using paired *t* - test analysis ($P=0.090$).

Seven lesions (36.84%) were improved in color (Fig. 3).

Two (11.11%) developed erythematous rash around the lesions which subsided after withdrawal of the treatment.

DISCUSSION

There are many non surgical modalities for the treatment of hypertrophic scars and keloids (1,8). Many of them have some disadvantages. Local corticosteroid injection causes pain and hypopigmentation of the scars. Pressure garments create discomfort especially in a hot climate as in Thailand. Topical silicone gel sheeting has been introduced as a treatment of hypertrophic scars and keloids since 1982(7). The mechanism of action is still unknown. Quinn *et al*(9) claimed that pressure was not required for the therapeutic effect. Ahn *et al*(4) found no histologic evidence that silicone had entered the scar. Hirshowitz *et al*(10) demonstrated that the effect of silicone to the scar could be from

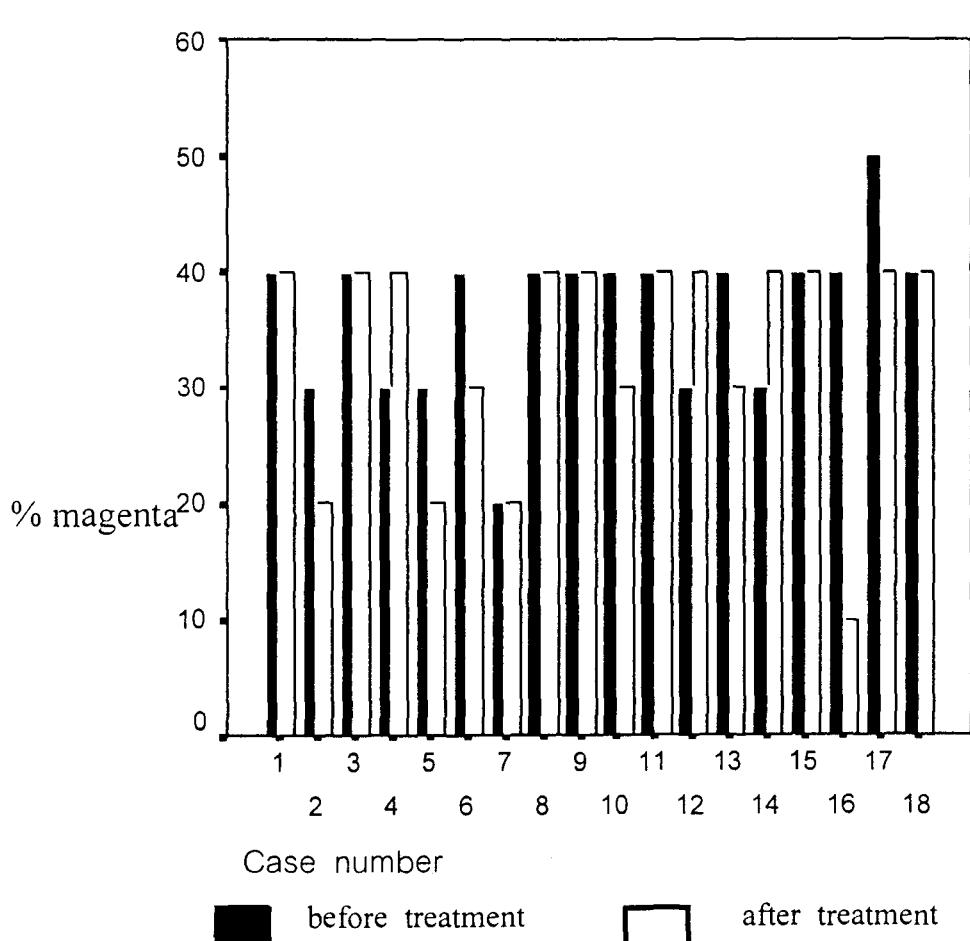


Fig. 3. Percentage of magenta of scar color before and after treatment.

its generation of static electricity. Mercer⁽¹¹⁾ studied 22 lesions with a mean scar age of 35 months treated with silastic gel achieving 86 per cent improvements. Ninety to ninety five percent improvement of the scars were also reported^(4,5,10). In our study, 66.67 per cent of the patients reported improvement by subjective evaluation and also 66.67 per cent of the scars treated with silicone gel sheet showed a reduction in height. The mean duration of the scars in our study was 5.7 years. This was longer than those in the previous literature. The long duration of scar could be one of the factors that affected the result of the treatment. In the review literature of treatment of keloids by

Lawrence⁽⁸⁾, he cited that the improvement rate by intra-lesional corticosteroid injection was between 50-100 per cent, by radiation alone it was 25-94 per cent and by laser it was 0-100 per cent. In comparison with our results, silicone gel sheeting should be one of the treatments for hypertrophic scars and keloids. Application of silicone gel sheet causes no pain. This gives some advantage over intra-lesional injection of corticosteroids.

Only 11.11 per cent of the patients had minor side effects from the application of the silicone gel sheets. The complications were not higher than in other literature,^(4,5,8) so the hot and humid weather did not increase this side effect.

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แผ่นซิลิโคนแบบยึดติดเอง : แนวทางการรักษาชนิดหนึ่งสำหรับแผลเป็นมูนและแผลเป็นคีลอยด์

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ได้ทำการศึกษาผลของการใช้แผ่นซิลิโคนแบบยึดติดเองรักษาแผลเป็นมูนและคีลอยด์ในคนไทยจำนวน 18 ราย ผู้ป่วยใช้แผ่นซิลิโคนนี้ปิดบนแผลเป็นมูนอย่างน้อย 12 ชั่วโมงต่อหนึ่งวัน ต่อเนื่องกัน เป็นเวลา 8 สัปดาห์ แบ่งการวัดผลของการรักษาเป็น 2 แบบ คือ 1. โดยความรู้สึกพอยใจต่อผลการรักษาของผู้ป่วยเอง 2. โดยการตรวจลักษณะการเปลี่ยนแปลงของแผลเป็นโดยใช้ สี ความสูงและน้ำหนัก กองการรักษาและหลังการรักษาเมื่อ 8 สัปดาห์ ผู้ป่วยมีอายุระหว่าง 6 ถึง 33 ปี (เฉลี่ย 21 ปี) ระยะเวลาเฉลี่ยของแผลเป็น 5.7 ปี ผู้ป่วย 12 รายจาก 18 ราย พอดีกับผลการรักษา ผู้ป่วยทั้งหมด 18 รายต้องการที่จะใช้วิธีนี้รักษาแผลเป็นมูนต่อไป ความสูง น้ำหนักและสี เปลี่ยนแปลงดีขึ้น 66.67%, 55.55% และ 36.84% ตามลำดับ หลังการรักษาแต่ไม่มีนัยสำคัญทางสถิติ

ผู้ป่วย 2 รายเกิดผื่นแดงที่รอยโรคขณะรับการรักษาและหายไปเมื่อเลิกใช้แผ่นซิลิโคน

คำสำคัญ : Keloid, Silicone Gel Sheet

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