Silicone versus Nonsilicone Gel Dressings: A Controlled Trial

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BACKGROUND. **Silicone gel dressings decrease scar volume and soften hypertrophic tissue, allowing it to be more easily controlled by other methods. Although silicone does not appear to be an essential component of the treatment, nonsilicone dressings have been reported to cause no change in physical parameters during a 2-month treatment period.**

OBJECTIVE. **To compare silicone and nonsilicone gel dressings in the treatment of keloids and hypertrophic scars, including a control group, and to evaluate the effectiveness of these treatments using two new assessment techniques.**

METHODS. **Patients were randomly chosen to receive silicone or nonsilicone gel dressings in a 4.5-month controlled prospective study. Scar size, induration, and symptoms were evaluated before and after the treatment. Scar color was visually measured using a color palette catalog, and a new device was developed to measure intracicatricial pressure.**

RESULTS. **All of the measured parameters were significantly reduced in both silicone- and nonsilicone-treated groups, as compared to the control, with no significant differences between them.**

CONCLUSION. **Silicone and nonsilicone gel dressings are equally effective in the treatment of keloids and hypertrophic scars.**

SILICONE GEL DRESSINGS have been shown to be effective for the treatment of keloids and hypertrophic scars, as first described in 1983.[1] They promote a decrease in scar size,[2,3] volume,[4] pain, itching, and erythema.[5] After treatment the scar tissue becomes softer, allowing it to be more easily controlled by other treatment methods, such as pressure[5] or intralesional corticosteroids.[6]

It has been shown that silicone dressings improve scar hydration, but silicone is not essential in the treatment.[2,7–9] On the other hand, there have been reports suggesting that nonsilicone occlusive dressings are not effective in the treatment of these scars.[10] They provide symptomatic relief, but no changes in physical parameters, when used for 2 months over keloids and hypertrophic scars.[11] The authors suggested that further studies should be performed in order to determine the effects of longer duration of treatment on physical scar parameters. In 1996 Ricketts et al.[12] demonstrated evidence for extensive connective tissue remodeling when either silicone or nonsilicone gel sheets were used for 4 months over hypertrophic scars.

Duoderm is a synthetic occlusive gel dressing that helps the stratum corneum maintain its capacity to retain water.[13–15] The only study of Duoderm for the treatment of keloids and hypertrophic scars did not include a comparative silicone dressing-treated group and it was performed over a short period of time (2 months).[11]

There have been few controlled studies of the effectiveness of silicone and nonsilicone gel dressings on scars.[10] Some of them[16–18] did not include a control group, or used different assessment methods,[1,3,4,17] such as pressure, making it difficult to isolate the individual effect of any of the methods used.

Even when a nontreated control group is included, it is still difficult to evaluate the results of the scar treatments. There is a lack of objective methods for the measurement of scar color[5,12,16,19] and scar induration, which are usually subjectively classified.[1,2] Novel

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objective methods for this type of evaluation are still needed.[4]

The purpose of the present study was to compare silicone and nonsilicone gel dressings in the treatment of keloid and hypertrophic scars, including a nontreated control group. Two new objective tools to evaluate the effectiveness of these treatments are presented: a method for color evaluation, using a 1000-color palette catalog, and a method to measure the intracicatricial pressure.

Materials and Methods

A clinical study was designed in which 26 patients with 41 hypertrophic or keloid scars were randomly chosen to receive silicone gel sheeting, nonsilicone gel sheeting, or nothing (control group). The groups were homogeneous with respect to the time of scar evolution. Patients between the ages of 15 and 53 years were eligible. Patients were included in the study if they had not received radiation or corticosteroids in the last 12 months and if the lesions were older than 3 months. The scars were clinically classified into hypertrophic or keloid scars. When the patient had two scars, one received a silicone dressing and the other a nonsilicone dressing. Some patients received a side-by-side treatment (silicone and nonsilicone dressings). If there were more than two scars, one was left as a nontreated control lesion. The total period of treatment was 4.5 months. Table 1 shows the patient number, information concerning each of the lesions, and treatment groups. The corresponding treatment group and keloids that have not received side-by-side treatment are indicated by an asterisk (*).

The silicone gel sheeting was flexible and adhering. The patients were instructed to use it 24 hr/day. Every 2 days the sheeting was removed and washed with water, and then reapplied to the underlying skin area which had also been washed. The sheeting was replaced after 30 days. The sheeting was held in place by medical tape.

The nonsilicone gel sheeting was flexible and adhering. The patients were instructed to use it 24 hr/day. Nonsilicone gel sheeting was removed after 1 week and replaced with fresh sheeting. The sheeting was held in place by medical tape.

The study conformed to the ethical guidelines of the 1975 Declaration of Helsinki, and it was approved by the SOBRAPAR Ethical Research Committee. The patients gave written consent for the study and were informed that they could leave the program at any time if they desired. They were monitored every 15 days in order to check that the gel dressings were being correctly used. On days 0, 30, 60, 90, 120, and 135, the following parameters were evaluated by the same researcher, except for the intracicatricial pressure, which was measured blindly by two researchers only on day 135:

- Symptomatic relief of pain and itching, if present before treatment; for statistical analysis the classifications "relief" versus "no relief" were used.
- Induration (hardness) of the scar, using a graded scale from 1+ (mild induration) to 4+ (severe induration).
- Linear measurements (length and width measured with a flexible transparent metric ruler applied to the lesion); for statistical analysis the following index was used: [(0–135-day value)/0-day value], that is, proportional decrease at the end of the study.
- Color measured in the morning, under natural sunlight, with a catalog of 1000 paint colors used for house decoration (Figure 1). Scar and adjacent healthy skin color were registered by comparison of the color sheet over the skin. We recorded our observations as "amelioration" versus "no modification of the contrast between the lesion color and the healthy skin." For statistical analysis, amelioration was considered to have occurred when the contrast between skin color and that of the lesion was reduced.
- Intracicatricial pressure, defined as "the necessary pressure to inject a 0.5 ml of triamcinolone solution (Theracort-triamcinolone, 20 mg/ml) into the scar tissue." It was measured in the three groups only at day 135, after the evaluation of the other parameters. A special informed consent was required for this procedure. Patients who agreed to the procedure had their intracicatricial pressure measured and are specified in Table 1. Some patients from the treatment groups believed that their scars had undergone a complete improvement and did not agree to participate in this procedure. A 5 cc plastic syringe was adapted in a pressure transducer with electric extensometers (0–20 bar) (Figure 2). Two values were recorded: one immediately after the injection and another 10 seconds later, and the average of these two readings was used for statistical analysis.

Statistical Analysis

The subjective variables (scar induration, pain, and itching) and color were submitted to either the chi-squared test or Fisher's exact test when applicable, while quantitative variables (linear measurements, intracicatricial pressure) were evaluated by Kruskall–Wallis (H) and Mann–Whitney (W) tests. Two statistical analyses were performed: the first involved all lesions; the second utilized only keloid scars that had received a single treatment (Table 1).

Results

Linear Measurements

When keloids and hypertrophic scars were considered, there was a statistically significant difference between the three groups (silicone, nonsilicone, and nontreated groups; $P = .0139$, length; $P = .0011$, width). This difference was accounted for by the control group, since when the silicone and nonsilicone dressing groups were compared there was no significant difference [$P = .5247$ (length), $P = .3354$ (width)] (Table 2).

Table 1. Patients and Lesions Considered in This Study

Patient/sex	Family History	Lesion	Cause	Region	Pressure (bar)	Time (years)	Group
1/M	−	1*	Acne	Presternal	2.214904	3.00	Silicone
2/M	−	2*	Acne	Presternal	1.319637	3.00	Silicone
2/M	−	3*	Acne	Shoulder		3.00	Silicone
3/F	−	4	Surgery	Abdomen		0.50	Silicone
2/M	−	5*	Acne	Dorsum		3.00	Silicone
4/F	−	6	Spontaneous	Presternal	1.183674	6.00	Silicone
5/F	+	7*	Surgery	Dorsum	1.149684	3.00	Silicone
6/F	+	8	Trauma	Dorsum	1.331634	1.50	Silicone
7/F	+	9*	Spontaneous	Presternal		2.00	Silicone
8/F	+	10	Spontaneous	Presternal		12.00	Silicone
9/F	+	11	Surgery	Abdomen		1.50	Silicone
10/F	−	12	Surgery	Abdomen	1.478593	1.50	Silicone
11/F	−	13	Surgery	Abdomen		0.30	Silicone
12/F	−	14*	Surgery	Ear	1.292644	3.00	Silicone
13/F	?	15	Surgery	Face		0.16	Silicone
14/F	−	16*	Ear ring	Ear	1.088701	15.00	Silicone
6/F	+	17	Trauma	Dorsum	1.103696	1.50	Nonsilicone
2/M	−	18*	Acne	Presternal		3.00	Nonsilicone
2/M	−	19*	Acne	Shoulder	1.349629	3.00	Nonsilicone
7/F	+	20*	Spontaneous	Presternal		2.00	Nonsilicone
8/F	+	21	Spontaneous	Presternal		12.00	Nonsilicone
4/F	−	22	Spontaneous	Presternal	1.241658	6.00	Nonsilicone
15/F	+	23*	Spontaneous	Presternal	1.137687	7.00	Nonsilicone
11/F	−	24	Surgery	Abdomen		0.30	Nonsilicone
9/F	+	25	Surgery	Abdomen		1.50	Nonsilicone
1/M	−	26*	Acne	Presternal	2.339896	3.00	Nonsilicone
14/F	−	27*	Ear ring	Ear	1.188673	15.00	Nonsilicone
3/F	−	28	Surgery	Abdomen		0.50	Nonsilicone
16/F	−	29	Surgery	Dorsum		0.50	Nonsilicone
2/M	−	30*	Acne	Dorsum		3.00	Nonsilicone
19/M	?	31*	Surgery	Abdomen	2.773237	8.00	Control
20/F	−	32*	Surgery	Trunk	1.366624	1.70	Control
21/F	−	33	Surgery	Abdomen	2.053249	0.60	Control
22/F	−	34*	Ear ring	Ear		3.00	Control
1/M	−	35*	Acne	Presternal	2.839732	3.00	Control
16/F	−	36*	Surgery	Dorsum		0.60	Control
23/F	−	37*	Infected wound	Upper limb		2.00	Control
24/F	−	38*	Herpes	Presternal		2.00	Control
24/F	−	39*	Herpes	Upper limb		2.00	Control
25/F	+	40*	Trauma	Breast	4.427782	10.00	Control
26/F	+	41*	Acne	Face	2.060433	3.00	Control

Time corresponds to the time of disease (in years) at the beginning of the study.
*Keloids that have received a single treatment, evaluated separately for statistical analysis.
Family history: +, present; −, negative; ?, unknown.

When only keloid scars were considered, results were the same as above for the three groups [$P = .001$ (length), $P = .001$ (width)]. When the silicone dressing group was compared to the nonsilicone dressing group, $P = .488$ (length) and $P = .644$ (width) (Table 3).

Color

It was observed, after day 30, that the color difference between the lesion and adjacent skin (protected from sun exposure by dressing) was reduced. These changes continued, with the scar color becoming more similar to skin color during 30–135 days of treatment. These changes are summarized in Table 4.

The first analysis of scar color, including keloid and hypertrophic scars, revealed no differences between silicone- and nonsilicone-treated groups, but showed statistically significant differences between the control and the treated groups ($P < .001$). When only keloid scars were considered, there was a similar, statistically significant difference between the nontreated and the treated groups ($P = .001$).

Figure 1. Sherwin Williams catalog of 1000 paint colors utilized in this study for color evaluation of scars and adjacent skin area. Sheets can be easily removed from the catalog and placed next to the scar in order to obtain precise color evaluation.

Itching and Pain

Although we have observed that pain and itching were reduced in the treated groups, it was not possible to detect statistical differences, with $P = .69234$ (itching) and $P = 0.65337$ (pain), probably because of the small number of patients.

Scar Induration

Considering keloid and hypertrophic scars, when the nontreated and treated groups were compared, a significant trend toward a decrease in scar induration of treated groups by clinical evaluation was seen ($P < .0001$), but no differences between silicone- and nonsilicone-treated groups were seen ($P = 1.0$). A similar, significant difference ($P < .0001$) was seen when only keloid scars were considered.

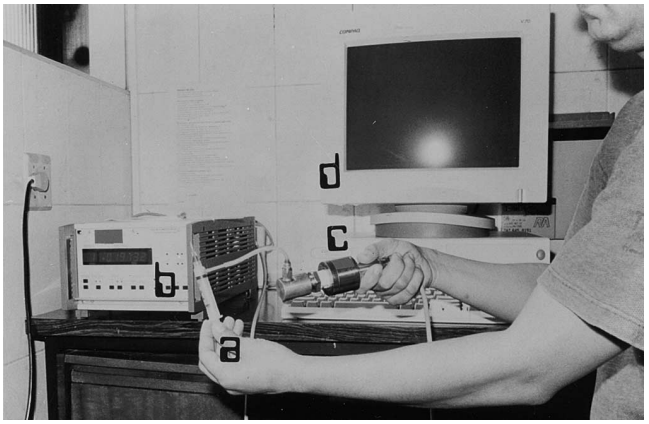

Figure 2. Intracicatricial pressure equipment. A 5 cc plastic syringe (a) is connected to the sensor cable (c), which contains the pressure transducer with electric extensometers (Hottinger Baldwin Messtechnik GmbH), specification P31AP/20 bar (0–20 bar). A technician assistant holds the cable and pressure levels are displayed on the screen (b), and data can be fed directly into a computer where the information can be analyzed (d).

Table 2. Mean Values of Objective Parameters Considering Keloids and Hypertrophic Scars

	Silicone Sheeting	*Nonsilicone Sheeting*	*Control (Nontreated Group)*
Time of disease* (years)	3.6537	4.1642	3.2636
Length index	0.0696	0.0903	0
Width index	0.1760	0.2079	0
Intracicatricial pressure (bar)	1.3824	1.3935	2.5868

*At the beginning of the treatment.
Linear measurements: length and width indexes
[(0–135-day value)/0-day value], i.e., proportional decrease at the end of the study.

Intracicatricial Pressure

Comparing treated and nontreated groups of keloid and hypertrophic scars, treated groups differed significantly from the nontreated group in intracicatricial pressure ($P = .0152$). The silicone-treated group did not differ from the nonsilicone-treated group ($P = .7963$) (Tables 2, 3, and 5). Considering only keloid scars, the treated groups differed from the control nontreated group ($P = .045$), although the silicone-treated group did not differ from the nonsilicone-treated group ($P = .7133$) (Table 5). Complications included irritative contact dermatitis, which was promptly relieved by removal of the gel for 5 hours and skin washing (Figure 3).

Discussion

Studies of scars are complicated by many variables,[20,21] such as the lack of a suitable animal model,[22] few objective methods for treatment evaluation,[4] and patient motivation in maintaining therapy.[21] Also, many of the studies have not been properly controlled.[10] An ideal randomized, prospective, and blind study with patients serving as their own controls is essentially impossible.[22] Also, the distinction between keloids and

Table 3. Mean Values of the Objective Parameters Considering Only Keloid Scars

	Silicone Sheeting	*Nonsilicone Sheeting*	*Control (Nontreated Group)*
Time of disease* (years)	4.3750	5.1428	3.53
Length index	0.1117	0.0861	0
Width index	0.1161	0.1435	0
Intracicatricial pressure (bar)	1.4131	1.5039	2.6935

*At the beginning of the treatment.
See Table 2 for definitions.

Table 4. Last Color Change During the Study

	30 days	*60 days*	*90 days*	*135 days*
%	21	27	43	9

% = percenteage of scars that underwent their last color change.

hypertrophic scars is not clear.[23–25] In several previous studies, other methods have been used, such as triamcinolone injection, excision, compression, and silicone treatment,[4,6,18,26,27] and it became difficult to isolate the effect of the dressing alone.[10]

In the present study, patients who had received other treatment methods were not accepted into the protocol. Silicone has been compared to nonsilicone gel sheet treatment and both were compared to a control group. The results demonstrate that silicone and nonsilicone gel sheets are similar, effective methods to treat keloids and hypertrophic scars. Visits every 15 days increased patient motivation and the correct use of the dressings. The statistical analysis of keloid scars alone allowed evaluation of more homogeneous groups, although it was not different from the analysis of the keloid and hypertrophic scar groups together. Based on our results, we agree with other authors, who consider these entities together, because of the close relationship between them.[28] The groups, however, were homogeneous concerning the time of disease. Because children are recognized to have a greater propensity to develop scar hypertrophy,[29] they were not accepted in the study.

The treatment period has not been uniform in the literature.[1,4,16,21] In the present study, color changes were observed until day 135, although most of the scars cleared up by day 90, suggesting at least a 3-month treatment with silicon and nonsilicone sheets. Both of the treatment methods equally improved the physical parameters of the scars. We agree with Phillips et al.[11] when they suggested that a 2-month nonsilicone gel sheet treatment might have not been sufficient. Although the number of patients is too small to make any conclusions about the effect of the gels on the scars or keloids arising from different causes (e.g., acne) or in different regions, and the data must therefore be considered preliminary, our results corroborate previous studies about silicone and nonsilicone gel dressings over hypertrophic scars.[12] We determined changes in physical parameters, without differences between the two treatments, with improvement of scar color, induration, and size, irrespective of the gender and family history of keloids.

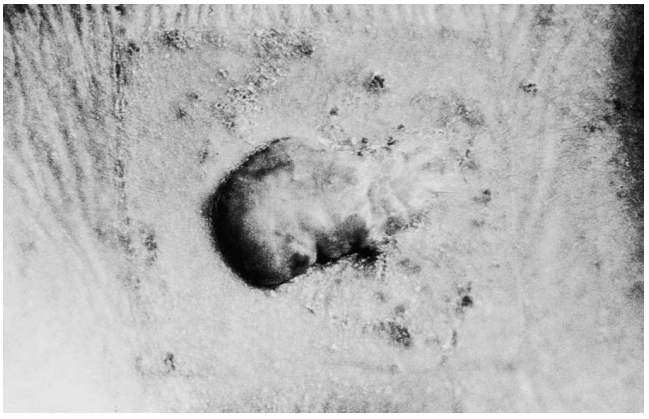

Figure 3. Keloid with dermatitis and small papules around it.

Table 5. Intracicatricial Pressure in the Three Groups

	Control	*Silicone*	*Nonsilicone*
n	6	8	6
Mean (bar)	2.586842	1.3824338	1.3935353

n = number of scars
Control, silicone, and nonsilicone: Kruskal–Wallis, $P = .0152$.
Silicon and nonsilicone: Mann–Whitney, $P = .7963$, df = 2.

The color method presented is simple, inexpensive, and easily reproducible. We believe that it can be safely used for scar color evaluation. It is important also to measure the color of adjacent healthy skin to decrease individual differences in skin erythema.[30] Blanching of scars during silicone sheeting treatment has been previously reported,[18,31,32] and our study has demonstrated that nonsilicone sheeting is equally effective in decreasing erythema. Some of the previous studies had considered only subjective clinical evaluation.[4,7,12,16] Methodologic color evaluation is important, because photographic documentation does not consistently depict the changes observed clinically.[29]

Intracicatricial pressure provided another objective measurement of the effectiveness of silicone and nonsilicone treatments. We believe that it reflects scar induration. Previous authors have observed a decreasing of scar induration, without objective measurements.[1,33] We agree with other studies, which report that even when complete clinical response is not obtained with gel dressings, scars become smooth and flattened, allowing them to be better controlled by other methods, such as triamcinolone injection[6,34] and pressure.[1]

Analyzing the results of the present study, which includes observations of untreated control scars, we conclude that if worn continuously, 24 hr/day, silicone and nonsilicone gel dressings are equally effective in the improvement of keloid and hypertrophic scars, and that both of the methods cause beneficial changes in the physical parameters.

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