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Please see cover letter immediately following.

**Johnson & Johnson Consumer Products Company**

**Comments Regarding the Recommendations  
of the General and Plastic Surgery Devices Panel  
of the Medical Devices Advisory Committee**

**June 8, 2002 Meeting**

TAB 1

**Johnson & Johnson Consumer Products Company**

**Comments:  
General and Plastic Surgery Devices Panel  
Meeting of July 8, 2002**

Introduction

Johnson & Johnson Consumer Products Company (CPC) herein submits comments relating to the General and Plastic Surgery Devices Panel of The Medical Devices Advisory Committee meeting of July 8, 2002. CPC provides these comments for FDA's consideration in classifying the silicone-sheeting product for scar management.

Specification of the type of device

A scar management device is typically a silicone sheet consisting of a silicone nonwoven layer bonded to an adhesive thermoplastic polyurethane film. Generally, a low-density polyethylene release film protects the body contact surface. Each sheet is typically sealed in an individual medical-grade paper pouch. The silicone sheet is intended for the management of old and new keloid and hypertrophic scars.

Action Requested

CPC requests that the silicone sheeting device for scar management be classified into Class I, General Controls, for over-the-counter (OTC) marketing, and also be exempt from section 510(k), Premarket Notification, of the FD&C Act. CPC also requests that the current device labeling remains the same with no other restrictions on the duration of use.

Classification Statement

CPC believes the scar management device should be classified into Class I, General Controls, exempt from section 510(k) requirements. As a result of the FDA Modernization Act, FDA is required to classify medical devices into the lowest classification that can reasonably assure their safety and effectiveness (Tab 3).

The definition of a Class I device declares that a device is Class I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. If there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, then a device is Class I if the device is not life-supporting or life -sustaining, or for a use which is of substantial importance

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**General and Plastic Surgery Devices Panel**

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in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury (Tab 4).

CPC and the General and Plastic Surgery Devices Panel believe the scar management device conforms to the definition of a Class I device. CPC concludes that there is sufficient historical evidence of safe use, including a lack of significant adverse events, to assure that general controls can assure safe and effective use of this device. It is clear the device is not life-supporting or life-sustaining, and is not intended for use in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury. After reviewing the information presented at the July 8, 2002 classification meeting, the panel voted to classify this scar management device into Class I based upon the elements of the above definition of a Class I device (Tab 5). We agree with this action.

CPC also believes the scar management device qualifies for a section 510(k) exemption. Section 206 (Premarket Notification) of the FDA Modernization Act establishes that a Class I device does not require a 510(k) submission unless it is intended for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury (Tab 6). The silicone sheeting is a relatively simple device that is designed to be used over closed, intact skin to improve the appearance of keloid and hypertrophic scars. It is CPC's judgment that the intended use of the scar management device is not of substantial importance in preventing impairment to human health, or does it present a potential unreasonable risk of illness or injury.

Safety and Effectiveness

Based upon the Panel discussion during the meeting, it is clear the panel members concluded that the silicone-sheeting product is safe, and it is effective a high percentage of the time. CPC agrees with the panel's opinion. Product safety has been demonstrated by many years of consumer use with no significant risks associated with this use. Over five hundred thousand products have been sold over the past five and one half years (Tab 7). Considering that each product is intended for multiple uses, this represents millions of individual applications. Literature references provided to the panel by FDA also support safety and effectiveness (Tab 3).

FDA also has concluded that silicone-sheeting products currently approved for marketing are substantially equivalent to preamendments devices for safety and effectiveness by reason of FDA's clearance for marketing of these products through the 510(k) process.

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Significant consumer use has not resulted in any identifiable safety issue. The Medical Device Reporting system lists only two adverse experiences associated with silicone-sheeting products. Neither of these consumer experiences was conclusively linked directly to the product (Tab 3).

Requirement for Use on Recommendation of a Health-Care Professional

At the July 8, 2002 meeting the panel voted to establish the scar management device as a device available on the recommendation of a health-care professional. CPC believes the panel was not fully aware that scar-management devices are currently widely available OTC when they rendered their judgment. CPC supports a continued OTC status for the silicone-sheeting device for scar management.

A prescription device is a device for which there cannot otherwise be reasonable assurance of its safety and effectiveness without restrictions on its sale, distribution or use because of any potentiality for harmful effects or collateral measures necessary for the device (Tab 8).

Silicone sheeting for scar management is a preamendments device, that is, it has been on the market before 1976. Since that time, through the 510(k) process, FDA has cleared approximately 70 devices in the Silicone Elastomer for Scar Management category. Since 1997, FDA has approved 35 devices in this category, all of which were approved for OTC use (Tab 9). We believe this represents at least hundreds of thousands of consumer OTC uses, with no significant corresponding public health issue.

Only two Medical Device Reports (MDRs) have been submitted as a result of broad consumer and professional use. Neither of these was judged to be definitively related to the device (Tab 3). In our opinion, this demonstrates a safety history that is consistent with an OTC device as opposed to having to have the order of a health professional. As suggested by one panel member at the meeting, silicone sheeting is a fairly simple product. Its use, to adhere to a consumer's skin, is similar in application to the millions and millions of adhesive bandages sold OTC and used safely for decades by consumers.

As FDA is aware, adhesive bandages are Class I OTC devices, exempt from Premarket Notification. These products generally consist of plastic and other synthetic materials. It seems that the intended use of adhesive bandages, which is to cover and protect open wounds, would present consumer issues of appropriate use comparable to the silicone-sheeting product. Consumers have safely and successfully used adhesive bandages without the supervision of medical professionals for more than 75 years. Silicone sheeting for scar

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management has the added safety benefit of being applied only over intact skin.

Health professionals do have a role in treating patients for the management of scars. Treatments could vary depending on the seriousness of the condition. However, for those consumers who wish to try an easy-to-use product without visiting a health professional, the silicone gel sheeting should be made available over-the-counter. An OTC product could benefit many, many disadvantaged consumers for whom this product would otherwise be unavailable because of inaccessible medical care or the cost associated with it.

CPC believes that the silicone sheeting for scar management can be sold over-the-counter with reasonable assurance of its safety and effectiveness.

Duration of Usage

At the panel meeting, the panel discussed imposing a 12-hour limit on the usage time for silicone sheeting. This opinion apparently was the result of information contained in just one MDR, for which the product was not definitively responsible. In that report, a consumer used a product for 39 hours of continuous use. While we believe 39 hours of continuous use is not appropriate, and, indeed, does not conform to instructions for use, we also believe that usage should not be restricted beyond the labeling instructions. Studies suggest (Tabs 10, 11, 12), and labeling indicates (Tab 2) that the appearance of scars is improved with increased wear time, up to 24 hours. Consumers should be allowed to continue the safe use of this OTC product by following the labeling instructions and current use practice.

Typically, labeling of currently marketed products instructs consumers to follow a conservative treatment regimen to minimize any potential unfavorable experience (Tab 2). Instructions generally include advising consumers 1) to start by initially using the product a few hours a day and gradually increasing usage up to 23-24 hours a day, thereby allowing the product to be the most effective, 2) to wash the product and affected skin at least daily, and 3) to reduce or discontinue use if irritation develops.

CPC believes these instructions are sufficient in providing consumers with adequate directions for use in order to gain the most benefit from the product in the safest manner. Although we recommend a 510(k) exemption for this product, continuation of adequate labeling for 510(k) exempt products would still be mandated by the provisions of Section 502 of the FD&C Act (Misbranded Drugs and Devices), and by 21 CFR Part 801, Labeling. These sections require device labeling to specifically identify the intended use, frequency and duration of application, route of application, and any other

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**Comments:**

**General and Plastic Surgery Devices Panel**

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directions necessary to properly instruct the consumer in safe and effective product use.

Summary

Consumers have been able to easily purchase and use silicone sheeting products to help reduce the appearance of keloids and hypertrophic scars for decades. Consumer experience has shown that these products have been used safely and successfully since they have been on the market. Considering the product's simplicity, relative ease of use, instructional labeling, and lengthy, safe history of consumer use, CPC believes FDA would be justified in making the decision to regulate this product as a Class I, over-the-counter device, exempt from 510(k) requirements.

August 30, 2002

David Krause, Ph.D.  
Executive Secretary, Medical Devices Advisory Committee  
General and Plastic Surgery Devices Panel  
Food and Drug Administration  
Center for Devices and Radiological Health  
9200 Corporate Blvd.--HFZ-410  
Rockville, MD 20850

**RE: Comments Regarding Classification of Silicone Sheeting for Scar Management: June 8, 2002 Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee**

Dear Dr. Krause:

Johnson & Johnson Consumer Products Company (CPC) is hereby submitting our comments regarding the recommendations put forth by the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee to the FDA on the classification of the preamendment device, silicone sheeting for scar management. The recommendations were made by the Panel at its June 8, 2002 meeting at the Gaithersburg Holiday Inn in Gaithersburg, Maryland.

To summarize the Panel's recommendations and CPC's respective comments:

<b>Panel's Recommendations on Silicone Sheeting for Scar Management</b>	<b>Summary of CPC's Comments</b>
Device should be Class I.	Agree
Device should require 510(k) submission.	Device should be 510(k) exempt.
Device should be distributed only through a licensed health practitioner.	Device should be over-the-counter (OTC).
Usage time for the device should be limited to 12 hours. (Panel discussion only)	Device labeling should remain as it is currently with no additional restrictions on usage.

CPC believes that the long history of safe and effective OTC use of silicone sheeting for scar management provides suitable support for a Class I OTC, 510(k)-exempt classification for this device. Further, the benefit to public health of such a classification would be access to this device for many disadvantaged consumers for whom this product would otherwise be unavailable because of inaccessible medical care or the cost associated with it.

Johnson & Johnson Consumer Products Company respectfully requests that you consider the comments in Tab 1 in your deliberations on your classification of this device.

This package contains the following:

- Tab 1**            Comments on the recommendations of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee to the FDA.
- Tab 2**            Appendix A. Examples of current labeling for silicone gel scar management products.
- Tab 3**            Arepalli, S., Classification of the Scar Management Device; Memorandum to General and Plastic Surgery Devices Panel; June 11, 2002.
- Tab 4**            21 CFR Part 860, Medical Device Classification Procedures, §860.3(c)(1).
- Tab 5**            Transcript of General and Plastic Surgery Devices Panel meeting, June 8, 2002, pp. 54-56.
- Tab 6**            Food and Drug Modernization Act of 1997, Section 206, Premarket Notification (a)(2), January 7, 1997.
- Tab 7**            Information Resources, Inc., sales data for the period January 1997 -- June 2002.
- Tab 8**            Transcript of General and Plastic Surgery Devices Panel meeting, June 8, 2002, Classification Questionnaire, question 11, p. 56.
- Tab 9**            CDRH Premarket Notification Database, search results for product code MDA.
- Tab 10**           Ahn, S. T., et. al., "Topical Silicone Gel: A New Treatment for Hypertrophic Scars", Surgery 106: 781-787, 1989.
- Tab 11**           Ahn, S. T., et. al., "Topical Silicone Gel for the Prevention and Treatment of Hypertrophic Scar", Arch. Surg. 126: 499-504, 1991.
- Tab 12**           Katz, B. E., "Silastic Gel Sheeting is Found to be Effective in Scar Therapy", Cosmetic Dermatology 5: 32-34, 1992.

If you have any questions or comments in reference to this submission, please contact me at (908) 874-1311.

Sincerely yours,

A handwritten signature in black ink that reads "Aileen Mroz". The signature is written in a cursive, flowing style.

Aileen Mroz,  
Manager, Regulatory Affairs  
Engineered Products

cc: S. Arepalli  
M. Shulman  
N. Pluhowski (3)  
M. Taraschi



# Cica-Care\*

## Adhesive Gel Sheet for Scar Care

- Self-Adhesive
- Durable
- Conformable
- Reusable
- Cost Effective
- Easy to Use

Cica-Care® gel sheet is a flexible, adhesive, semi-occlusive silicone sheet for the management of hypertrophic and keloid scars. Cica-Care employs the proven benefits of silicone gel sheets in scar therapy with the additional advantages of self-adhesiveness and durability.<sup>1</sup> The result is improved outcomes in scar management through cost-effectiveness and higher patient compliance.

### ADVANTAGES

#### ADHESIVE

The adhesive skin contact side is placed onto the scar while the upper side, supported by a thin silicone membrane, does not adhere. Therefore secondary fixation may not be required, making the product easier to use and more cosmetically appealing, which leads to higher patient compliance.

#### DURABLE

The silicone membrane and gel combines to provide excellent support, making Cica-Care more durable and less likely to "crumble" in comparison to other silicone gel sheets.<sup>1</sup>

#### CONFORMABLE

Cica-Care is a very flexible, conformable silicone gel sheet. Combined with its self-adhesiveness, Cica-Care can be easily used in many anatomical locations including earlobes and sternal areas, and it is more comfortable for the patient to wear.

#### REUSABLE

One piece of Cica-Care can be easily washed and re-used. Once it becomes difficult to clean, a new piece should be used.

#### COST-EFFECTIVE

Because of its durability and reusability, Cica-Care is a cost-effective scar therapy with high patient compliance due to comfort and ease of use.

### INDICATIONS

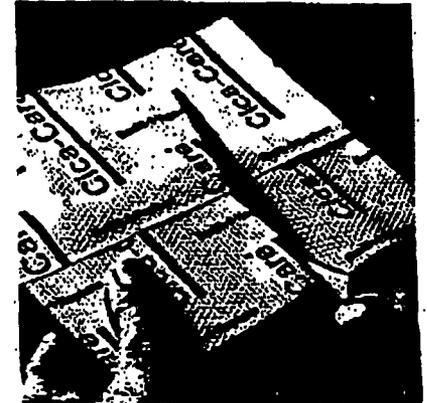
Temporary use in the management of both existing and new hypertrophic and keloid scars. Temporary use as a prophylactic therapy on closed wounds to prevent hypertrophic or keloid scarring.<sup>2</sup>

### PRECAUTIONS

In some patients a rash has been observed on the covered skin. This has been attributed to either poor hygiene or to the product being applied too tightly. Also, pruritus and superficial irritation of the skin have been associated with the use of gel sheets. On surgical incisions, use Cica-Care after sutures have been removed.

### CONTRA-INDICATIONS

Not for use on open wounds.



### APPLICATION

- 1) Cut a piece of Cica-Care to fit the scar or closed wound.
- 2) Place the sticky side on the scar. (Although Cica-Care is self-adhesive, it may also be held in place with a conformable tape like Hypafix® or a light elastic bandage.)
- 3) Wash Cica-Care twice daily in a mild non-oily soap solution and rinse in clean warm water. Wash the scar as well. Pat dry and re-apply to the dry, cleansed skin.

For patients with sensitive skin, begin by applying Cica-Care for 4 hours the first two days, 8 hours per day the next two days, and gradually increase the usage time by 2 hours per day until the patient is wearing Cica-Care 24 hours per day.

### REFERENCES

<sup>1</sup> Carney, SA, et al. Cica-Care Gel Sheeting in the Management of Hypertrophic Scarring. *BURNS*. (1994),20, (2), 163-167.

<sup>2</sup> Data on File



AVAILABILITY		
Code	Size	Box
6270	5" x 8" (nominal)	10 sheets

Each sheet is supplied individually sterilized

Distributed by:

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ALLERDERM LABORATORIES, INC.

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Petaluma, CA 94953-2070.

(800) 365-6868



**Mepiform**

en

**Adherent silicone dressing for scar care**

**Product description:** Mepiform is a thin and flexible dressing consisting of a laminate (polyurethane and non woven) covered with silicone gel.

**Mode of action (ref.):** Topical silicone gel has been empirically shown to have a positive impact on hypertrophic and keloid scars. The effect can be related to the semi-occlusive properties of the dressing.

**Intended use:** Mepiform is intended for the management of both old and new hypertrophic and keloid scars. It can also be used as a prophylactic therapy on close wounds to prevent hypertrophic or keloid scarring.

**Precautions:** Should maceration or rash occur, allow the skin to rest until the symptom has disappeared, then continue treatment gradually increasing therapy time. If the symptom persists, discontinue use and consult a physician for advice.

**Methods of use**

**Application**

1. Open the peel pack and remove the dressing.
2. If necessary, cut to appropriate size allowing overlap of minimum 1 cm.
3. When applying Mepiform make sure the area is dry. When used together with ointment or cream, ensure that the dressing covers the treated area.
4. Remove the release film and apply Mepiform over the scar / wound. Avoid stretching when applying over joints.

**Dressing change and removal**

1. Mepiform should optimally be worn for 24 hours a day. Remove the dressing once per day for inspection and washing of the skin. The dressing can then be reapplied.
2. Mepiform should under normal conditions be changed every 3 - 7 days or when the adherent properties of the dressing are no longer sufficient.
3. The dressing is water proof so you can wear the dressing while bathing and showering.

**Sterility and storage:** Sterility is guaranteed unless inner package is damaged or opened prior to use. Do not resterilise.

**Assortment**

Art.No	Size cm	Size inch	Pcs/shed cont.	Pcs/ transp.cont.
2931007	4 x 30	1,6" x 10"	5	25
293200	5 x 7,5	2" x 3"	5	30
293400	10 x 18	4" x 8"	5	25

Ref. Code: 82 (1987) Bore 12320-8-01, 899 ST et al (1991), Ann Surg (1988) 106, Ontario OL, Missoua PE (1988) / Fort Arns, Aug 201 10-14, 404 85 (1988) Data 1448-7, Corvey SA et al (1984) Bore 2470-7

Bleeding Wounds  
 Burns  
 Cushions  
 Minor Wounds  
 Moderate Wounds  
 Scar Management  
**Scar Management Pad**

### 2nd Skin® Scar Management Pad

A 3" x 4" strip made of 100% medical grade silicone with a breathable polyurethane membrane. When used as directed, the 2nd Skin® Scar Management Pad helps in the softening, smoothing, and flattening of hypertrophic or keloid scars.

#### Instructions for Use

1. Clean and dry hands and the scar site.
2. Remove the 2nd Skin® Scar Management Pad from the package and place on the area affected. Do not discard the original package.
3. The pad is adhesive but also can be secured by a lightly conforming bandage or tape if so desired. However, do not wrap too tightly, because it will lead to irritation of the scar area.
4. The pad may be worn up to 24 hours per day (a minimum of 12 hours per day is recommended). Upon removal, wash the scar site and pad in mild soapy warm water, dry and reapply. For best results, wear it every day.
5. Follow this procedure each day, washing and reapplying the Scar Management Pad for 30 days. At that time the pad will begin to lose the adhesive qualities. If this occurs, apply a secondary adhesive dressing over the pad. After approximately 30 days, a new Scar Management Pad should be applied.
6. Rashes and itching may occur in certain persons, usually due to poor hygiene at the scar area. Should rash or itching occur, application of the pad should be limited to 12 hour periods alternated with 12 hour periods of non-application. If symptoms persist, use of the pad should be discontinued.
7. The product can be worn in a gym or shower.
8. Store the pad in the original package when not using the pad.

#### WARNINGS:

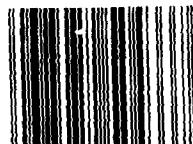
- Do not use on open wounds or third degree burns.
- Should not be used on persons with dermatological conditions or disorders.
- The extent of scar reduction will vary from person to person and will depend on the severity of the scar. Some scars may not be responsive to treatment.

If you have questions or comments call

**1-800-877-3626**

or e-mail us at [spenco@spenco.com](mailto:spenco@spenco.com)  
 Visit our web site at [www.spenco.com](http://www.spenco.com)

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Advanced First Aid™ for Adults  
**Scar Management Pad**

**SPENCO®**  
**2nd Skin**

Advanced First Aid™  
 for Adults  
 Helps Soften,  
 Smooth and  
 Flatten Scars

- Reusable
- Self-Adhesive
- For Management of Hypertrophic or Keloid Scars Caused by Surgery

Non-sterile Pad  
 3" x 4"

**Scar Management Pad**  
 Advanced First Aid™ for Adults

## HOW DO YOU APPLY SIL-K™?

### STEP 1

Everyday before use, wash the SIL-K™ sheet with mild soap and water, then rinse, and dry completely with a clean, dry towel. Wash and dry the scarred area also.

### STEP 2

Place SIL-K™, either side up, directly on your scar. The SIL-K™ sheet should overlap your scarred area by at least 1 cm (approximately 1/4 inch) all around.

### STEP 3

It is recommended that any hypoallergenic tape that best suits the individual's own skin be used to hold SIL-K™ in place. A soft wrap gauze tape may be also be used. Remember that SIL-K™ needs only to be in contact with your scar and does not require unnecessary pressure.

#### What are Hypertrophic and Keloid scars?

These scars are thick, raised and usually darker than normal skin color. And, they are both physically and psychologically painful.

#### Will my scar disappear completely?

The SIL-K™ SCAR CARE SYSTEM can soften, smooth and flatten your scar and dramatically improve the appearance of your skin. Keeping in mind though, that some evidence of the scar may remain.

#### Does the SIL-K™ come in different shapes and sizes?

Yes, Just like scars, the SIL-K™ becomes in many shapes and sizes to accommodate your needs. You can even cut SIL-K™ without damaging the sheet. Does the SIL-K™ SCAR CARE SYSTEM have any negative effects?

As with any topical device application to your skin, some type of skin reaction to SIL-K™ may occur. (Usually a mild sweat rash).

#### Can I wear the SIL-K™ while exercising or in water?

Yes, However, if you are bathing, do yourself and your SIL-K™ a favor and bathe it, too. Hygiene is very important.

#### Can children use the SIL-K™ SCAR CARE SYSTEM?

Yes. When used as directed, children can use the SIL-K™ SCAR CARE SYSTEM.

#### Where should I keep my SIL-K™ when I'm not using it?

When you're not using SIL-K™, keep the sheet in the convenient pouch provided in the package.

## SPECIAL RECOMMENDATIONS AND PRECAUTIONS

As with any topical device applied directly to the skin's surface, some type of reaction (usually sweat rash) is possible, though rare.

If you have a reaction, stop using SIL-K™ for 24 hours.

After 24 hours without product use, wash your scarred area and dry completely.

Try the SIL-K™ again for 1 hour the first day, and increase your wearing time 1 hour each day. If you continue to have a problem, stop use and consult your physician or pharmacist.

The SIL-K™ is **NEVER** used nor recommended for use on open wounds. Wait until the wound is closed and healed and where sutures or staples have been applied, wait until they have been removed and the site is healed and dry.

## RETURN POLICY

If, after you have used SIL-K™ for 90 days and have followed our easy instructions and you find no improvement in your Hypertrophic or Keloid Scar, you may return your SIL-K™ sheet for a full refund. You must first call Library Medical, Inc. to receive your confirmation number.

#### Call 1-800-711-8055

*Proof of purchase **MUST** accompany return!*

## SIL-K™ SCAR CARE SYSTEM

By Library Medical Incorporated

412-650-8211 Fax 412-650-8217

1-800-711-8055

## COMMON QUESTIONS & ANSWERS ABOUT SIL-K™ SCAR CARE SYSTEM



## SIL-K™ SCAR CARE SYSTEM

By Library Medical Incorporated

412-650-8211 Fax 412-650-8217

1-800-711-8055

## FREQUENTLY ASKED QUESTIONS

- Q. On what kinds of scars is SIL-K™ most effective?**
- A.** SIL-K™ is effective in the management of old and new scars that may form as a result of burns, surgical procedures, traumatic events and even the smallest of minor injuries, including insect bites or stings.
- Q. Can the SIL-K™ SCAR CARE SYSTEM prevent these terrible scars from forming?**
- A.** Yes, the SIL-K™ SCAR CARE SYSTEM, when used following surgery, may in fact, prevent the formation of Hypertrophic and Keloid scars.
- Q. Can the SIL-K™ SCAR CARE SYSTEM be used anywhere on the body?**
- A.** Yes, when used as directed SIL-K™ SCAR CARE SYSTEM can be used on any part of the body.
- Q. How long will it take until my scar becomes less-noticeable?**
- A.** The length of scar management varies from person to person. Use SIL-K™ daily as directed.
- Q. Do I have to wear the SIL-K™ SCAR CARE SYSTEM, everyday?**
- A.** Yes, you should wear the SIL-K™ daily. Start with two to three hours the first day and increase your wearing time one to two hours each day. You may wear SIL-K™ for up to 24 hours a day. For best results, simply follow our easy to use instructions. The more you wear it, the shorter your therapy time, the happier the patient.

## WHAT IS THE SIL-K™ SCAR CARE SYSTEM?

SIL-K™ SCAR CARE SYSTEM is a non-invasive medical application that reduces unsightly scars without surgery. This soft, durable silicone sheeting is reusable and washable and will not break down or disintegrate. A single sheet can be used for the duration of scar management.

## LOSE YOUR SCARS WITH SIL-K™

**SIL-K™ IS GUARANTEED**

**SIL-K™ IS CONVENIENT AND REUSABLE**

**LET SIL-K™ TAKE YOUR SCARS AWAY**

## THE AFFORDABLE SOLUTION FOR YOUR HYPERTROPHIC AND KELOID SCARRING...

Finally, the call of medical professionals at burn centers around the world will now be answered with the SIL-K™ SCAR CARE SYSTEM.

SIL-K™ is a safe and effective way to manage hypertrophic & keloid scars resulting from burns, surgical procedures, traumatic event and minor injuries. SIL-K™ may also be effective in the prevention of problem scarring. Applied over a scar daily, and following simple instructions, SIL-K™ will make your problem scars softer, smoother, and restore more normal color to the scarred area. Also, the SIL-K™ can relieve the painful burning and itching that is so commonplace to these terrible scars. SIL-K™ is Pure Medical Grade Silicone Sheeting. Amazingly, only one sheet of SIL-K™ is needed for the duration of your scar therapy.

Product Insert



**en** Adherent silicone dressing for scar care  
**de** Selbsthaftender Silikonverband zur Behandlung von Narben  
**fr** Pansement adhésif en silicone pour le traitement des cicatrices  
**es** Apósito adherente de silicona para el tratamiento de cicatrices  
**nl** Zelfklevend siliconen verband voor de behandeling van littekens  
**sv** Självhaftande silikonbandage för behandling av ärrar  
**it** Medicazione autoadesiva in silicone per il trattamento delle cicatrici  
**fi** Kinnittyvä silikonipasteliikeseuraus arkojen hoitoon  
**pt** Penso de silicone autoadesivo para o tratamento de cicatrizes  
**da** Selvklevende silikonebånd til behandling af ar  
**el** Αυτοκόλλητο σιλικονικό επίθεμα για τη θεραπεία ουλών  
**pl** Przyklejająca się opaska silikonowa do leczenia blizn  
**cs** Adhezní silikonový obvaz pro léčbu jizev  
**hu** Hegesztő szilikonos kötszer  
**no** Selvklevende silikonplaster til behandling av ar  
**sl** Lepilni silikonov obliževanje za zdravljenje brazgotin

**en** Silicone adhesive dressing for scar care  
**de** Elft  
**fr** Usage  
**es** Un  
**nl** Voor gebruik  
**sv** Engångsbruk  
**it** Monouso  
**fi** Kertakäyttöinen

CE 0086

STERILE EO

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TECHNOLOGY

Mepiform<sup>®</sup> Safetac<sup>®</sup>

en

**Adherent silicone dressing for scar care, with selective micro-adherence**

**Product description:** Mepiform is a thin and flexible dressing consisting of a laminate (polyurethane and non woven) covered with silicone gel

**Intended use:** Mepiform is intended for the management of both old and new hypertrophic and keloid scars  
It can also be used as a prophylactic therapy on close wounds which may prevent hypertrophic or keloid scarring

**Precautions:** Should maceration or rash occur, allow the skin to rest until the symptom has disappeared, then continue treatment gradually increasing therapy time.  
If the symptom persists, discontinue use and consult a physician for advice

**Methods of use**

Application

1. Open the peel pack and remove the dressing.
2. If necessary, cut to appropriate size allowing overlap of minimum 1 cm
3. When applying Mepiform make sure the area is dry. When used together with ointment or cream, ensure that the dressing covers the treated area.
4. Remove the release film and apply Mepiform over the scar / wound. Avoid stretching when applying over joints

Dressing change and removal

1. Mepiform should optimally be worn for 24 hours a day. Remove the dressing once per day for inspection and washing of the skin  
The dressing can then be reapplied
2. Mepiform should under normal conditions be changed every 3 - 7 days or when the adherent properties of the dressing are no longer sufficient.
3. The dressing is water proof so you can wear the dressing while bathing and showering.

**Sterility and storage:** Sterility is guaranteed unless inner package is damaged or opened prior to use. Do not resterilise

**Assortment**

Art No	Size cm	Size Inch	Pcs/shelf cont.	Pcs/transp cont.
293100	4 x 30	1,6" x 12"	5	25
293200	5 x 7,5	2" x 3"	5	30
293400	10 x 18	4" x 8"	5	25

Product Insert



The Standard for Scar Management™

- [HOME](#)
- [PRODUCT INFO](#)
- [FAQ'S](#)
- [NEWS](#)
- [STORE](#)
- [CONTACT](#)
- [LINKS](#)

## Frequently Asked Questions

- [Q. What kinds of scars does ReJuveness work on?](#)
- [Q. What are hypertrophic and keloid scars?](#)
- [Q. Can ReJuveness be used anywhere on the body?](#)
- [Q. Do I have to wear ReJuveness every day?](#)
- [Q. How long will it take until my scar gets less noticeable?](#)
- [Q. Will my scar disappear completely?](#)
- [Q. Does ReJuveness have any side effects?](#)
- [Q. Can children use ReJuveness?](#)
- [Q. Can ReJuveness prevent scarring disorders?](#)
- [Q. Does ReJuveness come in different shapes and sizes?](#)
- [Q. Where should I keep my ReJuveness when I'm not using it?](#)
- [Q. Can ReJuveness be used with other scar revision therapies?](#)
- [Q. Are there other ways to attach ReJuveness to skin besides ReJuveness Tape?](#)

Q. What kinds of scars does ReJuveness work on?

A. ReJuveness is ideal for managing both old and new scars resulting from burns, surgical procedures, and traumatic events.

[BACK TO TOP](#)

Q. What are hypertrophic and keloid scars?

A. These are scars that are thick, raised, and sometimes darker than your surrounding skin.

[BACK TO TOP](#)

Q. Can ReJuveness be used anywhere on the body?

A. Yes. When used as directed, ReJuveness can be used on any part of the body.

[BACK TO TOP](#)

Q. Do I have to wear ReJuveness every day?

A. Yes. You should wear ReJuveness daily. Start with 2 to 3 hours the first day and increase your wearing time 1 to 2 hours each day. For best results, you should wear ReJuveness for at least 8 hours a day; you can wear it for as long as 24 hours.

[BACK TO TOP](#)

Q. How long will it take until my scar gets less noticeable?

A. The length of scar management varies from person to person; results depend on the age and severity of your scar and whether you wear your ReJuveness daily as directed.

[BACK TO TOP](#)

Q. Will my scar disappear completely?

A. ReJuveness can soften, smooth, and flatten your scar and dramatically improve the appearance of your skin. Keep in mind, though, that there will always be some evidence of the scar.

[BACK TO TOP](#)

Q. Does ReJuveness have any side effects?

A. No, but as with any topical device applied directly to the skin's surface, some type of skin reaction to ReJuveness (usually sweat rash) is possible.

[BACK TO TOP](#)

Q. Can children use ReJuveness?

A. Yes. When used as directed, children can use ReJuveness.

[BACK TO TOP](#)

Q. Can ReJuveness prevent scarring disorders?

A. Yes. ReJuveness can prevent hypertrophic and keloidal scarring and the symptoms that accompany these disorders.

[BACK TO TOP](#)

Q. Does ReJuveness come in different shapes and sizes?

A. Yes. Just like scars, ReJuveness comes in many shapes and sizes to accomodate your needs. You can even cut ReJuveness without damaging the sheet.

[BACK TO TOP](#)

Q. Where should I keep my ReJuveness when I'm not using it?

A. When you're not using it, keep ReJuveness in the convenient pouch provided in the ReJuveness package.

[BACK TO TOP](#)

Q. Can ReJuveness be used with other scar revision therapies?

A. Yes. ReJuveness can be used as an adjunct with other therapies. Consult your physician for most adjunct therapy. ([see chart](#)).

[BACK TO TOP](#)

Q. Are there other ways to attach ReJuveness to skin besides ReJuveness tape?

A. Yes. ReJuveness can be placed under tight clothing, with ace bandages or other medical tapes. You can buy ReJuveness tape from your pharmacist or order it directly from ReJuveness at 1-800-588-7455. If you prefer you can also purchase it online at our [online store](#).

[BACK TO TOP](#)

Copyright 2000 ReJuveness Inc.



# Cica-Care\*

## About Cica-Care

About Cica-Care

About Scars

Life Stories

Family's Experience

Customer's Answers

Content's Purpose

Website Professionals

Why use Cica-Care

Appearance

How Cica-Care works

Time to use Cica-Care

How to use Cica-Care

Effectiveness

Clearing Cica-Care

**Cica-Care** is a self-adhesive gel sheet that helps improve the appearance of the majority of red, dark or raised scars. It has already been widely used by the medical profession with over a million units sold.



**Cica-Care** is durable, comfortable and re-usable, ideal for day and night use. It maybe used on children and adults making it suitable for the whole family. **Cica-Care** has been shown to be successful in improving older scars, however results are expected to be most effective in more recent scars.

Within 2-4 months, most scars you thought were permanent can be reduced and their appearance improved.

\*Trademark of Smith & Nephew



## Cica-Care\*

 [About Cica-Care](#)

 [About Scars](#)

 [User Stories](#)

 [Expert's Evidence](#)

**Questions & Answers**

 [Contact Us](#)

 [Medical Professionals](#)

### Questions and Answers

#### How is Cica-Care used and how long will it take for the scar to get better?

It can vary from person to person and from scar to scar. Some people may see an improvement in a matter of days. When used correctly, best results are seen after 2-4 months improvement time. For the first two days of scar reduction **Cica-Care** should be used for 4 hours per day. For the next two days, **Cica-Care** can be increased to 8 hours per day. After this, wear time should be increased by 2 hours per day until a minimum of 12 hours per day is reached. If possible, **Cica-Care** should be worn 24 hours per day. This build up is necessary to get the skin accustomed to the gel sheet.

continues..

*Menu*  [Previous question](#)  [More](#)

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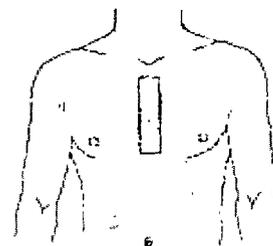
\*Trademark of Smith & Nephew

**Smith+Nephew**

```
function checkFrame(){ if(!window.parent.header | !window.parent.menu | !window.parent.main)
{ top.location.href = "index.html" } }
```

**Clinicel is a convenient scar management therapy. Follow these simple directions for best results:**

1. Remove the Clinicel cushion from its package, wash it with mild soap and water and dry it completely. Wash and thoroughly dry the scarred area.
2. Apply Clinicel directly to the scar. Clinicel can be held in place using a tight fitting shirt sleeve, stocking, panty hose or silimilar garment. If the cushion and your skin are clean, the cushion will stick and need very little support. Another method of holding Clinicel in place is with **Elastic net dressings** which are available in a convenient range of sizes at your local pharmacy. In some difficult-to-access areas, it may be preferable to secure the Clinicel cushions with hypoallergenic medical tape.



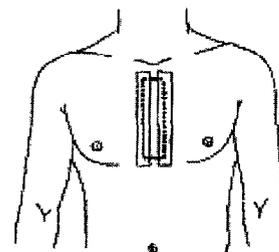
Wear Clinicel daily. Start with 2 to 3 hours and increase wearing time 1 to 2 hours each day. For best results, you should wear Clinicel 8 hours a day, and you can wear it longer. Be sure to wash the Clinicel cushion and your scar before each use.

The longer you wear Clinicel each day-and the more consistently you follow the Clinicel regimen-the faster you will see the benefits. No matter how long you choose to use it, however, you should need only a single durable, easy-to-clean Clinicel cushion, providing a cost-effective approach to scar healing.

**Precautions and Recommendations**

Clinicel is a safe, effective scar management system. Like any device applied directly to the skin, Clinicel may in rare cases cause a reaction, usually a sweat rash. Should this occur, stop using Clinicel for 24 hours. After 24 hours, you can reapply Clinicel. Wear it for one hour the first day and increase wearing time by one hour each day after that. If you continue to experience reactions, stop use and consult your physician or pharmacist.

Typically, the reaction is from the adhesives used in certain tapes. For that reason, you may have to experiment with different attachment methods to see what works best for you. See your pharmacist for advice on your particular needs.



**New!**

# CURAD<sup>®</sup>

# Scar Therapy<sup>™</sup>

Cosmetic Pad

*Clinically proven  
to make scars  
appear less visible.*



Before



After

21 Pads

**New!**

# CURAD<sup>®</sup>

# Scar Therapy<sup>™</sup>

Cosmetic Pad

**What does it do?**

Curad Scar Therapy Cosmetic Pad is clinically proven to make scars appear less visible.

Curad Scar Therapy Cosmetic Pad makes scars appear softer, smoother and flatter. It is effective on old and new scars on any part of the body, including the face. The flexible, breathable pads are easy to apply, comfortable to wear and suitable for sensitive skin.

**How long does it take?**

Clinical studies have shown results after 8 weeks. For best results, wear a pad every day for up to 24 hours. If used only at night, results may take longer. Using the pads for more than 8 weeks may further improve the results. The results vary from person to person and scar to scar.

**How is it applied?**

- Wash and dry the scarred area
- Cut pads to fit or apply side by side, depending on the size of the scar
- Apply pad directly on the scar
- If needed, secure pad in place with adhesive strip (included in package)
- Repeat procedure daily using a new pad every day
- Package contains 21 pads (3 weeks supply)

**Cautions:**

- Do not use on open wounds or burns
- Do not use if rash or irritation develops  
In case of severe reaction, consult a physician or pharmacist
- Do not use on infants under 3 years of age to prevent the risk of ingestion or choking
- The packaging of this product contains natural rubber latex which may cause allergic reactions

**Ingredients:** Polyurethane, Polyurethane film, Sodium Acrylates

Press to Open



## MEMORANDUM

**Date:** June 11, 2002  
**To:** General and Plastic Surgery Devices Panel  
**From:** Sam R. Arepalli, Ph.D.  
**Subject:** Classification of the Scar Management Device

---

Inadvertently a few medical devices were not classified at the time of Medical Device Amendments of 1976 (the 1976 Amendments) to the Food, Drug and Cosmetic Act (the Act) (21 USC 360C). These medical devices are currently regulated as unclassified devices via premarket notification (510(k)).

The 1976 Amendments as amended by the Safe Medical Device Act (SMDA) of 1990 and the FDA Modernization Act (FDAMA) of 1997 provide regulations for the classification and regulation of medical devices intended for human use. FDA is required to classify all medical devices, including the remaining unclassified medical devices into the lowest regulatory class that can reasonably assure their safety and effectiveness for their intended use.

The Act established three categories (classes) of medical devices depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes are Class I (general controls), Class II (special controls), and Class III (pre-market approval). General controls are sufficient to provide reasonable assurance of the safety and effectiveness of Class I devices. General controls include the following: prohibition against adulterated or misbranded devices, premarket notification (510(k)), banned devices, the quality system regulation that includes design controls and good manufacturing processes (GMPs), registration of manufacturing facilities, listing of device types, record keeping, etc. Class II devices are those that cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such devices. These devices are regulated using special controls and general controls. Special controls include guidelines (guidance documents), performance standards, postmarket surveillance, clinical data, labeling, tracking requirements, and other appropriate actions the Secretary of the Department of Health and Human Services deems necessary to provide such assurance. Class III devices are those for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness. These devices are life sustaining, life supporting, or substantially important in preventing impairment of human health, or they present unreasonable risk of illness or

injury. Class III devices are regulated by using "valid scientific evidence" to establish the safety and effectiveness of the device. Valid scientific evidence includes well-controlled investigations, partially-controlled studies, uncontrolled studies, well-documented case histories, and reports of significant human experience.

When most device types were classified in the late 1970s and early 1980s, most Class I and Class II devices were cleared for marketing via the 510(k) process. Some Class I devices were also exempted from 510(k) clearance. Now many Class I devices and a few Class II devices are exempt from 510(k) clearance because their safety and effectiveness can be reasonably assured by other general controls, particularly by the quality system regulation general control. Examples of class I exempt products include hydrogel wound dressings, manual surgical instruments. Class II devices include implantable surgical meshes, sutures, dura mater substitute devices etc. Class III devices include Interactive Wound Dressings, Adhesion Barriers etc.

FDA has regulated silicone sheeting intended for scar management as an unclassified pre-amendment medical device. It has been cleared for marketing under several names, including silicone sheeting, silicone elastomer, and silicone gel for hypertrophic and keloid scar management. Also, the agency cleared a hydrogel for the same intended use.

Your panel package includes information on the classification of medical devices. Please note that some slides of the presentation in Tab 1b on Device Classification/Reclassification Procedures have an asterisk (\*). The asterisked slides pertain to the classification of unclassified preamendment devices and are relevant to the classification of the scar management device. Tab 1b also contains the questionnaire that you will vote on as part of your recommendation on the classification of this device. Tab 1c lists our panel discussion topics for the classification of this device. Tab 1d includes the only two medical device reports (MDR) on the device. Tab 1e is a bibliography of 13 articles on the clinical use of silicone sheeting and 1 article on the clinical use of a hydrogel for the intended use of scar management.

### **Risks to Health**

FDA is proposing the following identification for the scar management device: A scar management device is a silicone sheeting product intended for use on uncompromised skin for scar management.

FDA regulates several silicone devices as Class III, Class II, Class I and unclassified devices. For example, the breast implant device, which has a silicone envelope and may contain a silicone gel filler is regulated as Class III medical device. Silicone chin, facial, etc. implants are regulated as Class II medical devices. Several other medical devices made of silicone are Class I devices and are exempt from 510(k) requirements (ex: drainage tubes). Silicone sheeting intended for the scar management is currently regulated as an unclassified medical device. Unlike the other silicone devices mentioned above, silicone sheeting intended for scar management is used on uncompromised skin.

FDA believes that the risk to health i.e., possible adverse skin reaction due to lack of biocompatibility exists.

FDA cleared about fifty pre-market notification (510(k)) applications for the scar management devices in the last five years. We searched medical device reports for the device adverse events. There are two adverse events reported (Tab 1e). The first adverse event was a significant blistering caused shortly after using gel sheeting followed by full thickness skin necrosis due to secondary infection. The blistering was not at the site of gel sheeting application, but in the areas nearby. It was determined by the reporting physician that the event was unrelated to the device but we could not rule out the possibility of the device involved. The other adverse event was severe red rash and flaky rough skin. This was determined as an isolated event and not likely that it was due to the use of the device.

The next page after this memorandum is a proposed regulatory identification for the scar management device.

\_\_\_\_\_  
Sam Arepalli, Ph.D.  
FDA/CDRH/ODE/DGRND/PRSB

\_\_\_\_\_  
Date

1. Ahn, S. T., et. al., "Topical Gel: A New Treatment for Hypertrophic Scars". *Surgery* 106:781-787, 1989.
2. Ahn, S. T., et. al, Topical Silicone Gel for the Prevention and Treatment of Hypertrophic Scar", *Arch. Surg.*, Vol. 126, 499-504, 1991.
3. Baum, T.M., et., al., Use of a Glycerin-Based Gel Sheeting in Scar Management, *Advances in Wound Care* 11:40-43, 1996.
4. Hirshowitz, B., et. al., "Silicone Occlusive Sheeting (SOS) in the Management of Hypertrophic and Keloid Scarring, including the Possible Mode of Action of Silicone, by Static Electricity", *Eur. J. Plast. Surg.*, Vol 16, pp 5-9, 1993.
5. Katz, B.E., "Silastic Gel Sheeting is found to be Effective in Scar Therapy", *Cosmetic Dermatology*, June 1992.
6. Ketchum, L.D., "Hypertrophic Scars and Keloids", *Clinics in Plastic Surgery*, 4:301-310, 1977.
7. Lee, R.c., & Doong, H., "Control of Matrix Production During Tissue Repair".
8. Mercer, N.S.G., "Silicone Gel in the Treatment of Keloid Scars", *Br. J. Plast. Surg.* 42:83-87, 1989.
9. Nicolai, J.P.A., et. al., "A Protocol for the Treatment of Hypertrophic Scars and Keloids", *Aesthetic Plast. Surg.*, 11: 29-32, 1987.
10. Ohmori, S., "Effectiveness of Silastic Sheet Coverage in the Treatment of Scar Keloid". *Aesth. Plast. Surg.*, Vol., 12, 95-99, 1988.
11. Perkins, K., et. al., "Silicone Gel: A New Treatment for Burn Scars and Contractures"., *Burns* 9:201, 1982.
12. Phillips, T. J., et. al., A Randomised Controlled Trial of Hydrocolloid Dressing in the Treatment of Hypertrophic Scars and Keloids, *American Society for Dermaologic Surgery*, 22:775-778, 1996.
13. Quinn, K.J., et. al.,, "Non-pressure Treatment of Hypertrophic Scars", *Burns*, 12:102, 1985.
14. Sawada, Y., et. al., "Treatment of Dermal Deth Burn Wounds with an Antimicrobial Agent- releasing silicone Gel Sheet", *Burns* 16:347, 1990.

TAB 4

U.S. Food and Drug Administration Center for Devices and Radiological Health

## Code of Federal Regulations

### Title 21 - Food and Drugs Revised as of April 1, 2002



[Code of Federal Regulations]  
[Title 21, Volume 8]  
[Revised as of April 1, 2002]  
From the U.S. Government Printing Office via GPO Access  
[CITE: 21CFR860.3]

[Page 159-160]

#### TITLE 21--FOOD AND DRUGS

#### CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

#### PART 860--MEDICAL DEVICE CLASSIFICATION PROCEDURES--Table of Contents

##### Subpart A--General

##### Sec. 860.3 Definitions.

For the purposes of this part:

(a) Act means the Federal Food, Drug, and Cosmetic Act.  
(b) Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

(c) Class means one of the three categories of regulatory control for medical devices, defined below:

(1) Class I means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health,

and which does not present a potential unreasonable risk of illness or injury.

(2) Class II means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(3) Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

(d) Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

(e) Life-supporting or life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

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(f) Classification questionnaire means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device.

(g) Supplemental data sheet means information compiled by a classification panel or submitted in a petition for reclassification, including:

- (1) A summary of the reasons for the recommendation (or petition);
- (2) A summary of the data upon which the recommendation (or

petition) is based;

(3) An identification of the risks to health (if any) presented by the device;

(4) To the extent practicable in the case of a class II or class III device, a recommendation for the assignment of a priority for the application of the requirements of performance standards or premarket approval;

(5) In the case of a class I device, a recommendation whether the device should be exempted from any of the requirements of registration, record-keeping and reporting, or good manufacturing practice regulations;

(6) In the case of an implant or a life-supporting or life-sustaining device for which classification in class III is not recommended, a statement of the reasons for not recommending that the device be classified in class III;

(7) Identification of any needed restrictions on the use of the device, e.g., whether the device requires special labeling, should be banned, or should be used only upon authorization of a practitioner licensed by law to administer or use such device; and

(8) Any known existing standards applicable to the device, device components, or device materials.

(h) Classification panel means one of the several advisory committees established by the Commissioner under section 513 of the act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the act or by the Commissioner.

(i) Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

(j) Petition means a submission seeking reclassification of a device in accordance with Sec. 860.123.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 56480, Sept. 19, 2000]

**CDRH** **FDA Home** **Search** **Contact**

Accessibility

TAB 5

sgg]

SG

1

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

GENERAL AND PLASTIC SURGERY DEVICES PANEL  
OF THE MEDICAL DEVICES ADVISORY COMMITTEE

OPEN SESSION

60th Meeting

Monday, July 8, 2002

1:20 p.m.

Gaithersburg Holiday Inn  
Two Montgomery Village Avenue  
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.  
735 8th Street, S.E.  
Washington, D.C. 20003-2802  
(202) 546-6666

1 MS. SHULMAN: Are we ready? the first  
2 part on the sheet is just your panel name and you  
3 can fill that out. That is administrative, and the  
4 date; the generic type of device.

5 Then the first question, is the device  
6 life-sustaining or life-supporting?

7 DR. WHALEN: We can just go around the  
8 table, and this is for voting members. So, we can  
9 start on this first question, please, with Dr.  
10 McCauley.

11 DR. MCCAULEY: The answer to the first  
12 question would be no.

13 DR. DUBLER: The answer to the first  
14 question is no.

15 DR. CHOTI: No.

16 DR. NEWBURGER: No.

17 DR. CHANG: No.

18 DR. DEMETS: No.

19 MS. SHULMAN: The first one is no. Is the  
20 device for use which is of substantial importance  
21 in preventing impairment of human health?

22 DR. WHALEN: Just to stagger the way we  
23 answer them, Dr. Dubler?

24 DR. DUBLER: No.

25 DR. CHOTI: No.

1 DR. NEWBURGER: No.

2 DR. CHANG: No.

3 DR. DEMETS: No.

4 DR. MILLER: No.

5 MS. SHULMAN: The second one is no.

6 Number three, does the device present a potential  
7 unreasonable risk of illness or injury?

8 DR. WHALEN: Dr. Choti?

9 DR. CHOTI: No.

10 DR. WHALEN: Dr. Newburger?

11 DR. NEWBURGER: No.

12 DR. CHANG: No.

13 DR. DEMETS: No.

14 DR. MILLER: No.

15 DR. MCCAULEY: No.

16 DR. DUBLER: No.

17 MS. SHULMAN: The third one is no. We now  
18 go to number four, did you answer yes to any of the  
19 above three questions? That answer is no.

20 Then we go to number five, is there  
21 sufficient information to determine that general  
22 controls are sufficient to provide reasonable  
23 assurance of safety and effectiveness?

24 DR. WHALEN: Starting with Dr. Newburger?

25 DR. NEWBURGER: Yes.

1 DR. MILLER: Yes.

2 DR. CHANG: Yes.

3 DR. WHALEN: Dr. DeMets?

4 DR. DEMETS: I will vote no.

5 DR. WHALEN: Dr. McCauley?

6 DR. MCCAULEY: Yes.

7 DR. DUBLER: Yes.

8 DR. CHOTI: Yes.

9 MS. SHULMAN: The answer to that one is

10 yes. On your sheets, you may mark whatever you

11 voted yourself. So, if the answer to that is yes,

12 it is classified into Class I.

13 So, we can skip two. We actually get to skip all

14 the way to the second page because all the rest of

15 the questions apply to Class II or Class III

16 devices.

17 Question 11 is a prescription question.

18 Can there otherwise be reasonable assurance of its

19 safety and effectiveness without restrictions on

20 its sale, distribution or use because of any

21 potentiality for harmful effect or collateral

22 measures necessary for the device? If you answer

23 yes, you are saying it is not a prescription

24 device. If you answer no, you are saying it is a

25 prescription device.



One Hundred Fifth Congress  
of the  
United States of America

AT THE FIRST SESSION

*Begun and held at the City of Washington on Tuesday,  
the seventh day of January, one thousand nine hundred and ninety-seven*

An Act

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Food and Drug Administration Modernization Act of 1997”.

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

- Sec. 1. Short title; references; table of contents.
- Sec. 2. Definitions.

TITLE I—IMPROVING REGULATION OF DRUGS

Subtitle A—Fees Relating to Drugs

- Sec. 101. Findings.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Annual reports.
- Sec. 105. Savings.
- Sec. 106. Effective date.
- Sec. 107. Termination of effectiveness.

Subtitle B—Other Improvements

- Sec. 111. Pediatric studies of drugs.
- Sec. 112. Expediting study and approval of fast track drugs.
- Sec. 113. Information program on clinical trials for serious or life-threatening diseases.
- Sec. 114. Health care economic information.
- Sec. 115. Clinical investigations.
- Sec. 116. Manufacturing changes for drugs.
- Sec. 117. Streamlining clinical research on drugs.
- Sec. 118. Data requirements for drugs and biologics.
- Sec. 119. Content and review of applications.
- Sec. 120. Scientific advisory panels.
- Sec. 121. Positron emission tomography.
- Sec. 122. Requirements for radiopharmaceuticals.
- Sec. 123. Modernization of regulation.
- Sec. 124. Pilot and small scale manufacture.
- Sec. 125. Insulin and antibiotics.
- Sec. 126. Elimination of certain labeling requirements.
- Sec. 127. Application of Federal law to practice of pharmacy compounding.

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- Sec. 128. Reauthorization of clinical pharmacology program.
- Sec. 129. Regulations for sunscreen products.
- Sec. 130. Reports of postmarketing approval studies.
- Sec. 131. Notification of discontinuance of a life saving product.

TITLE II—IMPROVING REGULATION OF DEVICES

- Sec. 201. Investigational device exemptions.
- Sec. 202. Special review for certain devices.
- Sec. 203. Expanding humanitarian use of devices.
- Sec. 204. Device standards.
- Sec. 205. Scope of review; collaborative determinations of device data requirements.
- Sec. 206. Premarket notification.
- Sec. 207. Evaluation of automatic class III designation.
- Sec. 208. Classification panels.
- Sec. 209. Certainty of review timeframes; collaborative review process.
- Sec. 210. Accreditation of persons for review of premarket notification reports.
- Sec. 211. Device tracking.
- Sec. 212. Postmarket surveillance.
- Sec. 213. Reports.
- Sec. 214. Practice of medicine.
- Sec. 215. Noninvasive blood glucose meter.
- Sec. 216. Use of data relating to premarket approval; product development protocol.
- Sec. 217. Clarification of the number of required clinical investigations for approval.

TITLE III—IMPROVING REGULATION OF FOOD

- Sec. 301. Flexibility for regulations regarding claims.
- Sec. 302. Petitions for claims.
- Sec. 303. Health claims for food products.
- Sec. 304. Nutrient content claims.
- Sec. 305. Referral statements.
- Sec. 306. Disclosure of irradiation.
- Sec. 307. Irradiation petition.
- Sec. 308. Glass and ceramic ware.
- Sec. 309. Food contact substances.

TITLE IV—GENERAL PROVISIONS

- Sec. 401. Dissemination of information on new uses.
- Sec. 402. Expanded access to investigational therapies and diagnostics.
- Sec. 403. Approval of supplemental applications for approved products.
- Sec. 404. Dispute resolution.
- Sec. 405. Informal agency statements.
- Sec. 406. Food and Drug Administration mission and annual report.
- Sec. 407. Information system.
- Sec. 408. Education and training.
- Sec. 409. Centers for education and research on therapeutics.
- Sec. 410. Mutual recognition agreements and global harmonization.
- Sec. 411. Environmental impact review.
- Sec. 412. National uniformity for nonprescription drugs and cosmetics.
- Sec. 413. Food and Drug Administration study of mercury compounds in drugs and food.
- Sec. 414. Interagency collaboration.
- Sec. 415. Contracts for expert review.
- Sec. 416. Product classification.
- Sec. 417. Registration of foreign establishments.
- Sec. 418. Clarification of seizure authority.
- Sec. 419. Interstate commerce.
- Sec. 420. Safety report disclaimers.
- Sec. 421. Labeling and advertising regarding compliance with statutory requirements.
- Sec. 422. Rule of construction.

TITLE V—EFFECTIVE DATE

- Sec. 501. Effective date.

SEC. 2. DEFINITIONS.

In this Act, the terms “drug”, “device”, “food”, and “dietary supplement” have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

“(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.”.

(c) SECTION 515(d).—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by adding after and below clause

(ii) the following:

“In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.”; and

(2) by adding after paragraph (5) (as added by section 202(2)) the following:

“(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

“(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

“(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

“(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

“(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

“(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.”.

**SEC. 206. PREMARKET NOTIFICATION.**

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), in the matter preceding paragraph (1), by adding after "report to the Secretary" the following: "or person who is accredited under section 523(a)"; and

(2) by adding at the end the following subsections:

"(1) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

"(m)(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register.

"(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted."

(b) SECTION 513(f).—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

"(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health)."

(c) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 205(b), is amended—

(1) in subparagraph (A)(ii)—

(A) in subclause (I), by striking "clinical data" and inserting "appropriate clinical or scientific data" and by inserting "or a person accredited under section 523" after "Secretary"; and

(B) in subclause (II), by striking "efficacy" and inserting "effectiveness"; and

(2) by adding at the end the following:

“(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).”.

**SEC. 207. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.**

Section 513(f) (21 U.S.C. 360c(f)), as amended by section 206(b), is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking “paragraph (2)” and inserting “paragraph (3)”; and

(B) in the last sentence, by striking “paragraph (2)” and inserting “paragraph (2) or (3)”; and

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

“(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

“(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

“(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

“(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.”.

**SEC. 208. CLASSIFICATION PANELS.**

Section 513(b) (21 U.S.C. 360c(b)) is amended by adding at the end the following:

“(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

“(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

TAB 7

Scar Management - Unit Sales Trend  
TOTAL U.S - F/D/MX

	Calendar Year 1997 ending Dec 28, 1997	Calendar Year 1998 ending Dec 27, 1998	Calendar Year 1999 ending Dec 26, 1999	Calendar Year 2000 ending Dec 24, 2000	Calendar Year 2001 ending Dec 23, 2001	Latest 52 Weeks Ending Jun 16, 2002
<b>Unit Sales</b>						
<b>Scar Management</b>	38,680	120,062	111,839	201,381	489,848	787,895
<b>Scar Management Pads</b>	27,579	64,913	31,670	79,186	242,351	301,912
CURAD SCAR THERAPY 1.5 INCH X 2.75 INCH SCAR TREATMENT PAD 21CT 7214002063	0	0	0	0	135,762	204,691
SPENCO 2ND SKIN 1 INCH X 4 INCH SCAR TREATMENT ADHESIVE PAD 1CT 3847250432	0	0	556	18,436	26,308	25,333
SPENCO 2ND SKIN 3 INCH X 4 INCH SCAR TREATMENT ADHESIVE PAD SILICO 1CT 3847250433	0	0	823	38,696	61,596	57,995
CLINICEL 2.8 IN X 2.8 IN SCAR TREATMENT GEL FILLED CUSHION 1CT 5802010101	0	372	2,544	1,301	4,690	2,937
CLINICEL 2.8 IN X 5.5 IN SCAR TREATMENT GEL FILLED CUSHION 1CT 5802010201	0	116	910	831	3,577	2,500
REJUVENESS 1.6 IN X 3.2 IN BANDAGE STRIP SILICONE 1CT 3504504800	22,990	52,223	22,021	13,889	2,601	1,857
REJUVENESS 1.6 IN X 4.8 IN BANDAGE STRIP SILICONE 1CT 3504504120	2,868	10,368	4,295	4,001	587	598
REJUVENESS 1.6 IN X 7.2 IN BANDAGE STRIP SILICONE 1CT 3504504180	946	1,500	334	60	15	161
REJUVENESS 1.6 IN X 10 IN BANDAGE STRIP SILICONE 1CT 3504504250	213	93	167	163	158	242
REJUVENESS 3 IN X 4.8 IN BANDAGE STRIP SILICONE 1CT 3504507120	563	240	21	121	12	1
CICA CARE 2.375 INCH X 5 INCH SCAR TREATMENT PATCH 1CT 4056512036	0	0	0	1,689	7,046	4,058
SIL K 1.6 IN X 4 IN SCAR TREATMENT PATCH 1CT 9972848201	0	0	0	0	0	1,111
SIL K 1.6 IN X 7 IN SCAR TREATMENT PATCH 1CT 9972848302	0	0	0	0	0	427
<b>Scar Management Ointments</b>	11,101	55,149	80,169	122,195	247,498	485,984
MEDERMA FIRST AID REMEDY GEL 0.7OZ 0259030320	0	0	0	3,157	98,364	222,244
MEDERMA FIRST AID REMEDY GEL 1.76OZ 0259030350	11,101	55,149	76,717	108,585	137,696	232,374
SPENCO 2ND SKIN FIRST AID REMEDY GEL 0.5OZ 3847240961	0	0	0	0	0	13,623
CARRINGTON CARRASYN HYDROGEL FIRST AID REMEDY GEL 3OZ 5330301030	0	0	3,452	10,453	11,437	17,742
<b>Unit Sales % Chg Yago</b>						
<b>Scar Management</b>	NA	210.4	(6.8)	80.1	143.2	191.3
<b>Scar Management Pads</b>	NA	135.4	(51.2)	150.0	206.1	130.6
CURAD SCAR THERAPY 1.5 INCH X 2.75 INCH SCAR TREATMENT PAD 21CT 7214002063	NA	NA	NA	NA	NA	618.9
SPENCO 2ND SKIN 1 INCH X 4 INCH SCAR TREATMENT ADHESIVE PAD 1CT 3847250432	NA	NA	NA	3,217.7	42.7	(5.7)
SPENCO 2ND SKIN 3 INCH X 4 INCH SCAR TREATMENT ADHESIVE PAD SILICO 1CT 3847250433	NA	NA	NA	4,600.1	59.2	0.6
CLINICEL 2.8 IN X 2.8 IN SCAR TREATMENT GEL FILLED CUSHION 1CT 5802010101	NA	NA	583.0	(48.9)	260.5	17.3
CLINICEL 2.8 IN X 5.5 IN SCAR TREATMENT GEL FILLED CUSHION 1CT 5802010201	NA	NA	680.9	(8.7)	330.5	45.5
REJUVENESS 1.6 IN X 3.2 IN BANDAGE STRIP SILICONE 1CT 3504504800	NA	127.2	(57.8)	(36.9)	(81.3)	(72.1)
REJUVENESS 1.6 IN X 4.8 IN BANDAGE STRIP SILICONE 1CT 3504504120	NA	261.6	(58.6)	(6.8)	(85.3)	(62.4)
REJUVENESS 1.6 IN X 7.2 IN BANDAGE STRIP SILICONE 1CT 3504504180	NA	58.6	(77.7)	(82.0)	(75.3)	431.8
REJUVENESS 1.6 IN X 10 IN BANDAGE STRIP SILICONE 1CT 3504504250	NA	(56.3)	78.9	(2.6)	(3.1)	46.3
REJUVENESS 3 IN X 4.8 IN BANDAGE STRIP SILICONE 1CT 3504507120	NA	(57.3)	(91.5)	488.3	(90.5)	(97.1)
CICA CARE 2.375 INCH X 5 INCH SCAR TREATMENT PATCH 1CT 4056512036	NA	NA	NA	NA	317.3	(22.9)
SIL K 1.6 IN X 4 IN SCAR TREATMENT PATCH 1CT 9972848201	NA	NA	NA	NA	NA	NA
SIL K 1.6 IN X 7 IN SCAR TREATMENT PATCH 1CT 9972848302	NA	NA	NA	NA	NA	NA
<b>Scar Management Ointments</b>	NA	396.8	45.4	52.4	102.5	248.3
MEDERMA FIRST AID REMEDY GEL 0.7OZ 0259030320	NA	NA	NA	NA	3,015.3	790.4
MEDERMA FIRST AID REMEDY GEL 1.76OZ 0259030350	NA	396.8	39.1	41.5	26.8	121.8
SPENCO 2ND SKIN FIRST AID REMEDY GEL 0.5OZ 3847240961	NA	NA	NA	NA	NA	NA
CARRINGTON CARRASYN HYDROGEL FIRST AID REMEDY GEL 3OZ 5330301030	NA	NA	NA	202.8	9.4	81.0

**TAB 8**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

GENERAL AND PLASTIC SURGERY DEVICES PANEL  
OF THE MEDICAL DEVICES ADVISORY COMMITTEE

OPEN SESSION

60th Meeting

Monday, July 8, 2002

1:20 p.m.

Gaithersburg Holiday Inn  
Two Montgomery Village Avenue  
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.  
735 8th Street, S.E.  
Washington, D.C. 20003-2802  
(202) 546-6666

1 DR. MILLER: Yes.

2 DR. CHANG: Yes.

3 DR. WHALEN: Dr. DeMets?

4 DR. DEMETS: I will vote no.

5 DR. WHALEN: Dr. McCauley?

6 DR. MCCAULEY: Yes.

7 DR. DUBLER: Yes.

8 DR. CHOTI: Yes.

9 MS. SHULMAN: The answer to that one is  
10 yes. On your sheets, you may mark whatever you  
11 voted yourself. So, if the answer to that is yes,  
12 it is classified into Class I.

13 So, we can skip two. We actually get to skip all  
14 the way to the second page because all the rest of  
15 the questions apply to Class II or Class III  
16 devices.

17 Question 11 is a prescription question.  
18 Can there otherwise be reasonable assurance of its  
19 safety and effectiveness without restrictions on  
20 its sale, distribution or use because of any  
21 potentiality for harmful effect or collateral  
22 measures necessary for the device? If you answer  
23 yes, you are saying it is not a prescription  
24 device. If you answer no, you are saying it is a  
25 prescription device.

TAB 9

**U.S. Food and Drug Administration Center for Devices and Radiological Health**

## Releasable 510(k) Search

**69 records met your criteria**

Product Code: *mda*



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#	Device Name	Applicant Name	510(K) Number	Decision Date
1	<u>MEDTRADE PRODUCTS SILICON</u>	MEDTRADE PRODUCTS LTD.	K014036	02/14/2002
2	<u>GELZONE</u>	IMPLANTECH ASSOCIATES, IN	K013732	02/07/2002
3	<u>CONFORM SHEETING, MODEL I</u>	IMPLANTECH ASSOCIATES, IN	K012419	10/24/2001
4	<u>ENSIL FABRIC</u>	GOTTFRIED MEDICAL, INC.	K010675	05/30/2001
5	<u>ACTIVHEAL SCAR MANAGEMENT</u>	ADVANCED MEDICAL SOLUTION	K010245	04/25/2001
6	<u>MEDTRADE PRODUCTS SILICON</u>	MEDTRADE PRODUCTS LTD.	K003979	03/19/2001
7	<u>EPI-DERM SILICONE GEL SHE</u>	BIODERMIS CORP.	K003948	01/29/2001
8	<u>KELO-COTE TOPICAL GEL</u>	ADVANCED BIO-TECHNOLOGIES	K002488	01/05/2001
9	<u>OLEEVA FOAM</u>	BIO MED SCIENCES, INC.	K002109	08/31/2000
10	<u>BLAINE SCARCARE PATCH</u>	BLAINE LABS, INC.	K001608	07/25/2000
11	<u>SPECTRUM DESIGNS SPECTRAG</u>	SPECTRUM DESIGNS, INC.	K992522	10/26/1999
12	<u>SCAREASE SHEETS &amp; SCAREAS</u>	PILLAR SURGICAL	K991970	10/25/1999
13	<u>SOOTHE &amp; SMOOTH SCAR CARE</u>	LIBRARY MEDICAL, INC.	K991312	08/20/1999
14	<u>SKIN 2 FORTE SILICONE SHE</u>	UNITED HOSPITAL TECHNOLOG	K990651	08/13/1999
15	<u>SILGEL STC-S</u>	NAGOR LTD.	K984029	08/05/1999
16	<u>CICACARE ROLL-ON GEL-SCAR</u>	SMITH & NEPHEW, INC.	K991968	07/30/1999
17	<u>SCARAID SILICONE GEL SHEE</u>	BIODERMIS CORP.	K992146	07/30/1999
18	<u>CICACARE MANAGEMENT FOR S</u>	SMITH & NEPHEW, INC.	K991957	07/20/1999
19	<u>TENDER TOUCH SILICONE GEL</u>	CAPITAL MARKETING TECHNOL	K991478	06/21/1999
20	<u>ADVANCED MEDICAL SOLUTION</u>	ADVANCED MEDICAL SOLUTION	K991630	06/11/1999
21	<u>EPI-FOAM SILICONE SHEETIN</u>	BIODERMIS CORP.	K991604	06/09/1999
22	<u>NEARLY ME RETOUCH SILICON</u>	CAPITAL MARKETING TECHNOL	K984213	04/14/1999
23	<u>SCAREASE &amp; SCAREASE ADHES</u>	SCAREASE, INC.	K984115	02/12/1999
24	<u>SILON SCAR STRIPS</u>	BIO MED SCIENCES, INC.	K982036	08/06/1998
25	<u>KELOCATE SHEETING</u>	ALLIED BIOMEDICAL CORP.	K982051	08/05/1998
26	<u>SPENCO SILICONE GEL SHEET</u>	SPENCO MEDICAL CORP.	K981902	06/25/1998
27	<u>EVANESCE SCAR MANAGEMENT</u>	MEDICAL SCIENTIFIC, INC.	K981387	06/10/1998
28	<u>SKAR-KARE SHEET</u>	LIFE MEDICAL SCIENCES, IN	K980563	05/20/1998
29	<u>REJUVENESS</u>	REJUVENESS PHARAMCEUTICAL	K974380	04/03/1998
30	<u>SILGEL TOPICAL GEL SHEET</u>	NAGOR LTD.	K974172	03/30/1998
31	<u>KMC "NEWSKIN"</u>	KMC INTL. CO.	K974143	03/27/1998
32	<u>MEPIFORM ADHERENT SILICON</u>	SCA MOLNLYCKE	K974354	03/05/1998
33	<u>SKAR-KARE</u>	TARGET HEALTH, INC.	K973271	11/19/1997
34	<u>KELOCOTE SCAR GEL AND KEL</u>	HANSON MEDICAL, INC.	K973572	10/21/1997
35	<u>PMT NEW BEGINNINGS GELSHA</u>	PMT CORP.	K972597	10/01/1997
36	<u>SCAR CARE</u>	TARGET HEALTH, INC.	K971009	07/29/1997
37	<u>MEDICAL Z, S.A. MEDIGEL Z</u>	MEDICAL Z, S.A.	K971916	07/29/1997

38	<u>DEGANIA SILICONE SIL-K</u>	DEGANIA SILICONE, LTD.	K971482	06/24/1997
39	<u>SCAR HEAL</u>	SPECIALTY SYSTEMS, INC.	K971468	06/10/1997
40	<u>SPECTRUM DESIGNS SPECTRAG</u>	SPECTRUM DESIGNS, INC.	K970702	05/12/1997
41	<u>IMPLATECH RP MEDICAL GRAD</u>	IMPLANTECH ASSOCIATES, IN	K964846	02/12/1997
42	<u>NOVAGEL SILICONE GEL SHEE</u>	BRENNEN MEDICAL, INC.	K963128	12/05/1996
43	<u>DURASIL (MODIFICATION)</u>	THE S. F. GROUP, INC.	K961410	09/03/1996
44	<u>MENTOR H/S SILICONE GEL S</u>	MENTOR CORP.	K962013	08/22/1996
45	<u>SILGEL TOPICAL GEL SHEET</u>	ROFIL MEDICAL USA, INC.	K960254	04/02/1996
46	<u>STERILIZED TRI BLOCK POLY</u>	SILIPPOS, INC.	K955664	02/28/1996
47	<u>KELOCOTE</u>	ALLIED BIOMEDICAL CORP.	K954413	11/29/1995
48	<u>DURASIL</u>	THE S. F. GROUP, INC.	K952612	11/22/1995
49	<u>SILK*SKIN SCAR TREATMENT</u>	SILK*SKIN CARE CO.	K953420	09/26/1995
50	<u>SILON SILICONE TEXTILE CO</u>	BIO MED SCIENCES, INC.	K952546	08/07/1995

**CDRH** **FDA** **Center for Devices and Radiological Health**

*(Database Updated August 5, 2002)*

**U.S. Food and Drug Administration - Center for Devices and Radiological Health**

# Releasable 510(k) Search

**69 records met your criteria**

Product Code: *mda*

**1 2**

graphics version

#	Device Name	Applicant Name	510(K) Number	Decision Date
51	<u>SILON SILICONE FOAM SHEET</u>	BIO MED SCIENCES, INC.	K946362	07/13/1995
52	<u>SILON(R) SILICONE THERMOP</u>	BIO MED SCIENCES, INC.	K945892	03/03/1995
53	<u>SKIN NEUVEAU SCAR TREATME</u>	PURITAS HEALTH CARE, INC.	K942339	11/28/1994
54	<u>TRI BLOCK POLUMER GEL SHE</u>	SILIPOS, INC.	K942695	11/10/1994
55	<u>SILK*SKIN SCAR TREATMENT</u>	PURITAS HEALTH CARE, INC.	K941197	08/11/1994
56	<u>EPI-DERM SILICONE GEL SHE</u>	BIODERMIS CORP.	K942156	06/13/1994
57	<u>NOVAGEL SILICONE GEL SHEE</u>	BRENNEN MEDICAL, INC.	K941125	05/31/1994
58	<u>MORELLE SOS TREATMENT, MO</u>	PITT ENTERPRISES (SILICON	K933811	05/12/1994
59	<u>JOBSKIN CONTINUING CARE</u>	JOBST INSTITUTE, INC.	K925583	04/04/1994
60	<u>PMT SILICONE SHEETING</u>	PMT CORP.	K935499	02/10/1994
61	<u>HASKON MEDICAL GRADE SHEE</u>	HASKON INTL., INC.	K934829	02/03/1994
62	<u>CICA-CARE SILICONE GEL SH</u>	SMITH & NEPHEW UNITED, IN	K935803	02/03/1994
63	<u>SILICONE GEL SHEETING</u>	SILIPOS, INC.	K932048	01/07/1994
64	<u>SILON SILICONE GEL SHEET</u>	BIO MED SCIENCES, INC.	K932214	01/06/1994
65	<u>PMT(R) SILICONE GEL SHEET</u>	PMT CORP.	K930409	09/01/1993
66	<u>SIL-K</u>	DEGANIA SILICONE, LTD.	K914701	01/31/1992
67	<u>SILICONE GEL SHEETING</u>	CUI CORP.	K913140	09/30/1991
68	<u>VINYL SILICONE ELASTOMER</u>	CROWN DELTA CORP.	K901990	09/14/1990
69	<u>SILICONE ELASTOMER PUTTY</u>	CROWN DELTA CORP.	K901991	09/14/1990

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*(Database Updated August 5, 2002)*

TAB 10

# Topical silicone gel: A new treatment for hypertrophic scars

Sang Tae Ahn, MD, William W. Monafo, MD, and Thomas A. Mustoe, MD, St. Louis, Mo., and Seoul, S. Korea

*A prospective, controlled clinical trial was designed to assess the efficacy of a new treatment of hypertrophic scars. Silicone gel sheeting was applied to 14 hypertrophic scars in 10 adults for 8 weeks. The treated scars and untreated, mirror-image or adjacent control scars were photographed, biopsy specimens were taken, and they were measured elastometrically before and after treatment. Photography and elastometry were repeated 4 weeks after treatment was discontinued. All the scars that had been treated for at least 12 hours a day were improved clinically after 4 weeks. There was further clinical improvement during the second 4 weeks of treatment. Elastometrically, the treated scars were improved significantly at 4, 8, and 12 weeks, compared with both their own treatment value and the control scars ( $p < 0.05$ ). Control scars were unchanged elastometrically. Clinical improvement persisted for at least 4 weeks after treatment was discontinued. The silicone gel sheeting was well tolerated, except for occasional transient rashes or superficial maceration—both of which resolved promptly when treatment was withdrawn. There was no histologic evidence of inflammation or foreign body reaction suggesting that silicone had entered the treated tissues. We conclude that this simple method of treating hypertrophic scar is efficacious, even in relatively chronic cases. The mechanism of action of silicone gel, which is apparently not related to compression, remains to be determined. (SURGERY 1989;106:781-7.)*

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HYPERTROPHIC SCARS, ESPECIALLY when they occur after extensive, deep burns, are difficult to treat and are presently not consistently preventable. Elastic compression garments, which were introduced about 25 years ago, are now widely or even routinely used for both the prevention and treatment of hypertrophic scars, which develop with monotonous regularity after deep burns, but these garments are uncomfortable, require prolonged and near-continuous use for many months, and, most important, are not consistently efficacious.<sup>1</sup> Although there is histologic evidence that prolonged scar compression tends to normalize and elongate the disordered whorls and clumps of collagen that microscopically characterize

hypertrophic scar, the available clinical evidence is anecdotal, because no controlled, prospective evaluation of elastic compression has been done.<sup>2</sup>

Previous reports from the United Kingdom suggested that the application of sheets of silicone gel over hypertrophic burn scars was regularly attended by softening and clinical improvement, but these studies were also uncontrolled.<sup>3-5</sup> In view of the frequency of this distressing and unresolved clinical problem, we believed it was useful and important to conduct this prospective, controlled trial to assess the efficacy of silicone gel in the treatment of hypertrophic scars.

## MATERIAL AND METHODS

Silicone gel sheets, 3.5 mm in thickness (Q7-9119, Silastic gel sheeting; Dow Corning Corp., Midland, Mich.), were applied to 14 hypertrophic scars in 10 adults for 8 consecutive weeks. Chemically the material is a cross-linked dimethyl and vinyl endblocked polydimethylsiloxane polymer with no added filler, reinforced with polyethyleneterephthalate mesh for strength. The general formula follows:

Presented at the Forty-sixth Annual Meeting of the Central Surgical Association, Banff, Alberta, Canada, March 8-11, 1989.

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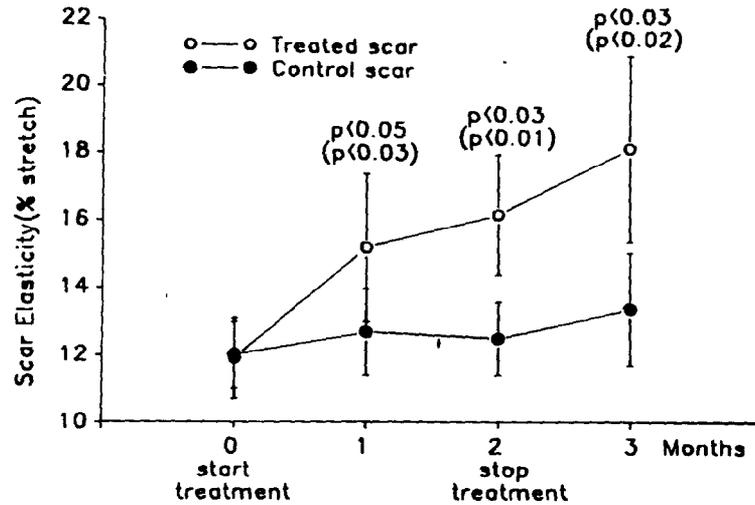
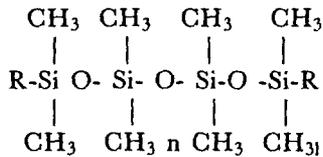


Fig. 1. Elastometric data (mean ± SEM). Each scar was measured six times at each interval and the results were averaged. Treated scars were more elastic at all posttreatment intervals compared with pretreatment evaluation. Control scars were unchanged. Treated scars were also more elastic than control scars at all intervals. The *p* values within parentheses refer to comparisons between treated and control groups at the same interval. The *p* values given without parentheses refer to comparisons of scars before treatment within the treated group (Student paired *t* test).



After informed consent was obtained, a 6 × 7 cm test area of scar was selected so that an untreated control area of similar dimensions and appearance was available from the same or paired anatomic site. The sheets were held in place by either a crepe bandage, gauze and adhesive tape, an elastic bandage, or an elastic compression garment, in those who were already wearing one on entrance to the study. The patients were advised to wear the gel for at least 12 hours a day, preferably 24 hours a day, and to briefly remove and clean it and the scar once or twice daily. To ensure that the gel was placed in the same location, water-insoluble ink was used to outline the rectangular test areas.

Before beginning the gel treatment, the test and control scars were photographed, biopsy specimens were taken, and they were measured elastometrically. The photographs and elastometric measurements were repeated at 4- and 8-week intervals, after which the treatment was stopped. Punch biopsy specimens were again obtained from test and control scars at this time. The photographs and elastometric measurements were repeated 4 weeks after the cessation of treatment. Clinical

effects were evaluated by both the patient and the investigators at the completion of treatment and again 4 weeks later.

**Photography.** Test and control areas were photographed on the same standard blue background. A color-control strip (Eastman Kodak Company, Rochester, N.Y.) was included in the field. An Olympus 35 mm OM II camera with a 50 mm macro lens, a T-32 electronic flash (Olympus Corporation, Woodbury N.Y.), and Kodachrome ASA 64 film were used. The lens aperture, exposure time, and subject distance were kept constant.

**Elastometry.** Objective measurements of scar elasticity were made with a hand-held elastometer, which we have described previously.<sup>6</sup> The device uses a constant-tension spring and an accurate strain gauge to distract two adjacent points of skin. The distance of distraction is measured and expressed as the percent stretch, according to the formula: % Stretch = Amount of distraction (mm) × 100/10 mm (original distance). As we have noted previously, this measurement closely correlates linearly with the reciprocal of Young's modulus, the classic descriptor of cutaneous elasticity.<sup>6</sup> The stretch of normal human skin is between 30% and 42%, with some intersubject variability, the SD being about 7% of the mean. All the scars in this study were considerably less elastic than normal (Fig. 1).

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Table I. Patient data

Patient			Scar			Silicone gel			Evaluation			
Case No.	Age (yr)	Sex	Cause	Mo	Site	Hr/day	Mo	Appli- cation	Score	Satisfaction	Compli- cation	Desire to continue treatment
1	78	F	Burn	5	Back	12	2	GT	4/4	Good	Soreness	Yes
2	37	M	Burn	23	Leg	18	2	CB	1/3	Average	Rash	Yes
3				25	Arm	18	2	CB	1/3	Average	Rash	Yes
4	57	M	Burn	2	Leg	18	2	GT	3/3	Good		Yes
5				2	Arm	18	2	GT	2/5	Average	Rash	Yes
6	33	M	Burn	13	Neck	24	2	EB	6/6	Good		Yes
7				14	Wrist	24	<1	EB	4/6	Average	Ulcer	Yes
8	19	M	Burn	7	Leg	24	2	J	4/5	Good	Ulcer	Yes
9				7	Wrist	24	<1	J	4/6	Good	Ulcer	Yes
10	21	F	Spider bite	9	Leg	24	2	CB	5/5	Good		Yes
11	53	M	Burn <sup>a</sup>	2	Flank	12	2	GT	2/3	Good		Yes
12	76	M	Burn	5	Arm	6	2	CB	0/3	Poor		No
13	43	F	Burn	48	Neck	5	1	GT	0/4	Poor		No
14	39	F	Incision and drainage	12	Back	4	2	GT	0/3	Poor	Itching	No

Legend GT, Gauze and tape; CB, crepe bandage; EB, elastic bandage; J, elastic compression garment.

**Biopsy specimens.** Two millimeter punch biopsy specimens that included the subcutaneous fat were taken from both the test and control scars with local infiltration anesthetic with 1% lidocaine. The biopsy specimens were carefully cut perpendicular to the scar surface in the hope that this would permit microscopic measurement of the thickness of the epidermis and the dermis on the hematoxylin-eosin-stained histologic sections, which were also rated by other criteria including vascularity, inflammatory changes, numbers of fibroblasts, and evidence of the presence of silicone in the tissue.

**Clinical evaluation.** Test and control scars were rated at the end of treatment (8 weeks) according to the following items: scar texture, color, thickness, durability, presence of pruritus, and (if applicable) the permissible range of motion. If, for example, four items had been noted as consequential before treatment and three of them were improved after treatment, the scar was scored 3/4. The patients were also asked to assess the result as good, average, poor, or unacceptable. Whether they wished to continue the treatment or apply the gel to other scars was also noted.

## RESULTS

The patients ranged in age from 19 to 78 years. Patients 1 and 12 were black; the remaining patients were white. All but two patients had sustained burns. One patient had a spider bite and the other had a keloid that had formed after incision and drainage of an abscess (Table I). The age of the scars ranged from 2 months

to 4 years. The silicone gel was held in place by a crepe bandage on the legs and arms. Gauze and adhesive tape was used for scars on areas with broad surfaces, such as the back, flank, or thigh. Compression garments were used for the thigh and wrist in the one patient who was still wearing them. An elastic bandage was used in the neck and wrist of one other patient.

Eleven of the 14 scars were treated for at least 12 hours each day. At the completion of treatment, all 11 of these scars were improved. Subjectively, the degree of satisfaction ranged from average to good; the scar scores ranged from 1/3 to 6/6. All of these patients wanted to continue treatment with the silicone gel (Table I).

Efficacy did not appear to be related to patient age, scar age, scar location, or the method of attachment.

The three scars that had been treated for less than 12 hours a day showed no evidence of clinical improvement; these patients discontinued the treatment after 1 or 2 months.

**Complications.** Superficial maceration of the scar occurred on three occasions. In every instance the gel had been applied beneath a compression garment or an elastic bandage. In one patient treatment was stopped prematurely after 1 month because of superficial skin erosion.

A rash developed beneath the gel in three treated scars; these were thought to be the result of poor local hygiene. One patient complained of pruritus beneath the gel. All side effects were minor and transient, however, and were promptly relieved by

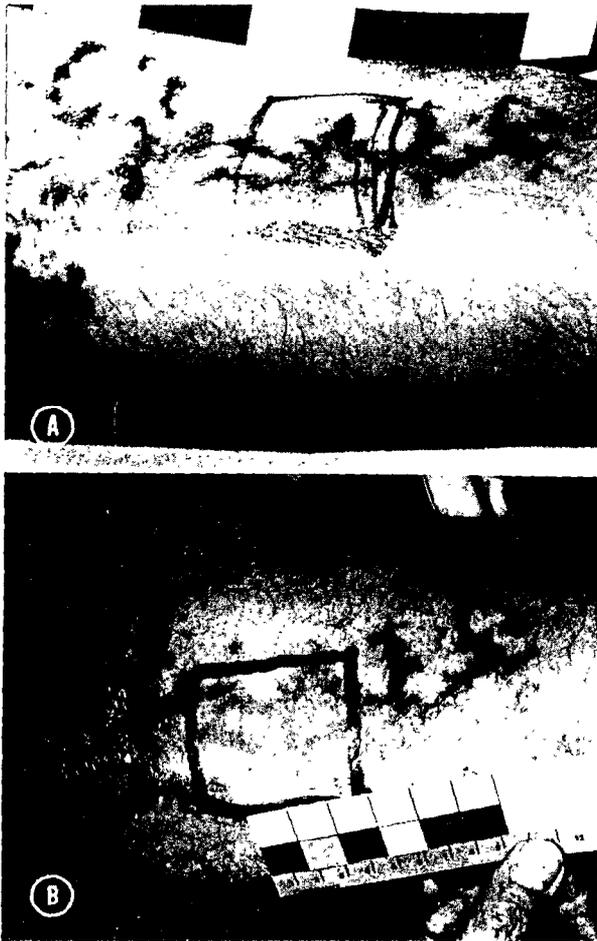


Fig. 2. Case 4. A, Before treatment. B, After 8 weeks of treatment

temporary removal of the gel or by decreasing the wearing time to 12 hours.

**Elastometry.** Six measurements were taken from each scar and averaged. Elasticity was increased in eight and nine scars treated for at least 12 hours a day for 2 months but was unchanged in most of the control scars and in the five scars that were treated for less than 12 hours daily or less than 1 month.

The elasticity of the treated scars was increased after 4 and 8 weeks of treatment compared with the pretreatment value (Student paired *t* test) (Fig. 1). The differences in elasticity between control and treated scars were also significant at 4 and 8 weeks (Fig. 1). The increase in elasticity of treated scars was still evident 1 month after treatment had ceased. Because the control scars were unchanged from their pretreatment value at all intervals, spontaneous maturation had evidently not occurred during the 12-week study interval.

**Biopsy specimens.** We were unable to measure scar thickness consistently in these small biopsy specimens because the subcutaneous fat that marked the deep dermal margin usually had become detached from the reticular dermis during the processing of the samples and because of the difficulty in obtaining precise perpendicular histologic cuts. There was no histologic evidence of inflammation or foreign body reaction in the treated scars. There was no significant change in their vascularity, the presence of rete pegs, or the number of fibroblasts or inflammatory cells per high-power field, when the slides were examined in blinded fashion.

### CASE REPORTS

**Case 4.** This 57-year-old man had a hypertrophic scar on the right thigh caused by a burn injury sustained 2 months previously. The scar became distinctly flatter, softer, and paler after 1 month of treatment and had regressed nearly completely by 2 months. His scar score was 3/3; the elastometric measurement of the treated scar had increased from  $7.7 \pm 1.3$  to  $14.0 \pm 0.8$ . The scar was still relatively flat, soft, and pale 1 month after treatment was stopped (Fig. 2).

**Case 6.** A 33-year-old man had a hypertrophic, contracted scar on the anterior portion of the neck as a result of a flame burn that had been sustained 13 months previously. The scar was red, hard, thick, and tender. It was susceptible to frequent breakdown. Neck extension was limited. After 8 weeks of treatment, the scar score was 6/6. The elastometric measurement had increased from  $15.2 \pm 1.4$  to  $26.8 \pm 1.6$ . Improvement was still present 1 month after cessation of treatment.

**Case 8.** This 19-year-old man has sustained a flame burn on his right thigh 7 months previously. The scar had been treated with an elastic compression garment without improvement. Two months after treatment with the silicone gel, the scar was softer and flatter and caused less discomfort (Fig. 3). The elastometric measurements were not significantly different, however.

**Case 10.** This 21-year-old woman had sustained a brown recluse spider bite in the left popliteal area 9 months previously. The hypertrophic scar had been treated with elastic compression without improvement. After 2 months of treatment with silicone gel, the scar was softer, flatter, paler, and more durable. The pruritus had subsided. The scar score was 5/5. The elastometric measurement had increased from  $6.4 \pm 0.2$  to  $9.8 \pm 0.5$ . Improvement was still present 1 month after treatment was discontinued.

### DISCUSSION

Hypertrophic scars characteristically form within the first 6 to 8 weeks after epithelialization has occurred.<sup>7</sup> During the subsequent "maturation" process, which lasts 2 or more years, partial or complete resolution typically occurs. Presumably, effective therapy would significantly alter this time course.<sup>8</sup>

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The present data clearly demonstrate that measurable clinical improvement results from the relatively short-term use of the Silastic gel on hypertrophic scar. There was both subjective and objective benefit after only 4 weeks in those patients who were able to wear the gel for at least 12 hours daily. Although the number of patients is small and the data must therefore be considered preliminary, it was also encouraging that benefit appeared to occur irrespective of the age of the scar and there was improvement in three scars that had failed to respond previously to compression garments.

Several important clinical questions are still yet to be answered. For example, there were no children in the study. Because children are generally recognized to have a greater propensity to develop scar hypertrophy, their response to the gel clearly needs investigation. It also remains to be determined whether the gel has a discernible effect in preventing hypertrophy if it is worn during the early phase of scar maturation (that is, beginning shortly after epithelialization has occurred). It also remains to be determined whether most patients will be able to tolerate wearing the gel over much more extensive scars than the small ones we have treated.

The mode of action of silicone gel is unknown. Quinn et al.<sup>4</sup> measured the pressures obtained at the scar surface beneath the gel, which was held in position in various ways (crepe bandage, adhesive tape, etc.). They recorded pressures between 1 and 12.8 mm Hg. The higher values, which may be sufficient to reduce some hypertrophic scars, were found infrequently and inconsistently. They concluded that pressure is not required for therapeutic effects. From other observations, they also concluded that changes in scar surface temperature or oxygen tension or the water vapor transmissivity of the gel were unrelated to the therapeutic effect. Two of our patients used elastic compression garments to secure the gel in place. Improvement occurred only in the scars treated beneath the gel (Fig. 3). Our data therefore tend to confirm that pressure is not required for a therapeutic effect. We found no histologic evidence that silicone had entered the scar, so a direct chemical reaction between gel and scar seems unlikely.

Hypertrophic scars are most frequently treated with compression therapy, a modality that has several serious disadvantages: (1) scars older than 6 to 12 months do not respond or respond poorly; (2) the elastic garments, which are uncomfortable, must be worn for a minimum of 9 months, the best results occurring with near-24-hour use; and (3) effective pressure (25 to 40 mm Hg) is not readily achieved in several important anatomic areas or during movement. Finally, the true response frequency of compression therapy is unknown,

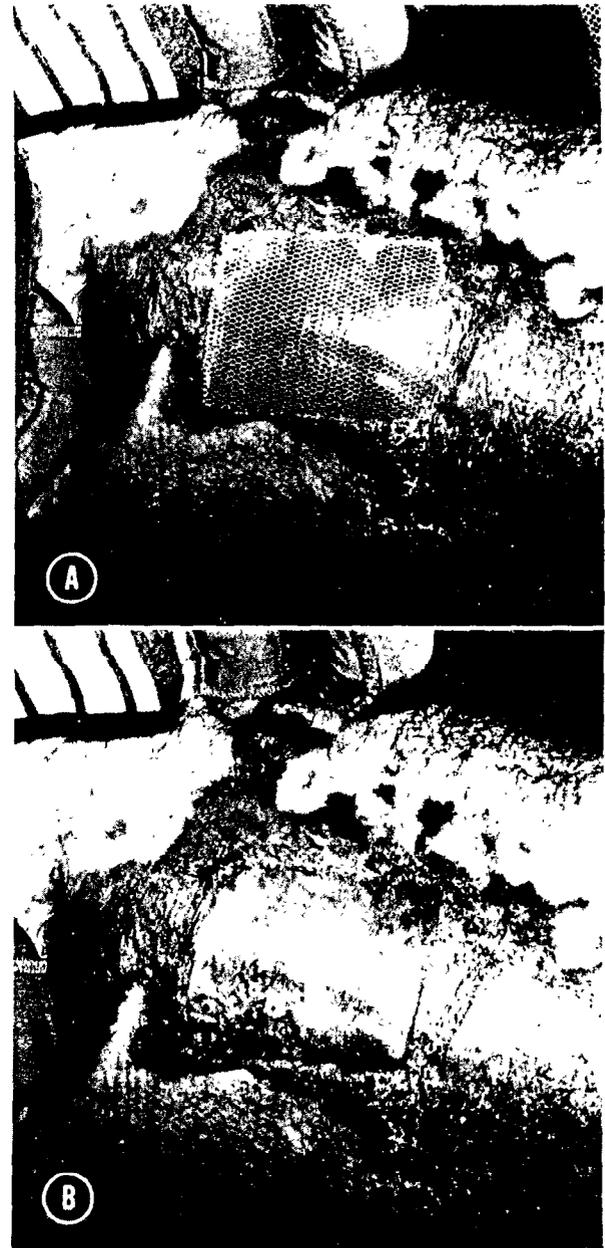


Fig. 3. Case 8. A, The gel is in place on the thigh scar. B, After 2 months, scar flattening is apparent.

because a controlled, prospective study has not been done despite its wide use for this purpose.

We made a concerted effort to obtain reliable color photographic documentation of the temporal changes in the scars, but the photographs do not consistently depict the impressive flattening that was observed clinically. It should be noted that, although flattening and softening of the scar did occur consistently, scar hyperemia persisted in many, if not most, instances.

In conclusion, 14 hypertrophic scars were treated with topically applied silicone gel. The scars that were treated for at least 12 hours a day for 2 months were improved, both clinically and as measured objectively by their elasticity. Improvement persisted 1 month after treatment had ceased. We found no histologic evidence of silicone leakage into the scars. Side effects were minor and resolved promptly. The mechanism of action of silicone gel is unclear and requires further investigation.

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#### DISCUSSION

**Dr. William R. Clark, Jr.** (Syracuse, N.Y.). The report addresses the control of hypertrophic scars, which is a major issue for every survivor of a significant thermal injury and which physicians as a group treat, if not with diligent neglect, at least very passively. It is a thought-provoking paper and deserves more attention than we usually give to preliminary reports.

The manuscript does not document how the control areas were treated. I wonder if they were covered with a pad of similar dimensions but with different compliances and different surface characteristics? It might add some validity to the observations stated and might help you be sure that you were not just observing a pressure phenomenon.

It also might be easier to interpret the results if the scars that were studied had been stratified in time to healing, whether they were in a grafted area or an area that healed spontaneously, and also stratified by the age and race of the patient.

The manuscript stated that 11 of the 14 scars studied were on an extremity or on the neck. These are anatomic sites where it is difficult to control for the tissue tension changes that result from normal motion.

Conventional wisdom would hold that for pressure therapy to be effective in modifying hypertrophic scars, in terms of their size and compliance, the pressure garments and appli-

ances need to be worn continuously, except when the patient is bathing or exercising vigorously. Dr. Mustoe, do you have any explanation for the apparent threshold effect you observed, in that these silicone gels were effective when worn for at least 12 hours a day and not less?

Finally, would you speculate on the mechanisms by which this silicone gel seems to be effective?

**Dr. Vatche H. Ayvazian** (St. Louis, Mo.). Have you been able to get the same success in difficult scars, scars that are rich in collagen and are not as vascular as some of the scars that we saw in the pictures? So, my question is about the types of the scars, about their collagen content and whether they were uniform or whorl-like, irregular deposit scars.

What was your experience with this gel over joints and the integrity of the skin? Were you able to get any improvement in function over these areas? Have you tried the gel with a compression garment?

**Dr. John Morton** (Rochester, N.Y.). We have found that for extremities and for the trunk the Jobst garment works quite well, provided the patient wears the garment as he or she is asked to do. The scars that do not do well in our experience are those of the face and the neck. Is it possible to apply the silicone gel successfully in these areas? How effective is the gel for controlling face and neck scarring?

**Dr. Gerald M. Fried** (Montreal, Quebec, Canada). You mentioned that you had some people that you had followed about 6 months after stopping the treatment. I wonder whether it is possible that you are just delaying the onset or recurrence of the hypertrophic scar—just pushing it back, rather than preventing its development.

**Dr. Mustoe** (closing). The first question, I think, was, Could these effects be due to pressure? We ourselves did not measure the pressure with a pressure transducer, but this was done as part of a PhD thesis by Karen Quinn from the bioengineering unit in Glasgow, Scotland, and, as I said, they never found pressure to be in excess of 1 to 2 mm.

We, and anecdotally the group in England, have used these silastic gel treatments, both underneath compression garments, in order to hold them in place, and simply secured by tape, and we saw no difference in the effectiveness of the treatment. Clearly, the mechanism of action is a question that merits further study. We are convinced that the effects are not due to pressure.

I add parenthetically that in the patients who were treated with compression garments, beneficial effects were seen underneath the gel, and not in areas still underneath the compression garment. So the gel effects were additional to any improvement by the compression garment.

On the control area, unless they were treated with compression garments, they were not treated with compression garments, they were not treated with anything, and so although I cannot rule out the effect of tape or dry gauze on the scars, I think that the effects of these are unlikely.

About speculation on the mechanism of action, this is the most inconclusive aspect of the study in that we have a treatment that we believe is effective, yet we are not sure why.

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Karen Quinn, in her PhD thesis, looked at multiple possible mechanisms of action and was unable to arrive at a conclusion.

The most likely mechanism may be a hydration effect. The silicone gel is partially occlusive. To test this hypothesis, we could vary the thicknesses of the gel and compare it with other occlusive dressings. This is work that needs to be done.

On whether we are merely delaying the onset of hypertrophic scars, in most of the patients these scars were well es-

tablished. Some of them were as long as 3 years after the burn. We still saw improvement. Our initial impression was that the red, early active scars would be the most responsive, but we have not been able to conclusively state that. Not all the scars respond. I cannot give you the exact parameters. We have now looked at about 25 patients, and the results are generally a 70% to 80% response rate.

TAB 11

# Topical Silicone Gel for the Prevention and Treatment of Hypertrophic Scar

Sang Tae Ahn, MD; William W. Monafo, MD; Thomas A. Mustoe, MD

• We studied the effects of a silicone gel bandage that was worn for at least 12 hours daily on the resolution 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-image 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 before 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 treatment of hypertrophic scar.

(Arch Surg. 1991;126:499-504)

Hypertrophic scar (HS) commonly attends burns. It may also develop after surgical incisions or other trauma that extends into the reticular dermis. Once formed, the subsequent course of HS is unpredictable; there may be partial or complete resolution, or the HS may remain permanently. This complication is especially severe in children. It causes much functional, cosmetic, and psychological morbidity.<sup>1,2</sup> Clinically, HS is less frequent and usually less severe in primarily sutured surgical incisions compared with burns and other wounds in which epithelialization is delayed; no histologic, compositional, or biochemical differences have been identified among HSs of differing origins, however. The cause of this protean biological phenomenon remains unknown.<sup>3</sup>

A variety of measures have been suggested to minimize the occurrence of HS and/or its severity, including notably the

meticulous closure of surgical incisions, the early excision and skin grafting of deep burns, and the early and prolonged use of elastic compression garments. None of these measures are consistently effective, however. In patients with burns, HS remains arguably the most important late complication. Indeed, despite the widespread use of elastic compression garments for the prevention and treatment of HS during the past 25 years, convincing demonstration of their efficacy is lacking, in part because simple, objective methods to demonstrate efficacy of this (or other) treatment has also been lacking.<sup>4</sup>

This communication describes the results in 48 patients who wore bandages of silicone gel sheeting for at least 1 month on a portion of their scar. One study arm comprised 29 patients with surgical incisions that were less than 3 months of age and had originally been closed primarily; HS in these patients was either not present or had only recently appeared. Serial measurements of the changes in scar volume were made. The purpose was to document whether the gel bandage lessened increases in scar volume and thus was preventative of HS.

The other study arm consisted of 19 patients with wounds that had already developed HS; most of these patients had originally sustained burns. Serial measurements of scar elasticity at test and control sites were performed. A preliminary report of this treatment in the first 10 of these patients has already appeared.<sup>5</sup> The purpose of this arm of the study was to assess further the efficacy of the gel bandage in the treatment of established HS and to extend the period of follow-up in the patients who were previously described.

The data suggest that this simple procedure inhibits the development of HS and also promotes its resolution, both on the clinical level and statistically as determined by objective measurements.

## PATIENTS AND METHODS

Both arms of the protocol were approved by the Washington University Human Studies Committee, St Louis, Mo.

### Patients With Surgical Incisions

Informed consent was obtained from 29 patients who ranged in age from 12 to 44 years who had undergone elective surgical procedures. A test area of scar that was either 2 or 3 cm in length was arbitrarily

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selected so that an untreated control area of the same length and similar appearance was available from either the same or a mirror-image anatomical site. Thirty-two scar pairs were originally entered into the study. The patients were instructed to wear a small silicone gel sheet (3 × 2 × 0.35 cm, Dow Corning Q7-9119, Silastic Gel, Dow Corning Corp, Midland, Mich) on the test area of scar for at least 12 hours each day, preferably for 24 hours, removing it only briefly to clean the scar and the gel sheet once or twice daily. The gel was held in place by a single strip of hypoallergenic adhesive tape. No treatment or dressing was used on the control scars. The boundaries of test and control sites were marked with ink. Photographs and impressions of the test and control sites, as described below, were made before treatment and at 1 and 2 months subsequently. When the trial was ended after 2 months, the appearance of the test scar compared with that of the control scar was rated by both the clinicians, and the condition of the patients was rated as improved or not improved.

Ten patients (11 scar pairs) did not complete 1 month of treatment and thus were nonassessable; most of these patients were men who were minimally concerned about the appearance of their truncal scars. This left 21 scar pairs in 19 patients that were assessable. Seventeen of these 19 patients were female. All but two of them were aged younger than 40 years. There were two blacks and one Hispanic. Ten of the 21 scar pairs were 1 month or less in age. The scar locations were as follows: abdomen, nine; breast, five; upper limb, three; neck, two; chest, one; and face, one.

### Scar Volume Measurement

Vinyl polysiloxane material (Baysilex Monophase, Cutter Laboratories, Berkeley, Calif) was used for making negative impressions of the scars. Three milliliters each of the blue base and the white catalyst pastes was mixed to exclude gross air bubbles carefully so that a uniform light blue color appeared within 30 seconds. The mixture was painted over the scar with the use of a spatula and allowed to set for 2 minutes, after which it was removed in an axial direction. Duplicate impressions were made from each test and control site. At least 30 minutes later, after setting was complete, the impressions were filled with a mixture of 5 g of dental stone (Den-Stone, Columbus Dental, St Louis, Mo) and 2 mL of water. One hour later, the positive scar impression, which comprised the dental stone, was removed from the negative impression mold. After drying to a constant weight for at least 24 hours, the impression was scraped down to the level of the normal skin adjacent to the scar with the use of a scalpel. After they were scraped, the impressions were reweighed, and the average weight of each scar site was computed. Scar weights were converted to scar volumes with the use of a previously determined volume-weight ratio of the dried dental stone, which was 0.51 mm<sup>3</sup>/mg (n = 5). All steps in these measurements of scar volume were performed by a blinded observer. The scar volume measurements were repeated at both 1 and 2 months in 15 of the 21 scar pairs. Four scar pairs were remeasured at 1 month only, and two pairs were measured at 2 months only.

### Patients With Established HS

In this arm of the study, silicone gel sheets were applied to 23 HSs in 19 patients for up to 7 months. After informed consent had been obtained, a test area of scar was selected so that an untreated control scar of similar dimensions and appearance was available from the same or a mirror-image anatomical site. The sheets were held in place either by a crepe bandage, adhesive tape, or an elastic bandage. Elastic compression garments were used by two patients. The patients were advised to wear the gel bandage for at least 12 hours each day, or preferably 24 hours each day, and to remove and clean it and the scar briefly once or twice daily. The treatment was stopped after 2 months. In six patients, treatment was resumed after 1 month had elapsed and continued for up to 8 months. The test and control scars were photographed and measured elastometrically, as described below, before treatment and at monthly intervals.

### Scar Elastometry

Scar elasticity was measured objectively with the use of a handheld elastometer that we have previously described.<sup>6</sup> Six measurements were taken of each scar and averaged. The measurements were made at study entry and at monthly intervals subsequently. Briefly, the device utilizes a constant-tension spring and an accurate strain gauge to distract two adjacent points of skin. The distance of distraction is

measured and expressed as the percentage of stretch by using the following formula:

$$\% \text{ Stretch} = \frac{\text{Amount of Distraction (in mm)}}{10 \text{ mm (Original Distance)}} \times 100$$

The normal values of human skin are between 30% and 42%, with an SD of 7%.<sup>6</sup> However, within each patient studied, the results from mirror-image scars were highly reproducible (SD, 1% to 2%), making paired comparisons with the patient serving as his or her own control meaningful and sensitive to change. Although these measurements could not be blinded because of obvious clinical improvement in the treated scars, the elastometer measurements were objective and therefore should not have been skewed by an unintentional bias.

The 19 patients ranged in age from 3 to 78 years. Twelve of them were males, five were black, and the remainder were white. All but four scars were the result of burns. Three scars were from surgical procedures; one had resulted from a spider bite. The scar ages ranged from 2 months to 4 years. The scar locations were as follows: leg, six; arm, six; trunk, four; wrist, three; neck, two; and back, two.

Test and control scars were rated clinically by both the patient and the investigator at the completion of treatment according to the following items: texture, color, thickness, durability, subjective symptoms, and range of motion (if applicable). If, for example, four items were rated as consequential before treatment and three of them were improved following treatment, a score of 3/4 was recorded. The patients were also asked to grade their result as good, average, poor, or unacceptable.

### Photography

A camera (Olympus 35 mm OM II) with a 50-mm macro lens was used to photograph the test and control scars of the patients in both study arms with film (ASA 64 Kodachrome). The lens aperture, exposure time, and subject distance were kept constant. An electronic flash was used in addition to standard overhead fluorescent lighting. Photographs were routinely obtained at study entry and after 1 and 2 months of treatment in both study arms. Additional photographs were made at later intervals in some of the patients in whom HS was already present at study entry and in those patients who desired to continue treatment.

### Data Analysis

The scar volume and scar elasticity measurements were analyzed with the use of the SAS system as implemented on a mainframe computer (IBM) with the assistance of the Department of Biostatistics, Washington University School of Medicine.<sup>7</sup> A repeated-measures analysis of variance with statistical contrasts was used to compare baseline values with values at subsequent time points. Unpaired *t* tests were used in comparisons of the elastometric data beyond the second month because of the comparatively few data at the later time points.

## RESULTS

### Patients With Surgical Incisions

The reliability of the duplicate scar weight measurements was excellent, as determined by simple intraclass correlations ( $r = .98$ ).

As expected, the changes in scar volume differed widely due to the well-recognized variability in individual propensity to develop this complication.

The differences in volume between control and test scar pairs (control volume - test volume) at study entry and after 1 and 2 months of treatment were analyzed with the use of the sign-rank test, as these data were nonparametric. Test and control scar volumes were the same at study entry ( $P = .26$ ). At both 1 and 2 months, however, control scar volumes were proportionately greater than test scar volumes ( $P = .03$  and  $P = .003$ , respectively). The presence of a treatment-time effect on test scar volume was also identified with the use of a repeated-measures analysis of variance ( $P = .03$ ) (Fig 1).

**Subset With Clinically Evident Hypertrophy.**—Assessment of the scar volume measurements in conjunction with the changes in clinical appearance of the scars suggested that

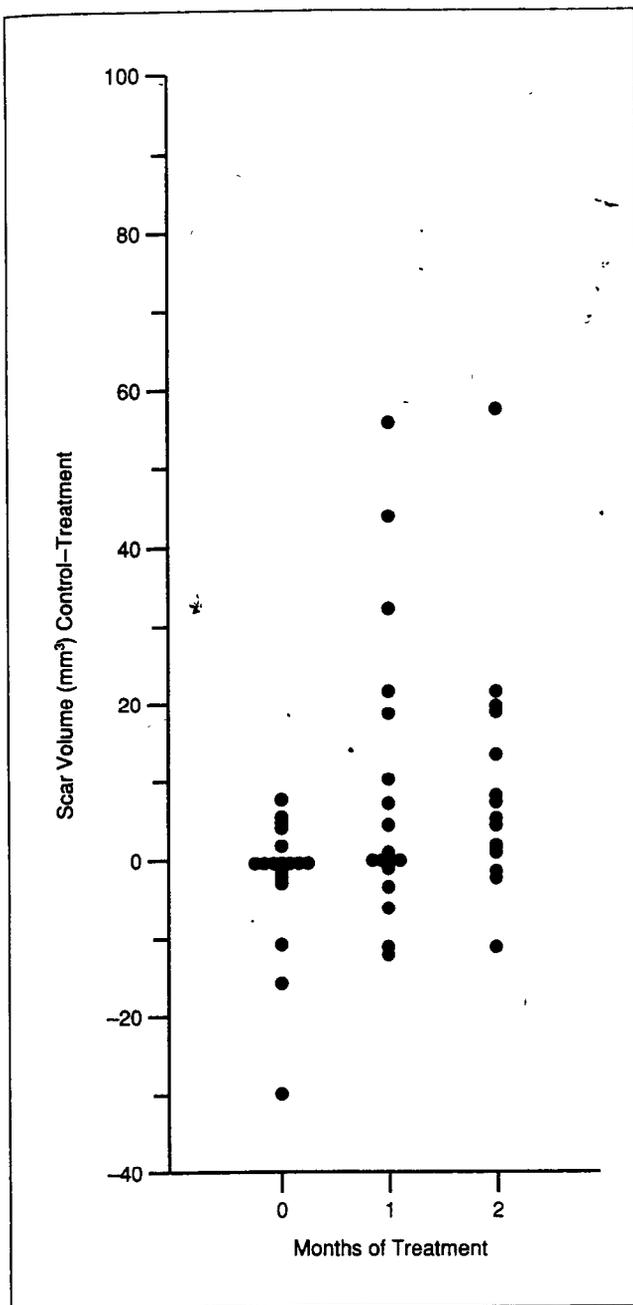


Fig 1.—The volume difference (in cubic millimeters) between each control and treated scar pair in the patients with surgical incisions at study entry and at 1 and 2 months. (Control scar volume - treated scar volume.)

a scar volume difference of more than at least 4 mm<sup>3</sup> was necessary to be clinically perceptible. In 10 patients, hypertrophy either did not develop clinically or was barely perceptible in either the control or test sites; their measured changes in scar volume were less than 10 mm<sup>3</sup> at both sites. This finding was not unexpected, as the incidence of clinically appreciable scar hypertrophy in primarily sutured surgical incisions is generally believed to be less than the incidence after burns or other trauma. In the remaining subset consisting of 10 scar pairs (nine patients), clinically significant HS had either appeared or become more severe in the control scars. The increment by which the increase in control scar

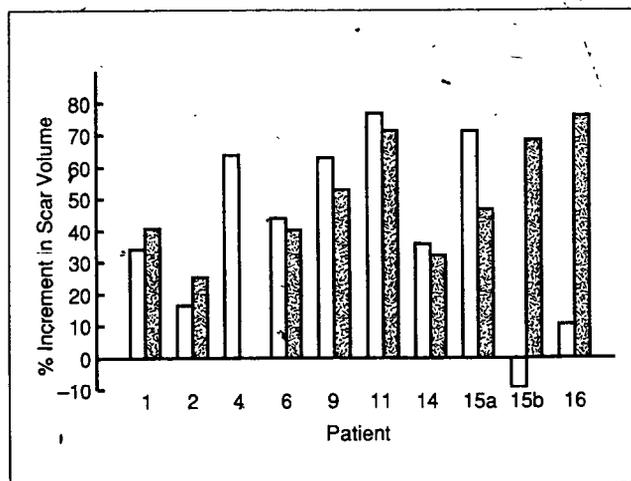


Fig 2.—Surgical incision cohort. The increment (percentage) by which control scars increased in volume vs treated scars in patients in whom the volume change in both scars exceeded 10 mm<sup>3</sup>. Data were computed by using the formula:

$$\left\{ \frac{(C/C_0 - T/T_0)}{(C/C_0)} \right\} \times 100,$$

where C = control, T = treated volumes, and subscript 0 = initial volume. Open bars indicate 1 month; hatched bars, 2 months.

volume exceeded that which had occurred in treated scar volume in these nine patients is shown in Fig 2. This ranged between 25% and 75%. In absolute terms, the range was between 4.6 and 82.4 mm<sup>3</sup>. All of these treated scars were noted to be clinically improved.

**Complications.**—No serious complication resulted from wearing the gel bandage. Two patients had minor contact dermatitis from the adhesive tape. This responded to decreasing the gel-wearing time to 12 hours. One patient experienced difficulty with maintaining contact of the bandage on her neck scar.

#### Patients With Established HS

All but one of 20 scars that had been treated for at least 12 hours each day were rated as good or average at the end of treatment (Table). Efficacy did not appear to be related to patient age, sex, or race, or to the scar location.

Scar elasticity increased by more than 5% stretch in 12 of 18 scars that had been treated for at least 12 hours each day for 2 months. Only two of the control scars demonstrated a comparable increase in elasticity. Statistically, test and control sites were equally inelastic at study entry ( $P = .89$ ). After 1 month, the elasticity of treated scars had increased compared with baseline ( $P = .019$ ); after 2 months, this increase in elasticity was more evident ( $P = .0001$ ). Control scar elasticity was no different from study entry at either 1 or 2 months. A difference in elasticity between treated and control scar pairs was evident both at 1 month ( $P = .005$ ) and at 2 months ( $P = .0001$ ) (Fig 3). The treatment effect plateaued after 2 months and was not affected by discontinuing the treatment for 1 month ( $P =$  not significant). Resumption of the treatment for 3 additional months had no major effect on scar elasticity in the six patients who continued it ( $P =$  not significant).

With regard to complications in these patients, we originally found that superficial skin maceration occurred occasionally beneath the gel.<sup>8</sup> Eliminating the use of elastic compression garments over the gel, emphasizing the importance of local hygiene, and decreasing the wearing time in hot weather eliminated those minor complications in patients who were enrolled in the study since the original report (Table).

Characteristics of Patients and Clinical Response to Treatment With Topical Silicone Gel in Patients With Established HS\*

Patient/ Age, y/ Sex/Race	Scar			Treatment			Evaluation		
	Cause	Duration, mo	Site	Duration, h/d	Duration, mo	Mode of Fixation	Score	Global Assess- ment	Complic- ation
1/78/F/B	Burn	5	Back	12	2	Tape	4/4	Good	Discomfort
2/37/M/W	Burn	23	Leg	18	3	Elast	1/3	Average	Rash
	Burn	25	Arm	18	3	Elast	1/3	Average	Rash
3/57/M/W	Burn	2	Leg	18	7	Tape	3/3	Good	Rash
	Burn	2	Arm	18	7	Tape	5/5	Good	Rash
4/33/M/W	Burn	13	Neck	24	5	Elast	6/6	Good	...
	Burn	14	Wrist	24	1	Elast	4/6	Average	Ulcer
5/19/M/W	Burn	7	Leg	24	2	Comp Garm	4/5	Good	Ulcer
	Burn	7	Wrist	24	1	Comp Garm	4/6	Good	Ulcer
6/21/F/W	Spiderbite	9	Leg	24	5	Elast	5/5	Good	Rash
7/53/M/W	Burn	2	Flank	12	6	Tape	2/3	Good	...
8/76/M/B	Burn	5	Arm	6	2	Elast	0/3	Poor	...
9/43/F/W	Burn	48	Neck	5	1	Tape	0/4	Poor	...
10/39/F/B	Keloid	12	Back	4	2	Tape	0/3	Poor	Pruritus
11/43/M/W	Burn	3	Arm	14	5	Elast	5/5	Good	...
12/21/F/B	Burn	3	Chest	12	2	Tape	2/4	Average	...
13/52/F/B	Burn	6	Leg	16	3	Tape	2/4	Average	...
14/39/F/W	Burn	4	Chest	20	3	Tape	1/4	Poor	...
15/23/M/W	Burn	3	Leg	15	2	Elast	3/3	Average	...
16/35/M/W	Burn	2	Chest	18	3	Tape	2/4	Average	...
17/14/M/W	Surgery	5	Arm	18	2	Elast	5/5	Good	...
18/21/M/W	Burn	2	Arm	24	2	Elast	3/3	Good	...
19/3/M/W	Surgery	3	Wrist	24	4	Elast	4/4	Good	...

\*HS indicates hypertrophic scar; Elast, elastic tape; and Comp Garm, elastic compression garment.

Fig 4 — T  
improvement  
months

Fig 5.—T  
Pretreatm

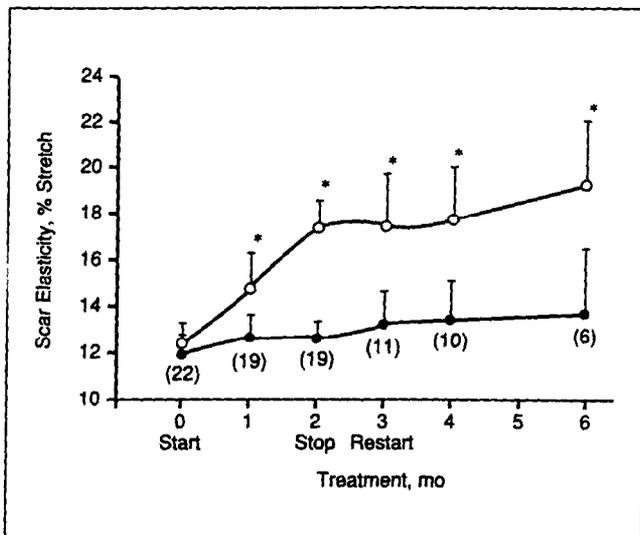


Fig 3.—Hypertrophic scar cohort. Changes in scar elasticity (percentage of stretch  $\pm$  SEM) in control (closed circles) and treated (open circles) scars. Significant intergroup differences at each time point and significant intragroup differences from time 0 are indicated by an asterisk. After 1 month,  $P = .0001$ .

#### COMMENT

Hypertrophic scar does not occur spontaneously in animals.<sup>8</sup> The lack of an experimental model is, not surprisingly, paralleled by a present lack of understanding of the biological

basis of this uniquely human, common, and troublesome disorder of wound healing.<sup>9</sup>

As the cause of HS is unknown, its therapy is necessarily empirical. Meticulous surgical technique and early permanent closure of chronic open wounds, such as burns, are widely recommended. But these measures do not necessarily prevent HS, which typically begins to appear within several months of the original insult and, in many instances, fails to resolve appreciably thereafter.<sup>1,2,10-12</sup>

The nonsurgical treatment of established HS is based mainly on the empirical recognition that its resolution may be accelerated by near-continuous pressure, as exerted by the widely used elastic compression garments. These garments must be worn for many months and are not consistently effective (Fig 4).<sup>13,14</sup> Indeed, controlled clinical data supporting their efficacy are lacking.<sup>4</sup>

The present studies were prompted by several uncontrolled clinical reports that stated that the topical silicone gel sheeting used here promotes resolution of HS.<sup>15-18</sup> Subsequently, other observations, also uncontrolled, suggest that true keloids—histologically similar to HS but with a different clinical course—also regress after treatment with topical silicone gel (the single keloid in the present series failed to respond).<sup>19</sup> The results of the present study, which includes observations on untreated control scars in each patient, confirm that if worn for at least 12 hours daily, topical silicone gel has a beneficial, clinically significant effect on HS, and that scar elasticity is measurably improved (Figs 5 and 6). Although there is a trend suggesting that both the clinical and elastometrically measured responses are inversely related to scar age, statistical significance was not reached ( $P = .09$ ) in this series of only 19 patients.

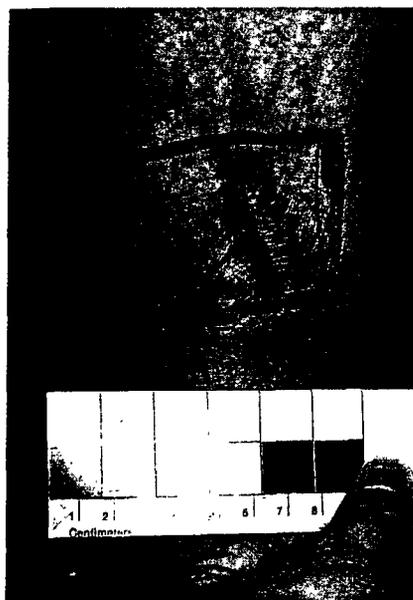


Fig 4.—This popliteal scar had been treated for 8 months with elastic compression without improvement. Left, Pretreatment. Right, After 2 months, the entire scar was treated for 2 more months, when this photograph was taken.

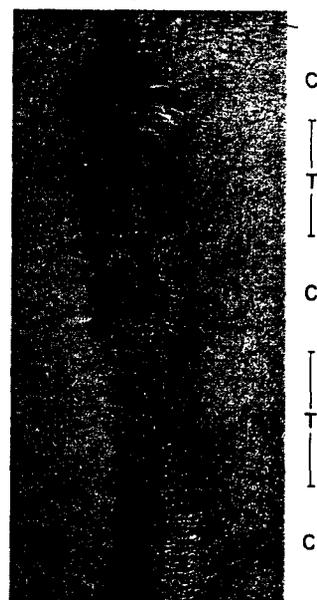


Fig 7.—This scar in an abdominal incision had been treated with silicone gel for 2 months. This patient added a second treatment area on his own volition. C indicates control scar; T, test scar.

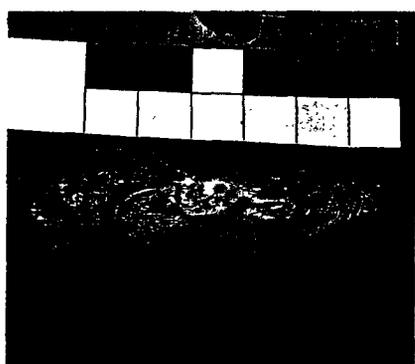


Fig 5.—This forearm scar had resulted from a second-degree burn 2 months previously. Left, Pretreatment. Right, Eighteen months after treatment.

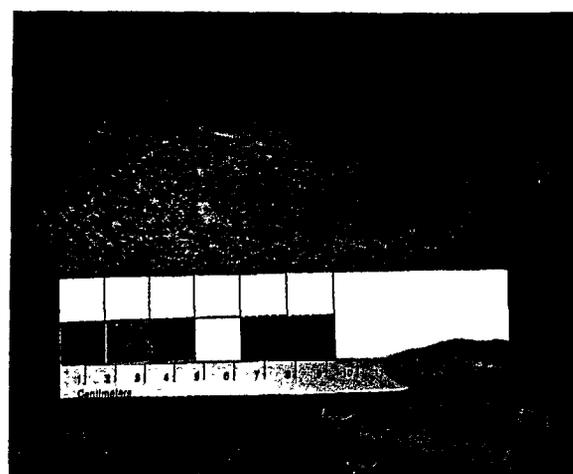
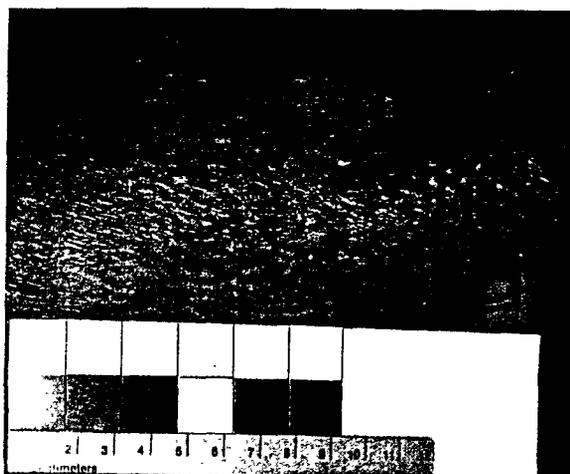


Fig 6.—This full-thickness burn had been excised and mesh-grafted 3 months previously. Elbow flexion and extension were both impaired. Left, Pretreatment. Right, Five months after treatment. The range of motion of the elbow is now full.

The data from the surgical incision study arm, which was initiated after therapeutic effects of the gel on HS became evident, indicated that silicone gel also had a distinct effect in impeding the formation of HS in surgical incisions (Fig 7). In view of the simplicity of this treatment and the absence of major side effects, this is a finding that, if confirmed, would have widespread clinical application and reduce the need for reconstructive surgery. It remains to be determined whether silicone gel will also prevent HS in patients with burns or other cutaneous trauma.

Although the mechanism of action of the silicone gel is unknown, several possibilities appear to have been reasonably excluded.<sup>16</sup> It is known that continuous pressure on the scar surface—about 30 mm Hg is necessary—will elongate and flatten some scars due to remodeling of the scar collagen.<sup>20</sup> However, Quinn et al<sup>16</sup> found that the pressure exerted by silicone gel sheeting was negligible (<3 mm Hg, even with crepe bandages). In this regard, two of our patients had failed to respond to protracted therapy with compression garments but responded to the silicone gel (Fig 4). Quinn et al<sup>16</sup> also excluded temperature effects and differences in oxygen transmission as mechanisms. The gel is occlusive, with a water vapor transmission rate lower than that of skin (4.5 vs 8.5 g/m<sup>2</sup> per hour). But other occlusive dressings, such as polyurethane film, have no effect, even if gel sheeting is placed over them (S.T.A. and T.A.M., unpublished data, 1989).<sup>16</sup> 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, changes in scar water content have not been directly measured, to our knowledge. It is possible that the specific degree of occlusion exerted by the gel is important, but this hypothesis remains to be tested. There is no evidence of silicone absorption either on our histological section,<sup>5</sup> or when analyzed by scanning electron microscopy microprobe analysis,<sup>16</sup> but a chemical effect has not been definitively excluded.

Our observations suggest that 2 months of wear is adequate, both for the prevention and for the treatment of HS, and that subsequent recurrence of hypertrophy is infrequent at most. In the patients with established HS, there was no change in scar elasticity 1 month after treatment had been stopped; no perceptible additional improvement in scar elasticity was observed in the six patients who wore the gel for up to 6 months (Fig 3). Similarly, on the clinical level, late recurrence has not been observed in the patients with HS who originally responded. Control HSs did not improve during the study interval. We recognize that, given sufficient time, control scars might improve subsequently, thus decreasing the difference here noted. However, accelerated resolution of HS would still provide a clinically important benefit. Elastometric measurements were technically impossible in the patients in the surgical incision study arm because of the narrow width of their scars relative to that of the attachment site of the

elastometer. We do not have long term follow-up of our patients with surgical incisions. But the early results are encouraging, and absence of significant complications and also the lack of a proved alternative treatment suggest a clinical role for silicone gel therapy.

We conclude that topical silicone gel is efficacious, both in minimizing the severity of HS in surgical incisions and in promoting the resolution of HS in patients in whom HS has already developed.

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Michael A. Province, PhD, Department of Biostatistics, Washington University School of Medicine, St Louis, Mo, provided statistical consultation.

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TAB 12

# Cosmetic

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COSMETIC DERMATOLOGY

# Dermatology



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# SILASTIC GEL SHEETING IS FOUND TO BE EFFECTIVE IN SCAR THERAPY

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Columbia University  
College of Physicians and Surgeons  
New York, N.Y.*

Silastic gel sheeting (SGS) is a soft, semioclusive scar cover made of cross-linked polydimethylsiloxane polymer that is indicated for use in both old and new hypertrophic or keloid scars. It was first reported to be an effective treatment for burn scars and contractures in 1982.<sup>1</sup> Thought to be due to pressure effects initially, Quinn found that efficacy of SGS was unrelated to pressure.<sup>2</sup> In a 3-year clinical trial, 75 of 92 patients with chronic hypertrophic or keloid scars were found to have some improvement with use of SGS after 2 months' treatment.<sup>3</sup> In another study, 40 of 46 chronic keloid scars were found to improve when treated with SGS for 6 months.<sup>4</sup> When compared with pressure therapy alone, SGS was found to be more effective. In a prospective, controlled trial, S.T. Ahn, M.D., and coworkers found SGS to produce significant improvement in 11 of 14 chronic hypertrophic scars when evaluated by elastometry and photography.<sup>5</sup>

*Although confirmed in its efficacy for treatment of chronic hypertrophic and keloid scars, only recently has SGS been found to prevent development of these scars.*

Although confirmed in its efficacy for treatment of chronic hypertrophic and keloid scars, only recently has SGS been found to prevent development of these scars. In a controlled analysis of fresh surgical incisions, SGS was found to significantly inhibit the formation of hypertrophic scars when used for at least 12 hours daily for 2 months.<sup>6</sup>

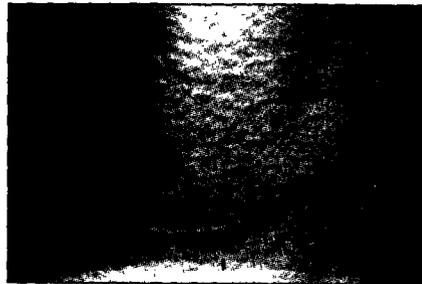
In one of the first accounts in the dermatologic literature, reported here are the results of treatment of both fresh and longstanding hypertrophic and keloid scars with SGS.

#### **SGS Protocol**

Patients were instructed to apply SGS to all scars in the same fashion. Each patient received a sterile tray of gel sheeting and were to trim a piece to fit the scar (overlapping surrounding normal skin) (see Figure 1). The shiny surface of the sheeting (not fabric mesh) was placed in contact with the skin and was attached with a dermatologic surgical tape. Patients were asked to wear the gel sheet for at least 12 hours (preferably 24 hours) a day. The material was washed daily with a soap and water solution and was replaced at 7- to 10-day intervals when it began to deteriorate. All patients wore the gel sheet for at least 2 months.



**Figure 1:** Measuring SGS to fit an abraded scar.



**Figure 2a:** Chronic hypertrophic scar before application of SGS.



**Figure 2b:** Flattening of scar after 3 months of SGS use.

#### Clinical Assessment

Scars were photographed before and after 2 months of SGS treatment. Two physicians and the patients themselves evaluated the SGS-treated scars by assessing the change in scar redness, elevation and subjective complaints (e.g., pruritus or pain).

#### Results

- *SGS and chronic scars:* This arm of the study included only chronic hypertrophic or keloid scars of at least 3 months' duration. Most scars had been present for at least 1 year. Eleven scars in 11 patients were evaluated after treatment with SGS for at least 2 months. Seven scars were improved and 4 were unchanged (see Figures 2a and 2b). In two other patients, each of whom had two scars treated with SGS concurrently, one scar improved and one remained the same. Therefore, in a total of 15 scars, 9 showed improvement. Follow-up for at least 6 months showed no change in these results.
- *SGS and fresh scars:* This group consisted of patients having only fresh scars present for less than 3 months. Eight scars in 8 patients were evaluated after treatment with SGS for at least 2 months. In 2 patients, there was a history of hypertrophic scar development; SGS treatment was begun within 2 months of recent surgery to prevent its recurrence. In 6 cases, long-

standing hypertrophic scars were completely excised and repaired with W-plasties. Scarabration was performed 8 weeks later.<sup>7</sup> In most cases, SGS therapy began as soon as reepithelialization occurred. In all 8 cases, development of hypertrophic scarring was not found after at least 6 months of follow-up (Figures 3a, 3b and 3c).

- *Complications:* One case of minor irritant dermatitis occurred under the gel. This problem cleared when the tape was applied less tightly. In one instance, a foul smell coming from the gel was remedied when daily washing of the gel was implemented.
- *Discussion:* Conventional treatment of hypertrophic and keloid scars has included steroid injection, surgical revision, radiation, laser, cryotherapy, compression and combination therapy. Many of these modalities have been associated with high rates of recurrence<sup>8</sup> and can be expensive, painful or require extensive treatment. Because of its simplicity, ease of use and relatively low cost, much attention has been focused recently on SGS and other "contact media." Research and clinical experience will determine whether these materials are any more beneficial than previous therapies.

In this investigation, within the group of chronic scars treated by SGS, 9 of 15 scars showed im-

provement (60%). Although a majority of scars responded to treatment, this is lower than the 70% to 80% response rate reported in the literature.<sup>3-5, 9</sup> This reasons for this variation are unclear.

Formation of hypertrophic scars usually occurs within the first 6 to 8 weeks after skin reepithelializa-

*From results of the treatment of fresh scars in this study, it appears that SGS is effective in the prevention of hypertrophic scarring when applied early in the wound-healing process.*

tion, with gradual "maturation" over the next 1 to 2 years.<sup>5</sup> For therapy to be effective, this sequence of events should be altered.

From results of the treatment of fresh scars in this study, it appears that SGS is effective in the prevention of hypertrophic scarring when applied early in the wound-healing process. However, the small sample size may have some bearing on the findings.



**Figure 3a:** Hypertrophic scar of chest before excision, W-plasty repair, scar-abrasion and application of SGS for 2 months.



**Figure 3b:** Close-up of Figure 3a.



**Figure 3c:** No recurrence of hypertrophic scar 9 months after SGS use was discontinued.

The mechanism of action of SGS is unclear. Physical and chemical effects of SGS on scarring have been explored.<sup>2,3</sup> Using pressure transducers, it was found that SGS exerted negligible pressures compared with the 15 mm Hg to 40 mm Hg required by pressure garments to achieve their effect. Thus, the therapeutic effect of SGS is not dependent on pressure. Temperature and oxygen tension changes also were investigated; no differences were noted between treated scars and normal skin. Studies of the bacteriology and mechanics of the gel sheet itself were noncontributory, and effects due to occlusion also were ruled out.

The water vapor transmission rate of SGS was found to be about half that of skin. A dramatic increase in water loss from the scar is noted on removal of the gel from skin. SGS may, therefore, work by affecting scar hydration. The reduction in water vapor loss is postulated to decrease capillary activity, thereby reducing collagen deposition and scar hypertrophy.<sup>10</sup>

The possibility of release of low-molecular-weight silicone fluid into tissues has been raised,<sup>2</sup> but histologic analysis of biopsy specimens from SGS treated scars showed no evidence of silicone leakage.<sup>5</sup>

Several minor complications have been described with use of SGS. Superficial maceration or erosion of the scar has occurred, usually due to excessive pressure. Occasional pruritus and rash also have developed, usually due to poor local hygiene. These problems resolved when the gel sheeting was removed temporarily or duration of use was reduced to 12 hours per day.

#### Summary

SGS is a safe and effective treatment for hypertrophic and keloid scars. In longstanding scars, variable improvement is seen with use of this material. In fresh scars, SGS appears to be effective in reducing the rate of recurrence of hypertrophic scars after full-thickness surgical revisions and scarabrasion. Adverse effects are minor and transient. □

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