Clinical Studies
Supporting the efficacy and safety of silicone sheeting

The efficacy and safety of silicone sheeting for the treatment and prevention of scars is supported by an abundance of clinical studies. In fact, there have been more controlled clinical trials performed on the treatment of scars using silicone sheeting than most other methods.

A Collection of Clinical Studies, Professional Articles and Reviews on the Efficacy of Silicone Sheet for the Treatment and Prevention of Hypertrophic Scars and Keloids

Topical Silicone Gel Sheet in the Treatment of Hypertrophic Scars and Keloids: A Dermatological Experience
“The silicone gel sheets resulted in moderate improvement in scar thickness, scar color and was noted to be effective to some degree in all tested. The material was easy to use and painless.”

Topical Silicone Gel: A New Treatment for Hypertrophic Scars
Ahn ST, Monafo W, Mustoe TA
Surgery 1989 Oct, 106 4:781-786
“the treated scars were improved significantly at 4, 8, and 12 weeks, compared with both their own treatment value and the control scars”
“We conclude that this simple method of treating hypertrophic scar is efficacious, even in relatively chronic cases.”

Silicone Gel Sheets Relieve Pain and Pruritus with Clinical Improvement of Keloid: Possible Target of Mast Cells.
Excerpts:
“Silicone gel sheet treatment is widely used to treat hypertrophic scars and keloids since it is easily applied and prevents scar pain and itching.”
“The pain and itching clearly decreased after 4 weeks of the silicone gel sheeting and disappeared after 12 weeks. Twelve weeks were required for a reduction in scar redness and elevation.”
“Silicone gel sheeting is effective and safe, especially with more severe symptoms of pain and itching possibly induced by mediators derived from increased mast cells.”

Silicone thermoplastic sheeting for treatment of facial scars: an improved technique.
Bradford BA, Breault LG, Schneid T, and Englemeier RL.
“Silicone thermoplastic sheeting has been used successfully in the management of hypertrophic and
keloid scars resulting from thermal burn injuries


The article provides evidence-based recommendations on prevention and treatment of abnormal scarring and, where studies are insufficient, consensus on best practice. The recommendations focus on the management of hypertrophic scars and keloids, and are internationally applicable in a range of clinical situations. These recommendations support a move to a more evidence-based approach in scar management. This approach highlights a primary role for silicone gel sheeting and intralesional corticosteroids in the management of a wide variety of abnormal scars. The authors concluded that these are the only treatments for which sufficient evidence exists to make evidence-based recommendations.

“Preventative recommendations included meticulous surgical technique, hypoallergenic taping, and silicone gel sheeting. Non-surgical scar treatments include triamcinolone injections, cryotherapy, silicone gel sheeting, pressure sheeting, and radiation therapy.”

This approach highlights a primary role for silicone gel sheeting and intralesional corticosteroids in the management of a wide variety of abnormal scars. The authors concluded that these are the only treatments for which sufficient evidence exists to make evidence-based recommendations.

**The effect of silicone gel sheets on perfusion of hypertrophic burn scars.**

**Effectiveness of Silastic Sheet Coverage in the Treatment of a Keloid Scar:**

**Silicone Gel Scar Treatment**

**Topical Silicone Gel Sheeting in the Treatment of Hypertrophic Scars and Keloids:**

**Exerpts**
“The silicone gel sheets resulted in moderate improvement in scar thickness, scar color and was noted to be effective to some degree in all tested. The material was easy to use and painless.”

**CONCLUSION.** Topical silicone gel sheeting is an effective method for the treatment of hypertrophic and keloid scars and may be considered useful in the treatment of these difficult cutaneous lesions.


**Silicone gel sheeting for the prevention and management of evolving hypertrophic and keloid scars.**
Fulton JE Jr. Institute for Skin Research, Newport Beach, California 92660, USA.
BACKGROUND. Hypertrophic scars and keloids remain a problem for surgeons. Topical and intralesional corticosteroids, positive pressure dressings, cryotherapy, and laser therapy are helpful but not uniformly successful. OBJECTIVE. To document the effectiveness of silicone gel sheeting in the prevention and/or reduction of evolving hypertrophic scars and keloids. METHODS. Silicone gel sheeting was placed over evolving scars in 20 cases. The dressing was worn for at least 12 hours a day. Biopsies were examined for the presence of silica in the tissue. RESULTS. Lesions improved during the treatment period in 85% of the cases. The mechanisms of action are unknown. Positive pressure was not necessary. No silica from the dressing was found at the wound site. CONCLUSION. Daily treatments with silicone gel sheeting should begin as soon as an itchy red streak develops in a maturing wound. The dressing is effective in reducing the bulk of these lesions.

Treatment of Hypertrophic and Keloid Scars with Silastic Gel Sheetings
Dockery GL, Nilson RZ
Journal of Foot and Ankle Surgery 1994 Mar-Apr; 33 2:110
EXERPT:
“Overall, the success rate (somewhat improved to greatly improved) for the treatment of hypertrophic and keloid scars is high (95%).”

Skin Disorders in Black Children
Laude TA ;Current Opinion Pediatrics, 1996 Aug 8 4: 381-385
“Keloids and hypertrophic scars in children are effectively treated with silicone gel sheeting.”

A Randomized, Placebo-Controlled, Double-Blind, Prospective Clinical Trial of Silicone Gel in prevention of Hypertrophic Scar Development in Median Sternotomy Wound
Background: Hypertrophic scarring caused by sternotomy is prevalent among Asians. The effectiveness of silicone gel in scar prevention may influence the decision of surgeons and patients regarding its routine use during the postoperative period.
Methods: The authors conducted a randomized, placebo-controlled, double-blind, prospective clinical trial. The susceptibility to scar development varied among patient; therefore, sternal wound would be divided into the upper half and lower half. Two types of coded gel prepared by an independent pharmacist were used on either half. Thus, selection and assessment biases and confounders were eliminated. Results: One hundred wounds in 50 patients were randomized into two arms, patients control and 50 silicone gels. The median age was 61 years and there were 35 men and 16 women. Ethnic distribution was 28 Malays, 18 Chinese and four Indians. No side effect caused by the silicone gel was noted. Ninety-eight percent of patients had moderate to good compliance. The incidence of sternotomy scar was 94 percent. At the third month postoperatively, the silicone gel wounds were scored lower when compared with the control wounds. The differences were statistically significant in all parameters, including pigmentation (p= 0.20), vascularity (p= 0.001), pliability (p= 0.001), height (p= 0.001), pain (p= 0.001), and itchiness (p= 0.02). Conclusions: The effect of silicone gel in prevention of hypertrophic scar development in sternotomy wounds is promising. There are no side effects and patients’ compliance is satisfactory. This study may popularize the use of silicone gel in all types of surgery to minimize the formation of hypertrophic scars in the early postoperative period. (Plast. Reconstr. Surg. 116: 1013, 2005.)
Topical silicone gel for the prevention and treatment of hypertrophic scar.
Ahn ST, Monafo WW, Mustoe TA.
Department of Surgery, Washington University School of Medicine, St Louis, Mo 63110.
Abstract
We studied the effects of a silicone gel bandage that was worn for at least 12 hours daily on the res-
olution of hypertrophic burn scar. In a second cohort, the prevention of hypertrophic scar formation in
fresh surgical incisions by this bandage was also evaluated. In 19 patients with hypertrophic burn scars,
elasticity of the scars was quantitated serially with the use of an elastometer. An adjacent or mirror-im-
age hypertrophic burn scar served as a control. Scar elasticity was increased after both 1 and 2 months
compared with that in controls. There was corresponding improvement clinically that persisted for at
least 6 months. In the other cohort, scar volume changes in 21 surgical incisions were measured be-
fore and after 1 and 2 months. Gel-treated incisions gained less volume than control incisions after both
intervals. Clinical assessment corroborated this quantitative demonstration of a decrement in scar
volume. We concluded that topical silicone gel is efficacious, both in the prevention and in the treat-
ment of hypertrophic scar.

Hypertrophic scars and keloids: etiology and management.
Keloid and hypertrophic scars have affected patients and frustrated physicians for centuries. Keloid and
hypertrophic scars result from excessive collagen deposition, the cause of which remains elusive. Cli-
nically, these scars can be disfiguring functionally, aesthetically, or both. A thorough understanding of
the pathophysiology and clinical nature of the scar can help define the most appropriate treatment strategy.
Although many articles have been published on the management of hypertrophic and keloid scars, there
is no universally accepted treatment protocol. Prevention of keloid and hypertrophic scars remains the
best strategy; therefore, those patients with a predisposition to develop excessive scar formation should
avoid nonessential surgery. Once a scar is present, there are many treatments from which to choose.
Hypertrophic scars and keloids have been shown to respond to radiation, pressure therapy, cryother-
apy, intraliesional injections of corticosteroid, interferon and fluorouracil, topical silicone or other dress-
ings, and pulsed-dye laser treatment. Simple surgical excision is usually followed by recurrence unless
adjunct therapies are employed. Biologic agents that are directed towards the aberrant collagen prolif-
eration that characterizes keloid and hypertrophic scars might be an important addition to the current
armamentarium of modalities in the near future.

Silicone Gel in the Treatment of Keloids
Murdoch GE, Salisbury JA, Gibson JR
ACTA Derm. Venereal 1990, 70/2 (181-183)

The Use of Silicone Gel in the Control of Hypertrophic Scarring
McNee J / Physiotherapy 1990, 76/4 (194-197)

Hypertrophic Sternal Scars: Silicone Gel Sheet versus Kenalog Injection Treatment
Sproat, JE, Dalcin A, Weitauer N, Roberts RS
Plastic and Reconstructive Surgery, 1991 90: 988-992
“This study demonstrates that silicone gel sheets provide earlier symptomatic relief and a more aesthetic
scar and are the preferred treatment of patients with symptomatic hypertrophic sternal scars.”

Silicone Occlusive Sheeting (SOS) in the Management of Hypertrophic Scarring, Including the Possible Mode of Action of Silicone
European Journal of Plastic Surgery, 16: 5-9

Silicone Gel: a New Treatment for Burn Scars and Contractures
Perkins K, Davey RB, Wallis KA
Burns 1982; p 201-204

Treating Hypertrophic Scars with Silicone Gel. A Preliminary Report of a Trial of Silastic Gel in the Treatment of Patients with Hypertrophic Burn Scars
Carney SA, Cason CG, Gowas JP
Journal of Wound Care 1993; 2:197-198

Evidence That Use of a Silicone Sheet Increases Range of Motion Over Burn Wound Contractures
Wessling N, Ehleben CM, Chapman V, May SR, Still JM
Journal of Burn Care and Rehabilitation 1985/6, p503-5

Oncologic Applications for Silicone Gel Sheets in Soft Tissue Contractures
Burkhardt A, Weitz J


Effects of silicone gel on burn scars.
Momeni M, Hafezi F, Rahbar H, Karimi H.

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