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Clinical Evaluation of a New Self-Drying Silicone Gel in the Treatment of Scars: A Preliminary Report

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Abstract. Topical silicone gel sheeting and intralesional steroids are the only evidence-based recommendable forms of treatment to control the quality of a scar. The advantages and disadvantages of both are well known. This study was undertaken to verify the efficacy of a new topical silicone treatment: a self-drying spreadable gel that needs no means of fixation and cannot be seen because of complete transparency. Fresh surgical scars treated with the tested product showed significantly better outcomes than those untreated in a prospective trial involving a group of 160 patients. Patient compliance was particularly good, especially for scars on exposed areas such as the face, where the traditional gel sheeting is frequently discontinued at an early stage by patients who object to its visibility. The results of the self-drying silicone gel have indeed been satisfactory. Considering the effective results obtained and the good patient compliance, the authors currently rate this concept of treatment as the first choice for preventing hypertrophy of recent scars.

Key words: Keloids—Scar hypertrophy—Scar treatment—Silicone gel

It has been estimated that in the developed world each year, 100 million patients acquire new scars [2], and that about 11 million new scars are keloids. In particular, 70% of keloids occur in children [20].

Scars vary greatly in quality, depending on individual and racial patient features, the nature of the trauma, and the conditions of wound healing. They frequently determine aesthetic impairment and may be symptomatic, causing itching, tenderness, pain, sleep disturbance, anxiety, depression, and disruption of daily activities [3]. Other psychological sequelae include posttraumatic stress reactions [21], loss of self-esteem [16], and stigmatization [8], leading to a diminished quality of life. Scar contractures also can determine disabling physical deformities [22]. All these problems are more troublesome to the individual patient when the scar cannot be hidden by clothes. The features of a postsurgical scar, which unfortunately often are independent of the surgeon's skills, can strongly influence the patient's judgment on the quality of the treatment received.

Despite the relevance of this issue and of much research, options for controlling the final quality of a scar are limited. As well described by Mustoe et al. [10] in 2002, many treatments have been suggested in the past 15 to 20 years, but only a "few of them have been supported by prospective studies with adequate control group." In the same paper, these authors also stated that "several new therapies showed good results," but only in "small scale trials." At the end of their in-depth analysis, they concluded that the only two treatments with sufficient evidence for internationally evidence-based recommendations for scar management are the topical application of silicone gel sheeting and the intralesional injection of corticosteroids. The former generally is indicated as both a preventive and therapeutic device, the latter as a therapeutic agent only.

Unfortunately, the precise mechanism of action for these two treatments still is unclear, whereas their advantages and disadvantages are well known. Topical silicone gel sheeting is cumbersome to keep on the scar, and patient compliance often is low for lesions in visible areas. Tapes or bandaging frequently is not accepted. It also may lead to skin

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Table 1. Classification of scars according to morphologic features

Grade 1 (normal)	Flat, soft, normal color
Grade 2 (mildly hypertrophic)	Slightly elevated, moderately hard, light to dark pink color
Grade 3 (hypertrophic)	Elevated (within wound margins),hard, dark pink to dark red color
Grade 4 (keloid)	Very elevated, larger than wound margins, very hard, red to brown color

irritation, which can require discontinuation of treatment, especially in hot climates. Steroid injections are painful and may lead to skin atrophy and dyschromies. They usually are contraindicated for large areas and for children. Topical self-drying silicone gel is a relatively recent Food and Drug Administration (FDA)-approved product developed to overcome the practical difficulties of topical silicone gel sheeting. It is spread thinly on the scar and allowed to dry before contact with clothes or application of makeup. We present a preliminary report on our experience with this new option in the field of scar control.

Materials and Methods

Between September 2003 and September 2004, the use of a new self-drying silicone gel (Dermatix™ - ICN-Valeant Pharmaceuticals Milano, Italy) was investigated with consenting patients who had recent postsurgical scars. The study enrolled 160 patients ranging in age from 5 to 82 years (average, 53.5 years). All had undergone surgery 10 days to 3 weeks previously by either one of the authors or both. Benign or malignant skin lesions needing excision were the main cause of surgery. However, scar revisions and cosmetic procedures (augmentation and reduction breast surgery) also were included. All scars were classified according to morphologic features, as shown in Table 1.

We classify a hypertrophic scar as a red or dark pink, raised (elevated), sometimes itchy scar confined within the border of the original surgical incision, with spontaneous regression after several months and a generally poor final appearance. A keloid is instead classified as a scar red to brown in color, very elevated, larger than the wound margins, very hard, and sometimes painful or pruritic, with no spontaneous regression.

All lesions and subsequent wounds were measured and photographed before treatment onset. Each patient was randomly assigned to one of the two following regimens: scar treatment with the self-drying silicone gel or no treatment initially. The location of the scars are specified in Table 2.

The self-drying silicone gel was applied twice a day for 4 months. However, additional applications were recommended after bathing or intensive sports. Among the gel-treated patients, no other therapeutic aids were adopted during the observation period. In the no treatment group, conventional treatments (pressure garments, intralesional steroids, or traditional silicone gel sheeting) were prescribed at follow-up visits if clear evidence of developing hypertrophies was observed by both authors.

Table 2. Location of the scars

	Treated (n)	Not treated (n)	Total (n)
Face	21	18	39
Dorsum	15	16	31
Chest	9	11	20
Abdomen	14	13	27
Arm	8	10	18
Leg	13	12	25
Total	80	80	160

All the patients were seen on a monthly basis for 4 months, and the final evaluation was performed by the two authors, a nurse, and the patient independently at 6 months. Scars were graded 1 to 4 on the basis of the criteria illustrated in Table 1. Final photographs were taken at this time. Six patients in the treated group who discontinued the applications of the gel between weeks 5 and 11 were withdrawn from the study. Two patients in the treated group and four patients in the no treatment group were lost to follow-up evaluation. The chi-square test was used to assess the statistical significance of the results.

Results

In the treated group, ~~six patients gave up the gel before the end of the study because they thought it was "not really necessary." Two more were lost to follow-up evaluation.~~ In the no initial treatment group, four patients were lost to follow-up evaluation. Therefore, 72 of 80 patients in the silicone gel group and 76 of 80 patients in the no initial treatment group were available for final evaluation.

The self-drying silicone gel caused no side effects such as maceration, rashes, or infections. Scar irritation was never an issue. All the patients felt the gel was easy to apply, but some complained of prolonged drying time. This was impractical, particularly in the morning when the patient was rushing for daily activities. The use of a hair dryer was suggested, and this solved the problem for most of the patients. The results are shown in Table 3.

The scars of the 72 patients in the treated group who completed the study were rated as follows: 48 as

Table 3. The results

	Total (n)	Grade 1 (n)	%	Grade 2 (n)	%	Grade 3 (n)	%	Grade 4 (n)	%
Treated	72	48	67	19	26	4	6	1	1
Not treated	76	21	28	35	46	20			26

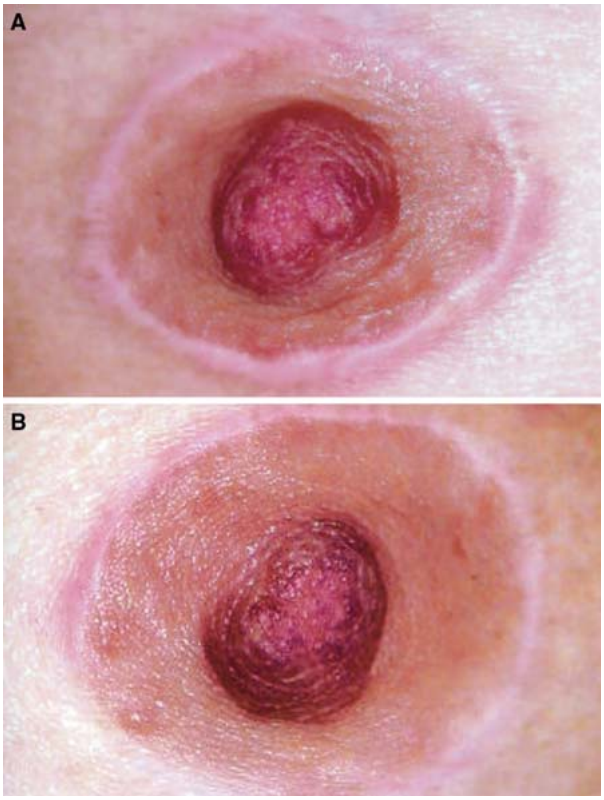

Fig. 1. (**A**) Mildly hypertrophic scar 15 months after reduction mastoplasty. (**B**) View 6 months after scar revision and silicone gel application.

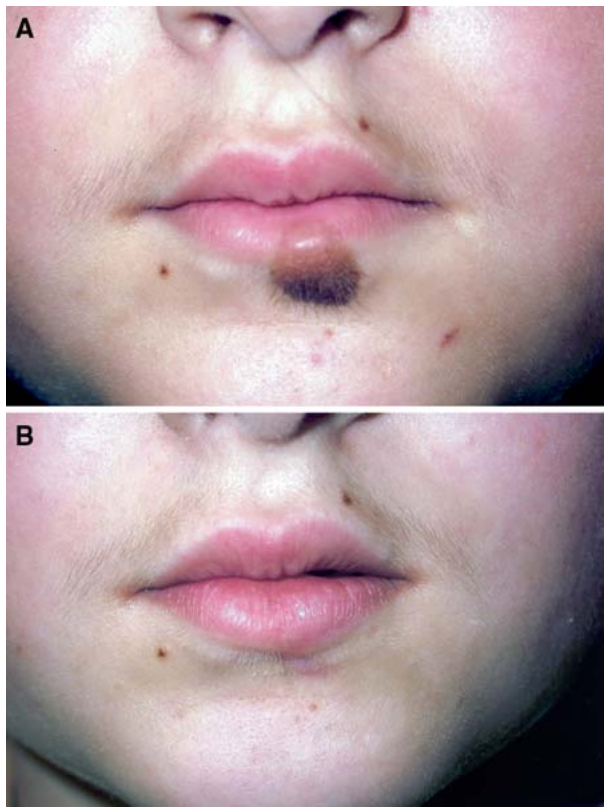

Fig. 2. (**A**) Large congenital hairy nevus of the lower lip. (**B**) View 6 months after surgical excision and silicone gel application.

grade 1 (normal mature, 67%) (Figs. 1–4), 19 as grade 2 (mildly hypertrophic, 26%), 4 as grade 3 (hypertrophic, 6%), and 1 as grade 4 (keloid, 1%).

The scars of the 76 patients in the ~~no initial treatment group~~ were rated as follows: 21 as grade 1 (normal mature, 28%) and 35 as grade 2 (mildly hypertrophic, 46%). In the remaining 20 patients (26%), frank hypertrophic scars were found to develop during the follow-up period, and the patients were directed to conventional treatments (Fig. 5). The scars of these patients were globally rated as grades 3 and 4. In these 20 patients, the scars were located on the face (ear only) (5 patients), chest (4 patients), dorsum (3 patients), arms (3 patients), legs (4 patients), and abdomen (1 patient). Every 3 to 4 weeks, 19 of these patients were treated with triamcinolone acetonide injections (3 to 6 applications) according to the following scheme:

- 20 to 40 mg in total (40-mg/ml solution) for 1- to 2-cm^2 lesions
- 60 to 80 mg in total (40-mg/ml solution) for 2- to 6-cm^2 lesions
- 80 to 120 mg in total (40-mg/ml solution) for 6- to 12-cm^2 lesions.

The treatment was started after follow-up evaluations: after 1 month of follow-up evaluation in 1 case, after 2 months of follow-up evaluation in 8 cases, after 3 months of follow-up evaluation in 10 cases, and after 4 months of follow-up evaluation in the final case.

In 6 of the 19 cases, with lesions located on the arms (2 patients), the legs (3 patients), or the chest (1 patient), we also performed a compression with custom-made garments to ensure pressures between 24 and 36 mmHg. In 3 of the 19 cases, with lesions located on the ear, the patients were submitted to

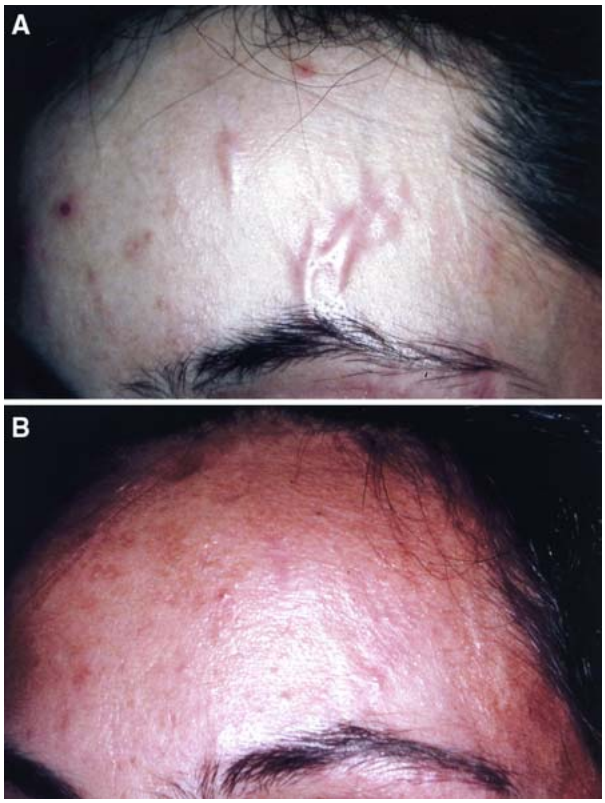

Fig. 3. (**A**) Posttraumatic hypertrophic scars 24 months after injury. (**B**) View 6 months after surgical revision and silicone gel applications.

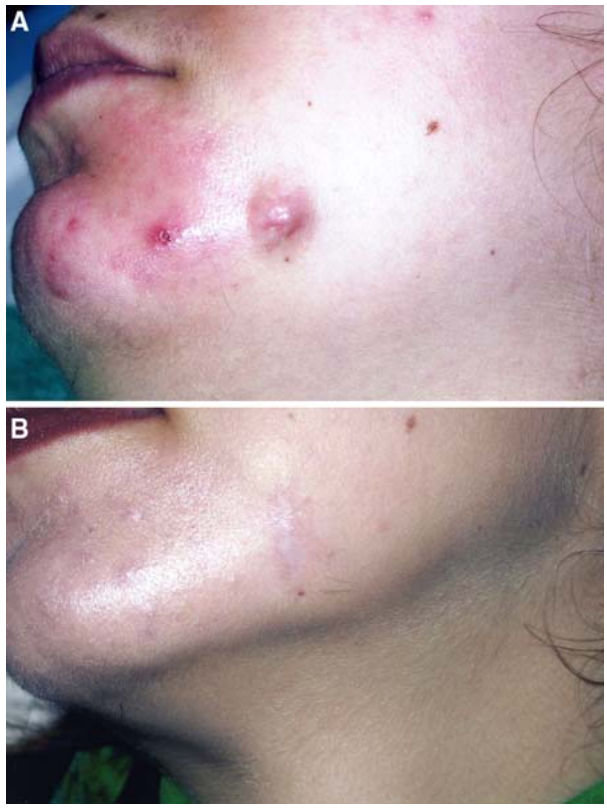

Fig. 4. (**A**) A keloid scar 5 months after surgical excision of sebaceous cyst of the left cheek. (**B**) View 6 months after surgical excision and silicone gel applications.

ear-clip compression and triamcinolone injections, as described earlier. One patient, with a keloid located on the posterior face of the conch, was first treated with triamcinolone acetonide injections. However, after four applications with no results, we decided to submit the patient to keloid excision and radiotherapy (for a total of 1,700 rads over five sessions).

To summarize, the patients treated with the self-drying silicone gel evidenced grade 1 scars in 67% of the cases at the end of the observation period, as compared with 28% of the cases in the no initial treatment group. Grade 2 scars rated 26% in the treated group, as compared with 46% in the no initial treatment group. Grades 3 and 4 scars rated 7% in the treated group and 26% in the no initial treatment group. The difference in scar quality between the treated and no treatment groups is statistically significant ($p < 0.001$).

Discussion

Since the early 1980s, silicone gel sheeting has been widely used in the treatment of hypertrophic scars and keloids [6,7,13,17,19]. Several clinical studies and reviews [1,4,5,14,18] confirm its efficacy, and since the International Advisory Panel on Scar Management published the International Clinical Recommendations on Scar Management in 2002 [10], the popularity of gel sheeting has expanded even further.

Gel sheeting is effective for scar control, but patient compliance with the method is not always satisfactory. When the scars are located in visible areas, especially on the face, patients can experience psychological discomfort with the visibility of the treatment. In warm climates, skin reactions are relatively common, often leading to treatment interruption. In other cases, skin reactions may be determined by tapes, often used to keep the gel sheeting in place. All these disadvantages, reported frequently in the literature [1,9,11,12,15], are well known to any physician dealing with scars.

The results obtained in the current study prove that the tested product is effective in speeding up maturation and in reducing the hypertrophy rate of fresh surgical scars.

Conclusions

Self-drying silicone gel is appealing because no fixation is required; it is invisible when dry; and sun blocks, makeup, or both can be applied in combination. However, on areas of the body covered by clothes, it must be perfectly dry before the patient dresses, and this may not always be practical.

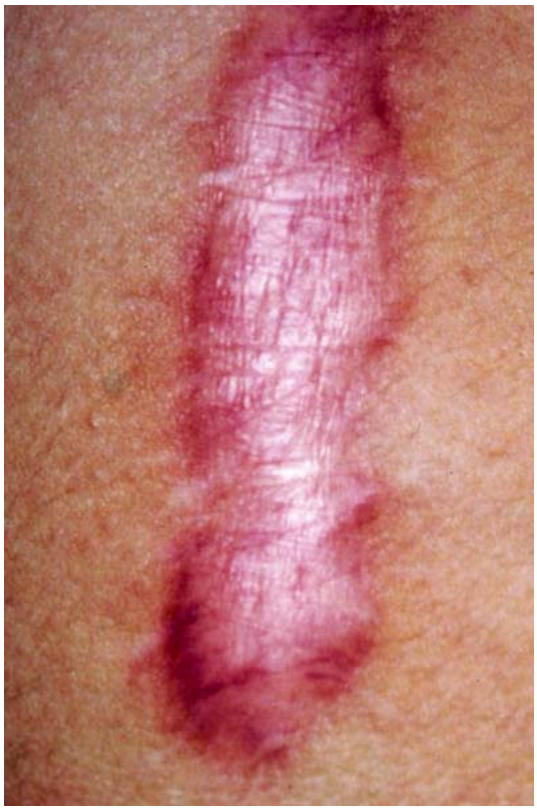

Fig. 5. A bad scar not treated.

Friction by clothes also may contribute to early removal of the silicone film. These features suggest that the reported product could currently be the most recommendable agent for scar treatment, especially in visible areas.

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