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

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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 patients; therefore, sternal wounds were divided into the upper half and the 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, 50 control and 50 silicone gels. The median age was 61 years and there were 34 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 ($p = 0.02$), 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.)

Median sternotomy hypertrophic or keloid scarring is prevalent among cardiac surgical patients. A previous report showed the incidence to be approximately 30 percent in Caucasians and greater than 50 percent in the Asian population.[1] During the first 2 months of scar maturation, there is a tendency for hypertrophic scar development, and this is exceptionally high in the sternal region. This was the observational finding in postoperative patients during their follow-up in this hospital. Therefore, this study was conducted to find a possible solution to this problem.

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The silicone gel sheet used in a previous study to treat early hypertrophic scarring in cosmetic breast surgery usually results in resolution of the scar within first 2 months. The control group did not improve during the study period, despite the belief that early hypertrophic scars might improve over time.[2] In those who responded to the treatment, the scar usually did not recur. In those patients with old, established hypertrophic scar, the continuous 2 months' usage of silicone gel did not show much improvement.[2] Thus, the measure of scar prevention during wound epithelialization and the early phase of scar maturation is important.

Prophylactic use of a silicone gel sheet in cosmetic breast reduction surgery had shown good results when compared with the control wound in the opposite breast.[3] However, study of its prophylactic use in sternotomy cardiac patients had not been documented in the literature. The majority of patients complain of itchiness and pain at the sternotomy hypertrophic scar during their postoperative visits. The tendency of scar formation varies between individuals; thus, the intervention and control wound for this study should be on the same patient. The study wound was divided into upper and lower halves, and this technique was similar to that used in the study by Sproat et al.[1]

The reason for conducting this study was the high incidence of symptomatic sternotomy hypertrophic scar in this hospital; currently, there are no available data on the incidence and extent of sternotomy hypertrophic scar in the Asian population. Previous studies that used the silicone gel sheet showed many side effects and skin maceration. However, the semiliquid form of silicone gel used in this study has little reference. Therefore, its efficacy was assessed in this study. There were also no randomized, blinded, controlled trials that demonstrated its prophylactic use in keloid-prone areas such as the sternum. The success of its prophylactic role will create new issues such as its routine use in all cosmetic operations, the explanation of methods available for scar reduction during informed consent, and patients' demand for such measures before surgery. A new consensus may develop worldwide in the near future with regard to prophylactic scar reduction for all operations. Successful scar preventive measures can prevent a patient's functional, cosmetic, and psychological morbidity.[2]

Patients and Methods

This randomized, placebo-controlled, double-blind, prospective clinical trial was conducted between April of 2003 and March of 2004. A sample size of 100 wounds was included in this study after considering the difference of score between the two groups, with an alpha error of 5 percent and a study power of 95 percent.

Patients

The inclusion criteria were those patients with a sternotomy wound after coronary bypass surgery or cardiac valvular surgery. The exclusion criteria were those patients with severe wound infection or with a history of allergy to silicone gel. Of the 53 patients who were initially included in the study, three discontinued postoperative follow-up in this hospital. This was because of the distance of their residence from the hospital.

The study was approved by the university research committee in November of 2002 and further approved by the university ethical committee in February of 2003. The study was conduced in accordance with the International Conference of Harmonization good clinical practice guidelines. The university research department provided the grant for this study.

Sample Preparation

An independent pharmacist helped in the blinding process of the placebo and the silicone gel sample. Both types of control and silicone gel samples were prepared alike in term of appearance, smell, and consistency. In this study, the conventional silicone gel sheet was not used; instead, a semiliquid, stick type of silicone gel (Scarfade, Hanson Medical, Inc., Kingston, Wash.) was used. The contents of control gel are water, glycerin, propylene glycol, and hydroxyethyl cellulose. A random number table was used for the coding and randomization of the gel samples. Both types of gel were placed into separate containers and labeled. The samples were then kept inside an envelope so that both the doctor and patients were blinded by this process.

Two arms of 50 control and 50 silicone gels were included in this study. The sternotomy wound was divided into the upper half and the lower half. Both halves of the wound were randomized into control or intervention wounds, and the instructions of gel application to which

halves of the wound were labeled at the envelope and container. When the envelope was given to the patient, a detailed explanation of which of the coded gel to apply at which halves of the wound was reinforced.

Patients were recruited during the outpatient follow-up. The study was explained in the patient's own language. The study information and instruction sheets were given to ensure understanding. The sheet included the doctor's telephone numbers for the convenience of the patients in the event that they needed further assistance. Consent was obtained from the patients in the presence of a nurse, who acted as a witness. Instruction was given to apply the gel two times per day, once in the morning and once before sleep. Gel application started from the second week until the third month of the postoperative period.

Assessment of Scars

A digital camera was used to record the serial changes of sternotomy wounds in two views (front and side) during each follow-up visit for the purpose of comparison. The same physician who was blinded to the study scored all the wounds so that any interobserver differences were eliminated. This was performed at the second week, the sixth week, and the third month of the postoperative outpatient follow-up. A proforma sheet was used to collect the patient data and wound score. The Vancouver Scar Scale was selected for the study because it is widely used for scar assessment.[4] All the wounds in this study had been standardized in all possible aspects, such as age of the wound, length of the incision, location over the sternum, type of surgery, suture material, and single surgeon performing skin closure. The Vancouver Scar Scale is shown in Table I.

Those patients with hypertrophic scar were referred to a plastic surgery unit for scar management. After completion of data collection, the decoding of blinded samples was performed with the pharmacist's help. The data were recorded and analyzed using SPSS version 11 (SPSS, Inc., Chicago, Ill.). The Wilcoxon signed rank test was used to test for any significant difference of various scar parameters between the two groups.

The reason for using the same patient as the control was because each patient has a different susceptibility to scar formation. Thus, both groups should match each other in terms of scar susceptibility. In addition, it also helps in matching both control and intervention groups with regard to patient age, gender, medical conditions, and compliance. Therefore, the common confounding factors and biases encountered during patient selection would have been eliminated.

Skin biopsy was not included in this study because a previous study of a similar nature (comparison study of silicone gel sheet with pressure garment versus pressure garment alone for burn wound) was conducted by Dr. Husin Marijan in this hospital, but the majority of patients refused skin biopsy. The small numbers of biopsy specimens obtained by him showed that the visual analog score corresponded well with the histopathologic findings (M. Hussin, unpublished data, 2000). The study by Beusang et al. had also confirmed that the visual analogue score corresponded very well with the skin biopsy finding.[5] The university ethical committee supported the patient choice of excluding skin biopsy for this study.

RESULTS

A total number of 100 wounds in 50 patients were included in this study. This is because each patient's wound consisted of half control wound and half intervention wound.

The patients' ages ranged from 26 to 77 years. The median age was 61 years and the interquartile range was 54.75 to 65.25 years.

TABLE I
Vancouver Scar Scale

	Score					
	0	1	2	3	4	5
Pigmentation	Normal	Hypopigmentation	Hyperpigmentation			
Vascularity	Normal	Pink	Red	Purple		
Pliability	Normal	Supple	Yielding	Firm	Banding (rope-like)	Contracture
Height	Flat	1 to 2 mm	2 to 5 mm	>5 mm		
Pain	None	Occasional	Requires medication			
Itchiness	None	Occasional	Requires medication			

There were 34 men (68 percent) and 16 women (32 percent) in the study. There were 28 Malays (56 percent), 18 Chinese (36 percent), and four Indians (8 percent). There were no differences regarding the tendency to form hypertrophic scar among the different ages, sexes, and races.

The surgical procedures performed were 45 cases of coronary bypass grafts, two aortic valve replacements, two mitral valve replacements, and one case of a combination of mitral valve replacement and coronary bypass surgery. The comorbidities found in the study population were 19 with none (38 percent), four with diabetes mellitus (8 percent), 10 with hypertension (20 percent), 14 with diabetes and hypertension (28 percent), two with renal impairment (4 percent), and one with chronic obstructive airway disease.[4] The comorbid factors did not have any effect on hypertrophic scar formation in this study.

Thirty-seven patients (74 percent) had good compliance and never forgot to apply the gel. The 12 patients (24 percent) who had moderate compliance sometimes forgot to apply the gel. The one patient (2 percent) who had poor compliance forgot most of the time to apply the gel because he did not have any scar. Compliance can be affected by good wound healing, as in this patient. This finding demonstrates the difficulty of compliance as a preventive measure before the occurrence of problem.

There was no side effect of the silicone gel noted in any of the 50 patients. There was no side effect seen in those treated with the control gel either. One patient had an initial small, superficial wound infection. He resumed gel application after the wound healed.

There were only three patients who did not develop any hypertrophic scar. The incidence of sternotomy hypertrophic scar was 94 percent (47 of 50). We noted a few patients with early scars that had developed at the thoracoabdominal folds with the patient bending forward (Fig. 1). This may indicate the maximum skin tension area. However, there were patients who still developed hypertrophic scars at the upper half of the wound without forming any early scar at the thoracoabdominal fold.

There were different levels of response to the silicone gel among patients. The scars formed at the silicone gel site were usually less than at the control site. The front and lateral views of one of the patients that had keloid scar at the control site and normal skin without scar at the silicone site are shown in Figure 2.

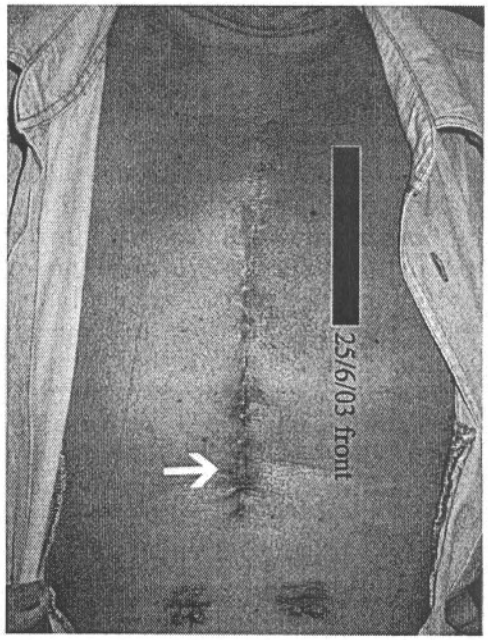

FIG. 1. Initial scar may develop at the thoracoabdominal skin fold (*arrow*).

During the first baseline assessment during the second week of the postoperative period, all of the patients had a score of zero (normal) for all scars. The mean scores of the different parameters for the three visits are summarized in Figure 3. The control group showed a gradual increase of scar score in all parameters. The silicone group showed a decrease in the mean score of pigmentation, pain, and itchiness between the second and third visits. The scores were slightly higher in the scar parameters vascularity, pliability, and height but were still markedly lower compared with the control group.

During the third visit for scar assessment at the third postoperative month, there were significant differences noted between the control and silicone groups in the following parameters: scar pigmentation ($p = 0.02$), vascularity ($p = 0.001$), pliability ($p = 0.001$), height ($p = 0.001$), pain ($p = 0.001$), and itchiness ($p = 0.02$).

DISCUSSION

The definition of hypertrophic scar by Peacock in 1970 is a scar raised above the skin level that stays within the confines of original lesions, whereas keloid is a scar raised above skin level that proliferates beyond the confines of original lesion.[6] There are many possible fac-

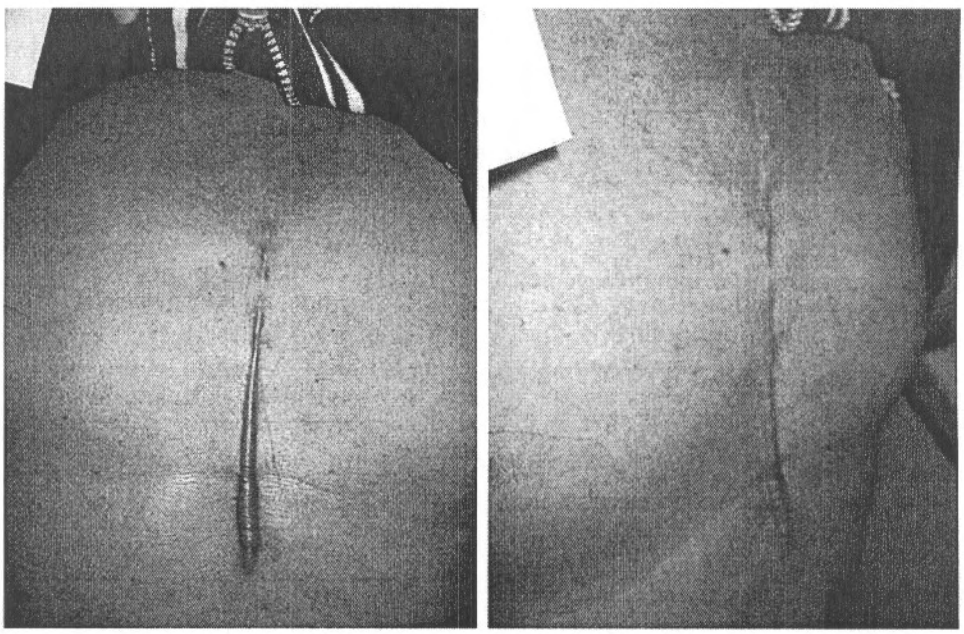

FIG. 2. (*Left*) The frontal view of the sternotomy wound shows that the upper half (silicone gel) was normal but that the lower half (control) had developed keloid. (*Right*) The lateral view of the sternotomy wound shows that the upper half (silicone gel) was normal but that the lower half (control) had developed keloid.

tors resulting in different scar susceptibilities. These variations are found in different anatomical regions, races, wound depths, injury types, and may be influenced by infection, skin tension created against Langer's lines, genetic factors, and prolonged immunologic responses. Immunologic responses are considered to be important because of the Langerhans cells, T lymphocytes, mast cells, and keratinocytes that help in the activation of fibroblasts by means of growth factors, which in turn produce excessive extracellular matrix.[7] The sternal region is a classic region that produces hypertrophic or keloid scar. The closure of sternotomy wounds that cross the skin tension-line will easily result in formation of hypertrophic scar.[8] As explained by Lawrence,[9] when the skin surface is closed perpendicular to Langer's lines, there will be vertical pressure created within the compressed subcutaneous tissue. This pressure is more on the skin surface, because of the nonpliable sternal bone. The constant outward pressure of subcutaneous tissue on the skin may result in scar formation.

Silicone materials are synthetic polymers containing a silicon-oxygen backbone and organic groups attached directly to the silicon atom by silicon carbon bonds. Depending on the length of the polymer chain and the degree of cross-linking, the silicone can be a fluid, gel, or rubber.[10] Silicone is inert and does not inhibit microbial growth, but it can act as a bacterial barrier. Under the electron microscope, the surface of the silicone gel sheet is flat and has no pores. Because it has a water vapor transmission rate lower than skin, the water that accumulates below the silicone gel sheet can cause skin maceration.[11]

An Australian research group developed the earliest silicone gel sheet. It was used for scars that were located at anatomical depressions and flexures under the pressure garments. The researchers used them at 6 to 8 weeks after burn injury when the scars started to develop.[12] Quinn et al. introduced the nonpressure treatment of hypertrophic scars in 1985.[13] The silicone gel sheet needs to be in contact with the skin surface for as long as possible. Previous reported indicate that the duration of silicone sheet use usually ranged from 12 hours to 24 hours daily. It needs to be washed and reapplied after 24 hours. However, it causes pruritus (80 percent), rash (28 percent), maceration (16 percent), and foul smells (4 percent) in a hot climate.[3,14] If the above side effects develop, patients are advised to discontinue immediately and resume using it once the symptoms have resolved. The modification of this semiliquid sticky form of silicone gel has

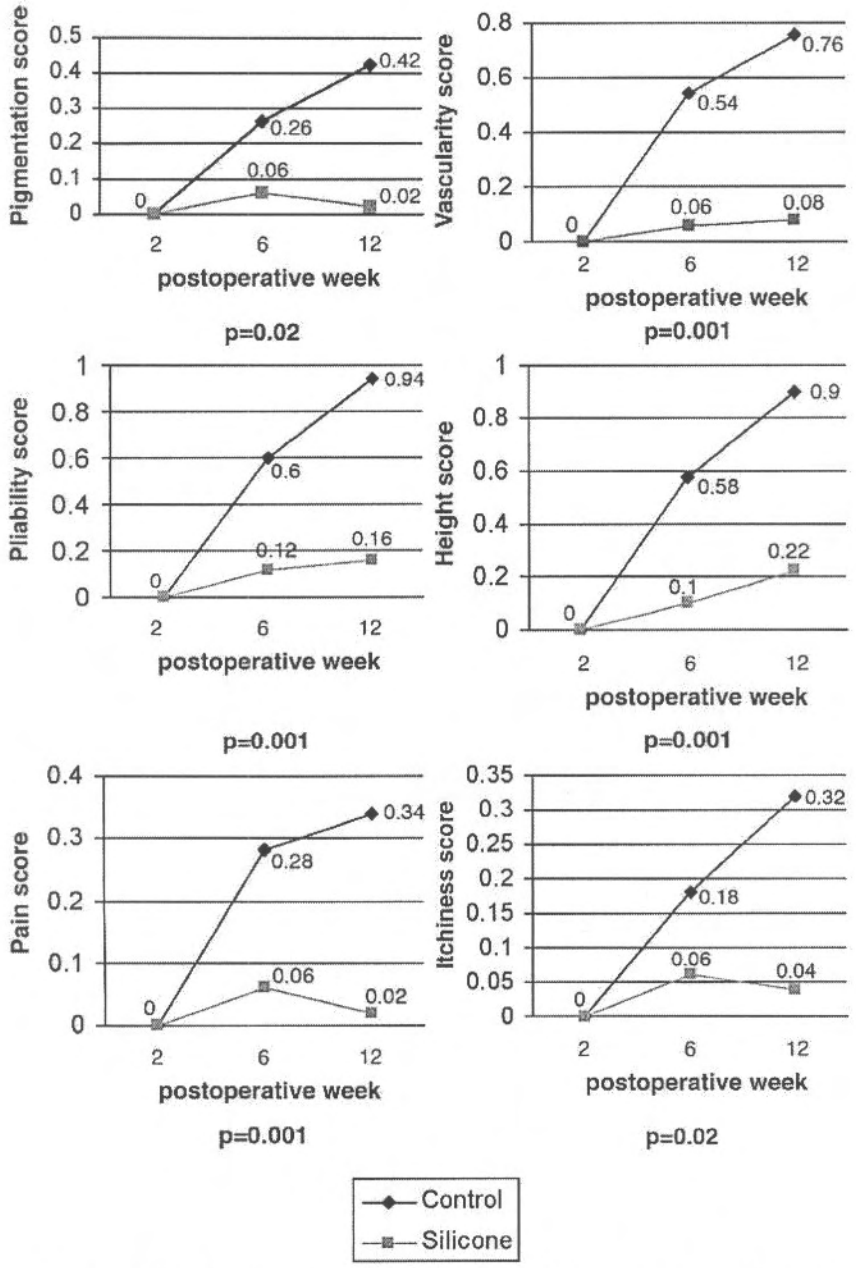

FIG. 3. (*Above, left*) Scar pigmentation. (*Above, right*) Scar vascularity. (*Center, left*) Scar pliability. (*Center, right*) Scar height. (*Below, left*) Scar pain. (*Below, right*) Scar itchiness.

eliminated the above side effects and improved patient compliance. The previous report found silicone cream to be useful in children.[15]

Many studies had shown the efficacy of silicone gel sheet for treatment of hypertrophic scar.[1,3,16–18] The study by Ahn et al. had shown the effectiveness of silicone in the treatment of chronic scar to a greater extent.[19] The exact mechanism of action by which silicone gel works is still unknown. Many have agreed that it acts at the stratum corneum, which reduces evaporation and restore homeostasis. Therefore, it reduces mast cell activity, edema, vasodilatation, and excessive extracellular matrix formation. Some other explanations are the changes of temperature, pressure effect, oxygen tension at the scar, and hydration, and some even postulate that the effect of static electricity on silicone helps in the alignment of collagen deposition.[20] The biopsy sample of the scar that was treated with silicone gel was not found to have any foreign body reaction or

silicone in the tissue. McCauley et al. had cultured the human skin fibroblast and were able to demonstrate the decrease of its proliferation when the culture bottles were coated with silicone gel.[21] Many hydration and occlusion studies had been performed following the scar hydration principles, but results varied in different centers.[22,23]

In the past, silicone gel was normally used in scar treatment rather than prevention. The hesitancy to use it as a preventive measure was attributable to the uncertainty of scar formation in different patients, the cost-effectiveness of such treatment, and concerns regarding safety in the early postoperative wound. The study by Clugston et al. that had assessed silicone gel sheet application on the hairless guinea pig during the first week of postlinear incision wound healing was able to demonstrate no adverse effect as compared with the control wound.[24]

The patient age distribution in this study was comparable to other studies that treated sternotomy scars.[1,25] The gender ratio showed male patients to be twice as numerous as female patients, which might indicate that male patients with heart disease were more prevalent in this locality. The patients' ethnic distribution corresponded well with the population that resides around the Kuala Lumpur region, with the majority of them being Malays and Chinese. This study did not show any difference in the tendency to develop hypertrophic scar among the different races (with different skin colors) in this population. In the past, studies had shown that the Caucasians were less susceptible to hypertrophic scarring as compared with the African and Asian populations.[26] The ratio for this difference ranged between 1:15 and 1:35.

The majority of open-heart operations performed in this hospital are coronary bypass for ischemic heart patients. Ischemic heart disease is one of the most common diseases among the aging population of Malaysia. The patients' comorbidities did not seem to have any effect on scar development in these patients. The general belief of delayed wound healing usually found in diabetic and renal patients was not confirmed by this study. Only one diabetic patient had a superficial wound infection, and the wound healed after a few days of dressing.

Compliance with therapy was good in 74 percent of patients, with just two applications per day. The semiliquid, sticky gel is easy to apply and stays on the skin for many hours. Some patients did not understand the importance of the preventive role of gel application during the early phase of wound healing when the scar was still not prominent. Compliance improved when patients noticed early scar formation. There were no demonstrable side effects associated with use of this semiliquid, sticky type of silicone gel. The effect of a thin layer of semiliquid silicone gel will be similar to that of a sheet covering, except that no maceration occurs.

Nevertheless, hypertrophic scar formation was observed in 94 percent of the patients, with the majority of them being in the control group, although some scars still occurred in the silicone group. The scars in the silicone wound were much smaller compared with those in the control group. The final assessment at the end of the third month showed that the differences observed between the two groups were statistically significant. These results were comparable to other studies that assessed the use of silicone gel in scar management.[1–3,11–13,15–18]

Conclusions

There is a high incidence of sternotomy hypertrophic scarring encountered in this hospital in Malaysia. This semiliquid form of silicone gel is effective in prevention of hypertrophic scar development in sternotomy wounds. The early scars noted at the thoracoabdominal skin folds of some patients suggest that skin tension may have a role in scar formation. There were no side effects found with this type silicone gel, and patient compliance was satisfactory. A longer follow-up after cessation of silicone gel treatment is required to assess for any recurrence.

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Discussion

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

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The prevention and treatment of hypertrophic scars has received increased recognition over the past 10 years, and the options for treatment are expanding, with a number of new approaches in the pipeline.[1,2] Understanding of the pathogenesis of hypertrophic scars has been hampered by the relative absence of animal models, although a model we have developed[3] offers promise for future progress.

A number of studies have supported the efficacy of silicone gel sheeting in both the treatment and the prevention of hypertrophic scars[1] since its first description by Perkins et al.,[4] and subsequent studies by Quinn[5] and Ahn and Mustoe.[6,7] This carefully conducted, double-blind, prospective study in which the patients served as their own control adds important new information regarding the efficacy of silicone in an alternative formulation for prevention of hypertrophic scars in an Asian population.

The design of this study was very rigorous. The double-blind, placebo-controlled design makes it probably the most carefully designed study of silicone in hypertrophic scars to date. Previously, most studies have been performed in Caucasians. The problem of hypertrophic scars is significant among Asian patients, as attested to by the 94 percent incidence of development of hypertrophic scars in the control group despite an older-age population (average age, 61 years). Silicone gel sheeting is widely used in East Asian countries, and this study convincingly supports the use of silicone products.

The mechanism of action of silicone has remained elusive, but several studies support early speculation that hydration of the stratum corneum is the critical mechanism. Quinn et al. ruled out pressure, temperature, and a chemical effect from silicone absorption,[5] and Ahn et al.[6] confirmed the absence of absorption of silicone. In vitro studies have supported an inhibitory effect of hydrated epithelium on collagen synthesis,[1,2] and more recent studies have ruled out an important influence of the oxygen permeability of silicone.[8] The mechanism is important in sorting out the variety of silicone products and other products that are marketed to reduce scarring without rigorous clinical studies.

Most previous studies on silicone have been performed with silicone gel sheeting. Using the rabbit ear model of hypertrophic scarring, sticky silicone gel sheeting was more efficacious than nonadherent gel sheeting.[9] The latter is less effective as a semiocclusive dressing, which supports the hypothesis that hydration of the stratum corneum is important. In this study, a paint-on gel was used, which has the advantages of ease of use and the ability to be applied in areas where use of gel sheeting is difficult. The study lends strong support to the hypothesis that any silicone gel formulation is potentially effective if it is an effective semiocclusive dressing.

Other non-silicone-based gels that produce effective hydration of the stratum corneum may very well be efficacious, but thus far there is an absence of well-conducted studies such as this one to provide evidence. Nevertheless, the

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use of taping[1] to reduce scarring most likely works by this mechanism. In summary, this well-conducted, rigorous study provides convincing evidence for the efficacy of an applied silicone gel in preventing median sternotomy hypertrophic scars in an Asian population.

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