

Silicone Scar Gel

Clinical Evaluation

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1. Overview

The following clinical review is compiled from the clinical study validation, professional literatures and information provided by medical doctors with experience of using Silicone Scar Gel and other sources.

ScarMD™ Silicone Scar Gel (OEM product of Silderm™ Silione Scar Gel) is intended for the management of closed hyperproliferative (hypertrophic and keloid) scars.

ScarMD™ Silicone Scar Gel is a lightweight, self-drying Silicone Scar Gel for the treatment of scar. Silicone Scar Gel rapidly dries to form a sheet; this Silicone Scar Gel Sheet layer is gas permeable, flexible and waterproof. Silicone Scar Gel forms a bond with the stratum corneum (the outer layer of dead skin cells) forming a protective barrier on scar site while assisting with hydration. This creates an environment which allows the scar to mature through normalized collagen synthesis cycles, and improves the physiological and cosmetic appearance of the scar.

2. Contraindications

Avoid direct contact with eyes, mucous membranes, third degree burns and open wounds.

3. Indications

Silicone Scar Gel is intended for the management of closed hyperproliferative (hypertrophic and keloid) scars..

4. Technical Background

Topical silicone gel sheeting and intralesional steroids are the only evidence-based recommendable forms of treatment to control the quality of a scar. The advantages and disadvantages of both are well known. Topical silicone gel sheeting is cumbersome to keep on the scar, and patient compliance often is low for lesions in visible areas. Tapes or bandaging frequently is not accepted. It also may lead to skin irritation, which can require discontinuation of treatment, especially in hot climates, so sheets must be washed carefully and often to prevent complications. Steroid injections are painful and may lead to skin atrophy and dyschromies. They usually are contraindicated for large areas and for children^{1,2}.

Research in product development has focused on developing silicone-based products that have the same efficacy as silicone gel sheeting, but are useful on more areas of the body and better accepted by patients. To that end, brands of silicone gel sheeting with increased durability and adhesiveness have been introduced to improve the ease of use and patient acceptability of silicone gel sheeting treatment. Other formulations of silicone that may be easier to apply and maintain than sheeting also have been developed².

A kind of topical self-drying silicone gel is a relatively recent marketed product which was developed to

overcome the practical difficulties of topical silicone gel sheeting. The new formulation of silicone gel applied from a tube forms a thin flexible sheet over the newly epithelialized wound or more mature scar. It is spread thinly on the scar and allowed to dry before contact with clothes or application of makeup. Results from clinical trials and clinical experience suggest that silicone gel is equivalent in efficacy to traditional silicone gel sheeting but easier to use².

5. Mechanism of Action

Studies have shown that silicone gel sheeting decreases evaporation of water from the skin and increases hydration of the stratum corneum. The silicone sheet that forms on the skin after application of silicone gel has similar effects on water loss and hydration of the stratum corneum. A growing body of evidence suggests that the beneficial effects of all silicone-based products on scars are mediated by occlusion and hydration². This creates an environment which allows the scar to mature through normalized collagen synthesis cycles, and improves the physiological and cosmetic appearance of closed hyperproliferative (hypertrophic and keloid) scar.

6. Clinical information

Silicone Scar Gel is intended for the management of closed hyperproliferative (hypertrophic and keloid) scars..

Silicon, in various formulations, has been used in the prevention of keloid or hypertrophic scars since 1980s, when scientific articles demonstrated the benefit of these products on scars resulting from surgical incisions, burns and trauma, and other causes. The results from most studies indicate a significant improvement in the final quality of scars, from various etiologies, after the use of silicone gel based products³.

The results of recent comparative clinical studies^{5,1,4,6,7} indicate that silicone gel applied from a tube is as effective as silicone gel sheeting in the management of abnormal scarring.

A randomized, double-masked, placebo-controlled clinical trial evaluated the efficacy of silicone gel in preventing hypertrophic scarring after median sternotomy in Asian patients. Half of the wound was treated twice daily with silicone gel, and the remaining half with a placebo gel. Although a hypertrophic scar or keloid developed for most patients (94%), the half of the wound treated with silicone gel typically showed less scarring than the control half of the wound. At 3 months after surgery, the scars that developed during silicone gel treatment were significantly flatter, less red, and more pliable and associated with less pain and itching than the control scars. No side effects were associated with the silicone gel treatment, and the patients self-reported a high degree of compliance, with 98% of them reporting that they usually or always applied the gel as prescribed⁵.

A subsequent study also demonstrated that treatment with silicone gel is effective in preventing abnormal scarring after surgery¹. A hypertrophic scar or keloid developed in only 7% of the patients treated with silicone

gel, compared with 26% of the patients who received no treatment. There were no side effects of silicone gel treatment, and all the patients reported that the gel was easy to apply¹.

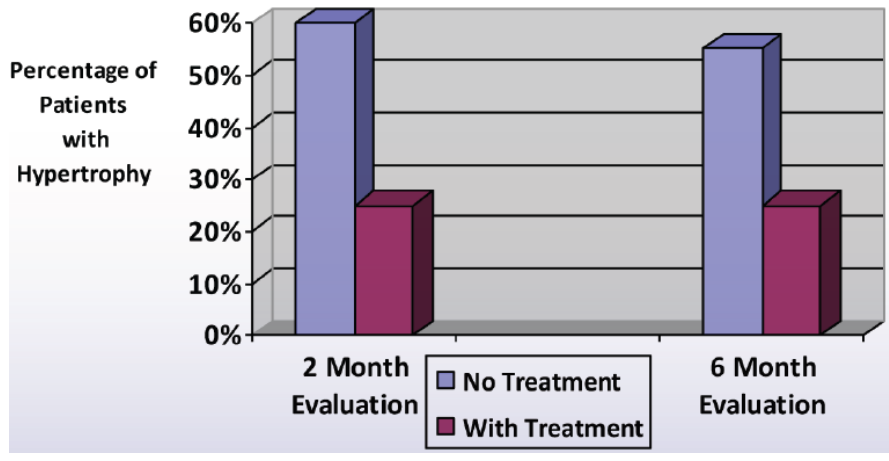
In the study performed by Neerja Puri and Ashutosh Talwar, Thirty patients with scars of different types including superficial scars, hypertrophic scars, and keloids were treated with silicone gel application⁴. After treatment, improvement was noted in the scars. Sixty percent scars were graded as normal (Grade I), while 20% were graded as mildly hypertrophic (Grade II). Twenty percent of scars were of Grade III and IV at the end of study; 10% in each grade. Side effects were few. Allergic reaction to silicone gel was seen in one case and mild desquamation was seen in 2 cases. Thus it is concluded that Topical silicone gel is safe and effective treatment for hypertrophic and keloidal scars. It is easy to apply and cosmetically acceptable.

A recent prospective study compared silicone gel with silicone gel sheeting and no treatment in the management of abnormal scarring⁶. The study enrolled 30 patients with bilateral immature scars, hypertrophic scars, or keloids. One scar of each patient was treated with silicone gel, silicone gel sheeting, or a combination of these treatments (silicone gel during the day, silicone gel sheeting at night), and the other scar served as an untreated control. All three silicone-based treatment regimens provided statistically significant improvement for symptoms of itching, irritation, and skin maceration compared with no treatment, and the scars in each treatment group were more pliable and less elevated and erythematous than the untreated control scars. Silicone gel was at least as effective as silicone gel sheeting. Patient scores for the difficulty of treatment were higher with silicone gel sheeting, and patient scores for their willingness to comply with treatment were higher with silicone gel.

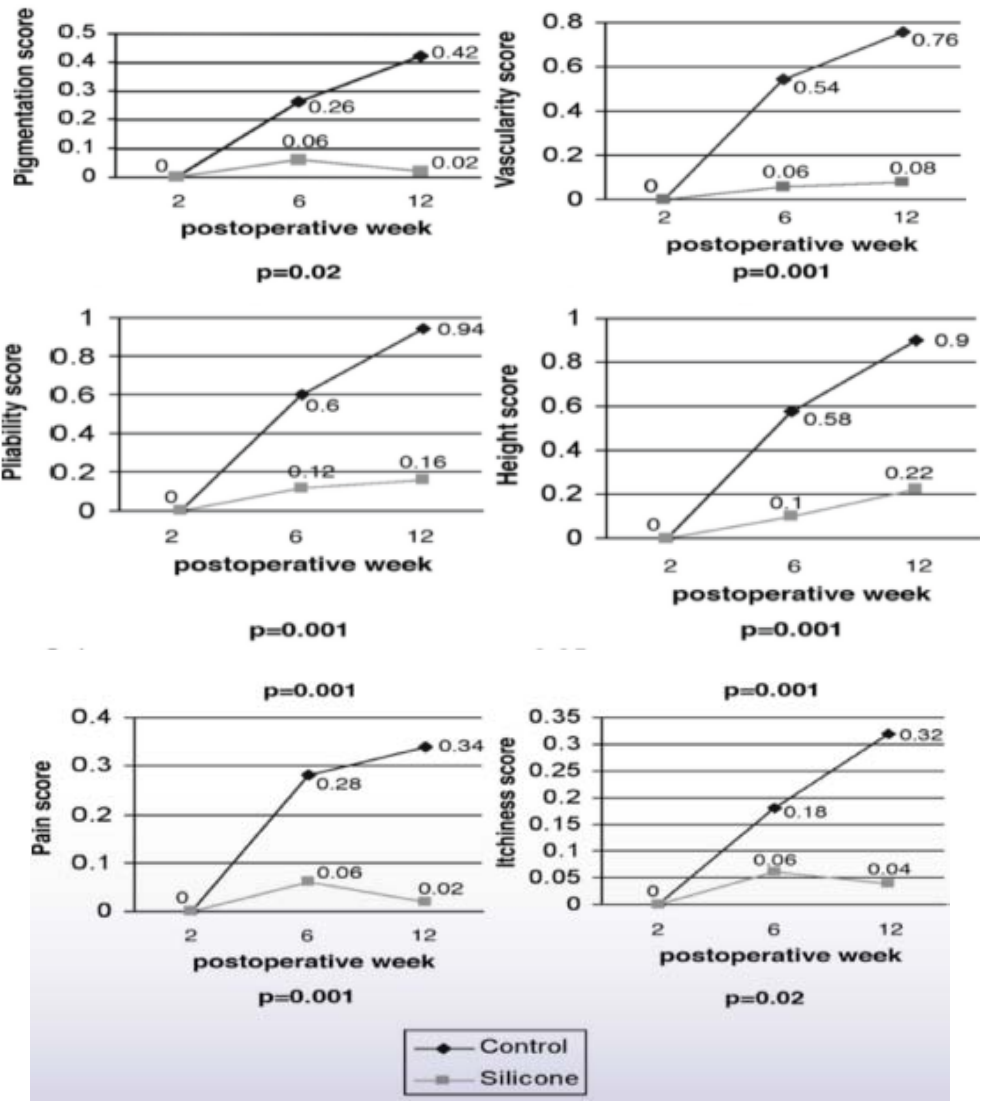
A second prospective study compared silicone gel with silicone gel sheeting for the management of scarring after surgical removal of a benign skin lesion⁷. Scars treated with either silicone gel or silicone gel sheeting showed significant improvement in redness and hardness during the study, and scar elevation, pain, and itching decreased in both treatment groups. After 6 months of treatment, there was no statistically significant difference between the treatment groups in any efficacy parameter. Patient ratings of comfort favored silicone gel over sheeting, with 88% of the silicone gel patients rating the comfort of their treatment as “good” or “very good” compared with 53% of the silicone gel sheeting patients.

There is data on several thousand patients, proving the effectiveness of the silicone in SilDerm™ Scar Gel. Several meta-analysis of the data have been carried out and these consistently show that patients scars improve over a 2-3 month period by up to 80%, as measured by patient satisfaction. The clinical trials generally use visual end points for the measurement of effectiveness of the treatment. New data has focused on the use of more objective, quantitative measurements of the reduction in redness, volume, pain and itchiness of scars.

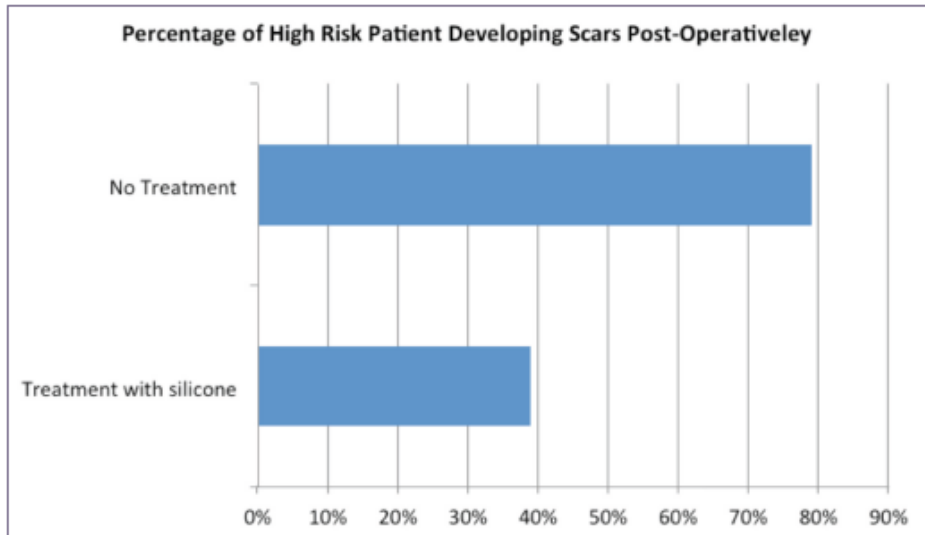
‘Over a period of 6 months, the reduction in scarring with post-operative scars is significantly more with silicone in a study involving 20 patients’



'Silicone has been proven to significantly reduce the incidence of scarring compared to placebo'



All the criteria that were measured in this study, showed a difference with placebo. These are the main symptoms that patients complain of and therefore proving that patients will see a difference if silicone is used in the treatment of their scars. In addition, silicone has been prove to prevent scars compared to placebo, when compared to no treatment' in a 100 wounds on 50 patients. This study was a randomised, placebo controlled, double-blind prospective clinical trial. One hundred wounds in 50 patients were randomized into 50 control and 50 silicone gel.



7. Summary

As a new formulation of silicone, Silicone Scar Gel dries to form a sheet layer on the skin. This provides a protective barrier on scar site while assisting with hydration. This creates an environment which allows the scar to mature through normalized collagen synthesis cycles, and improves the physiological and cosmetic appearance of closed hyperproliferative (hypertrophic and keloid) scar.

Based on the information from clinical literatures and clinical practices, it showed that Silicone Scar Gel is an useful tool for the management of closed hyperproliferative (hypertrophic and keloid) scars.

8. References

1. Massimo Signorini, M.D., and Matteo Tretti Clementoni, M.D.
Clinical Evaluation of a New Self-Drying Silicone Gel in the Treatment of Scars: A Preliminary Report
Aesth. Plast. Surg. 2007 (31):183-187
2. Thomas A. Mustoe
Evolution of Silicone Therapy and Mechanism of Action in Scar Management
Aesth Plast Surg (2008) 32:82–92
3. Henrique N. Radwanski, Wanda Elizabeth, Messiere Y Correa, Adilson Farrapeira, Tiago José Refosco, and Ivo Pitanguy
Silicone Gel in Plastic Surgery Scars: Prospective Clinical Study
Rev. Bras. Cir. Plást, 2010; 25(3): 428-33
4. Neerja Puri and Ashutosh Talwar

The Efficacy of Silicone Gel for the Treatment of Hypertrophic Scars and Keloids

J Cutan Aesthet Surg. 2009 Jul-Dec; 2(2): 104–106

5. Kin Yoong Chan, M.R.C.S.Ed., Chee Lan Lau, B.Sc.Pharm., Syed Mohd Adeeb, M.S., Sathappan Somasundaram, F.R.C.S., and Mohd Nasir-Zahari, F.R.C.S.

A Randomized, Placebo-Controlled, Double-Blind, Prospective Clinical Trial of Silicone Gel in Prevention of Hypertrophic Scar Development in Median Sternotomy Wound

Plast Reconstr Surg. 2005 Sep 15;116(4):1013-20; discussion 1021-2

6. Chernoff WG, Cramer H, Su-Huang S.

The efficacy of topical silicone gel elastomers in the treatment of hypertrophic scars, keloid scars, and post-laser exfoliation erythema.

Aesthetic Plast Surg. 2007 Sep-Oct;31(5):495-500.

7. Fonseca Capdevila E, Lo´pez Bran E, Fern´andez Vozmediano JM, de la Torre Fraga JC, Querol Nasarre I, Moreno Jim´enez JC

Prevention of postexcisional scar sequelae of benign cutaneous lesions.

Piel, in press