

ABSTRACT

Objective: Since the early 1980s, topical silicone sheets have been used in the treatment of hypertrophic scars and keloids. This study aimed to determine the optimal duration and application of these sheets.

Design: multi-centered therapeutic study. **Setting and participants:** A total of 224 patients were included in this study; 205 patients with hypertrophic scars and 19 patients with keloids. Patients received treatment with a topical silicone sheet. Treated scars varied in age, ranging from two weeks to 62 years and treatment time ranged from one month to 16 months. Assessment of the scars was performed by the use of standardized study forms and digital photography.

Measurements: Skin therapists objectively assessed the scars on its color, thickness, and elasticity. Patients themselves subjectively assessed their perception of their scar and their experience with the usage of the topical silicone sheet.

Results: After applying the topical silicone sheet, all scars, regardless of type of scar and maturity, improved significantly in color, thickness, and elasticity.

Conclusion: In this study, treatment with the topical silicone sheet showed significant improvement on both hypertrophic scars and keloids. Best results were reached when the silicone sheet was applied at least four hours per day.

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ORIGINAL RESEARCH

Topical Silicone Sheet Application in the Treatment of Hypertrophic Scars and Keloids

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EXCESSIVE SCAR MANAGEMENT and prevention is a significant part of daily practice. Over the past decades many studies tried to find the ultimate treatment for hypertrophic scars and keloids, but little is known about the optimal duration and a good preventive therapy is still lacking.^{1–4} Skin injury due to surgery or trauma, generates a wound that heals with scar tissue. Most scars become somewhat raised and red, which disappears spontaneously after remodeling.^{4–9} However, some scars remain raised and red by the deposition of excess collagen fibers, ultimately leading to hypertrophic scars or keloids.^{3,10–15} Management and treatment of these scars can be difficult. Keloids do not always respond successfully to treatments such as corticosteroids, pressure garments,

cryotherapy, interferon, 5-fluorouracil, and laser therapy. Simple surgical excision is usually followed by recurrence.^{1,2,4,5,10–15,20,21}

Liquid silicone, introduced in the 1970s, was the first silicone therapy to treat hypertrophic scars and keloids,¹⁹ followed by topical silicone sheets in the early eighties. Its clinical efficiency and efficacy appears to be safe and successful.^{20–24} Its effectiveness seems to be the result of the occlusion and hydration rather than the silicone itself.^{4,8,12,23,25–30} It is thought to be acting as a stratum corneum and therefore reducing capillary hyperemia and edema and reducing fibroblast activity, thus decreasing collagen deposition.^{2,3,6,13,16,21,31} Topical silicone sheet (TSS) application is now widely used as a curative treatment on

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hypertrophic scars; however, the optimal duration of treatment and way of application has not been specified. Application time ranges from 12 to 24 hours a day, while treatment time ranges from one month to one year.^{2,3,6,13,15,18,20,21,30,32–37}

The aim of this study was to investigate how the therapeutic effects of TSS on both hypertrophic scars and keloids can best be achieved.

METHODS

For this prospective, nonrandomized multicenter study, skin therapists with experience with scar treatment all over the Netherlands were selected to investigate the use of TSS for the treatment of excessive scarring. The skin therapists are well-trained healthcare professionals who work in their own practice and have a lot of experience with different types of scars and assessment of scars.

The silicone sheets (Scarban) were supplied by the manufacturer (Laprolan B.V., the Netherlands). The sheets contain 100 percent medical silicone and can be applied on intact skin only. The instructions for use were to cover the scar overlapping the borders of the scar with at least 2cm. The sheet was to be applied three hours the first day and if there were no adverse reactions, application was to be prolonged for 1 to 2 hours each day until the sheet was worn 20 to 24 hours a day. The sheets had to be cleansed daily and could be reused for 4 to 8 weeks. From the start of the study, all patients with hypertrophic scars and keloids willing to participate and able to

score their scars were included. Hypertrophic scars and keloids were defined as hyperemic, raised, and/or firm scars. Keloids were differentiated from hypertrophic scars by their history and appearance beyond the confines of the original lesion. Patients that already received another form of treatment of the scar were excluded. Patients served as their own control in time. Informed consent was obtained prior to the study. A digital camera captured photographs to keep record of the results of treatment. All photos were re-evaluated by the researcher and an experienced plastic surgeon to determine if the scars were true hypertrophic or keloid scars. At the start of the study, midway (between 3–6 months, depending on the timing of the next appointment) and at the end, the skin therapist completed a standardized study form to assess and score the scar objectively for its color, thickness, and elasticity on a four- or five-point scale. Color was specified as normal (1), pink (2), red (3), or deep red (4 points). Thickness, measured with a ruler, was specified as 0 mm (1), 0–1mm (2), 1–2mm (3), or >2mm (4 points) above skin level. Elasticity was assessed by palpation and specified as normal (1), slightly resistant (2), evidently resistant (3), firm (4 points), or cord-like (5). Patients assessed and scored their scars for general appearance, cosmetic burden, pain, itching, and straining using a visual analogue scale (VAS 1–10 points) on which they could also indicate side-effects of this TSS treatment.

The age of the scars was

specified in months: 3mos, 3–6mos, 6–12mos or >12mos. Time of application was grouped into: <8hrs, between 8–16hrs, or >16 hrs a day. To study the optimal treatment duration to achieve maximal results, total treatment time was specified in <3mos, 3–6mos, 6–9mos, or >9mos. Cause and location of the scars were specified to study their possible influence on the outcomes. Causes were described and locations were specified. Patient age was subdivided in <30 years of age or >30 years of age.

Statistical analysis. All calculations were performed using Statistical Package for the Social Sciences (SPSS) for Windows Version 20. Data are presented as mean \pm SD. The level of significance was set as $p < 0.05$. To analyze changes in color, thickness, and elasticity of scars over three time points, the repeated measures analysis of variance (ANOVA) test was used with *post-hoc* pairwise comparisons performed with a Bonferroni correction. Although there was no normal distribution of our data, the results were similar when a nonparametric Friedman test was performed; therefore repeated measures ANOVA outcomes could be reported. To compare significant differences between the subgroups a Kruskal-Wallis test was performed with *post-hoc* pairwise comparisons performed with a Bonferroni correction.

RESULTS

Patient and scar characteristics. Two hundred twenty-four patients with

TABLE 1. Patient characteristics

	TOTAL N (%)	HYPERTROPHIC SCAR N (%)	KELOID N (%)
PATIENTS	224 (100)	205 (91,5)	19 (8,5)
SEX FEMALE	181 (80,8)	168 (82,0)	13 (68,4)
AGE IN YEARS/ MEAN (SD)	38,90 (16,76)	39,74 (16,72)	29,72 (14,61)
SCAR AGE IN DAYS/ MEAN (SD)	1077,56 (2403,33)	1010,79 (2426,27)	1831,71 (2038,71)
LOCATION			
Thorax	26 (11,6)	18 (8,8)	8 (42,1)
Abdomen	36 (16,1)	33 (16,1)	3 (15,8)
Mamma	48 (21,4)	48 (23,4)	0
Face	23 (10,3)	20 (9,8)	3 (15,8)
Upper leg	20 (8,9)	20 (9,8)	0
Lower leg	11 (4,9)	10 (4,9)	1 (5,3)
Arm	27 (12,1)	27 (13,2)	0
Wrist	7 (3,1)	7 (3,4)	0
Back	12 (5,4)	9 (4,4)	3 (15,8)
Neck	7 (3,1)	7 (3,4)	0
Hand	2 (0,9)	2 (1,0)	0
Unknown	5 (2,2)	4 (2,0)	1 (5,3)
CAUSE			
Surgical	165 (73,7)	155 (75,6)	10 (52,6)
Burn	11 (4,9)	11 (5,4)	0
Trauma	30 (13,4)	28 (13,7)	2 (10,5)
Other	18 (8,0)	11 (5,4)	7 (36,8)

hypertrophic scars (n=205) and keloids (n=19) were included. All of them received treatment with a topical silicone sheet. Patient characteristics are shown in Table 1.

The locations of the scars were distributed variably. Discontinuation of treatment was reported in 40 patients (17.9%), 19 due to side-effects, and seven

patients because they did not see any treatment results.

Outcome measures. All results are shown in Tables 2 and 3.

Color: Analysis showed scar color scores decreasing 1.2 points in patients with hypertrophic scars ($p<0.0005$) and 0.9 point ($p=0.001$) in keloids.

Thickness: Scar thickness scores decreased 1.2 points in patients with hypertrophic scars ($p<0.0005$) and 1.5 points ($p<0.0005$) in keloids.

Elasticity: Scar elasticity scores decreased 1.8 points in patients with hypertrophic scars ($p<0.0005$) and 1.3 points ($p=0.006$) in keloids.

Different scar ages: There were no significant differences between the four scar age groups in hypertrophic scars for color outcome at the end of treatment ($p=0.111$), but there was a significant difference between the groups for the end results for thickness ($p=0.016$) with *post-hoc* comparison showing a difference between scar age group <3mos and the 3–6mos group ($p=0.004$) and the scar age group <3mos and the >9mos group ($p=0.019$). This significant difference was also seen for elasticity ($p=0.031$) with *post-hoc* comparison revealing this difference again between scar age group <3mos and the >9mos group ($p=0.028$).

When the keloid group was divided into different scar ages, there were only two scar age groups (<3mos and >9mos); therefore, an analysis with *post-hoc* comparison could not be performed.

Application time: Due to the small number of patients in the

TABLE 2. Outcome measures in hypertrophic scars

CHANGES IN SCAR	BASELINE t=0 FREQUENCY	PERCENT	FOLLOW UP t=2 FREQUENCY	PERCENT	PROPORTIONAL CHANGE	P-VALUE
COLOR						
Normal	21	10.2	96	49.5	▲79.4%	
Pink	39	19.0	88	45.4	▲58.2%	
Red	111	54.1	9	4.6	▼91.5%	
Very red	34	16.6	1	0.5	▼96.9%	
N	205		194			<0.0005
THICKNESS						
Normal	19	9.3	100	51.5	▲81.9%	
0–1mm	51	25.0	65	33.5	▲25.4%	
1–2mm	79	38.7	20	10.3	▼73.4%	
>2mm	55	27.0	9	4.6	▼82.9%	
N	204		194			<0.0005
ELASTICITY						
Normal	16	7.8	104	53.6	▲85.5%	
Lightly resistant	46	22.5	66	34.0	▲33.8%	
Evidently resistant	32	15.7	12	6.2	▼60.5%	
Hard/contractured	110	53.9	12	6.2	▼88.5%	
N	204		194			<0.0005

P values determined by repeated measures ANOVA test

keloid group, application time and treatment time were analyzed for both hypertrophic scars and keloids together. When divided into three groups of time of application, statistical analysis showed significant results are achieved for

color ($p=0.048$) and thickness ($p=0.010$) regardless of application time of the sheet per day. However, a *post-hoc* comparison showed that for a better effect on thickness, the sheet should be worn at least four hours per day ($p=0.036$). For

elasticity, no significant results were found. Also, no statistical difference between the groups for the results of color, thickness, and elasticity at the end of treatment was seen.

Treatment time: When divided

TABLE 3. Outcome measures in keloids

CHANGES IN SCAR	BASELINE t=0 FREQUENCY	PERCENT	FOLLOW UP t=2 FREQUENCY	PERCENT	PROPORTIONAL CHANGE	P-VALUE
COLOR						
Normal	0	0	4	22.2	▲22.2%	
Pink	7	36.8	14	77.8	▲52.7%	
Red	10	52.6	0	0	▼52.6%	
Very red	2	10.5	0	0	▼10.5%	
N	19		18			0.001
THICKNESS						
Normal	0	0	5	27.8	▲27.8%	
0–1mm	0	0	4	22.2	▲22.2%	
1–2mm	4	21.1	7	38.9	▲45.8%	
>2mm	15	78.9	2	11.1		▼85.9%
N	19		18			<0.0005
ELASTICITY						
Normal	1	5.3	5	27.8	▲80.9%	
Lightly resistant	5	26.3	9	50.0	▲47.4%	
Evidently resistant	3	15.8	3	16.7	▲5.4%	
Hard/contractured	10	52.6	1	5.6		▼89.4%
N	19		18			0.006

P values determined by repeated measures ANOVA test

into four groups of treatment time, statistical analysis showed a significant result of treatment time for color ($p=0.001$), but not for thickness ($p=0.449$) nor elasticity ($p=0.721$). *Post-hoc* analysis did not reveal statistically significant

differences between the treatment time groups.

Gender: There was only a significant difference in thickness pre-treatment between males and females ($p=0.031$) of which females ($n=180$) showed a mean thickness

score of 2.85 compared to 3.19 in men ($n=43$).

General appearance and cosmetic burden: The score of general appearance increased from 3.6 to 6.3 points at the end of treatment for hypertrophic scars

($p < 0.0005$). For keloid scars, the scores increased from 3.1 to 5.4 points at the end ($p < 0.0005$). Cosmetic burden outcomes improved significantly throughout the treatment for all patients. Patients' scores for cosmetic burden decreased from 6.1 to 4.5 points ($p < 0.0005$) for hypertrophic scars and from 6.6 to 5.6 points for keloids ($p = 0.087$).

Itching, pain, and straining:

Scores for itching decreased significantly for hypertrophic scars from 3.9 to 2.5 points ($p < 0.0005$) and from 5.6 to 3.9 points for keloids ($p = 0.008$). Scores for pain decreased from 3.5 points to 2.1 points in hypertrophic scar patients ($p < 0.0005$) and from 4.3 to 2.4 points in keloid scar patients ($p = 0.012$). Scar straining scores decreased from 3.9 to 2.3 points for hypertrophic scars ($p < 0.0005$) and from 3.2 to 2.2 points for keloid scars, although not significantly ($p = 0.123$).

Side effects: Of the 224 patients who received treatment with the topical silicone sheet, 25 (11.2%) reported side effects. The most prominent side effect was itching or irritated skin. Twenty-seven patients (12.1%) reported being inconvenienced by the diminished adhesive power of the sheet, which can be posed as a side effect of the usability.

DISCUSSION

This large prospective study on the treatment of hypertrophic and keloid scars with topical silicone sheet application shows significant improvement in color, thickness, and elasticity for both hypertrophic

scars and keloids.

Until today, little is known about the optimal duration of treatment with TSS and the way of application. Application time ranges from 12 to 24 hours a day, while treatment time ranges from one month to one year.^{2,3,6,13,15,18,20,21,30,32-37} The authors' study proved that treatment of scars older than 12 months can still be useful. Little has been published in the literature on whether TSS treatment is still useful for matured hypertrophic scars and keloids. Only a few studies specified the ages of scars and results were variable. The authors' study is in accordance with Wittenberg et al³⁰ who found no significant changes in scar outcome after TSS treatment between scars differentiated between < 12 mos and > 12 mos of age. Ahn et al³² initially did not find a relation between scar age and outcomes,³² but in a second study in which a distinction between scars < 3 mos and above was made, a nonsignificant relation between younger scars and improvement in elasticity was found.¹⁸ Another study mentioning scar ages, with an average scar age of 8.5 to 9 years, showed only improvement in pliability, but not in color and thickness, based on two months of treatment.²⁸

In this study, TSS treatment proved that significant results are achieved in the improvement of color and thickness regardless of application time of the sheet per day, but best results were reached when the silicone sheet was applied at least four hours per day. For elasticity, no significant results

were found. A guideline on how long the sheets should be applied during the day is not available. Research indicates application times ranging from 12 hours per day,^{15,18,20,30,35,37} between 12 to 24 hours per day,^{2,21,32,36} 20 hours per day,³³ 23 hours per day⁷ to 24 hours per day.^{3,6,34} The authors recommend applying the sheet for at least four hours per day.

There are also no guidelines regarding treatment period. Several studies describe variable periods from one month,^{18,32,36} two months,^{15,21,35} three months,^{3,18,37} 2 to 6 months,⁶ six months,^{2,30,34} to one year.³³ In the authors' study, a treatment period of at least three months seems to be sufficient, and a treatment period of at least six months prevents the recurrence of a well-treated scar.

This study confirms that topical silicone sheets are easy to use, noninvasive, and painless and cause few side effects.^{16,18,21-23,37} The authors' patients were overall satisfied with the acquired results. After treatment, patients had less itching, pain, and straining on the scar and there was significant improvement in the scar's general appearance and diminished cosmetic burden.

The results of this study are based on measurements of the primary changes, which were assessed by skin therapists. Color was assessed visually and measured against a standard color chart. There are some studies in which a spectrophotometer⁶ or a Laser-Doppler flowmetry have been used.³⁰ Whereas in this study scar thickness was measured with a

ruler, other studies have used ultrasound.^{6,36} To study the effects of TSS treatment on scar elasticity, the authors based their results on assessment by palpation; however, an elastometer would be more accurate.^{5,18,24,30}

For the younger scars group, the results were probably positively influenced by the spontaneous improvement over time as well.^{7,9,30,36,38} Unfortunately with this study's results, it is not possible to clarify which part of the improvement is related to maturation of the scar. It is also not clear when the best moment is to commence therapy. It has been described to start as soon as full epithelialization is reached,^{7,32,36} 48 hours postoperative,² to 2 to 3 weeks post-injury,^{1,8} with the key factor in silicone sheet treatment appearing to be to restore the water barrier by total occlusion in an early stage and thus normalizing the skin's barrier function.^{4,8,12,23,25–30}

Even so, this study showed that regardless of the age of the scar, treatment is always effective for both hypertrophic and keloid scars. It also showed that treatment of scars older than 12 months can still be effective. TSS is now used as a preventive treatment, as well as a curative treatment. Few studies have tried to prove its preventive efficacy^{2,18,21}; therefore, further extensive research on the preventive efficacy of topical silicone treatment is recommended.

CONCLUSION

This large prospective study shows significant improvement in

color, thickness, and elasticity for both hypertrophic scars and keloids after treatment with a topical silicone sheet. Beginning treatment for hypertrophic scars is recommended when the scar is younger than three months, although this study shows that treatment is effective for matured scars and keloids as well. For optimal effectiveness, the authors recommend applying the topical silicone sheet for at least three months and for at least four hours a day.

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