# Effectiveness of Silicone Sheets in the Prevention of Hypertrophic Breast Scars

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**A clinical study was designed in which 20 women who were to undergo bilateral McKissock reduction mammaplasties were requested to use a precut silicone elastomer sheet over the scars of one breast, starting at the time of suture removal. The patients were instructed to use the silicone sheet for 12 hours each day for 2 months. Evaluation of the scars at 2 months revealed that 60% of the nontreated scars were hypertrophic and only 25% of the treated scars were hypertrophic. The difference was found to be statistically significant ($p < 0.05$). The use of the sheets was discontinued after 2 months and the beneficial effect remained at the 6-month evaluation.**

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Since first reported in the literature in 1982 [1], silicone gel and elastomer sheets have been used extensively in the treatment of hypertrophic scars [2–5]. It is only recently that their use to prevent such scars has been explored. A well-designed study [5], in which topical silicone gel was used to treat hypertrophic burn scars and fresh incisions, yielded encouraging results. In this study, each patient served as their own control and the scars were examined in blinded fashion with volumetric determination of the scars. However, several other studies, which were not properly controlled, have produced data that, at best, are only of anecdotal value. In some studies, multiple manipulations on the hypertrophic scars, which included pressure garments, surgical excisions, W-plasties, and the application of silicone sheets, were performed. It is, therefore, difficult to isolate the effect of any one of the methods used [6–7]. In other studies in which hypertrophic scars were treated with silicone sheets, before-and-after results were demonstrated, but no equivalent control scar in the same patient and in a similar part of the body was provided [8–9]. In these studies, it is not possible to determine what would have occurred as a result of scar maturation over time without any treatment.

A good model to evaluate the effectiveness of silicone sheets in the prevention of hypertrophic scars would be an elective surgical procedure in which hypertrophic scars are often formed, performed bilaterally. Treating the scar on one side and using the opposite side as the untreated control could provide the much-needed data regarding the effect of silicone sheets.

Reduction mammaplasties, which often demonstrate hypertrophic scars and are bilateral procedures, fit this model. In each of a group of reduction mammaplasty patients, the scars of the treated versus the untreated side were compared.

## Materials and Methods

A clinical study was designed in which 20 women who were to undergo bilateral McKissock reduction mammaplasties participated, after providing their informed consent. At the time of suture removal on postoperative day 14, each patient received a precut silicone elastomer sheet (Pitt Enterprises, Queensbury, NY) to be placed over the scars of one breast (Fig 1). The sheet was secured in place with a few Steri-Strips (3-M Company, St. Paul, MN) and the brassiere (Fig 2). The patients were instructed to use the silicone sheet for 12 hours each day for 2 months. Half the patients (N = 10) used the silicone sheet on the breast that corresponded to her dominant hand and the other half (N = 10) used the sheets on their nondominant side. The patients received follow-up appointments at 1, 2, and 6 months. The scars were evaluated by their appearance after 2 months of treatment. They were evaluated again at 6 months, even though the sheets had not been used after the second month. Photographs of the scars were taken at the beginning of treatment

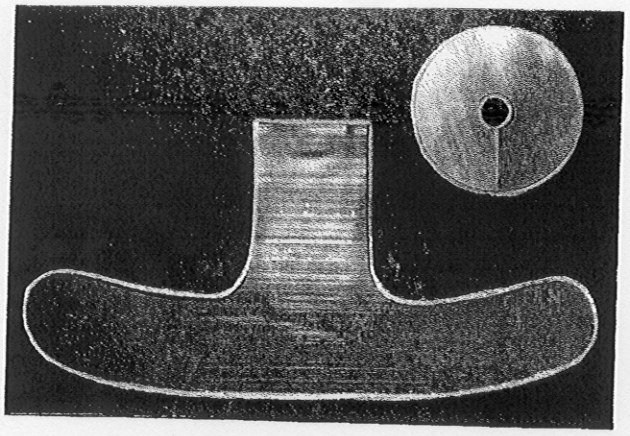


*Fig 1. Sheets of silicone elastomer, packaged precut for reduction mammaplasties, used for this study.*

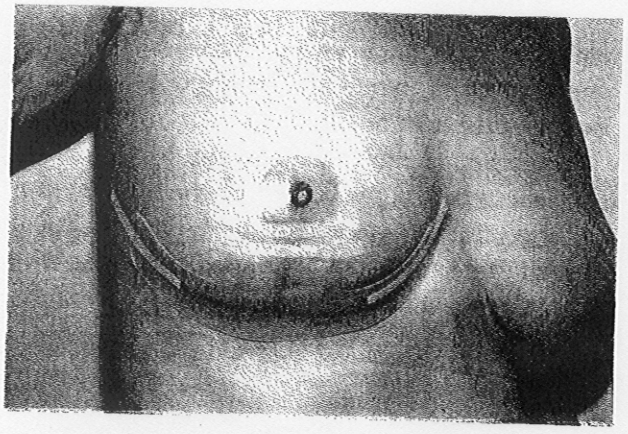


*Fig 2. Each patient was instructed to use a silicone sheet over the scars of one of her breasts for 12 hours daily. The sheet was secured in place with a few Steri-Strips and the patient's brassiere.*

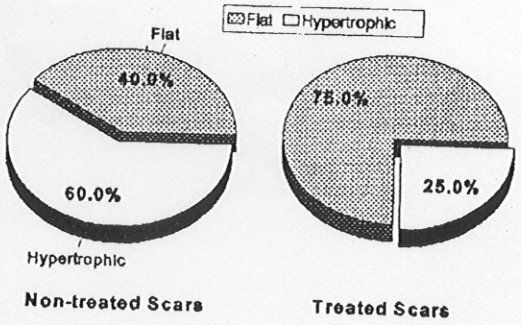
and subsequently, at 2 and 6 months. The scars were rated as hypertrophic if they were raised over the level of the surrounding normal skin. They were rated as flat if they remained at the level of the surrounding skin, as judged by clinical observation during the office visit.

## Results

At 2 months, hypertrophic scars were observed on 60% of the nontreated breasts, but only on 25% of the treated breasts. This difference was statistically significant with a $p$ value of $<0.05$. At 6 months, the results were very similar, although the treatment had been discontinued after the second month. Nontreated breasts demonstrated 55% hypertrophic scars, while treated breasts maintained the same 25% seen at month 2. The results are shown in Tables 1 and 2.

**Table 1. Evaluation of the Scars at 2 Months**

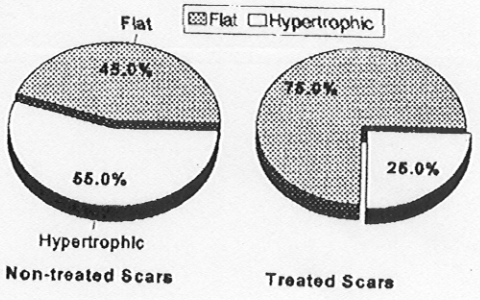
| Scar Type | Nontreated Scars | Treated Scars | Chi-square |
|---|---|---|---|
| Flat | 8 (40%) | 15 (75%) | $p < 0.05$ |
| Hypertrophic | 12 (60%) | 5 (25%) | $p < 0.05$ |
| Total | 20 (100%) | 20 (100%) | |




Total breasts evaluated: N = 40 (20 patients).

**Table 2. Evaluation of Scars at 6 Months**

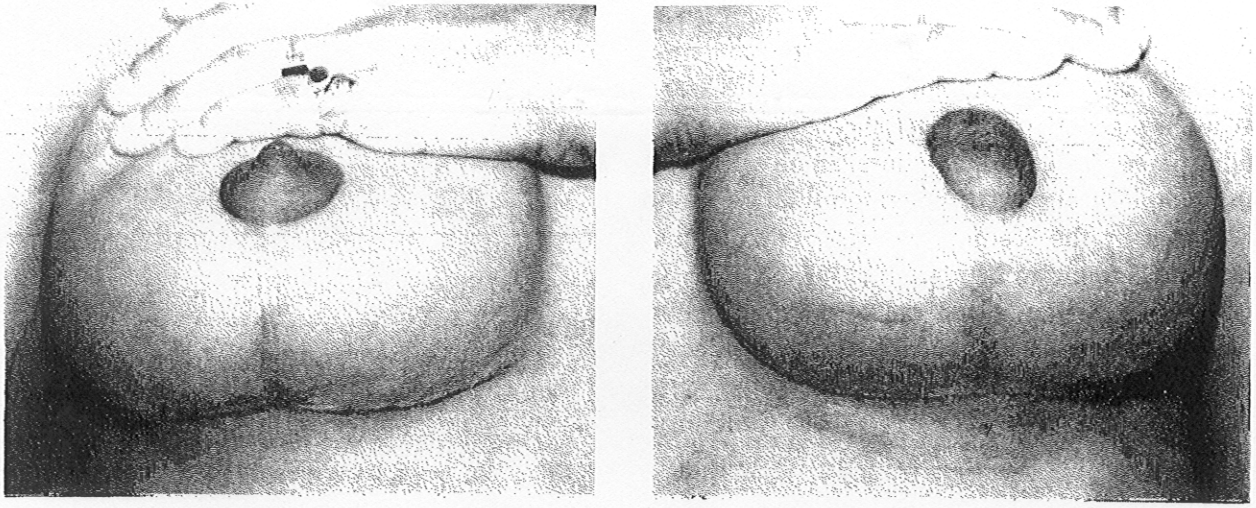
| Scar Type | Nontreated Scars | Treated Scars | Chi-square |
|---|---|---|---|
| Flat | 9 (45%) | 15 (75%) | $p < 0.05$ |
| Hypertrophic | 11 (55%) | 5 (25%) | $p < 0.05$ |
| Total | 20 (100%) | 20 (100%) | |




Total breasts evaluated: N = 40 (20 patients).

The average appearance of the scars at 2 months is shown in Figure 3. If the patient was prone to form hypertrophic scars, the beneficial effect on the treated side, compared to the nontreated side, was even greater (Fig 4).

The results obtained suggest that silicone sheets used for 12 hours daily during the first 2 months after surgery, are effective in preventing the formation of hypertrophic scars in a significant number of patients. The effect is maintained at least up to the sixth month, even though the



A B

*Fig 3. This 24-year-old patient demonstrates the average results observed at 2 months: a flatter scar on the treated side (B) when compared to the nontreated side (A).*

*Fig 4. In this patient, the treated right side shows a more dramatic result when compared to the hypertrophic left side.*

use of silicone sheets is discontinued after the second month.

Although no patients were lost from the study, minor complications in 2 patients required discontinuing the treatment for a short period of time. One patient developed a rash in the area covered by the silicone sheet due to poor local hygiene. The other patient had minor superficial skin maceration from using the silicone sheet during the summer when it was very hot and humid. These problems were transient and responded to cleansing and control of sweating by remaining in air-conditioned surroundings whenever possible.

Compliance was monitored by observing the impression of the sheets on the skin during frequent office visits, as well as assurance by the patient that instructions had been followed conscientiously.

## Discussion

The mechanism of action of silicone sheets on hypertrophic scars is not well understood. Initially thought to be due to pressure effects, Quinn and colleagues [2, 3] found that the efficacy of silicone gel sheeting was unrelated to pressure. While working on her doctoral thesis at the Bioengineering Unit in Glasgow, Scotland, Quinn found that the action of silicone sheets does not depend on pressure, changes in temperature, or changes in partial pressure of oxygen on the scar. The water vapor transmission rate of silicone gel was found to be about half that of skin (4.5 vs. 8.5 $g/m^2/hour$). Since the scar surface does not appear to be wet, nor does maceration regularly occur with prolonged wearing, the gel may promote hydration of the scar. However, other occlusive dressings that promote scar hydration, such as polyurethane film, have no effect on scars.

Davey and associates [10], believe that the relatively impermeable silicone gel acts in the same way as the stratum corneum. It reduces water vapor loss and restores homeostasis to the scar, thereby reducing capillary hyperemia, collagen deposition, and hypertrophic scar formation.

In an alternate theory, it has been suggested that a chemical interaction occurs between silicone released from the gel sheet and the scar. When a piece of silicone gel sheet is placed on filter paper and left for 24 hours, an oily print of the sample is observed. When the filter paper is analyzed by the scanning electron microscope, silicone is found to be present [2–3].

Research performed on cultured human skin fibroblasts demonstrated a decrease in proliferation when the culture bottles were coated with silicone gel or elastomer [11]. This inhibitory effect of silicone on fibroblast growth could presumably be responsible for flatter scars.

The possibility that low molecular weight silicone fluid could be released into tissues has been raised [2], but a study that evaluated punch biopsies of scars treated with silicone gel sheets failed to show evidence of a foreign body reaction or the presence of silicone in the tissue examined [4]. In that study, hematoxylin-eosin-stained histological sections of 2-mm punch biopsies were examined using only light microscopy. This might not have been the best method for detecting very small amounts of silicone within the skin.

At present, our understanding of the mechanism of action of silicone sheets is incomplete, but clinical experience has demonstrated that they are effective in the treatment and prevention of hypertrophic scars. A recent study [12] has shown that silicone gel sheets provided earlier symptomatic relief and was preferred as treatment by patients with symptomatic hypertrophic sternal scars, over triamcinolone acetonide injections. Adverse effects of treatment of scars with silicone sheets appear to be minor and transient.

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