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The Efficacy of Topical Silicone Gel Elastomers in the Treatment of Hypertrophic Scars, Keloid Scars, and Post–Laser Exfoliation Erythema

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Abstract.
Background: Dermatix is a Food and Drug Administration (FDA)-registered substantial equivalent to silicone gel sheeting for the prevention and management of hypertrophic scars and keloids.
Methods: A 90-day prospective study evaluated the efficacy of Dermatix, silicone gel sheeting, and a combination of these treatments in improving scars for 30 patients. Each patient had a bilateral scar that served as an untreated control. The outcome measures included profilometry analysis of scar topography before and after punch biopsies of the control and treated scars, symptoms associated with the scars, and patient evaluations of the ease of treatment.
Results: The results showed better resolution and improvement of scars with Dermatix treatment or the combined use of Dermatix and silicone gel sheeting than with silicone gel sheeting alone. Wound erythema was reduced, and collagen architectural reorientation was demonstrated histologically. Patients rated Dermatix as easier to use than silicone gel sheeting. Both Dermatix and silicone gel sheeting reduced symptoms of itching, irritation, and skin maceration.
Conclusion: The results of this study indicate that Dermatix is a useful treatment for the management of abnormal scarring.

Key words: Hypertrophic scar—Keloid—Silicone gel—Silicone gel sheeting

Hypertrophic scars develop for approximately 39% to 68% of patients after surgery and for 33% to 91% of patients after burns [13,15]. The incidence of hypertrophic scarring appears to be highest in dark-skinned populations [10]. Keloids also are most commonly seen in dark-skinned individuals [2]. The prevalence of keloids in black and Hispanic populations has been estimated to be 4.5% to 16% [2].

Although a variety of therapeutic methods have been attempted, most medical and surgical specialties treating these problematic scars agree that they are notoriously difficult to treat [7]. Currently, more than 50% of our population is 45 years of age or older. With more minimally invasive procedures becoming available, more patients are seeking elective surgical procedures for aesthetic reasons. Because cutaneous laser exfoliation procedures are on the rise, there also has been an increased incidence of facial hypertrophic scars.

Although the more deeply pigmented races are susceptible, a persistent hypertrophic scar or keloid may develop for any person after a traumatic injury or surgical procedure [1]. These types of scars are more common in areas that demonstrate a slow wound healing response such as the anterior chest or the breasts, or in movement-dependant areas such as the scapula, the elbow, or the knee [14]. By definition, a hypertrophic scar usually is raised and erythematous, but remains within the confines of the original traumatic wound [11]. In contrast, a keloid is a more nodular lesion that extends beyond the margins of the initial wound [11].

Wound healing involves many complicated, concurrent processes that occur in three phases: an inflammation phase, a granulation tissue formation phase, and a matrix formation or remodeling phase [5]. Studies have shown that these phases are not purely sequential, but have a significant amount of overlap [9]. Perhaps due to this overlap of phases, a

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great deal of study has gone into understanding the regulation of these phases with the hope of being able to gain tighter control of the overall process and the outcome of wound healing [6].

For decades, scars were accepted phenomena. Patients were told that little could be done about them and that they had to accept the appearance of their scars. Yet most patients do not accept that "nothing can be done" and will accept even a slight improvement in the overall appearance of a scar as compared with a disfiguring result, which can have a very adverse effect on self esteem. The negative consequences of disfiguring scars have motivated researchers to attempt modification of the healing process to improve the appearance of scars and to reduce the physical and emotional disabilities that result from abnormal scarring.

A variety of treatments for hypertrophic scars and keloids have been advocated in the past. These include intralesional steroids, cryosurgery, radiotherapy, pressure therapy, silicone gel sheeting, laser therapy, excisional surgery, and topical silicone gels [12]. Recurrences remain common, and patient satisfaction is variable [12].

Findings recently have shown topical silicone gel to be effective in the prevention of hypertrophic scarring, with beneficial results similar to those provided by silicone gel sheeting and pressure dressings [4]. An advantage of a silicone gel is its ease of application and effortless maintenance. This study aimed to determine the efficacy of topical silicone gel in the treatment of hypertrophic scars, keloid scars, and erythematous scars resulting from laser exfoliation.

Methods

A total of 100 consecutive patients (64 females and 36 males) presenting with scars were screened for enrollment in this study. At screening, 140 scars were evaluated. Of these 140 scars, 71 were located on the face, 25 on the abdomen, 10 on the breast, 8 on the neck, 5 on the sternum, and 1 on the buttock. Scars still in the erythematous and raised stage of healing, hypertrophic scars, and keloid scars were deemed appropriate for study. Scars determined to be dormant and mature by virtue of their flatness, lack of erythema, or lack of pigmentation were excluded from this study.

Patients who had bilateral active scars were included in the study. For each patient, one scar was treated and the other was used as an untreated control. Each patient was assigned to one of three treatment groups. The patients in the first group applied the polysiloxane derivative Dermatix (Valeant Pharmaceuticals International, Aliso Viejo, CA) to the treated scar twice daily (morning and evening). The patients in the second group applied Epi-derm silicone gel sheeting to the epidermis daily and left it in place through the morning and night. The patients in the third group applied Dermatix in the morning and silicone gel sheeting at night.

The treated and control scars were examined at visits after 30, 60, and 90 days. Evaluations included erythema, surface topologic elevation, and overall softening of the scar. Skin surface texture and architecture were measured objectively using a computer-assisted digital imaging program (optical profilometry), and scar elevation was analyzed. Subjective evaluations of the healing scars were made by the patients and the physician at each visit using linear analog scores. Histologic punch biopsies were obtained before and after treatment for specific examination of the orientation and pattern of the collagen fibers.

Results

The treated scars showed improvement as compared with the untreated control scars for all parameters in each of the treatment groups. However, the scars treated with Dermatix showed better leveling than the scars treated with silicone gel sheeting (Table 1). The difference between the treatments was maximized at 90 days. On day 90, the mean elevation of the scars treated with Dermatix was 0.79 mm, as compared with 1.39 mm for the scars treated with gel sheeting. The untreated control scars in the Dermatix and gel sheeting treatment groups showed a similar higher elevation on day 90 (1.96 and 1.94 mm, respectively). The decrease in mean scar height from baseline was 1.5 mm with Dermatix, 1.0 mm with silicone gel sheeting, and 0.35 mm for the untreated control scars. Facial scars appeared to have better results with the Dermatix gel than with the silicone gel sheeting.

The scars treated with Dermatix also showed earlier and greater dissipation of erythema than the scars treated with silicone gel sheeting (Fig. 1). The decrease in mean erythema scores from baseline to day 90 was 4.26 units with Dermatix treatment and 2.52 units with silicone gel sheeting treatment. By comparison, the decrease for the untreated control scars was 0.77 units in the Dermatix group and 1.21 units in the silicone gel sheeting group.

Overall, 60% of the control scars involved in the study were symptomatic, but patients described minimal symptoms related to pain, burning, or itching for scars treated with Dermatix gel, silicone gel sheeting, or both. Treatment with either Dermatix or silicone gel sheeting reduced symptoms of itching, irritation, and skin maceration as compared with untreated scars (Table 2), but there were more patient complaints of itching or maceration with the silicone gel sheeting than with Dermatix.

The treated scars showed greater elasticity or pliability than the untreated control scars. Patient perceptions of the softening of treated scars were comparable with those for Dermatix and gel sheeting

Table 1. Scar elevation on day 90

Dermatix treatment group (n = 10)			Gel sheeting treatment group (n = 10)		
Patient identification no.	Control scar height (mm) at day 90	Treated scar height (mm) at day 90	Patient identification no.	Control scar height (mm) at day 90	Treated scar height (mm) at day 90
1	1.2	0.4	11	1.3	0.8
2	2.3	0.9	12	2.4	1.6
3	1.7	0.3	13	1.5	1.1
4	1.1	0.4	14	0.9	0.7
5	2.9	1.1	15	2.7	1.8
6	1.8	0.4	16	1.5	0.8
7	1.6	0.3	17	1.8	1.3
8	3.4	2.1	18	3.7	3.1
9	1.1	0.7	19	1.4	0.9
10	2.5	1.3	20	2.2	1.8
Mean	1.96	0.79[a]	Mean	1.94	1.39[a]
SD	0.79	0.58	SD	0.83	0.73

SD, standard deviation
[a] $p < 0.001$ vs untreated control scar in same patient (paired *t*-test)

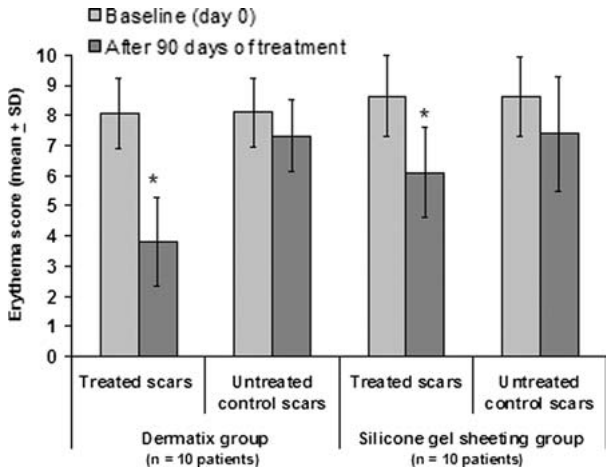

Fig. 1. Erythema scores for scars treated with Dermatix or gel sheeting and for untreated control scars. Erythema was rated on a linear analog scale from 0 (none) to 10 (red). *$p < 0.001$ vs untreated control scar in same patient at day 90 (paired *t*-test).

treatment. Patients subjectively ranked Dermatix far superior to gel sheeting in ease of use, however, (Fig. 2) and in their willingness to comply with the treatment regimen.

At histologic examination, the collagen bundles appeared looser and were more parallel to the surface of the skin in the treated scars than in the thick swirled bundles of collagen in the untreated control scars (Fig. 3). Mast cells are known to be important in the remodeling phase of wound healing [9], and the number of mast cells was increased in the scars treated with either Dermatix or silicone gel sheeting. There were a normal number of mast cells in the untreated control scars.

The third group of patients was asked to use Dermatix during the day and gel sheeting at night on the treated scar. At histologic examination, scars treated with both Dermatix and silicone gel sheeting once again showed improvements in erythema, scar height, skin elasticity, skin texture and reorganization of the collagen fibers, and increased mast cells. A relatively fast rate of erythema resolution (Table 3) and a decrease in scar height (Table 4) were noted for the treated scars in these patients. The mean reduction in scar height demonstrated by profilometry for the treated scars was 1.5 mm after an average of 39 days, as compared with a 0.75-mm mean reduction in height of the untreated control scars after an average of 81 days (Table 4). The patients who used Dermatix gel adjunctively with silicone gel sheeting had the most favorable perception of their treatment (data not shown).

Discussion

Evaluation of patients with more than one scar in this study provided a unique ability to use the patient's own skin as a control for comparing the effects of Dermatix, silicone gel, or a combination of these treatments on active scars. The results showed improvement of scars on all parameters in each treatment group, but Dermatix treatment was favored in patient acceptability.

It has long been known that pressure therapy for healing scars or hypertrophic scars can accelerate the remodeling phase of healing [3]. A drawback to topical silicone sheeting has been the difficulty that many patients have keeping the sheeting in place throughout the night without taping. Moreover,

Table 2. Scar-associated symptoms of itching, irritation, or skin maceration rated on day 90 using a linear analogue scale from 0 (none) to 10 (worst)

Dermatix treatment group (n = 10)			Gel sheeting treatment group (n = 10)		
Patient identification no.	Control scar	Treated scar	Patient identification no.	Control scar	Treated scar
1	7.5	2.6	11	8.5	7.1
2	8.2	4.8	12	8.7	5.9
3	7.1	5.1	13	9.5	8.4
4	6.4	2.1	14	8.6	7.2
5	5.5	1.5	15	5.4	2.5
6	7.9	2.4	16	7.9	4.8
7	8.2	2.1	17	8.2	5.8
8	2.5	2.4	18	9.1	6.4
9	1.2	0.8	19	6.5	3.1
10	1.5	0.4	20	3.8	1.5
Mean	5.60	2.42[a]	Mean	7.62	5.27[a]
SD	2.81	1.51	SD	1.82	2.25

SD, standard deviation
[a]$p \leq 0.001$ vs untreated control scar in same patient (paired *t*-test)

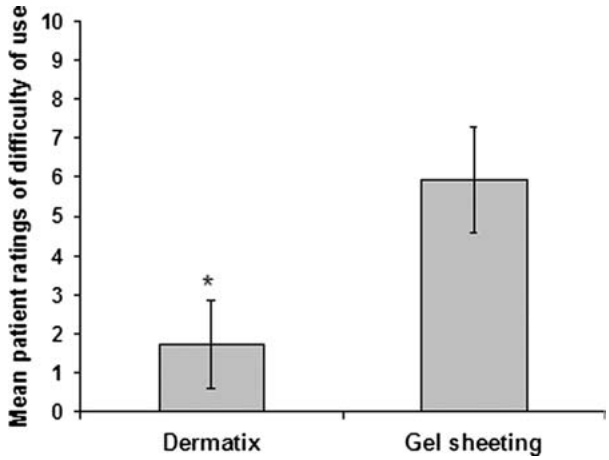

Fig. 2. Patient ratings of the difficulty using Dermatix vs gel sheeting. Patients in the treatment groups that used either Dermatix or gel sheeting rated treatment ease of use on a linear analog scale from 0 (easy) to 10 (difficult). *$p < 0.001$ vs gel sheeting (*t*-test).

patients frequently object to wearing silicone sheeting during the day because of its unsightliness.

The advent of topical silicone gel adds an important element to the armamentarium of the physician treating scars and healing wounds. The greatest advantage offered by Dermatix is its ease of application and effortless maintenance yielding improved patient compliance. Dermatix is easier to use as a treatment method for areas such as inframammary surgical scars, the face, and areas of movement associated with joints. The end result of this therapy is improvement in scar height and decreased erythema with improved skin texture and elasticity.

Histologic examination of the scar tissue treated with Dermatix in this study consistently showed decreases in sclerotic collagen as compared with untreated scars. A favorable safety profile of Dermatix also was demonstrated. In contrast to the silicone gel sheeting, Dermatix caused no skin breakdown whatsoever.

The mechanism whereby healing scars and hypertrophic scars are altered by silicone gel treatment is unknown. The gel dries to form a thin, transparent, and durable silicone sheet. It has been hypothesized that the silicone sheet causes a change in the surface energy of the skin that helps to align the extracellular matrix and subsequently allows the fibroblasts to align the collagen more parallel to the surface of the skin, resulting in involution of scars [8]. The results of the current study suggest that silicone gel treatment also may increase the number of mast cells in the cellular matrix of the scar with subsequent accelerated remodeling of the tissue.

It was interesting to note that patients' self-assessment of their scars was heavily weighted toward improvement when they were using the combination of Dermatix and silicone gel sheeting. It seems likely that Dermatix provided an interface whereby the gel sheeting was able to conform and adhere better than when used alone. As we are attempting to improve patients' appearance and associated self-esteem, this subjective measurement of treatment effectiveness may perhaps be one of the most important considerations.

Conclusion

Silicone topical elastomer gel (Dermatix) offers an effective addition to the armamentarium of the physician treating healing surgical wounds and traumatic wounds as well as hypertrophic scars and keloids.

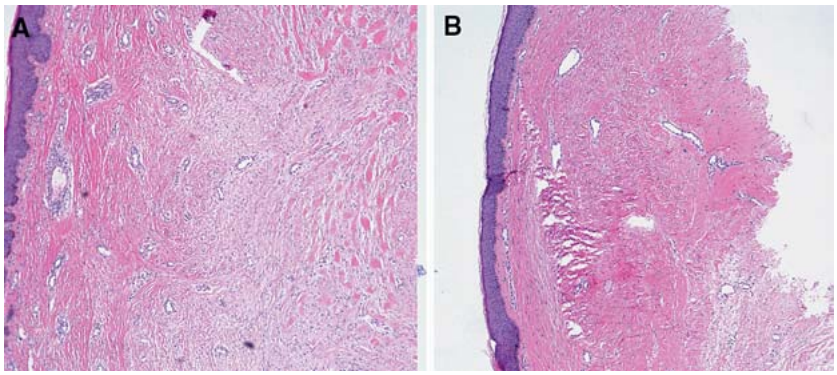

Fig. 3. Histologic evaluation of an excised keloid treated with Dermatix (**A**) and an untreated control keloid (**B**). Scars treated with Dermatix showed normalization of collagen fiber organization and an increased number of mast cells.

Table 3. Time to improvement of erythema in patients treated with a combination of Dermatix and silicone gel sheeting

Adjunctive Dermatix and silicone gel sheeting treatment group (n = 10)		
Patient identification no.	Time to improvement of erythema for control scar (day of study)	Time to improvement of erythema for treated scar (day of study)
21	90	45
22	90	45
23	90	30
24	90	45
25	90	30
26	90	30
27	90	30
28	90	30
29	90	45
30	90	45
Mean	90	38
SD	0	7.9

SD, standard deviation

Table 4. Time to improvement of scar elevation in patients treated with a combination of Dermatix and silicone gel sheeting

Adjunctive Dermatix and silicone gel sheeting treatment group (n = 10)				
Patient identification no.	Day	Control scar height (mm)	Day	Treated scar height (mm)
21	90	1.8	30	1.2
22	90	1.5	30	0.8
23	90	0.9	45	0.4
24	90	1.7	45	0.7
25	90	2.8	45	2.1
26	90	1.6	30	1.3
27	90	2.1	45	1.1
28	45	1.7	45	0.6
29	45	2.9	45	2.4
30	90	0.8	30	0.1
Mean	81	1.78	39	1.07[a]
SD	19.0	0.69	7.7	0.72

SD, standard deviation
[a] $p < 0.001$ vs untreated control scar in same patient (paired *t*-test)

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