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REVIEW

Evolution of Silicone Therapy and Mechanism of Action in Scar Management

Thomas A. Mustoe

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Abstract Silicone-based products are widely used in the management of hypertrophic scarring and keloids. This review discusses the range of products available and the clinical evidence of their efficacy in preventing excessive scarring and improving established scars. Silicone gel sheeting has been used successfully for more than 20 years in scar management. A new formulation of silicone gel applied from a tube forms a thin flexible sheet over the newly epithelialized wound or more mature scar. Results from clinical trials and clinical experience suggest that silicone gel is equivalent in efficacy to traditional silicone gel sheeting but easier to use. The mechanism of action of silicone therapy has not been completely determined but is likely to involve occlusion and hydration of the stratum corneum with subsequent cytokine-mediated signaling from keratinocytes to dermal fibroblasts.

Keywords Hydration · Hypertrophic scar · Keloid · Occlusion · Silicone gel · Silicone gel sheeting

Topical silicone therapy is widely used to improve the signs and symptoms of hypertrophic scars and keloids and to prevent the development of abnormal scarring. Over the past several years, a wide range of silicone-based products have become available for scar management.

Silicone gel sheeting (SGS) has proven effectiveness in scar management, but its use poses several limitations. Some parts of the body are not suitable for SGS use. It is impractical to use sheeting on large areas or near joints, and it cannot be used easily on the face or other areas where the contours or motility of the skin make it difficult to ensure adequate contact and coverage [21]. Taping often is needed to secure the sheeting to the skin. Also, patients may be reluctant to use the sheeting on unclothed areas during the day, and compliance with treatment is often a concern [6]. Finally, sheets must be washed carefully and often to prevent complications such as rashes and infection.

Research in product development has focused on developing silicone-based products that have the same efficacy as SGS, but are useful on more areas of the body and better accepted by patients. To that end, brands of SGS with increased durability and adhesiveness have been introduced to improve the ease of use and patient acceptability of SGS treatment [21]. Other formulations of silicone that may be easier to apply and maintain than sheeting also have been developed, and both cream containing silicone oil and silicone gel applied from a tube currently are marketed for use in scar management.

Silicone Gel Sheeting

Perkins et al. [31] first observed the potential usefulness of SGS for the treatment of burn scars and contractures in the early 1980s. Within the next few years, several uncontrolled studies documented the successful use of SGS in the treatment of hypertrophic scars and keloids [24, 30, 33]. Our group reported the first controlled comparative study demonstrating the efficacy of SGS treatment in scar management [1, 2]. Subsequently, four randomized controlled trials [6, 21, 22, 40] provided strong evidence that SGS is effective in the treatment of hypertrophic scars (Table 1).

T. A. Mustoe (✉)
Division of Plastic Surgery, Northwestern University School of Medicine, 675 North Street Clair 19-250, Chicago, IL 60611, USA
e-mail: tmustoe@nmh.org

Table 1. Controlled comparison studies on the efficacy of silicone gel sheeting (SGS) in scar management

Study	Patients	Intervention	Scar evaluation	Outcome
Ahn et al. [1, 2]; prospective, within-subject comparison study	Study arm 1: 29 patients who underwent surgery within the past 3 months Study arm 2: 19 patients with established hypertrophic scarring	SGS treatment compared with no treatment of scars from the same or a mirror image site within a patient for 2 months (study arm 1) or up to 7 months (study arm 2)	Volume measured using negative impression mold; elasticity measured using elastomer	Scars at surgical wounds treated with SGS had significantly less volume than scars at untreated wounds SGS treatment of established hypertrophic scars produced a significant increase in scar elasticity not seen in untreated scars
Sproat et al. [40]; prospective, randomized, investigator-masked, within-subject comparison study	14 patients with poststernotomy hypertrophic scars	SGS treatment on half of scar compared with intralesional steroid injection treatment of other half of scar for 12 weeks	Appearance evaluated from photographs; length, height, and width; changes in symptoms	Patient preference, time to improvement of symptoms, and masked observers' assessment of scars based on photographs favored SGS treatment over steroid treatment
Carney et al. [6]; prospective, randomized, parallel-group comparison study	42 patients with hypertrophic scars	Cica-Care SGS treatment compared with Silastic SGS treatment, with no treatment on portions of the same scar or on different scars in the same patient for 6 months	Color, texture (hardness), extensibility	Statistically significant higher percentage of scars showed improvement in color and hardness with each brand of SGS than with no treatment; significantly greater increase in extensibility with SGS than with no treatment
Lee et al. [21]; prospective, randomized, parallel-group comparison study	26 patients with hypertrophic scars	Sil-K SGS treatment compared with Epiderm SGS treatment for 6 months	Color, texture (hardness), regularity (smoothness), elevation	Improvement in scar color, hardness, smoothness, and elevation after 6 months of treatment with each brand of SGS
Cruz-Korchin [10]; prospective, within-subject comparison study	20 women who underwent bilateral breast reduction	SGS treatment of one breast compared with no treatment of other breast for 2 months	Scar hypertrophy determined by whether scar was raised over surrounding skin	Wounds treated with SGS showed statistically significant reduction in the incidence of hypertrophic scarring compared with untreated wounds
Niessen et al. [28]; prospective, randomized, within-subject comparison study	155 women who underwent bilateral breast reduction	Sil-K or Epiderm SGS fixed with Micropore on portions of the scars compared with Micropore alone on the remaining portions of the scars	Hypertrophic scarring determined by scar height (raised above skin level); width and height measured with a ruler and using ultrasound; blood flow measured using Doppler laser flowmetry; color measured using chromameter	No difference in the occurrence of hypertrophic scarring on SGS-treated vs untreated sites

Table 1. continued

Study	Patients	Intervention	Scar evaluation	Outcome
Borgognoni et al. [5]; prospective, parallel-group comparison study	20 patients with recurring keloid who underwent another surgical excision	SGS treatment compared with no treatment for 3 months	Keloid recurrence determined by scar height (flat = no recurrence; height < 50% of excised keloid = partial recurrence; height > 50% of excised keloid = recurrence)	Reduced incidence of keloid recurrence among patients treated with SGS compared with untreated patients
de Oliveira et al. [11]; prospective, randomized, parallel-group comparison study	26 patients with 41 hypertrophic scars or keloids	SGS treatment was compared with nonsilicone gel sheeting treatment and with no treatment for 4.5 months	Length and width measured using flexible ruler to include height; hardness measured by observation and intracicatrial pressure; color; pain; itching	Statistically significant decreases in linear measurements, redness, and hardness for scars treated with either SGS or nonsilicone gel sheeting but not for untreated scars
Gold et al. [15]; prospective, randomized, parallel-group, comparison study	96 patients (46 high risk with history of abnormal scarring) who underwent skin surgery	SGS treatment in addition to normal postoperative care compared with normal postoperative care alone for 6 months	Development of abnormal scar (criteria for abnormal scar not reported)	SGS treatment reduced the incidence of hypertrophic or keloid scarring in high-risk patients
Li-Tsang et al. [22]; prospective, randomized, investigator-masked, parallel-group comparison study	45 Chinese patients with hypertrophic scars	SGS treatment in addition to deep massage compared with deep massage alone for 6 months	Thickness measured using ultrasound; pigmentation measured using spectrocolorimeter; pliability; pain; itching	Statistically significant reduced thickness and greater pliability of scars treated with SGS compared with scars not treated with SGS
Maján [23]; prospective, randomized, parallel-group comparison study	11 surgical patients	SGS (Mepiform) treatment compared with no treatment initiated from 2 weeks to 2 months after surgery	Height, pigmentation, pliability, and thickness rated on Vancouver Scar Scale	Scars treated with SGS appeared to have decreased height and pigmentation and increased pliability compared with untreated scars (results not analyzed statistically)

SGS, silicone gel sheeting

Other controlled studies [5, 10, 11, 15, 23] have shown that prophylactic treatment with SGS can be effective in preventing the development of excessive scars (Table 1). To our knowledge, Niessen et al. [28] reported the only controlled clinical study that failed to find a preventive effect of SGS treatment on hypertrophic scarring. The reasons why prophylactic SGS treatment was not effective in their study are unclear, but the investigators suggested that the SGS treatment may have been initiated too early (immediately after surgery).

A metaanalysis of 13 controlled studies reported through 2001 (including the Niessen et al. [28] study) found significant effects of SGS sheeting in reducing the incidence of hypertrophic scarring among high-risk individuals, increasing scar elasticity, and reducing redness [29]. On the whole, the controlled clinical studies that have been reported provide convincing evidence that SGS is effective in preventing and alleviating excessive scarring. The results of these studies provide an evidence-based rationale for the current widespread use of SGS in scar management.

Cream Containing Silicone Oil

The hypothesis that silicone oil leaking from SGS might be responsible for the effects of SGS on scarring [33] led to the investigation of the effects that topical formulations containing silicone oil have on scarring. In one study, treatment with a cream containing 20% silicone oil covered with gauze led to only slight improvement of hypertrophic scars or keloids in 22% of 36 patients, whereas treatment using the cream covered with an occlusive water-impermeable plastic film led to more substantial improvement of scars in 82% of 11 patients [35]. Subsequently, in an uncontrolled study investigating the effects of a cream containing 20% silicone oil, keloids of 15 Chinese patients were treated using cream covered with a self-adhesive, air-permeable, water-impermeable film (Tegaderm: 3M, St. Paul, MN) at least 12 hours daily for 6 months [44]. The treatment produced a significant decrease in scar elevation and symptoms.

These two studies suggest that silicone cream is potentially useful in scar management. However, it should be noted that silicone cream has shown good efficacy only when used with an occlusive dressing [35]. Silicone cream used without an occlusive dressing has minimal effects on scarring [35].

Silicone Gel in a Tube

A self-drying topical silicone gel was developed from the same basic long-chain silicone polymer used for SGS. The gel, available in a tube, is applied in a thin layer to the skin. It dries to form a thin, transparent, flexible, gas-permeable, water-impermeable silicone sheet that adheres to the skin and improves scarring (Fig. 1).

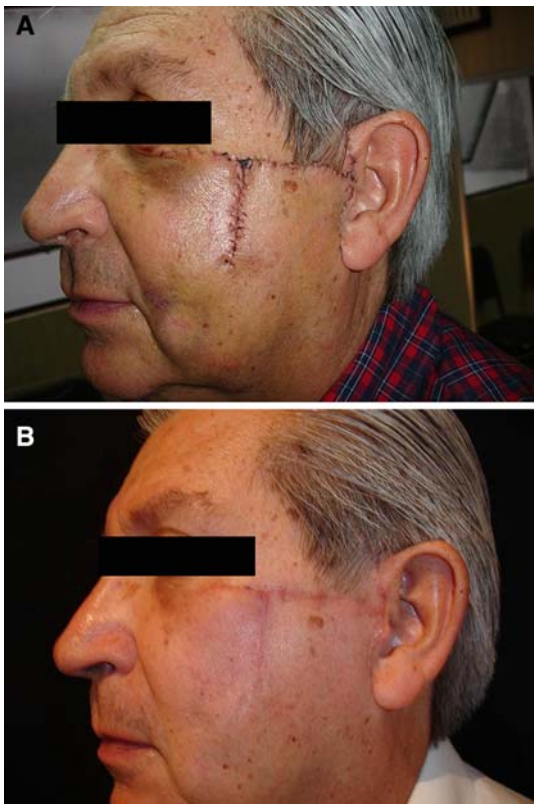

Fig. 1. Before and after views of silicone gel treatment in scar management. (**A**) Patient with full thickness surgical wound before treatment. (**B**) After 2 months of treatment with Dermatix Ultra. Photographs were kindly provided by Dr. Guerrerosantos, plastic surgeon, Guadalajara, Jalisco, Mexico.

The results of recent comparative clinical studies [7, 9, 12, 38] indicate that silicone gel applied from a tube is as effective as SGS in the management of abnormal scarring (Table 2). A randomized, double-masked, placebo-controlled clinical trial evaluated the efficacy of silicone gel (Scarfade: Hanson Medical, Inc., Kingston, WA, also marketed as Dermatix: Valeant Pharmaceuticals International, Alison Viejo, CA) in preventing hypertrophic scarring after median sternotomy in Asian patients [7]. Half of the wound was treated twice daily with silicone gel, and the remaining half with a placebo gel. Although a hypertrophic scar or keloid developed for most patients (94%), the half of the wound treated with silicone gel typically showed less scarring than the control half of the wound.

At 3 months after surgery, the scars that developed during silicone gel treatment were significantly flatter, less

Table 2. Studies on the efficacy of silicone gel (formulated in a tube) in scar management

Study	Patients	Intervention	Scar evaluation	Outcome
Controlled comparative studies				
Chan et al. [7]; prospective, randomized, double-masked, within-subject comparison study	50 Asian patients who underwent median sternotomy	Twice-daily silicone gel on half of wound compared with placebo gel on other half of wound from postoperative week 2 to month 3	Vancouver Scar Scale scores of pigmentation, vascularity, pliability, height, pain, and itchiness	Scars that developed during silicone gel treatment were significantly flatter, less red, and more pliable and associated with significantly less pain and itching than scars that developed during placebo treatment
Signorini and Clementonil [38]; prospective, randomized, parallel-group comparison study	160 patients who underwent surgery	Twice-daily silicone gel treatment compared with no treatment initiated from 10 days to 3 weeks after surgery for 4 months	Scar quality (normal mature, slightly hypertrophic, hypertrophic, or keloid scar based on color, hardness, elevation, and relationship to wound margins)	Scar quality was significantly better in the silicone gel group than in the no treatment group at the 6-month follow-up visit: the incidence of hypertrophic or keloid scarring was 7% in the silicone gel group compared with 26% in the no treatment group
Chernoff et al. [9]; prospective, within-subject comparison study	30 patients with bilateral hypertrophic scars, keloids, or scars still in an erythematous and raised stage of healing	Silicone gel, SGS, or a combination of treatments for one scar compared with no treatment for the bilateral scar for 3 months	Elevation and texture measured using optical profilometry; erythema; pliability; severity of symptoms	Scars treated with silicone gel, SGS, or silicone gel/SGS were statistically significantly less elevated. less red, and associated with fewer symptoms than untreated scars
Fonseca Capdevila et al. [12]; prospective, parallel-group comparison study	132 patients who underwent removal of a benign skin lesion	Silicone gel treatment compared with SGS treatment initiated within 1 month of surgery	Height; redness; pliability; itching; pain/tenderness	Silicone gel and SGS were both effective in improving scar redness, hardness, elevation, pain, and itching; there were no statistically significant differences between silicone and SGS on any efficacy parameter at the month 6 follow-up
Large-scale observational study				
Sepehrmanesh [37]; prospective, open-label, noncontrolled study	1,522 patients with scars	Silicone gel typically used twice daily for at least 2 months	Height; color; pliability; itching; pain/tenderness	Improvement in scar color, pliability, height, itching, and pain/tenderness after silicone gel treatment of approximately 70% to 85% of patients
Small case series				
Murison and James [25]; prospective, noncontrolled study	6 patients with excessive scars (most at least 2 years old)	Silicone gel used for 8 weeks	Vancouver Scar Scale scores of elevation, redness, hardness, itching, tenderness; collagen content and blood flow measured using intracutaneous spectrophotometry	All scars showed improvement in redness, elevation, hardness, and itching, and pain was reduced in symptomatic scars

red, and more pliable and associated with less pain and itching than the control scars. No side effects were associated with the silicone gel treatment, and the patients self-reported a high degree of compliance, with 98% of them reporting that they usually or always applied the gel as prescribed.

A subsequent study also demonstrated that treatment with silicone gel (Dermatix) is effective in preventing abnormal scarring after surgery [38]. A hypertrophic scar or keloid developed in only 7% of the patients treated with silicone gel, compared with 26% of the patients who received no treatment. There were no side effects of silicone gel treatment, and all the patients reported that the gel was easy to apply.

A recent prospective study compared silicone gel with SGS and no treatment in the management of abnormal scarring [9]. The study enrolled 30 patients with bilateral immature scars, hypertrophic scars, or keloids. One scar of each patient was treated with silicone gel (Dermatix), SGS (Epi-derm: MatTek Corporation, Ashland, MA), or a combination of these treatments (silicone gel during the day, SGS at night), and the other scar served as an untreated control. All three silicone-based treatment regimens provided statistically significant improvement for symptoms of itching, irritation, and skin maceration compared with no treatment, and the scars in each treatment group were more pliable and less elevated and erythematous than the untreated control scars. Silicone gel was at least as effective as SGS. Patient scores for the difficulty of treatment were higher with SGS, and patient scores for their willingness to comply with treatment were higher with silicone gel.

A second prospective study compared silicone gel with SGS for the management of scarring after surgical removal of a benign skin lesion [12]. Scars treated with either silicone gel (Dermatix) or SGS showed significant improvement in redness and hardness during the study, and scar elevation, pain, and itching decreased in both treatment groups. After 6 months of treatment, there was no statistically significant difference between the treatment groups in any efficacy parameter. Patient ratings of comfort favored silicone gel over sheeting, with 88% of the silicone gel patients rating the comfort of their treatment as "good" or "very good" compared with 53% of the SGS patients.

Published noncomparative studies [25, 37] also have suggested that silicone gel is equivalent to SGS in efficacy (Table 2). A large, community-based, open-label, observational study evaluated the efficacy of silicone gel (Dermatix) for 1,522 patients with scars [37]. Scar parameters of color, pliability, height, itching, and pain/tenderness were improved after at least 2 months of silicone gel treatment in 70% to 84% of cases according to physician assessments, and in 70% to 85% of cases according to patient assessments. Both patients and physicians expressed high levels of satisfaction with silicone gel treatment with respect to ease of use, duration of treatment, cosmetic outcome, and tolerability.

A case series of six patients who had excessive scars treated with silicone gel (Dermatix) for 8 weeks also has been reported [25]. For five of the patients, the scar was at least 2 years old. All the scars showed improvement of redness, elevation, hardness, and itching after treatment, and the four scars associated with pain or tenderness also showed improvement in these symptoms. Spectrophotometric intracutaneous scope measurements obtained for five of the six patients supported the results of the clinical assessments, showing a consistent decrease in collagen content and increased blood flow in treated scars. Patients rated the efficacy of treatment as moderate (2 patients), good (1 patient), and very good (3 patients). All the patients reported that the gel was simple and easy to use.

The results of the clinical studies reported to date indicate that silicone gel and SGS have equivalent efficacy in the management of abnormal scarring after surgery, and patients may find silicone gel more comfortable to use. The evidence suggests that silicone gel, like SGS and occlusive silicone cream, is effective in softening and reducing scars, reducing redness, and improving symptoms of pain and itching in most patients.

Mechanism of Action

The mechanism of action of silicone-based products in scar management has not been completely determined, but the beneficial effects of SGS on scars are not mediated by pressure or by changes in oxygen tension or blood flow [26, 33]. Similarly, the effects likely are not attributable to silicone release and entry into scar, because biopsies of scars treated with SGS have shown no evidence of a foreign body reaction [1]. An increase in skin surface temperature could be involved because the skin surface temperature of hypertrophic burn scars under SGS is increased by 1.7°C [26], and temperature increases of this magnitude can significantly increase collagenase activity and could affect scarring [4]. Development of a static electric field also may be involved, because it has been proposed that the negative static electric field generated by friction between SGS and the skin could cause collagen realignment and result in the involution of scars [18]. In fact, cushions consisting of a silicone occlusive covering filled with silicone oil provide a stronger static electric field than SGS and are at least as effective as SGS in normalizing excessive scars [19]. However, there is no evidence currently that the static electric field produced by silicone products causes changes in the extracellular matrix of scars.

Studies have shown that SGS decreases evaporation of water from the skin and increases hydration of the stratum corneum [14, 33]. The silicone sheet that forms on the skin after application of silicone gel and the combination of silicone cream and an occlusive dressing presumably have similar effects on water loss and hydration of the stratum corneum. A growing body of evidence suggests that the beneficial effects of all silicone-based products on scars are mediated by occlusion and hydration.

In the study reported by Sawada and Sone [35] comparing silicone cream covered with gauze and silicone cream occlusive dressing, improvement in scar quality was significantly greater with the silicone cream occlusive dressing. These results suggest that occlusion is an important component in the mechanism of action of silicone-based treatment of scars.

In a subsequent study by the same investigators, silicone-free cream occluded with a water-impermeable plastic film was significantly more effective than a vaseline control in improving hypertrophic scars and keloids [36]. The results with silicone-free occlusive dressing were similar to the investigators' previous findings with silicone cream occlusive dressing, leading them to suggest that hydration and occlusion are the primary basis of silicone's therapeutic action on scars [36].

Results of other clinical studies support this suggestion. Treatment of keloids for 2 months with a water-impermeable, non–silicone-based occlusive dressing was found to be effective in reducing scar elevation, erythema, tenderness, and pruritus, suggesting that occlusion alone can be effective in the treatment of excessive scarring [3]. Moreover, in a study reported by de Oliveira et al. [11], sheets of occlusive silicone gel and occlusive nonsilicone gel appeared to be similarly effective in improving hypertrophic scars and keloids.

We have investigated the effects of SGS (Cica-Care: Smith & Nephew, Largo, FL) in a rabbit model of hypertrophic scarring [34]. As expected, SGS effectively reduced scar hypertrophy in this model system. A polyurethane dressing (Op Site: Smith & Nephew, Largo, FL) that is approximately 20% more occlusive to water, and Tegaderm, which is approximately fivefold less occlusive, did not have similar beneficial effects on scarring. Our original interpretation of these results, given the similarity in the water vapor transmission rates for the polyurethane dressing and SGS, was that the scar-reducing property of silicone gel is not dependent on the occlusive nature of the gel [34]. Further experiments, however, have led us to the belief that occlusion is indeed an essential component in the mechanism of action of silicone gel, but magnitude of occlusion is critical for effective treatment. Nonocclusive dressings are ineffective, but SGS or silicone gel, which occlude and hydrate tissue similarly, are similarly effective in reducing hypertrophic scars in the rabbit model system.

Silicone Therapy and Epidermal-Dermal Signaling

Several studies have found that silicone-related products can affect the activity and growth factor production of cultured fibroblasts from hypertrophic scars and keloids [16, 20]. Unfortunately, the relevance of these results is not clear, because in clinical silicone products are placed on the epidermis and do not have direct contact with dermal fibroblasts.

It is likely, however, that silicone products act on the epidermis to initiate signaling cascades that affect dermal fibroblasts. The epidermis has a well-known regulatory role in dermal fibroblast extracellular matrix production. Delayed epithelialization during wound healing increases the risk of hypertrophic scarring [13], and removal of the stratum corneum by tape stripping causes inflammation and activation of keratinocytes and stimulates their production of cytokines that activate dermal fibroblasts to increase collagen production [27].

In vitro studies using co-cultures of keratinocytes and fibroblasts or monocultures of fibroblasts and conditioned medium from keratinocytes have shown that keratinocytes release substances, presumed to be cytokines, that stimulate fibroblast proliferation and inhibit their synthesis of collagen [13, 17]. In an *in vitro* two-chamber cell culture model investigating the interaction between epidermis and dermal fibroblasts, fibroblast proliferation and collagen and glycosaminoglycan production in the bottom chamber were significantly inhibited when keratinocytes that had formed a differentiated epithelium in the upper chamber were exposed to Hanks solution rather than air on their apical surface [8]. Importantly, exposure of the epithelium to silicone oil did not have a similar inhibitory effect on fibroblasts. These results suggest that hydration, rather than silicone itself, can modulate the effect of keratinocytes on skin fibroblasts by affecting their production of soluble factors [8].

Potential Role of Occlusion and Hydration in Silicone Therapy

The function of the skin epithelium is to conserve water and serve as a barrier to microbial infection. The stratum corneum normally contains a gradient of water and is responsible for water conservation, but its function is disrupted when the skin is wounded. After a full-thickness wound, transepidermal water loss (TEWL) is increased and can take longer than 1 year to recover to basal levels [41].

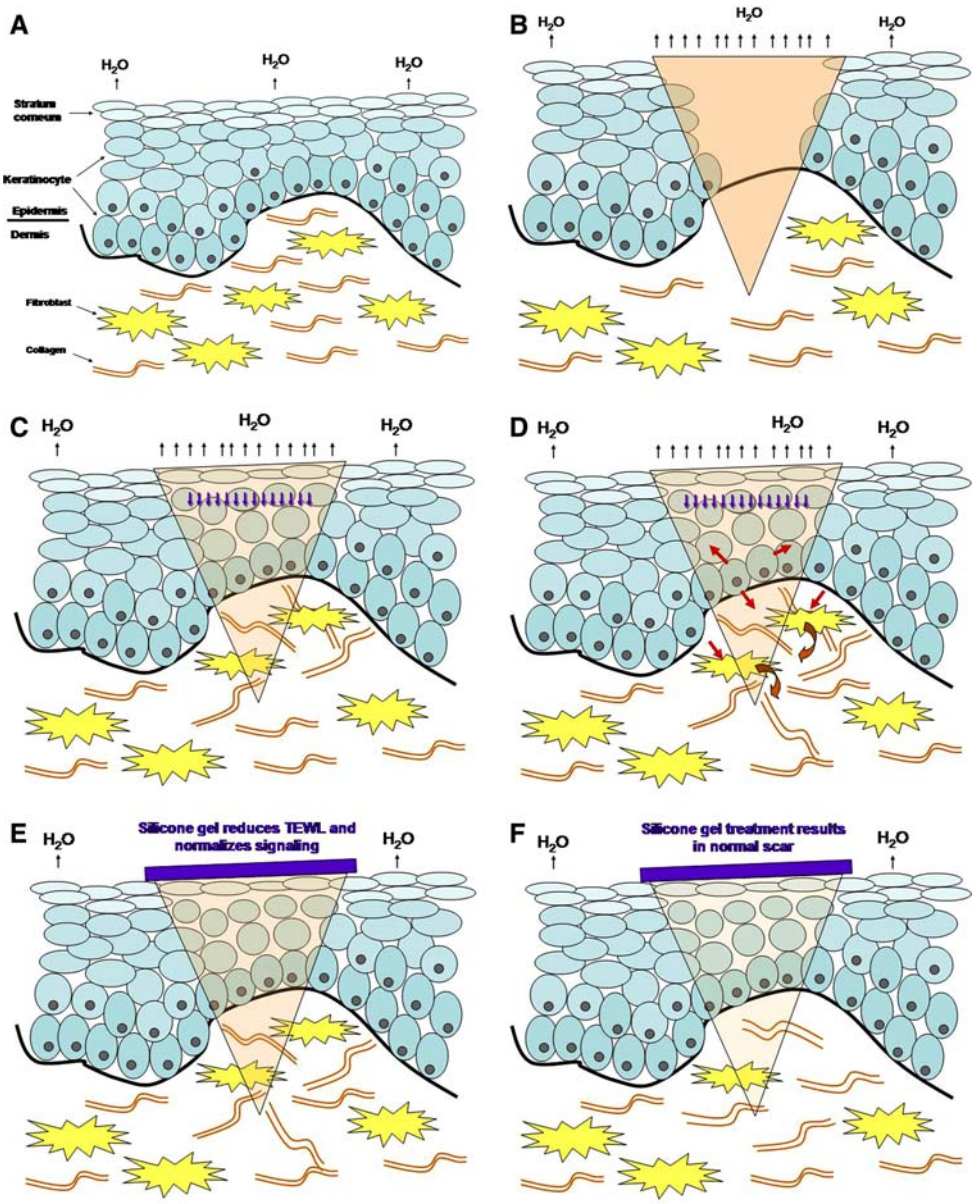

Fig. 2. Proposed mechanism of action of silicone gel in scar management. (**A**) Normal skin with mature stratum corneum and minimal transepidermal water loss (TEWL). (**B**) Partial- or full-thickness injury. (**C**) At 1 to 2 weeks after wounding, reepithelialization is completed, but the stratum corneum is immature and allows abnormally high levels of TEWL. Dehydration of the stratum corneum is signaled (*blue arrows*) to keratinocytes, perhaps via an osmotic gradient. (**D**) Keratinocytes are stimulated to produce cytokines (*red arrows*), which in epidermal-dermal signaling activate dermal fibroblasts to synthesize and release collagen. Excessive collagen production leads to abnormal scarring. (**E**) Treatment of the reepithelialized wound or the scar with silicone gel restores the barrier function of the stratum corneum, reducing TEWL and turning off the stimulation of keratinocytes. Keratinocytes stop producing cytokines that activate dermal fibroblasts. (**F**) After 2 to 3 months of silicone gel treatment, collagen deposition has normalized, and there is no scar hypertrophy.

In addition, TEWL is greater with hypertrophic scars and keloids than with atrophic scars or normal skin [41]. An increase in superficial skin water content measured by high-frequency conductance has been reported for these abnormal scars [41], although the changes in TEWL are more reliable and substantial. The stratum corneum of hypertrophic scars and keloids absorbs water more readily than normal skin [41], suggesting that the reservoir of water normally hydrating keratinocytes may be depleted. Abnormally high levels of water loss from the epidermis and dehydration of keratinocytes might stimulate these cells to produce cytokines that lead to changes in the dermis and increased collagen production by fibroblasts. In fact, in cultured keratinocytes exposed to a solution with high osmolarity (a model system for keratinocyte dehydration/dessication that occurs when the epidermal barrier is disrupted and TEWL is elevated), levels of proinflammatory interleukin mRNAs are increased [43]. These findings suggest a mechanism by which the hydration state of keratinocytes that could lead to signaling that affects fibroblasts production of collagen.

Although application of SGS to skin causes hydration of the stratum corneum, the extent of hydration is less than that produced by a plastic film, and the increase in hydration compared with normal skin decreases after repeated treatment [42]. These results have been interpreted to suggest that the semi-occlusive nature of SGS improves scars by providing adequate but not excessive hydration [42]. A plausible explanation for the mechanism of action of silicone-based products, therefore, is that occlusion causes a decrease in TEWL and normalizes the hydration state of keratinocytes, which then signal dermal

fibroblasts to downregulate extracellular matrix production (Fig. 2). This explanation is consistent with clinical findings that occlusion is essential for the efficacy of silicone cream and can have beneficial effects on abnormal scars even in the absence of silicone, and with *in vitro* findings of the interactions between keratinocytes and dermal fibroblasts.

If this hypothesis is correct, any product that provides occlusion may be beneficial in wound management, but the magnitude of occlusion may be critical and may differ between silicone products and other occlusive dressings, or even among silicone products. Dressings that are too permeable to water may be ineffective on scars because they fail to block water loss and restore homeostasis and normal epithelial-dermal signaling, whereas dressing that are too occlusive may cause skin maceration. Clinical studies [33] and studies using our rabbit hypertrophic scar model [34] may have found that occlusive dressings were less effective than SGS in scar management because the dressings used were more occlusive than SGS.

This suggested mechanism of action is consistent with the reported ability of silicone therapy to improve both old and new scars. Normal scars generally mature in 6 months, but hypertrophic scars take longer to mature, and keloids may continue to evolve for many years. To our knowledge, the time course for recovery of TEWL to basal levels in hypertrophic scars and keloids has not been studied, but it is likely to take years for TEWL to normalize in abnormal scars [41]. If TEWL remains abnormal throughout the course of scar maturation and the therapeutic effects of silicone therapy are mediated by occlusion, hydration, and normalization of TEWL, silicone products would be predicted to be effective in improving excessive scars that are several years old.

Perspective and Conclusions

Results from clinical trials and the rabbit hypertrophic scar model suggest that occlusive silicone-based products are similarly effective in reducing and preventing excessive scarring. The mechanism of action of these products is likely to be occlusion, and the similar occlusive properties of silicone gel and SGS explain their equivalent efficacy in scar management.

The similar mechanisms of action of silicone gel and SGS have been confirmed in the rabbit model. Although few comparative clinical data are available for many of the silicone-based products, to the extent that they have similar occlusive properties, their efficacy can be predicted to be similar, and indeed, the reported clinical studies suggest that silicone gel is at least as effective as SGS in scar management. All the products are safe. Minor side effects such as rash sometimes associated with SGS can be avoided by appropriate hygiene and care of the sheets. Therefore, factors beyond efficacy and safety that might be excepted to increase patient compliance with treatment and improve scar outcomes [39], such as greater ease of use, better acceptability to patients, and lower cost, should be considered when clinicians are choosing among the various products. Our clinical experience with silicone products has suggested to us that silicone creams with a sticky consistency are not well accepted by patients, but we have used silicone gel and SGS successfully with many patients.

Silicone gel currently is the preferred silicone therapy because silicone gel has fundamental advantages over SGS. For effective treatment, occlusion must be achieved by close apposition of the silicone product and the scar, and that is easier to achieve and more practical with silicone gel than with SGS, especially near joints and on areas with contours. Many patients object to the appearance of SGS and do not want to use it on visible areas not covered by clothing. In contrast, silicone gel is well accepted by patients because it forms a nearly invisible sheet and dries fairly quickly when applied correctly in a thin layer. The ability to use makeup over silicone gel to camouflage scars also is an advantage of the gel formulation for some patients.

Silicone therapy has a primary role in scar management. Although it may not be uniquely useful in this respect (non–silicone-based occlusive dressings also may be useful), a silicone-based product may represent the easiest way to achieve an effective level of occlusion in an inexpensive, nonirritating manner. The magnitude of occlusion provided by silicone therapy appears to be critical, because other occlusive treatments such as vaseline and plastic film have been shown to be ineffective in scar management, presumably because they do not provide an appropriate level of occlusion. Few studies have investigated the effects of moisturizers on abnormal scars. Notably, however, treatment of hypertrophic scars and keloids with a moisturizer has been reported to have no effect on scar elevation or erythema [32]. These findings lend support to the hypothesis that normalization of the skin's barrier function, and not simply hydration of the stratum corneum, may be an important component of the mechanism of action of silicone therapy in reducing abnormal scarring.

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