# **USE OF MEDIGEL-Z IN REHABILITATION**

# STUDY OF 106 BURN PATIENTS

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#### Abstract:

The authors, rehabilitation physicians in a specialized burn centre, studied various products, silicone gels and foams, which they use in the treatment of hypertrophic scarring. They conducted a study of 106 burn patients whose scars were treated with Medigel-Z patches or cuffs. Results were either good or excellent in 80 of the cases (75.5%) with an effect on sliding motion and hypertrophy. Out of

these 80 cases, 30 patients showed excellent results with a definite effect on local inflammation. Results were average in 16 cases and there were 10 failures (9.4%).

The facility of its use, the various forms in which it is supplied, as well as the product's long lifespan (3 to 6 months for the cuffs and 6 to 7 months for the patches) were also of interest to the authors.

Burn specialists have been interested in compression in the treatment and prevention of hypertrophic scarring since the 1960's. However, some scars do not respond to conventional compression or are located in "difficult" areas (raw areas, flexion folds, overlap areas of clothing). In those cases, compression garments are often accompanied by the foams of varying density, flexibility and thickness that are available on the market. Whether supplied as adhesive patches or otherwise, these flat surface products require some manipulation in order to attain the thickness required to fill certain concave sites.

# Different product types

#### A. Foams

Silicone foam (Silastic, Dow Corning Inc.) was first used in the treatment of hypertrophic scarring in the 1980's. Its handling and its combination with various supporting elements solved some of the problems of conventional foams². This type of product offered numerous benefits (easy to use, usable on all sites, light and adaptable to various densities, clean, absorptive capacity); it could also be used as a vehicle, or carrier of medication. On the other hand, its friability and fragility, increasing with the size of the surface

to be treated, made it costly; furthermore, its absorptive capacity meant that it would not keep the skin moist, a difficult problem for rehabilitation specialists, and one that did not exclude the risk of malodorous maceration.

#### B. Silicone Gels

Silicone gels have been used by Perkins, in Australia<sup>4</sup>, in the treatment of burns since 1982. This author used silicone sheets of 10 cm x 10cm, made of transparent, flexible and chemically inert gel. Initially, Perkins had used this gel together with compression garments so as to make them more comfortable; the isolated action of the gel was discovered empirically, in the absence of any compressionÊ: in fact, the silicone alone made the scars more flexible and smoother. No physiopathogenic explanation was proposed for this phenomenon; the important fact was the effectiveness of the silicone application - without any compression.

In April 1985, Prof. Reid, of the Glasgow Children's Burn Centre, together with the team of Karen Quinn (Biological and medical Engineering Laboratory) published their study on the properties of silicone gel, and attempted to explain its action<sup>5</sup>. In 1987, Karen Quinn had a new study published in which she examined various physicochemical and bacteriological parameters of silicone sheets fitted with a sort of tulle<sup>6</sup>.

We used Spenco gel sheets (10 x 10 cm) as a single application on hypertrophic scars and we quickly observed a hydration action, a cutaneous softening and a whitening of the scar, all linked to the use of the product. These observations have been discussed in an earlier article<sup>3</sup>.

This product had very few side effects and could be used under various clothing and appliances for specific compression. However, it also had numerous disadvantages:

- ☐ fragile, leading to rapid granulation
- ☐ significant maceration when used under a compression orthotic
- $\square$  available only in sheets of 10 x 10 cm.

We quickly turned to another product in the same line, known by the name "Second Skin", with some interesting properties: hydrating, analgesic, anti-inflammatory capacity, covering a larger surface (available in sheets of 40 x 40cm). This product has essentially been used as a simple application for comfort in conjunction with the use of large appliances and corsets.

Easy to use, this product also self-destructed in 36 hours, thereby eliminating any risk of maceration or ulceration; it also had a significant hydration capacity from the first few hours on, together with an analgesic and definitely anti-inflammatory effect. However, its therapeutic effect was noticeable only during the first few hours of application, and lacking any compression capacity, it was difficult to place underneath clothing or orthotics.

Finally, the silicone "PAD" sheets, available in two thicknesses: they are flexible, although of high density; however, they do produce significant maceration.

Gels are frequently used with other types of appliances, whether they are made of high or low temperature thermoformed material.

The double face or interface role acts as a sliding aide for the "Kinetic hand", in particular, for amputations, footwear and functional rehabilitation (manufacture of gloves coated with polymers, for professional use).

We have been using these types of products for a long time as "packing" interface between the skin and appliances for amputees or soles for burned feet. From the stock of available products, we also selected malleable silicones of a putty type, used in dentistry for making impressions.

Our experience in the field of rehabilitation of burn patients led us to test the products of the Médical Z firm, since several requirements still needed to be met:

□ efficient sliding
 □ double face
 □ elasticity of the elements (compromise between sliding motion and compression)
 □ hydration
 □ durability
 □ reduced aggressivity
 □ cleanliness
 □ transparency, a useful attribute when these products are used with transparent orthotics (such as orlene masks for the face)

#### C. Medigel-Z

□ differences in density

Medigel-Z is a product resulting from the synthesis of a copolymer and class H1 medical mineral oil. The basic molecule, the structure of which cannot be revealed, comprises several blocks linked by a chain of carbon atoms. The

structure of these blocks allows for a regular and stable polymerization. Of interest to our study, this product has features similar to that of silicone, but with its elasticity and flexibility, it is more like latex. It is available either as a patch or transparent gel, packaged in different ways: transparent sheets of 10 cm x 10 cm, larger sheets "fitted" with synthetic fabric (20 x 20 cm, 30 x 40 cm, 40 x 50 cm), "cuffs" (cylindrical sheets with synthetic fabric) 24 cm long, and now available in 5 circumferences (from 12 to 55 cm), cuffs called "Digi-Tub" for the fingers, and finally, an elastic fabric bandage 120 cm long and 10 cm wide.

#### **Patients**

Our study focused on 106 patients suffering from serious burns and with one or more treatment sites over the body. The study lasted from January 1993 to June 1994. The affected sites were as follows:

☐ face/neck : 30 cases ☐ hands : 50 cases ☐ chest : 20 cases

□ limbs (upper and/or lower): 80 cases
The sites of interest to us had been treated with grafts or directed cicatrization:

□ sites treated with grafting : 55

□ sites treated with directed cicatrization : 51.

# **Equipment and Method**

#### A. Equipment

We used the Medigel-Z patches with fabric support. These were cut out as needed and paired with compression garments. They were applied mainly to flat surfaces (chest...), or to parts of limbs (dorsal face of hands, flexion folds, achillean regions, instep).

The transparent Medigel-Z sheets were used mainly on the face (eyelids...) and the neck, under orlene orthotics. We also treated the limbs as soon as the first generation cuffs were ready. They had the benefit of being elastic, although they were of large calibre.

The later availability of several cuffs of different diameters allowed us to treat other limb sections more easily, specifically the fingers, and to produce real tailor-made gloves, albeit in an amateur way.

#### B. Method

We established a protocol for the treatment of the various skin problems of burn patients.

#### 1. Static Application

This type of application involves mainly noncompression cuffs or patches as well as immobilized patients and/or those who tolerate little or no restrictive appliances. Thus, the placement of patches between a cast and a sensitive skin allows for the use of an appliance previously rejected.

The hydration action is easy to objectivize, but the limit between maceration and hydration must be defined. Consequently, the duration of application of the gels must be calculated on the basis of skin reaction. It is particularly important to be able to alternate hydrating products with absorbent products of the hydrophillic polyurethane foam type. In actual fact, the skin must be hydrated without the risk of maceration. The vitopression test allows for the objective monitoring of the anti-inflammatory action. When gels were no longer applied, it was observed that the vitopression test was more definite; thus, it is in the patient's best interest to continue using the product.

The ichthyotic phenomenon is contemporaneous to the burn and raises numerous problems, particularly at the junction of healthy skin and grafted skin and at the mobile sites (cracking, delayed underlying cicatrization...). Aside from the application of creams, the application of silicone gel patches limits this phenomenon, but only temporarily. As is the case for hydration, treatments must be alternated. The itching linked to these phenomena follows their evolution. However, the static treatment must be quickly replaced by a dynamic treatment: the purpose of rehabilitation is to provide increased functional freedom, and is thus synonymous with dynamic treatments.

#### 2. Dynamic Application

The dynamic treatment (i.e., complementary to compression or dynamic positioning) allows for a more comfortable use of the appliance.

The silicone and assimilated sheets can be used in several ways. They can be used alone or in conjunction with compression garments and various appliances. The objective is to improve articular amplitude by acting on the skin's flexibility.

The cuffs coated with copolymers are the option of choice, used alone for one or more articulations. Available in sections 24 cm long, they are easy to put in place and their softening action, together with compression, allows for the conventional rehabilitation therapy (without hindering motion) of patients with light to moderate injuries. Under compression garments, the spontaneous sliding motion between the elastic fabric and the supporting fabric of the cuffs is noticeable.

The integument being relatively strong, the cuffs can be worn all day long. However, only the airier compression garments are recommended at night. At any rate, the patient must be continuously monitored for any potential problems.

In the case of patients with more serious injuries (retractions, adhesions, remote cutaneous attractions, hypertrophy in process, etc.), Medigel-Z has been used with different types of appliances.

We considered the dynamic role of Medigel-Z in the case of gypsotomies, since it then also becomes compressive. It is applied on adhesion or retractible plate attachment sites and submitted to the compression of the appliance.

n the case of a thoraco-brachial cast, it is essential to ensure that the axilla is well defined (all the while taking into account the neurovascular bundle!) and to provide a true deltoid cap, thereby guaranteeing the stability of the appliance.

At D+1 or D+2, the cap and the brachial section are removed in order to measure the articular gain; a new cast is prepared with a supplement of Medigel-Z at the visible sites. This process is repeated daily for the next three days.

At the conclusion of this process, the thoracobrachial cast is completely removed, the gel sheets are examined, cleaned and dried, the skin is also examined, cleaned and dried, and a new cast is prepared, and the same procedure is repeated.

This technique applies to all articulations : wrists, fingers, elbows, knees, etc.

#### 3. Use and Indications

Medigel-Z was used with compression garments 77 times and used alone 29 times. It was used for its anti-inflammatory action (42 cases), in order to soften the skin (53 cases) or for its anti-ichthyotic action (11 cases).

#### **Evaluation Criteria**

#### A. Subjective Evaluation Criteria

#### 1. Visual Examination

The visual examination allowed us to assess:

- ☐ the degree of inflammation, according to the coloration of the skin (bright red to light pink)
- □appraisal of the topography (more or less hypertrophy) and the quality of the skin (marked or not...)
- □ Epithelial condition (ichthyosis, cracks...).

#### 2. Palpatory Examination

Palpation allowed us to evaluate:

- □ the flexibility of the skin: from the inability to mobilize a plate to the ability to perform rolled folds.
- ☐ the in depth value of the adhesions
- ☐ the intensity of the pain (two-fold estimation : by the examiner and by the patient)
- ☐ the hydration of the skin.

#### **B.** Objective Evaluation Criteria

- ☐ The most important examination for the assessment of the inflammation is the vitopression test.
- ☐ The thickness of the skin fold is measured by an adipometer.
- ☐ The articulation results allow us to calculate any gains achieved after skin softening.
- ☐ The neurological exam establishes a cartography of the change in superficial sensitivity.
- □ A test, a variant of the Schöber Test, assesses the difference in cutaneous stretching.

- ☐ The patient's ability to undergo new constrictive treatments points to the efficiency of the copolymers (gypsotomies)
- ☐ The comparison of the photographs taken before, during and after the treatment reveals functional and skin gains.
- ☐ The data provided by the ultrasound examination complete these results.

# Results

Results were excellent in 30 cases: significant lessening of the inflammation and hypertrophy and a good sliding motion. No allergic reactions were observed.

Results were good in 50 cases: satisfactory efficacy with respect to sliding motion and hypertrophy, with no allergies. However, in some cases, the product type had to be changed. Results were deemed average in 16 cases, mainly because of minor tolerance problems which led to the implementation of a repeated treatment.

Finally, 10 failures were recorded due to problems with allergies, maceration, etc. requiring the application to be halted permanently.

In total, 80 cases out of 106 (75.5%) produced good or excellent results and only 10 failures (9.4%) were recorded.

# **Discussion**

Our experience with Medigel-Z in its different forms highlighted two types of benefits in comparison to the silicone-based products available on the market:

- □Use-related benefits: easy to use, several options, favours the acceptance of the appliance, potential change in various types based on the cutaneous programs, etc.
- ☐ Product-related benefits: transparency (in the case of the 10 x 10 cm patches), variable density, cleanliness, elasticity, strength.

The older-generation silicone sheets available on the market quickly crumble, even if handled with care. Foams tear easily, even though they can be rejoined. Copolymers (Medigel-Z) can be used for six months if they are properly maintained (hand washed with "triclocarban" or with an organic mercury agent, dried between two towels, away from a heat source). However, the cuffs require special handling, since they are more fragile. The strength of the product is remarkable based on our experience in the rehabilitation field.

After this 6-month period, the product appears to keep its effectiveness, but we are personally unable to comment on its chemical stability.

The patches, less subject to different multidirectional mechanical constraints are more durable than the cuffs whose elasticity does not appear to be altered.

In conclusion, in our study, the Medigel-Z patches had a lifespan between 6 to 7 months, and the cuffs between 3 to 6 months.

We regret the perhaps too great slenderness of the cuffs currently available; this should change with a new generation of products.

It must also be noted that elastic bandages coated with the same polymer are also available. These appear to be quite interesting. They allowed us to treat poorly accessible sites such as the axilla, the neck, the armpit, etc.

The product's disadvantages concern the risk of maceration and allergies. The disadvantages linked to its use are its opacity (requiring close monitoring), the absence of adhesion or autoadhesion and a delicate or non-existent stability of the mould.

#### Conclusion

The use of these new materials in scarring maturation requires an objective study of the reasons for their effectiveness.

For this reason, a more complete assessment of our results, including stretching, sliding motion, cutaneous fold tests, together with the more conventional visual and functional articulation tests, is now underway.

This assessment could not be complete without the use of paraclinical examinations such as ultrasound or cutaneous thermoscanning. However, we can already state that the benefits of Medigel-Z outweigh its disadvantages and that the rapidity of the cutaneous, articular (and thus functional) gains, result in a shorter stay for burn patients in a specialized rehabilitation centre

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# SILICONES, HANDS

# AND SKIN CICATRIZATION

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Paper presented at the "30e Congrès de la Société Française de la Chirurgie de la main (30th Convention of the French Society for Hand Surgery), G.E.M. 94 (Paris, December 7-10 1994) during the round table "Rehabilitation and physical treatment of the burned hand".

#### HISTORICAL REVIEW

Silicones were first used in the treatment of burns during the 1960's. MILLER J. <sup>14</sup> (1965), SPIRA M. <sup>19</sup> (1967) published articles on the treatment of hand burns with silicone garments.

BATDORF J. and CAMMACK<sup>3</sup> presented another study in 1969 on the same topic.

However, it wasn't until **1982** that PERKINS<sup>16</sup> and his research group in Australia systematically used and studied silicone gels (Spenco Medical Corporation MD - 3071), due to the problems they encountered in the treatment of some burn sites (anatomically depressed or concave areas, flexion folds) and during motion.

In April **1983**, DOW CORNING, an international manufacturer of silicone-based products, developed an identical silicone gel (X7 - 9119), that they had tested at the Royal Hospital of GLASGOW (United Kingdom). QUINN K.J. <sup>17-18</sup> and her team directed this study; the objective was to highlight the effectiveness of silicone gels and determine their mode of action.

AHN S.T., MONAFO W., and MUSTOE T.<sup>1</sup> published their work on silicone gels in 1989 (St-Louis - USA, Seoul - KOREA), attempting essentially to prove their effectiveness in a rational manner through photographs, elastometry, biopsies and clinical evaluations.

Since then, silicones have been systematically used in the treatment of burns, as well as in the prevention of hypertrophic scarring (AHN S. 1991<sup>2</sup>).

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# MODE OF ACTION

In 1983, QUINN<sup>17-18</sup> and her team were the first to study the different factors able to explain the action of silicones.

- 1. Pressure: Scars are flattened by applying a mercury pressure of about 30 mm. The pressure measured under the silicone sheets by QUINN were negligible, lower than 3 mm of mercury, even under dressings.
- 2. Temperature: No significant and lasting change in skin temperature under silicone.
- 3. Oxygen transmission: No alteration.
- 4. Pharmacology: (Work of AHN<sup>2</sup> S. 1991): Electronic microscopic studies revealed no evidence of silicone in skin biopsies.
- 5. Occlusive effect and skin hydration: (Even though the other occlusive dressings were shown to be inefficient). The reduction in water evaporation allowed for a better hydration of the stratum corneum, a better diffusion towards the skin surface of the soluble proteins involved in the inflammation (BERANEK 1990)<sup>4</sup>, a reduction in capillary growth and collagen deposits (DAVEY 1991)<sup>5</sup>, which might in a secondary way, contribute to the reduction in hypertrophic scarring. In 1990, 1992, SAWADA and SONE<sup>20 to 25</sup> published articles on their work on occlusive dressings with either vaseline-base or silicone-base creams. In their opinion, silicone did not appear to be the essential ingredient. They feel the therapeutic effectiveness on hypertrophic scars is due more to the occlusive effect and resulting skin hydration.
- 6. Static electricity: In 1993, after extensive work, HIRSCHOWITZ<sup>8</sup> proposed the hypothesis that a phenomenon of static electricity, via occlusive dressings containing silicone, had a beneficial, if partial, effect on cutaneous cicatrization.

The multiplicity of silicones available on the market led us to formulate the following question:

# WHICH SILICONE TO CHOOSE?

Silicones can be divided into 2 main families:

- ♦ silicone "putty"
- ♦ silicone "gel"

#### 1) SILICONE "PUTTY"

- A. COMMERCIALIZATION:
- in dentistry for impressions
- prevention and treatment of hypertrophic scars

- B ADMINISTRATION EFFECTS: Fundamentally different, thereby allowing us to identify 2 main groups: silicones reticulating:
- by condensation,
- or by addition,

At the clinical level, this difference leads to specific uses.

Condensation silicones are obtained by mixing a polymethylsiloxane basic paste with a triethylsilicate reagent - the mass goes from a plastic phase to an elastic phase, but liberates alcohol molecules which easily evaporate.

Addition silicones (vinylpolysiloxane) are obtained by mixing equal parts of a base and catalyst of equivalent consistency, a material minimally sensitive to preparatory manipulations, with an excellent elasticity, a constant volume, a lower toxicity and chemically neutral.

#### 2) SILICONE "GELS"

These are dimethylsiloxane polymers in patch form, usually reinforced by a polyester fabric. They are used for the prevention and treatment of hypertrophic scars in burn patients.

# **EQUIPMENT AND METHOD**

#### Equipment:

1. We performed a retrospective study over a period of 15 months (November 1993 to January 1995) of 95 patients:

Diagnosis	Silicone Putties	Silicone Gels	Medigel Z	TOTAL	Number of Patients
Burns <sup>1</sup>	39	51	14	104	66
Hypertrophic scars <sup>2</sup>	14	8	8	30	16
Burned Hands <sup>1</sup>	21	7	0	28	7
Burned hands with hypertrophic scars <sup>2</sup>	18	4	2	24	6
TOTAL	92	70	24	186	95

- 1: Initial Period
- 2 : Etiology other than burn

#### Method:

On the basis of the patient assessments and our opinion, we attempted to define the qualities of the silicone "putties" and "gels" available on the market and most frequently used: accuracy of the moulding, self-adhesion, flexibility and rigidity, comfort, durability, washability, lifespan, how supplied, commercialization, criteria which we ranked from 0 to 4 and laid out in a table format.

# DISCUSSION

Silicone "putties" allow for accurate moulding, display good self-adhesion and can be recharged; rigid, they allow for articular postures; they are sufficiently solid, but provide a low degree of comfort; they can be washed with water and soap or they can be sterilized. Their lifespan is long (3 months to 1 year).

Silicone "gels" mould perfectly to the hypertrophic scars, have no self-adhesion, are very flexible; used alone, they do not allow for any articular posturing, but the continued mobility can sometimes be advantageous. They are not durable or easily washed, fragile and their lifespan is shorter (2 weeks to 3 months); however, they do have two main benefits: their comfort and probably greater effectiveness on cutaneous trophicity (all studies of silicone action have been performed using silicone "gels"); they carry a slightly higher cost.

#### EXAMPLES:

- 1. CHILDREN: who have cutaneous injuries to the palm, regardless of the etiology (burn, post-surgical scarring, adhesions...). We often had difficulty in providing accurate appliances. Based on the principle that any traction leads to a worsening of the adhesions, we prepared silicone compressive "putties" (recharged, attached with Velcro or sandwich splint), or gel splints. These appliances are easy to make, well tolerated, inexpensive; remoulding is recommended during the treatment in order to attain perfect accuracy. They are worn at night until the cicatrization process is complete.
- 2. *ADULTS*: the same principle led us to manufacture silicone "putty" splints, or splints coated with silicone "gels" for the treatment of palm scarring, adhesions of the 1st commissure, or for a simply aesthetic purpose.

### CONCLUSIONS

At the completion of this comparative study, our preference is for :

- dental silicone addition "putties" which feature all the qualities of their category at a significantly lower cost
- and Medigel-Z for its effectiveness, its greater durability and efficient commercialization under various forms.

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