



Systematic Review: Duration of Applying Silicone Gel Sheet on Hypertrophic or Keloid Scars

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Abstract

Objective: The purpose of this review was to explore how many hours per day silicone gel sheets should be applied with patients with hypertrophic or keloid scars to best increase pliability and reduce thickness.

Methods: Electronic database searches were carried out using CINAHL Plus with Full Text and PubMed. Eight articles published between 1991 and 2011 met the inclusion criteria.

Results: Silicone gel sheets were effective in reducing scar thickness and increasing scar pliability. Studies that employed 24-hour application of silicone were generalizable because they were high quality studies. However, although studies used less than 24-hour application were effective, they had limitations making generalizability impossible. Additionally, washing the silicone gel sheet and the skin underneath every day was recommended to avoid skin breakdown, which in turn affected the duration of the sheet application.

Conclusion: This review suggests that silicone gel sheets should be worn 20 to 22 hours a day on hypertrophic or keloid scars, taking into account the necessity of important instructions, i.e., washing the sheet and scar daily.

Keywords: Silicone Gel; American Occupational Therapy Association (AOTA);

Introduction

Hypertrophic scars are red, raised, and sometimes itchy scars that are confined to the border of surgery, burn injury, or any other injuries, whereas, keloids are more raised, itchy and rigid scars which extend over the normal tissues and beyond the border of the original injury [11]. Li-Tsang, et al. point out that scars affect the cosmetic appearance of a person, and interfere with activities of daily living, especially when the scar is contracted causing joint stiffness and deformities [7]. Scar formation can last from 6 months to several years depending on the severity of the injuries and wound complications [7].

Many techniques and approaches for management of hypertrophic and keloid scars are widely used by clinicians, for instance, surgery, silicone gel sheets, pressure garments, and corticosteroid injections [11]. Silicone gel sheets have been proven to be effective in treating hypertrophic and keloid scars [3]. The

sheets soften, reduce, and flatten scars, but the way they work are not clear [9].

Although the mechanism of the action of silicone gel sheets is not known [4], some mechanisms have been postulated to explain the efficacy of the silicone gel such as hydration, pressure, temperature, oxygen transmission, and silicone absorption [10]. For example, hydration can decrease the fibroblast's activity and lessen collagen formation through hydrating the stratum corneum and lubricating the surface of the scar [7].

One important factor in assessing scars is the method of scar evaluation. Li-Tsang, et al. state that some studies used photos to observe changes but they provide basic information about scar size and appearance [7]. Other studies utilized standardized evaluation such as Vancouver Scar Scale (VSS) to document changes in pigmentation, vascularity, thickness, and pliability.

Nikkonen, Patkinen, and Al-Qattan point out that “the minimum number of hours for silicone sheets to produce a significant response is not known” [7]. Unfortunately there is no evidence about how many hours per day patients should apply silicone gel sheets on scars. Some doctors and therapists recommend 24-hour use of silicone gel, while others suggest 12 hours of application are sufficient. Some silicone gel manufacturers recommend only 6-hour application. Thus, there is no consensus in clinical settings about the duration of silicone gel application. It is important for therapists and patients to know whether or not there is a difference between, for example, 12 and 24 hours of silicone gel use. This review aim to answer the following question: “How many hours per day should silicone gel sheets be applied with patients with hypertrophic or keloid scars to best increase pliability and reduce thickness?”

Methods

This review included only randomized control trials, two-group nonrandomized studies such as cohort, and one group studies, that is, only levels I, II, and III of evidence were included, based on the guidelines of American Occupational Therapy Association (AOTA) for critical appraisal.

The type of participants included were male and female who have hypertrophic or keloid scars, including all ages because efficacy of silicone gel is not related to age [6]. Studies that involve comparisons between two types of silicone gel were eligible. However, studies that combine silicone gel with other modalities such as pressure garments or corticosteroid injections were excluded because it is difficult to separate the effectiveness of silicone gel sheets. Most importantly, studies were included only if the duration of silicone gel application was mentioned. All types of injuries that caused scars were included.

Search strategy was electronically conducted on CINAHL Plus with Full Text and PubMed, using the following key words: silicone gel, silicone gel sheeting, hypertrophic, keloid, thickness, and pliability. The identified articles were published between 1991 and 2010. One reviewer assessed the title and abstract of potentially eligible articles, and extracted data based on the AOTA guidelines, for example, study design, level of evidence, intervention and outcome measure (Table 1).

Author/Year	Study Objectives	Level/Design/Participants	Intervention and Outcome Measures	Results	Study Limitations
Carney, <i>et al.</i> 1994	To assess the efficacy and safety of 2 types of silicone gel: silastic gel sheeting (SGS) and cica-care (CC) in the management of hypertrophic scars.	Randomized Controlled Trial. Level I 42 participants (2-60 years old).	Comparison of 2 groups: SGS group and CC group. The groups were very similar at the baseline. Each patient applied the silicone sheet on one segment of the scar and no treatment on the other segment. Silicone sheet was worn as many hours per day as possible. There were monthly follow-ups for 6 months of treatment and then 3 months and 6 months after it was discontinued. Photograph and a standard assessment were used to rate color, texture, general condition of scars. Use instructions: 1.Wash and dry silicone sheet 2.Stop using silicone in case of irritation until problem was resolved. 3.Discontinued silicone if severe irritation, flaking weeping or blistering of the skin occurred.	After months of treatment there was significant improvement of scar areas treated with CC (93%) SGS (86%), compared with 12% of untreated scars. There was no significant difference between the groups in the number of hours per day (17.4/18.5) that the gel was worn on the scar.	

Cruz-Korchin, 1996	To examine the effectiveness of silicone sheets in prevention of hypertrophic breast scars.	Two group, non-randomized design. Level II 20 women who underwent bilateral McKissock reduction mammoplasties.	participants were instructed to apply silicone on one breast for 12 h/day for 2 months, and apply nothing on the other breast. There were follow ups at 1, 2 and 6 months.	The silicone sheets used for 12 hours daily during the first 2 months after surgery are effecting in preventing the formation of hypertrophic scars.	
			Photograph was used. For assess the scar, if it was raised it was rated as hypertrophic, and if it was at the level of the skin, it was rated as falt. Use instructions were not mentioned.		
Lee, Ngim, Chan, and Ho, 1996	To determine the efficacy of the new silicone sheet. Sil-K, in treating hypertrophic scars.	Two groups, nonrandomized (cohort design) Level II. 26 participants with 45 scars (3-52 years old). 11M, 15F.	There were 2 groups: Sil-K silicone group and Epiderm (conventional gel sheet). Scars were randomly assigned to groups. Both silicone sheets were applied on the scar 24 h/day for 6 months. Photographs were taken. Therapist rated scars based on following assessment criteria: color, texture, thickness, and regularity. Use instructions: 1.Wash and dry silicone sheet 2.Stop using silicone in case of irritation until problem was resolved.	Sil-K was as effective as Epiderm in treating hypertrophic scars.	

<p>De Oliveira, <i>et al.</i> 2001</p>	<p>To compare silicone and nonsilicone gel sheets in the treatment of keloids and hypertrophic scars and evaluate these treatments using two new assessment techniques.</p>	<p>Randomized Controlled Trial. Level I 26 patients (15-53 years old) with 41 hypertrophic or keloid scars.</p>	<p>The 41 scars were assigned randomly to 3 groups: silicone gel sheet, nonsilicone gel sheet, control group. Silicone gel sheet was applied for 24 hours per day. There were evaluated on days, 0, 30, 60, 90, 120, and 135, in respect to hardness, pain, itchinness, and color. Use instructions: Wash silicone every 2 days. Silicone type was not mentioned.</p>	<p>Scar thickness of treated groups was significantly decreased. Scar thickness of silicone and nonsilicone groups was reduced significantly comparing to the control group. Silicone and nonsilicone gel sheets are equally effective in the treatment of keloids and hypertrophic scars.</p>	
			<p>The nonsilicone gel sheet was not known.</p>		
<p>Nikkonen, Pitkanen, and Al-Qattan, 2001</p>	<p>To explore the problems associated with the use of silicone gel sheeting for hypertrophic scars in hot climate and Saudi population.</p>	<p>One group nonrandomized design. Level III 25 participants (2-36 years). 10M, 15 F.</p>	<p>Silicone gel (Cica-care) was applied on the scar. Patients were followed up for a minimum of 2 years. There were seen monthly. Scar assessment was done using Vancouver scale. Silicone gel was applied 4 h/day the first 2 days, then 8 h/day the second 2 days...till 24 hours a day. Use instructions: 1.Wash and dry silicone daily 2.Stop applying silicone if irritation occurs until problem was resolved.</p>	<p>The scar improved in all subjects. Poor compliance was not associated with poor response. Subjects with poor compliance who showed excellent response used silicone 12-14 h/day. Problems of silicone sheets: 1. Skin breakdown or skin rash were solved by stopping using silicone until skin healed. Then silicone was resumed and no further complication. 2. Excessive sweating led to skin maceration was resolved by more frequent washing of silicone gel. 3. Foul smell was resolved with better skin hygiene.</p>	

<p>Li-Tsang, <i>et al.</i> 2006</p>	<p>To determine the efficacy of silicone gel (Cica-Care) on severe post-traumatic hypertrophic scars among the Chinese population.</p>	<p>Randomized Controlled Trial. Level I 45 participants (29.5+17.60 years old), 29 M, 16 F.</p>	<p>Control group instructed to have 15 mins of deep massage twice a day. Silicone group instructed with the same protocol plus applying silicone gel sheet (Cica-care) for 24 h daily for 6 months. The tissue ultra sound palpation system was employed to measure scar thickness. Vancouver scale was used to evaluate the scar pliability. Visual Analog Scale was used to assess pain. Photograph was also used.</p>	<p>There was a significant difference between the 2 groups in scar thickness and scar pliability over 6-month intervention. Scar thickness reduced and pliability increased in silicone group.</p>	
<p>Majan, 2006</p>	<p>To compare the efficacy of a self-adherent soft silicone dressing (Mepiform) with leftalone management of hypertrophic scars using the Vancouver Scar Scale.</p>	<p>Randomized Controlled Trial. Level I 11 female participants (21-43 years old)</p>	<p>Subjects were assigned to silicone and no treatment groups. Silicone was applied for 23 hours a day. Participants were evaluated at baseline, monthly up to six months and after 12 months. Photograph was used at baseline and after 12 months. VSS was used for scar evaluation</p>	<p>All scars in both groups improved. However, the improvement was greater in the treatment group. The doctor assessment of overall silicone sheet performance was very good or good in all participants.</p>	<p>The sample size gives a low power to detect significant differences between the treatment and the control groups</p>

<p>Momeni, Hafezi, Rahbar, and Karimi, 2008</p>	<p>To study the efficacy of silicone gel applied to hypertrophic burn scars, in reducing scar interference with normal function and improving cosmesis.</p>	<p>Randomized controlled trial. Double blind. Level I 34 participants with hypertrophic and homogenous burn scar. 1.5-60 years. 16 M, 18 F</p>	<p>Silicone gel (Cica-Care) was applied on one segment of a single scar of each patient, and placebo (self-adhesive propylene glycol and hydroxyethyl cellulose sheeting) on the other segment. Both silicone and placebo sheets were applied for 4 h/day with a 4 hour daily increment to 24 h/day. Measure: A digital camera taking front and profile views during each follow up. Vancouver scale (excluding height) Use instructions: 1. Wash silicone daily 2. Stop silicone if side effects develop (e.g. rash and maceration) Measurements were taken after 1 month and 4 months)</p>	<p>No statistical difference in the baseline characteristics. In the 1 month follow up, no statistical difference in the scores between the groups except vascularity scale. In the 4 month follow up, All scores except pain were significantly lower in the silicone gel group compared with the control group. No side effects of the silicone gel were noted in any case.</p>	
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Table 1: Studies listed chronologically and according to study objectives, level of evidence, study design, participants, intervention and outcome measures, results, and study limitations.

This review is composed of: abstract, introduction, method, results, discussion, and conclusion.

Results

As mentioned earlier, there are no studies investigating the duration of silicone gel application per day. Therefore, the selected articles were carefully examined to determine if there was a consensus among them, and to ensure that each study had no confounding factors affecting the results.

Description of studies

Conducting the search, mentioned above, only eight studies [1-3,6,8,10,12] met the inclusion criteria. These studies were conducted in the following eight countries: France, United States,

Singapore, Brazil, Saudi Arabia, Hong Kong, Spain, and Iran. This indicates that the participants were from wide range of ethnicities and cultures.

The studies were five randomized control trials, level I [1,3,7,8,10], two cohorts, level II [2,6], and one group pretest posttest study, level III [12]. Four studies [2,7,8,10] of the seven that involved 2 groups or more compared silicone gel sheet with no treatment or placebo, while two articles [1,6] compared between 2 different silicone gel brands. The last study of the seven [3] had three groups: silicone gel sheet, nonsilicone sheet and control group.

Outcome measure

Standard assessment forms were used in all studies, except one [2], in order to evaluate scar color, thickness, pigmentation, and pliability. Four studies used Vancouver Scar Scale which was the most popular scar assessment tool [7,8,10,12]. One study [7] used a more objective method (the tissue ultrasound palpation system) to measure scar thickness and pigmentation.

Additionally, six studies [1,2,6,7,8,10] utilized photograph that was used as a secondary method to assess and observe scar improvement. Patients' opinions about scar evaluation were also investigated in 2 studies [1,8].

Effectiveness of silicone gel sheets

In this context, the word "effective" means that silicone gel significantly reduced scar thickness and/or increased pliability. Silicone gel sheets were effective in all studies except one [8] that found that differences between treatment group and control group were not significant.

In the two studies that involve comparison between 2 different types of silicone gel, all types were effective (Silastic Gel Sheeting, Cica-Care [1], Sil-K, and Epiderm [6]). Cica-Care silicone gel was used in three studies [7,10,12], and Pitt Enterprise silicone was employed in one study [2]. The authors of one research did not mention what kind of silicone gel they used in their study [3].

Instructions use of silicone gel sheets

The following instructions use of silicone sheets were mentioned in most studies [1,3,6,10,12]:

- Wash the sheets daily.
- Stop using the sheets in case of irritation until problem was solved.
- Discontinue the sheet if severe irritation occurred.

Duration of silicone gel application

Twenty four hours/day

There are four studies [3,6,7,10] addressing 24-hour application of silicone sheets. Participants in 2 different randomized controlled trials [3,7], in which silicone gel was effective, applied silicone for 24 hours per day. Momeni, *et al.* [10] conducted a randomized controlled trial and instructed subjects to gradually apply silicone

sheets starting with 4 hours/day with a 4-hour daily increment to 24 hours/day. The sheet significantly improved scars. Similarly, in the cohort study [6], it was found that 24-hour application of silicone gel sheets was effective in both silicone treatment groups.

Twelve – eighteen hours/day

In this category, three studies had less than 24-hour use of the silicone gel. In randomized controlled trial, Carney, *et al.* [1] compared 2 types of silicone gel and found that there was no difference between the groups in the average of the number of hours per day (17.4/18.5) that the silicone was worn on scar. There was significant improvement when silicone gel sheets were applied for 17-18 hours a day. Cruz-Korchin [2] conducted a cohort study to examine the effectiveness of silicone gel sheet in prevention of hypertrophic breast scar. He found that using the sheets for 12 hours daily for 2 months after reduction mammoplasty surgery was effective in preventing scars. Nikkonen, *et al.* [12] carried out one group pretest posttest study to explore the problems associated with the use of silicone gel in hot climate, and found that subjects who were not fully compliant showed significant improvement. Those subjects applied silicone gel sheets for 12-14 hours a day.

Discussion

There was consistency in measuring scars among the studies. The most common assessment used in most studies was Vancouver Scar Scale (VSS). Other studies used similar assessment scales, for instance, Lee, *et al.* [6] rated scars based on color, texture and thickness and regularity. Texture, for example, had three scale: 0 (harder or firmer), 1 (remained the same), and 2 (soft and supple). However, no single study mentioned reliability and validity of the scar scales including VSS. In general, VSS is acceptable since it is the most reliable scar assessment [5].

All studies except one [8] demonstrated that silicone gel sheets were effective. Majan [8] conducted a randomized controlled trial, and found that there was no significant difference between the groups because the sample size was small (11 subjects) giving low power to detect significant differences between the groups. Another explanation could be the short duration of follow up (only 2 months), which is inadequate because scar remodeling and scar synthesis can last for a year [12].

Excluding Majan's study [8], the other seven studies were divided, in terms of the duration of silicone gel application per day,

into two: 24-hour application and 12-18 hour application. Although 24-hour use of silicone gel was effective, the number 24 was not justified in these studies [3,6,7,10]. However, 24-hour application for months is not realistic for some reason. First, all of these studies instructed the participants to wash the silicone and skin daily, which is less than 24 hours per day. Second, patients need to take the silicone sheet off during, for example, showering. Third, they may want to stop wearing silicone during social events if the scar is on body areas that are usually exposed like face. Twenty to twenty two hours of silicone application per day are acceptable for patients, making them more complaint and giving them sufficient time for any purposes they need to take the sheet off.

On the other hand, the important question to clinicians and patients is “what is the minimum number of hours for silicone sheets to produce a significant improvement?” For example, are 12 hours adequate? Carney, *et al.* [1] conducted a randomized controlled trial to assess two types of silicone and reported only the average number of hours for each group (17.4 & 18.5). This average could have been based on a wide range, for instance, between 14 and 24 hours. Thus, clinicians cannot rely on this finding. Cruz-Korchin [2] found that applying silicone gel sheets after breast reduction surgery for 12 hours daily prevented hypertrophic scar. However, the issue with this cohort study was that it included only women who had scar in only one area. And applying silicone sheets for two months was not enough as stated earlier. Additionally, this kind of surgery was cosmetic which often results in no scarring. Therefore, the finding of this study cannot be generalized to other population. Nikkonen, *et al.* [12] concluded that subjects who did not completely comply with the treatment protocol, applying silicone gel for 12-14 hours/day, showed good response. The expression good response does not tell if the improvement was statistically significant. Nonetheless, the participants were only three subjects, and as stated by the authors, this observation required a large number of subjects for generalization.

Another important factor that influenced the duration of silicone gel application was the irritation caused by the sheet. Thus, it was always recommended to wash the silicone once or twice (as needed) daily, and to wash the skin under the silicone in order to avoid any skin irritation [4]. Furthermore, different brands of silicone gel sheets may have had an impact on the results of these studies. However, the mechanism of the silicone is not known [9].

Conclusion

In summary, there is no straightforward and clear answer to the research question. However, three randomized controlled trials (level I) and one cohort study (level II) had a consensus that 24-hour application of silicone gel sheets were effective. Studies that included less than 24-hour application were not generalizable as discussed above. Therefore, the following are recommended based on this systematic review:

- Apply silicone gel sheets gradually (so that the patient will get used to them) until there are worn 20-22 hours per day
- Wash the sheets at least once a day, and twice a day or more in hot climate to avoid irritation to the skin.
- Wash the skin underneath the sheets to prevent sweating, bad odor, and breakdown of skin.
- Further research is needed to examine the minimum number of hours for silicone gel to produce significant improvement.

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