Comparison of a Silicone Gel-Filled Cushion and Silicon Gel Sheeting for the Treatment of Hypertrophic or Keloid Scars

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BACKGROUND. **The exact mechanisms of action responsible for the effectiveness of silicone gel dressings are unknown, although it has been proposed that static electricity generated by friction could be the reason for their anti-scarring effects.**

OBJECTIVE. **We compared the efficacy of a cushion of silicone filled with liquid silicone gel reported to induce greater negative static-electric charge with silicone gel sheeting in the treatment of hypertrophic and keloid scars.**

METHODS. **The size, volume, symptoms (tenderness and itching), and signs (color and induration) of hypertrophic (10 patients) or keloid scars (22 patients) were measured at baseline at 16 weeks following use of either the silicone gel cushion or silicone gel sheeting, as determined by random assignment.**

RESULTS. **Both the silicone gel cushion and the silicone gel sheeting treatments were effective in decreasing scar volume, 53.0% and 36.3%, respectively. The percentages of keloids and hypertrophic scars benefiting from the silicone cushion and the silicone sheeting were similar with respect to reduction in tenderness (36.3% vs 33.3%), itching (45.5% vs 33.3%), and redness (0.1% vs 0.1%), and in the degree of softening (45.5 vs 25.0%).**

CONCLUSIONS. **Both the silicone gel cushion and the silicone gel sheeting treatments were effective in the treatment of keloids and hypertrophic scars, although no statistically significant differences were found between the two treatment modalities.**

HYPERTROPHIC SCARS and keloids commonly develop after traumatic insult to the skin. In addition to the cosmetic disfigurement, these scars can be pruritic or painful, or can be secondarily infected.[1] The therapeutic management of these scars remains challenging. Treatment options include occlusive dressings, compression therapy, intralesional corticosteroid or interferon injections, cryotherapy, radiotherapy, surgical excision, and laser therapy.[2–13] Since hypertrophic or keloid scars treated by some of these methods can have a high recurrence rate, occlusive dressings such as silicone gel sheeting offer patients an efficacious and less aggressive method of treatment.[2–5]

Although the exact mechanisms of action of silicone gel dressings are unknown, it has been proposed that static electricity generated by friction-activated silicone sheeting could be the reason for its anti-keloidal effects.[14] A silicone gel-filled cushion of silicon sheets was developed with an increased negative static-electric charge which has been reported to induce scar regression as well as symptomatic improvement.[14] We compared the efficacy of a silicone gel-filled cushion and silicone gel sheeting for the treatment of hypertrophic and keloid scars.

Methods

Thirty-two patients in generally good health who had their hypertrophic (10 patients) or keloid scars (22 patients) at least 7 months (range 7 months–35 years) were included in the study. The scars ranged in size (largest dimension) from 1–25.8 cm. Written informed consent was obtained for each enrolled patient. A single keloid or hypertrophic scar per patient was chosen as the study lesion. The study lesion length and width was measured with a caliper and an impression mold was made to determine the scar volume. Scar color (pink, red, black), tenderness (none, slight, moderate, severe), itching (none, slight, moderate, severe), and induration (slight, moderate, severe) was obtained from each study patient. A silicone gel-filled cushion was placed on the study lesions of 50% of the patients after randomized selection. Silicone gel sheeting was applied to the remaining patients. The silicone gel-filled cushion or the silicone gel sheeting were worn at least 10 hours /day by the patient during the course of the 4-month study. The patients were assessed at baseline and at specified intervals by the investigators during the 4-month study period. Measurements and as-

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sessments were obtained at baseline and weeks 2, 4, 8, 12, and 16.

Thirty-two patients were enrolled in the study (14 black, 18 white, 28 women, 4 men). The patients ages ranged from 25 to 70 years of age. Nine patients failed to complete the study due to either noncompliance with protocol rules or were lost to follow-up. Each patient rated their assigned therapy at the end of the week 16 treatment period by recording their level of satisfaction using a visual analog scale from 1 to 10 cm in length. Statistical analysis was performed by repeated measures of analysis of variance.

Results

Twenty-three patients completed the 4-month study. There was a reduction in study lesion volume in both treatment groups. The median scar volume at baseline was 0.44 mm^3 (silicone gel-filled cushion group) and 1.35 mm^3 (silicone gel sheeting group). The median scar volume at the end of treatment was 0.26 mm^3 (silicone gel-filled cushion group) and 0.94 mm^3 (silicone gel sheeting group). Ten of 11 patients (90.9%) had a reduction of scar volume in the silicone gel-filled cushion group, while all 12 patients (100%) had a reduction in scar volume in the silicone gel sheeting group. The mean percent volume reduction in the silicone gel-filled cushion group was 53.0% (range 5.1%–89.5%, SD = 32.8) versus 36.3% (range 6.7%–89.8%, SD = 28.7) in the silicone gel sheeting group (see Table 1). One patient in the silicone gel-filled cushion group had an 8% increase in scar volume at the end of the study. There was no statistically significant difference in volume reduction between the two treatment groups.

One patient in the silicone gel-filled cushion group and one patient in the silicone gel sheeting group had a baseline red scar color which changed to pink by the end of the study. None of the study lesions in the silicone gel-filled cushion group darkened in color; however, one pink scar in the silicone gel sheeting group changed to a red color by week 16.

Five study lesions with moderate or severe induration scores softened to either none or slight with silicone gel-filled cushion treatment versus three study lesions in the silicone gel sheeting group. None of the scars became harder with treatment in any of the groups.

Four patients whose scars were moderately or severely tender at baseline improved to either none or slight tenderness in both treatment groups. But while none of the study lesions in the silicone gel-filled cushion group became more tender, one in the silicone sheeting group worsened to severely tender.

Five study lesions that were either moderately or severely pruritic improved to either slightly or nonpruritic in the silicone gel-filled cushion group versus four in the silicone gel sheeting group. One study lesion in the silicone sheeting group that was slightly pruritic at baseline became moderately pruritic at the end of treatment. None of the scars treated with the silicone cushion became more pruritic during the study period. Overall, 61% (14 of 23) of patients recorded a satisfaction level of 9 or higher on the 0–10 visual analog scale of satisfaction.

Complications were limited to one patient who developed a mild folliculitis noted at week 12 who had been using the dressing continuously. Upon decreasing the total wear time to 10 hours, as per protocol guidelines, the folliculitis resolved without treatment.

Discussion

Our results showed that the majority of patients had a reduction of scar volume with either treatment. Although not statistically significant, there was a trend toward an increased symptomatic response in the silicone gel-filled cushion-treated group. None of the patients in the silicone gel-filled cushion group worsened with respect to pruritus, tenderness, or induration during the course of the study. The mechanism of action of these treatment devices remains speculative. Occlusion has been reported to decrease interleukin-1, a proinflammatory cytokine that can increase fibroblast glycosaminoglycan synthesis and induce the production of interleukin-6, an activator of fibroblast synthesis of matrix components.[15] Although not measured in this study,[4] the interaction between the negatively charged ions of the silicone gel-filled cushion and ionic charges of the tissue fluids has been reported as an important mechanism in scar regression.[14]

Although favorable efficacy reports with intralesional injections, radiation, and laser and surgical excision have been cited, many patients are not amenable to

Table 1 Efficacy of Silicone Gel-Filled Cushion or Silicone Gel Sheeting Treatment of Keloid and Hypertrophic Scars

Scar Parameters	*Silicone Gel-Filled Cushion*	*N*	*Silicone Gel Sheeting*	*N*
Mean scar volume reduction	53.0%	10	36.3%	12
Reduced tenderness	4	11	4	12
Reduced pruritus	5	11	4	12
Lighter scar color	1	11	1	12
Scar softening	5	11	3	12

the pain induced by these aggressive therapeutic options. The newly developed silicone gel-filled cushion offers the keloid/hypertrophic scar patient an efficacious alternative to silicon gel sheeting and the more aggressive methods of treatment. Whether application of these silicon devices after surgical excision would reduce keloid recurrence is worthy of future investigation.

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Commentary

I read this article with interest. I think this article further defines the usefulness of silicone gel in the treatment of these difficult cutaneous lesions. All of the patients reported had a reduction in scar volume with either the silicone gel-filled cushion or the silicone gel sheeting. The symptomatic responses are, for the most part, similar, based on such a small sample size.

Most researchers feel that occlusion and hydration are the major factors involved in the mechanism of action for these products. This appears to me another useful delivery system for delivery of silicone gel. Whether or not a static-electric charge difference plays any role is not answered by this article—measurements were not taken and compared to the silicone gel sheeting for any discernable differences. Further research into these areas would prove very useful.

Silicone gel sheeting, and now silicone gel-filled cushions, are useful modalities for the reduction of hypertrophic scars and keloids. They should be included in the armamentarium of physicians caring for these individuals. They can make a painless difference to some very grateful patients.

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