REVIEW ARTICLE

A Review of the Biologic Effects, Clinical Efficacy, and Safety of Silicone Elastomer Sheeting for Hypertrophic and Keloid Scar Treatment and Management

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Silicone elastomer sheeting is a medical device used to prevent the development of and improve the appearance and feel of hypertrophic and keloid scars. The precise mechanism of action of silicone elastomer sheeting has not been defined, but clinical trials report that this device is safe and effective for the treatment and prevention of hypertrophic and keloid scars if worn over the scar for 12 to 24 hours per day for at least 2 to 3 months. Some of the silicone elastomer sheeting products currently on the market are durable and adhere well to the skin. These products are an attractive treatment option because of their ease of use and low risk of adverse effects compared to other treatments, such as surgical excision, intralesional corticosteroid injections, pressure therapy, radiation, laser treatment, and cryotherapy. Additional controlled clinical trials with large patient populations may provide further evidence for the efficacy of silicone elastomer sheeting in the treatment and prevention of hypertrophic and keloid scars. The purpose of this article is to review the literature on silicone elastomer sheeting products and to discuss their clinical application in the treatment and prevention of hypertrophic and keloid scars.

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Hypertrophic and keloid scars are abnormal scars that develop after wound healing in some individuals. A keloid is characterized by an overgrowth of scar tissue beyond the borders of the original wound. Hypertrophic scars consist of an abundance of scar tissue confined to the original wound site.[1] The development of hypertrophic scars and/or keloids after an injury may be especially problematic for patients because the unsightly scar may restrict range of motion, cause symptoms of pruritus and pain, and serve as a constant visible reminder of the trauma endured in the past.[2–5] Although the etiology of hypertrophic and keloid scars is unclear, they occur only in humans and are more common in dark-skinned individuals, patients younger than 30 years of age, and those with atopic symptoms.[6,7] An association with hormone levels has also been noted. Keloids often occur during puberty, worsen during pregnancy, and improve after menopause.[7] Although hypertrophic and keloid scars may serve as body art in some cultures,[8] most patients desire to minimize the appearance of such scars. Several treatment and prevention modalities exist, such as surgical excision, radiation, laser treatment, pressure therapy, intralesional corticosteroid injections, cryotherapy, application of silicone products, and various topical and oral medications.[9] Silicone has been proposed as the main form of noninvasive treatment for hypertrophic and keloid scars and has demonstrated significant improvements in scar elasticity in patients prone to abnormal scarring.[10–12] More than 60 silicone elastomer products have been marketed since 1990.[13] This review will focus on the treatment and prevention of

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hypertrophic and keloid scars with silicone elastomer sheeting, a medical device that is used to soften, flatten, and blanch hypertrophic and keloid scars to produce a more aesthetically acceptable scar and increase range of motion by improving scar elasticity. In addition, silicone elastomer sheeting has been shown to reduce symptoms of pruritus and pain associated with hypertrophic and keloid scars.[14,15]

Properties of Silicone Elastomer Sheeting

Many prescription and over-the-counter silicone products are available for the treatment and prevention of hypertrophic and keloid scars (Table 1). The information presented in this review article has been compiled by searching the United States Food and Drug Administration (FDA) Center for Devices and Radiological Health 510(k) Premarket Notification Database, using the search term "MDA," which is the product code for silicone elastomer products for scar management. After nonsilicone products and duplicate entries were deleted, more than 60 products remained.[13] The differences among the products generally lie in their physical characteristics. Available products include silicone elastomer sheeting with and without a fabric backing, polyurethane foam, pressure garments, splints, fabric bandages that have one surface coated with silicone gel, silicone gels, ointments, sprays that dry to form a thin coat of silicone over the skin surface, and silicone liquid and strips enhanced with vitamin E and/or steroids.[16–37]

Silicone elastomer sheeting products used for the treatment and prevention of hypertrophic and keloid scars have similar chemical features. The element silicon bonds with oxygen, forming a siloxane molecule. Repeating siloxane units form polysiloxanes, to which methyl groups may attach. The resulting molecules, polydimethylsiloxanes, are also known as silicone polymers and may be cross-linked to form gels and elastomers. A high degree of cross-linking yields a rubbery, solid elastomer. Conversely, less extensive cross-linking creates a silicone gel. As the degree of cross-linking increases, the silicone becomes more durable, but less adherent.[38] To maximize the durability and adhesiveness of silicone elastomer sheeting, some products combine a silicone elastomer that has a relatively low degree of cross-linking with an expanded polytetrafluoroethylene membrane to create an interpenetrating polymer network (IPN; Figure 1). The IPN has greater durability than the silicone elastomer alone but still retains good adhesion to the skin.[39]

TABLE 1. Types of Silicone Products Available for Scar Prevention and/or Therapy[13]

Product type	*Number of available products*
Silicone elastomer sheet	43
Silicone gel	11
Silicone-filled cushion	2
Foam with silicone interface	3
Silicone spray	1

Proposed Mechanisms of Action

Knowledge of the physical features of silicone elastomer sheeting may aid in understanding its mechanism of action. There are several hypotheses that try to explain the efficacy of silicone sheeting in treating hypertrophic and keloid scars; several studies have gathered evidence supporting or refuting each, but no distinct mechanism has been defined. Possible mechanisms include increased temperature,[40] hydration caused by occlusion of the underlying skin,[41–46] increased oxygen tension,[47] direct action of the silicone oil,[44] and polarization of the

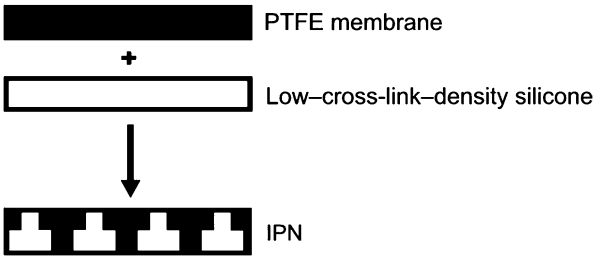

Figure 1. Low–cross-link–density silicone is cross-linked through a polytetrafluoroethylene (PTFE) membrane, resulting in an interpenetrating polymer network (IPN), which has greater physical strength and durability than the low–cross-link–density silicone elastomer alone and retains its adhesive properties.[39]

scar tissue caused by the negative static electric charge generated by movement of the silicone.[48] Silicone sheeting may also correct aberrant immunologic processes, which if left unchecked, may alter the tissue repair process and ultimately result in the formation of hypertrophic and keloid scars.[15,49,50]

Increased Temperature The surface temperature of 18 hypertrophic scars has been shown to increase from 29 to 30.7°C ($p = .001$) in 16 patients treated with silicone gel sheeting. Since slight increases in temperature can increase collagenase activity,[51] it has been hypothesized that silicone gel sheeting improves hypertrophic and keloid scars by increasing the breakdown of collagen by the collagenases through an increase in skin temperature.[40,52,53]

Hydration Effects Many investigators have studied the hydration effects of silicone elastomer sheeting on the stratum corneum.[41–46] Quinn and colleagues[44] have observed that, when applied to a scar, the treated skin area loses water via evaporation at a rate of half that of the untreated skin area. After removal of the silicone gel, the water loss from the underlying treated skin area increases significantly for a period of 15 to 20 minutes. Because fluid has not been seen or felt on the scar or silicone gel, these researchers have postulated that the stratum corneum can act as a water reservoir.[44] In a separate study, Sawada and Sone[54] have also suggested that occlusion and hydration are the principal modes of action of a silicone cream/occlusive dressing. It should be noted, however, that this hydration effect has also been obtained with creams and dressings without silicone.[55–56] Chang and colleagues[42] further elucidated this mechanism by examining the cellular effects of silicone and hydration with an in vitro keratinocyte-fibroblast culture model. The proliferation of fibroblasts and their collagen and glycosaminoglycan production was inhibited in the hydration-treated group with no apparent change in fibroblast activity in the silicone-treated group.

The clinical efficacy of increased hydration for flattening and blanching of hypertrophic and keloid scars and improvement of pruritus, pain, and edema was assessed by comparing the effects of a hydrating cream with a hydrating dressing in 20 patients. During a treatment period of 2 months, the researchers found a significant reduction in itching ($p < .03$) and reduced pain ($p < .08$), as well as increased pliability (10%) associated with both treatments. These results suggest that hydration of a scar over a prolonged period can improve the above symptoms.[43] As a possible explanation for this phenomenon, Beranek[57] proposed that hydration of a scar decreases capillary activity and thus local collagen deposition.

Preliminary laboratory studies have shown that silicone elastomer sheets have high oxygen permeability.[47] This observation has led to the hypothesis that the mechanism of action of silicone elastomer sheeting is twofold: (1) Silicone elastomer sheets increase hydration and oxygen tension in the stratum corneum by limiting the escape of moisture while allowing oxygen access to the skin surface, which is in turn more permeable to oxygen when hydrated. (2) Oxygen tension is believed to be important in scar improvement because angiogenesis and tissue growth are stimulated in response to tissue hypoxia in a healing wound.[47,58]

Not all researchers agree that silicone elastomer sheeting increases skin hydration. One study compared the hydration effects of silicone gel sheeting with plastic film over 7 days on the stratum corneum. Measured hydration was significantly less in the skin occluded with silicone gel sheeting than skin occluded with plastic film ($p < .005$). After 7 days, hydration in skin covered with silicone gel sheeting was significantly less than that on the first day of the study ($p < .005$), suggesting that the hydrating effect of silicone gel sheeting decreases with repetitive daily treatment. These results do not support the hypothesis that silicone gel sheeting causes hypertrophic scar and keloid shrinkage via a hydrating effect.[46]

Direct Action of Silicone Oil Quinn and colleagues[44] noted that silicone gel sheeting created an oily im-

print on filter paper after being in contact with it for 6 hours and hypothesized that this silicone oil, along with hydration, is responsible for the mechanism of action of silicone gel sheeting. In an in vivo study comparing silicone gel sheets to polyurethane membranes applied to healthy skin, the presence of silicone was detected in the stratum corneum of skin exposed to silicone gel sheets using Fourier transform infrared attenuated total reflectance spectroscopy. The researchers found the concentration of silicone in the stratum corneum decreased with depth, indicating that the silicone probably did not reach the underlying viable layers of skin.[41] Shigeki and colleagues[59] also demonstrated the in vitro release of silicone-related compounds from a silicone gel sheet and their water-soluble distribution into the skin. Other researchers have not detected the presence of silicone in skin that had been treated with silicone gel sheeting.[14,60]

Polarized Electric Charge Results from several trials suggest that a negative charge within a silicone cushion causes polarization of the scar tissue and leads to scar shrinkage.[48,61–63] Application of a silicone oil–filled cushion to hypertrophic and keloid scars in 30 patients resulted in flattening and blanching of the scars and improvement of symptoms in 63.3% of patients within 6 months. Twelve patients showed scar improvement within 2 to 3 weeks, and 24% of patients exhibited scar resolution within 12 months. Improvement in scar appearance in patients treated with silicone gel sheeting requires treatment for several months. The researchers attribute the rapid improvement of some patients to the presence of a negative static electric charge generated by the silicone cushion. Such a charge is unique to the silicone cushion because of the dynamic movement of the silicone oil contained within the cushion. In contrast, any charge present on silicone gel sheeting dissipates once humidity increases under the sheet. A follow-up study by Berman and Flores[64] found both silicone gel cushion and silicone gel sheeting to be effective in the treatment of scars with no statistically significant differences between these two treatments.

Amicucci and coworkers[62] also compared the effects of a silicone gel cushion versus silicone occlusive sheeting in the treatment of hypertrophic and keloid scars. Over a few weeks to 5-month period, a cessation of itching and burning, followed by a flattening of the scar, was noticed in 78.2% of patients treated with the silicone gel cushion and 52.3% of patients treated with silicone occlusive sheeting (52.3%). Amicucci and coworkers[62] concluded that the silicone gel cushion treatment produces a faster response.

Immunologic Effects Investigators examining the effect of commercially available silicone gel sheeting (Cica-Care, Smith & Nephew, Memphis, TN) on six patients noted the disappearance of pain and pruritis after 12 weeks, which may be attributed to a decrease in the number of mast cells and the enhanced expression of Fas antigen by lesional fibroblasts after 24 weeks of treatment in one of the patients.[15] In a separate study with silicone gel sheeting, Santucci and colleagues[65] obtained biopsies from hypertrophic and keloid scars at baseline and at 12 weeks. After silicone treatment, they observed a reduction of spindle-shaped cells and an increased number of lymphocytes that strongly expressed CD11a/CD18 (LFA-1) adhesion molecules. Results from other in vitro studies suggest that silicone sheeting may act by down-regulating fibrogenic cytokine TGF-β2 or increasing bFGF and IL-8 levels.[45,49,50] Nonsilicone occlusion studies of clinically normal skin are of equal importance and have found increased levels of epidermal mononuclear cells and morphologic alterations in the Langerhans cells after occlusion.[66–68]

Clinical Efficacy of Silicone Elastomer Sheeting Products

The efficacy of silicone elastomer sheeting for the treatment and prevention of hypertrophic and keloid scars has been evaluated in several small clinical trials. Owing to the difficulty of inclusion of an active treatment group in these studies, some of them used no treatment as the control arm.

Treatment Trials

Perkins and colleagues[69] first described successful treatment of burn scars with silicone elastomer sheeting in 1983. Attempts by other researchers to document the efficacy of silicone treatment have followed.[10,70–82] Ahn and colleagues[14] applied silicone gel sheeting to 14 hypertrophic scars in 10 patients for a period of 8 weeks, leaving an area of each scar untreated to serve as a control. Eleven of the 14 scars were treated for at least 12 hours per day. Elasticity, as measured by a hand-held elastometer, was increased at 1 ($p < .03$) and 2 ($p < .01$) months in the treated scars compared with baseline and untreated scars ($p < .05$ and $p < .03$, respectively). Scar texture, color, thickness, durability, presence of pruritus, and range of motion were evaluated subjectively. All of the patients that wore the silicone gel sheeting for at least 12 hours per day indicated a desire to continue treatment after the study period.[14] Similar results were obtained when silicone gel sheeting was applied to one-half of a hypertrophic scar or keloid in 21 patients for 12 weeks;[83] the other half of the scar received no treatment. Subjective evaluation of these scars by a physician indicated moderate improvement in 10 of 21 patients (47.6%) and minimal improvement in 9 of 21 patients (42.9%).

Two types of silicone gel sheeting (Silastic gel sheeting, Dow Corning, Midland, MI; and Cica-Care, Smith & Nephew) were compared to no treatment in 42 patients with 47 hypertrophic scars. The two types of silicone gel sheeting were similar. After 6 months, 93% of the scar areas treated with Cica-Care and 100% of the scar areas treated with Silastic gel sheeting were rated as improved, compared with only 38% in the control group.[84]

Additional studies have confirmed the efficacy of new silicone vehicles in the treatment of scars. Eisen[85] conducted an open-label pilot study with a topical liquid containing 12% silicone, 0.5% hydrocortisone, and vitamin E (Scarguard, Red Rock Laboratories, LLC, Great Neck, NY). After 8 weeks of topical liquid scar treatment, 9 of 12 patients reported a reduction in erythema and overall appearance, 6 patients reported a decrease in induration, and 5 patients noted the scar was less raised. Even though Baumann and Spencer[86] reported no benefit in the cosmetic outcome of scars after topical application of vitamin E, vitamin E has been advocated as an anti-inflammatory agent capable of reducing the number of fibroblasts and retarding the accumulation of collagen.[87] A separate study found silicone gel sheets enhanced with vitamin E to be superior over silicone alone in the treatment of hypertrophic and keloid scars.[88]

de Oliveira and colleagues[55] have found that the silicone component of scar dressings may not be necessary for efficacy in scar management. In their study, they compared treatment of hypertrophic and keloid scars with silicone versus nonsilicone dressings versus no treatment in 26 patients with 41 scars. After 4.5 months, the treated groups had significantly shorter ($p = .01$) and narrower ($p = .001$) scars than the control group. Additionally, scar color was significantly paler ($p < .001$) and induration was significantly decreased ($p < .0001$) in the treatment groups compared with the control group. No significant differences were noted between the groups treated with silicone and nonsilicone dressings.

The efficacy of silicone gel sheeting in the treatment of hypertrophic and keloid scars has not been demonstrated in all studies of the device. Tan and colleagues[89] studied the differences between no treatment, application of silicone gel sheeting, and injection of triamcinolone acetonide in 20 patients with keloids. Results showed that triamcinolone acetonide injection was superior to both silicone gel sheeting ($p < .05$) and no treatment ($p < .05$) with respect to scar size, color, texture, and symptoms of pain and pruritus. There was no significant difference between the same parameters in scars treated with silicone gel sheeting and those that were not treated. Similarly, results from a separate study show that when hypertrophic scars were divided

into three sections and each section was assigned silicone gel sheeting, flashlamp-pumped pulsed-dye laser, or no treatment, there was no significant difference noted among the three sections with regard to blood flow, elasticity, scar volume, or histologic assessment.[90]

Prevention Trials

The prevention of hypertrophic and keloid scar formation by silicone elastomer sheeting has also been studied.[10,72,83,91–94] In a controlled trial of 20 women who were undergoing bilateral reduction mammaplasties, silicone elastomer sheeting was applied to the scars on one breast on Postoperative Day 14, whereas the scars on the other breast remained untreated.[92] The silicone sheets were held in place with adhesive skin closures (Steri-Strips, 3 M, St. Paul, MN) and a brassiere and were worn for 12 hours per day for 2 months. After 2 months, 60% of the untreated scars and 25% of the treated scars had become hypertrophic ($p < .05$). The treatment effect remained after evaluation at 6 months, at which time 55 and 25% of untreated and treated scars, respectively, exhibited hypertrophy ($p < .05$). Similar results were obtained from a separate study, in which 29 patients with surgical incision scars from procedures occurring 8 months or less before the study wore silicone elastomer sheeting on portions of their scars.[91] Each patient served as his or her own control by leaving a portion of the scar untreated. The silicone sheeting was worn for 12 to 24 hours per day for 2 months and improvement when compared to baseline was measured at 1 and 2 months by objective assessment of scar volume. Upon evaluation at 1 and 2 months, scar volume of control scars was greater than that of test scars ($p = .08$ and $p = .003$, respectively). A treatment–time effect on test scar volume was identified ($p = .03$).

A positive treatment effect is not always reported when hypertrophic and keloid scars are treated with silicone elastomer sheeting.[93,94] A total of 155 patients undergoing bilateral breast reduction received treatment with silicone elastomer sheeting or silicone gel on half of their scars and no treatment on the other half of their scars.[94] The investigators reported that 64.3% of patients developed hypertrophic scars after 3 months and concluded that neither silicone elastomer sheeting nor silicone gel had an effect on prevention of hypertrophic scarring. In another study, 66 patients undergoing minor dermatologic surgery were stratified as either high or low risk for abnormal scarring based on history of development of hypertrophic or keloid scars[93] and were randomized to treatment with silicone elastomer sheeting or routine wound care. The treatment group applied silicone sheeting to their wounds 48 hours after surgery and wore the sheets for 12 to 24 hours per day for 6 months. No significant difference was detected between the treatment and control groups; however, a subset of patients in the high-risk group whose surgery was identified as "scar revision" derived benefit from treatment with silicone elastomer sheeting, and only 4 (36%) of the treated patients had scar recurrence. Scars recurred in 10 scar revision patients (83%) in the control group ($p = .035$).

The published studies conducted to assess the efficacy of silicone gel sheeting for improvement of hypertrophic and keloid scars have shortcomings. All of the studies suffer from a small sample size, lack of objectivity in measurement of parameters that assess efficacy, lack of standardization of the patient population, and lack of control over patient compliance. Because of the similarities in the characteristics of hypertrophic and keloid scars, the two types of scars are often not evaluated separately, and the age and origin of the scars, although usually reported, are not analyzed consistently. Perhaps enrollment of larger numbers of patients with more uniform scar characteristics would provide further evidence regarding the efficacy of silicone elastomer sheeting for treatment and prevention of hypertrophic and keloid scars. Furthermore, patient compliance with silicone gel sheeting may be increased with enhanced patient education in the form of handouts and detailed multimedia.[95]

Safety Experience

Silicone elastomer sheeting is generally well tolerated by patients with hypertrophic and keloid scars.[96–102] A discussion of the safety of silicone elastomer sheeting encompasses both a description of the adverse events encountered in clinical trials and a report of studies designed to detect the presence of silicon in skin that has been in contact with silicone. Adverse events that have been reported in clinical efficacy trials are mild and include pruritus,[98,100,102] contact dermatitis,[96–102] skin breakdown,[100,102] skin maceration,[98,100] dry skin,[98] and odor emanating from the gel sheet.[100] Adverse effects occurred infrequently and were commonly associated with poor hygiene.[96–102] Pruritus and skin rash, skin breakdown, and skin maceration usually resolved within 12 to 48 hours after the removal of the gel sheet.[96–100] In some cases, treatment was resumed without incident after a change in the brand of the silicone gel sheet.[100] It is important to note that not all episodes of skin rash occurred in the skin under the gel. In some instances, skin irritation and rash were observed under the adhesive tape holding the gel in place.[96,98,100,101] Alcohol may be used to remove this adhesive tape to avoid inadvertent removal of layers of skin.[101] Dry skin was treated with application of moisturizer to the scar and episodes of malodorous gel sheets were resolved with institution of better hygiene by washing the scar and gel sheet more frequently with mild soap and water.[98,100] These adverse effects can be avoided by building up wearing time, beginning with approximately 2 hours per day and gradually increasing to 12 to 24 hours per day as tolerated.[7,103–105]

The paucity of adverse events reported in clinical trials of silicone gel sheeting suggests that the presence of silicon in the skin does not contribute to the incidence of adverse events. Silicone elastomer sheeting products are safe and have minimal potential to cause harm, as substantiated by the absence of case reports in the literature describing serious adverse effects. If adverse effects do occur, they can be managed by temporary interruption of therapy, reduction of wearing time, and instruction in better hygiene.[7,103–105]

Clinical Use for Scar Management

Silicone elastomer sheeting can be used for the treatment of hypertrophic and keloid scars resulting from many types of wounds, including burns, other accidental injuries, or surgical incisions.[9,105,106] Because the reasons for development of hypertrophic and keloid scars are not clear, the mechanisms of action of many of the available treatments are unknown, and treatment responses vary among different scars. Many clinicians adopt a multimodal approach to the treatment and prevention of hypertrophic and keloid scars. Treatment options other than silicone elastomer sheeting include intralesional injection of corticosteroids, radiation, laser treatment, surgical excision, cryotherapy, and pressure therapy.[7,9,107–109] Silicone elastomer sheeting is generally used in conjunction with other minimally invasive treatments as a first-line treatment for small, minor hypertrophic, and keloid scars.[9] Recalcitrant scars, or those that are very large or particularly serious, are usually treated with more invasive measures, but silicone elastomer sheeting may still be used as an adjunct to increase the likelihood of scar improvement.[9,109]

The ease of use of silicone elastomer sheeting and its lack of serious adverse effects make it an attractive alternative to more invasive treatments, such as intralesional injection of corticosteroids, radiation, laser treatment, surgical excision, cryotherapy, and pressure therapy.[9] Surgical revision of scars carries the risks common to all surgical procedures, and the recurrence rate of hypertrophic and keloid scars after surgical revision is high (45%–100%).[110–113] Injection of corticosteroids into the scar can cause significant pain, skin atrophy, depigmentation, and telangiectasias.[114] Pressure therapy is expensive because pressure garments are custom-made and must be replaced as they wear out and a patient grows or loses or gains weight.[103,104] Pressure garments can also be uncomfortable and patient compliance is poor.[102,108,115] Radiotherapy is controversial because of the possibility of carcinogenesis.[109] High scar recurrence rates have been noted with laser therapy,[9] and cryotherapy commonly causes permanent hypopigmentation.[116]

It is generally accepted that prevention of hypertrophic and keloid scar formation is easier than treatment of an established scar.[9,104] Silicone elastomer sheeting has been used in the prevention as well as treatment and is particularly well suited to both uses because it exposes the patient to very little risk of adverse events, in contrast to treatments such as surgical excision, radiation, intralesional corticosteroid injections, and laser therapy.[9]

Some silicone elastomer sheeting products are available over the counter and are often purchased by patients upon recommendation of a health-care professional. Methods of application of silicone elastomer sheeting to scarred skin include fixation with gentle adhesive tape and/or covering with a tubular bandage.[104,117,118] Some products, such as antibiotic ointment (Neosporin, Johnson & Johnson, New Brunswick, NJ), silicone scar sheets (Scar Solution, Johnson & Johnson), and scar healing strips (BAND-AID brand scar healing strips, Johnson & Johnson), are self-adhesive and thus offer the advantage of not requiring adhesive tape.[28,119] Other means of application combine silicone therapy with pressure therapy, such as silicone orthoses, pressure garments with a silicone interface, and inflatable silicone inserts that can be used in concave areas or on soft tissue.[39,105]

Researchers who have studied the application of silicone elastomer sheeting in clinical practice have found that the sheet must be worn for at least 12 hours per day for 2 to 3 months to be effective.[7,9,104,107,109,118] Patients may notice slight improvements in the appearance and feel of their scars within 1 week, and more noticeable improvements may be evident after the full treatment period.[106] The sheet and the scar should be gently but thoroughly washed with mild soap and warm water at least once daily, and the sheet should be replaced when it begins to disintegrate. It is important to note that silicone elastomer sheeting should not be used on open wounds or unhealed skin.[7,9,104,107]

Conclusions

During the past 30 years, silicone sheeting products have been refined to maximize adhesiveness and durability, making them easier to use. Other treatment options for hypertrophic and keloid scars, such as intralesional injection of corticosteroids, radiation, laser treatment, surgical excision, cryotherapy, and pressure therapy, may be associated with problematic adverse effects and require involvement of a physician or physical therapist. Silicone elastomer sheeting, however, is available over the counter and requires only minimal monitoring by a physician for safe and effective use.

Although the mechanism of action of silicone elastomer sheeting has not been completely elucidated, it appears to be an effective means of treating and preventing hypertrophic and keloid scars and can be used with little risk of serious adverse effects. Data regarding efficacy of silicone elastomer sheeting products for the treatment and prevention of hypertrophic and keloid scars may provide further evidence by execution of larger, controlled clinical trials. Silicone elastomer sheeting can also be used as part of a multifaceted approach to scar management and can be used in combination with other effective therapies. Clinicians have recommended that silicone elastomer sheeting be in contact with the scar for 12 to 24 hours per day for 2 to 3 months, with removal permitted for routine hygiene. Adverse events such as pruritus, rash, maceration, and odor can be managed by temporary interruption of treatment and regular washing of the sheet and the scar.

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COMMENTARY

This article by Berman and colleagues is an important review for practitioners who face the challenge of treating hypertrophic scars and keloids in their clinical practices. The article very nicely describes the differences between these difficult to treat lesions and reviews their etiologies as well as offers the various treatment options used to treat hypertrophic scars and keloids. It describes the properties of silicone elastomer sheetings and goes over the various proposed mechanisms of actions for silicone elastomer sheetings. These include increased temperature, hydration as a result of occlusion of the underlying skin, increased oxygen tension within the scars, direct release of silicone into the skin, and polarization of the scar by negative static charge. Most of the early literature seemed to focus on the hydration/occlusion principle for the mechanism of action of silicone elastomer sheetings, although no one has yet to fully elucidate how these products work to flatten hypertrophic scars and keloids.

The authors review the major clinical trials that support the use of silicone elastomer sheetings in the treatment of these lesions and further strengthen the case that these products should be utilized when clinicians are confronted with these lesions. As noted in the article by Mustoe and colleagues,[1] silicone gel sheets have a major role in the initial therapeutic approach to hypertrophic scars and keloids, with more controlled clinical trials having been performed than with most other treatment modalities. The authors then end with a review of the potential adverse events with these materials, but the majority of clinical trials have confirmed their safety profile.

I have utilized silicone gel sheets in my clinical practice for a number of years. The research we have performed and published suggests that they have an effect on flattening these raised lesions and returning the color back toward normal and may have a preventative effect in those individuals with a history of abnormal scarring.[2–4] The literature suggests that this treatment is best used on what are typically defined as fresh scars, those less than 2 years old. Reports of hypertrophic scars and keloids present for longer durations, however, have also responded to this treatment modality.

In my practice, anyone who has a hypertrophic scar or a keloid is initially treated with a silicone gel sheet. On occasion, this is the only therapy we will utilize. The patient is instructed to wear the sheet for upwards of 12 to 24 hours per day and are told it may take upwards of 2 to 3 months before an effect may be seen. As described in the article by Mustoe and coworkers,[1] other treatment options, such as intralesional corticosteroids, are also useful early and are the standard of care for these lesions. So, in my practice it is customary for my patients to receive combination therapy, with both intralesional cortico-

steroids, given in the office, and topical silicone gel sheeting, to be used at home. This gives the patient some ownership in his or her therapy, something that I feel important in treating many patients. Also on occasion, laser therapy, mainly with the pulsed dye laser or the intense pulsed light source, is also added to the therapeutic combination, to help reduce the vasculature to the lesions.

Hypertrophic scars and keloids are, at present, difficult-to-treat skin lesions. Silicone elastomer sheetings, of many varieties, have shown the test of time since their original descriptions in the burn literature in 1982[5] and my first report in the dermatologic literature in 1993.[2] Although their exact mechanism of actions has not been fully elucidated, they work clinically and are safe and quite frankly should be part of all hypertrophic scar and keloid therapy for your patients.

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