

SilDermTM

Beauty through Science

Clinical Summary

Introduction:

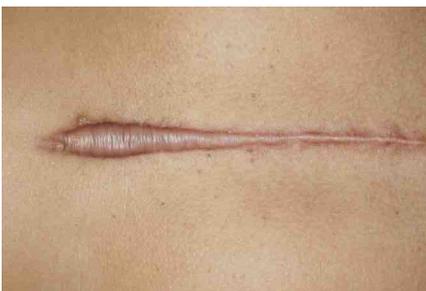
Since the introduction of silicone in the early 1980s, its therapeutic effects on predominantly the treatment and prevention of hypertrophic scars have been well documented in the literature.^{i, ii}

Silicone Gel is the main stay of treatment for Plastic Surgeons and Dermatologists and it is the unique properties of silicone that make it effective and safe for treating and preventing scars. The summaries below all show that SilDermTM Scar Gel can be used effectively to treat and prevent scars.

What are Scars?

Scars are produced as a result of a trauma to the skin. All wounds produce scars and they are part of the normal healing process, but pathogenic or abnormal scars result when the bodies self-regulation of the healing process goes awry and the body continues to produce too much collagen, even after the wound has healed. Abnormal scars are red and raised, sometimes painful and itchy and can cause both physiological and psychological distress to the patient.

There are three main types of scars:



Keloids

Keloids are common amongst certain skin types and can be the result of a trauma or sometimes just appear. More than 80% of Keloid patients complain of itching, and 50% complain of pain associated with the Keloid.



Hypertrophic Scars

These follow the area of the wound and are usually linear. Burn scars are a type of hypertrophic scar and tend to cover a wider area.



Acne Scars

Acne scars are called Atrophic scars and are small pitted indentations in the skin. The scars are sometimes red but this can fade over time



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SilDermTM Scar Gel - Mode of Action:

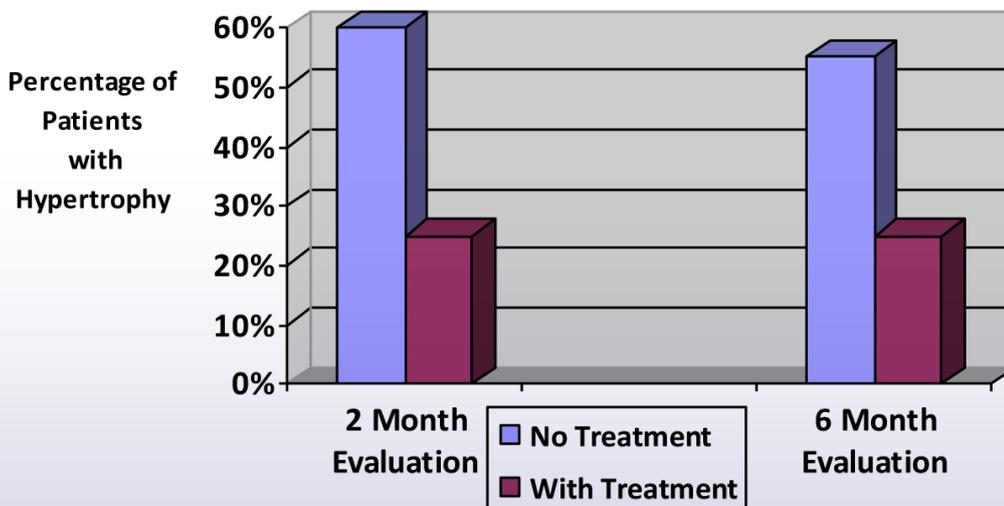
Silicone in various formats has been used since the 1980's to treat red and raised scars. The efficacy of silicone has been established in many peer reviewed studies^{iii,iv}. Recent work has focused on the mode of action of silicone on the treatment of scars. The most recent theory is that occlusion is the main factor that contributes to the effectiveness of silicone on the treatment of scars. The occlusion of silicone has been proven to reduce the overproduction of collagen by regulating the transforming growth factor β (TGF β).^v

Data has proven that although this is the main mode of action, other semi-occlusive dressings are not as effective as silicone at treating scars^{vi}. This implies that there is something specific about silicone that above all else has an effect on flattening scars, reducing the redness and minimising the pain and itchiness.

SilDermTM Scar Gel - Effectiveness:

There is data on several thousand patients, proving the effectiveness of the silicone in SilDermTM 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 focussed on the use of more objective, quantitative measurements of the reduction in redness, volume, pain and itchiness of scars.

^vOver a period of 6 months, the reduction in scarring with post-operative scars is significantly more with silicone in a study involving 20 patients.

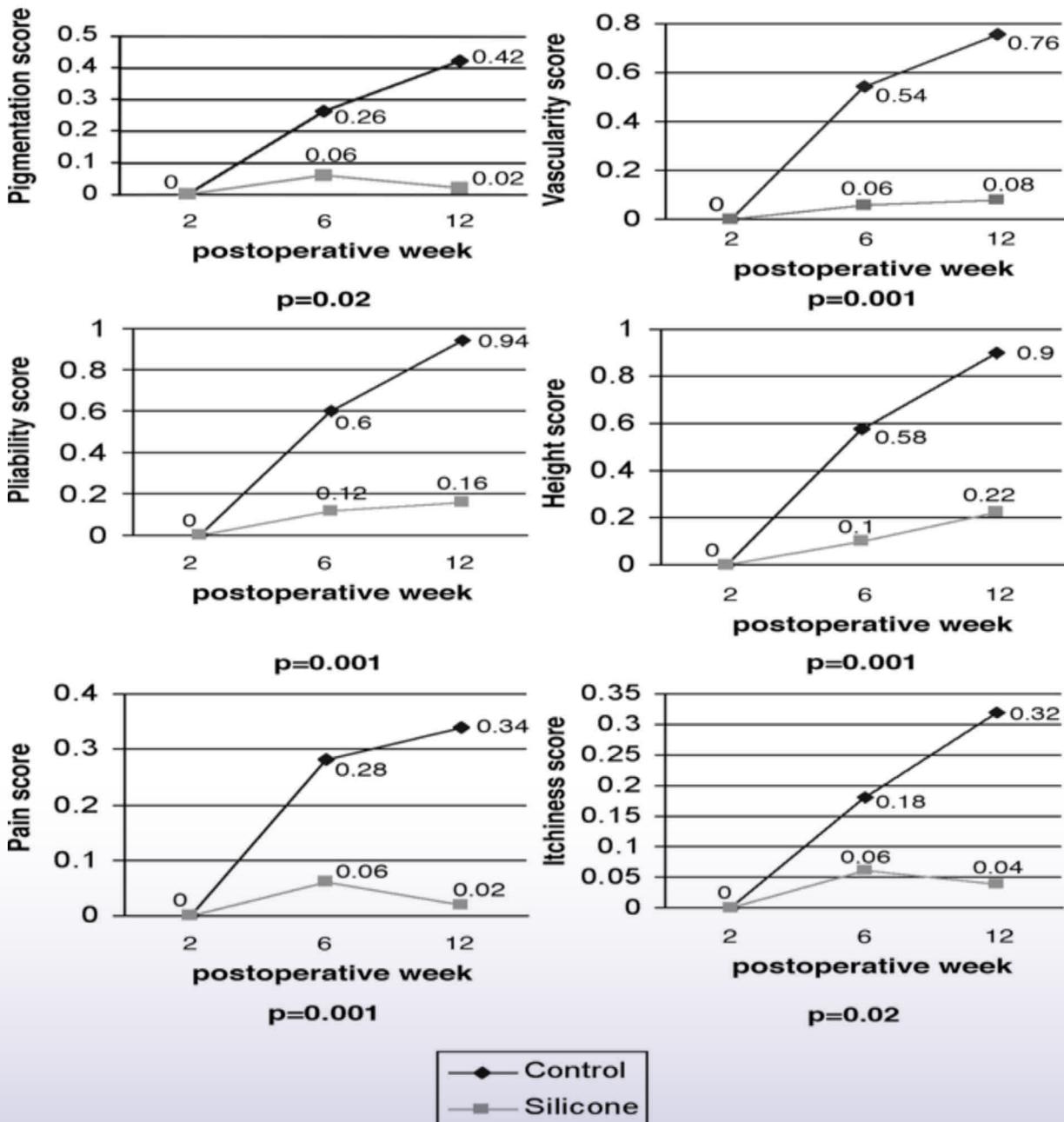


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‘Silicone has been proven to significantly reduce the incidence of scarring compared to placebo’^{viii}



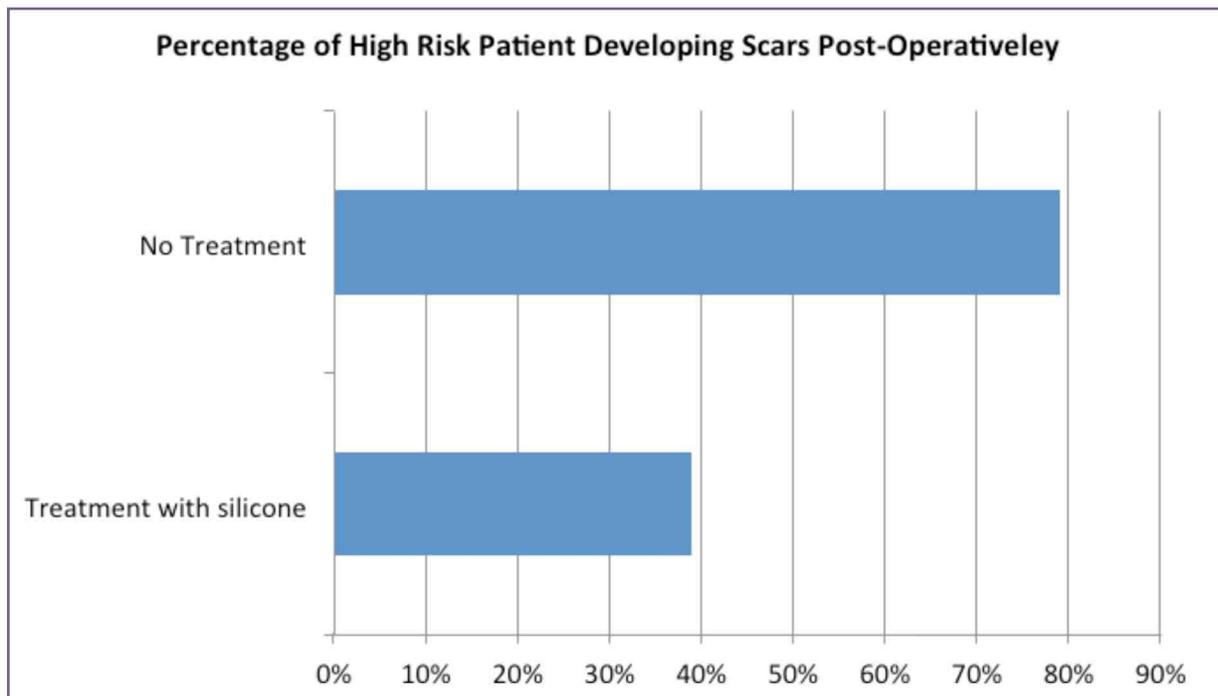
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All the criteria that were measured in this study, showed a difference with placebo. These are the main symptoms that patients complain of and therefore proving that patients will see a difference if silicone is used in the treatment of their scars.

'In addition, silicone has been prove to prevent scars compared to placebo'^{ix}, 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.



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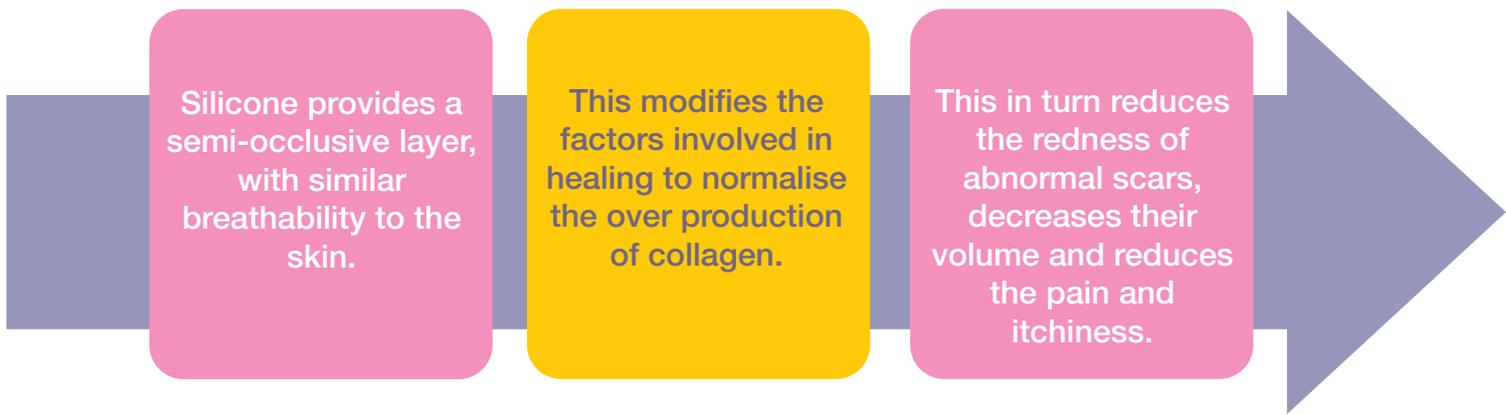
SilDerm™ Scar Gel is a unique formulation of silicone that dries to form an ultra-thin layer on the skin. This provides a semi-occlusive layer, with similar breathability to the skin. This modifies the factors involved in healing to normalise the production of collagen. This in turn reduces the redness of abnormal scars, decreases their volume and reduces the pain and itchiness.



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Clinical studies have proven the effectiveness of silicone at treating all types of scars, whether they are new scars, old scars, large scars or small scars.

'The recommendations from the clinical reviews are clear - silicone should be used first line in all types of scars' ⁱⁱⁱ



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Scar Type	Prevention of hypertrophic and keloid scars	Immature hypertrophic scars	Linear hypertrophic scars
Recommended Clinical Treatment	Silicone should be considered as first line prophylaxis	If erythema persists >1 month then treat with silicone	Silicone should be the first line therapy
			
Scar Type	Widespread burn hypertrophic scars	Minor keloids	Major keloids
Recommended Clinical Treatment	Silicone combined with pressure garments*	Silicone combined with intralesional corticosteroids	Referral to clinicians with a special interest in keloids

*Limited significant evidence remains for the efficacy of pressure garments.

SilDerm™ Scar Gel offers a unique and cost effective way to treat a major problem and improve a patient's quality of life.

- i Sawada Y, Sone K. Hydration and occlusion treatment for hypertrophic scars and keloids. Br J Plast Surg. 1992;45:599-603.
- ii Fulton JE., Jr Silicone gel sheeting for the prevention and management of evolving hypertrophic and keloid scars. Dermatol Surg. 1995;21:947-51.
- iii Mustoe TA, et al. International clinical recommendations on scar management. Plast Reconstr Surg. 2002;110:560-71.
- iv Durani P, Bayat A. Levels of evidence for the treatment of keloid disease. J Plast Reconstr Aesthet Surg. 2008;61:4-17.
- v Wound Repair Regen. 2010 Mar-Apr;18(2):235-44.Occlusion regulates epidermal cytokine production and inhibits scar formation.
- vi Dermatol Surg. 1996 Sep;22(9):775-8.A randomized controlled trial of hydrocolloid dressing in the treatment of hypertrophic scars and keloids
- vii Cruz-Korchin; Effectiveness of silicone sheets in the prevention of Hypertrophic breast scars; Anh Plas Surg; 1996;(3);345-348
- viii Chan_KY_et_al_Plastic and Reconstructive Surgery September 15, 2005;Volume 116;Issue 4;pp: 1013-1020;A Randomized, Placebo-Controlled, Double-Blind, Prospective Clinical Trial of Silicone Gel in Prevention of Hypertrophic Scar Development in Median Sternotomy Wound
- ix Dermatol Surg. 2001 Jul;27(7):641-4.;Prevention of hypertrophic scars and keloids by the prophylactic use of topical silicone gel sheets following a surgical procedure in an office setting.

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