

Evaluation of a self-adherent soft silicone dressing for the treatment of hypertrophic postoperative scars

- **Objective:** The primary objective was to compare the efficacy of a self-adherent soft silicone dressing (Mepiform) with 'left-alone' management of hypertrophic scars using the Vancouver Scar Scale. Secondary objectives were to follow photographs of the scars, patients' opinions of the scars, and doctors' and patients' assessments of the overall dressing performance, safety and tolerance.
- **Method:** An exploratory open randomised controlled clinical investigation was undertaken on 11 female patients aged 21–43 years with postoperative scars (nine following breast surgery, two following lower abdominal-glutealplasty). Treatment was initiated between two weeks and two months (mean 4.7 weeks) after surgery. Ten patients completed the 12-month investigation; one patient in the treatment group discontinued for personal reasons.
- **Results:** All parameters in the Vancouver Scar Scale improved in both groups, although patients treated with the soft silicone dressing showed greater and more rapid improvements compared with the non-treated patients, while their assessments of the condition of the scar were more favourable. Medical staff rated the overall dressing performance as 'very good' or 'good'. One adverse event was reported – local skin irritation at the site of the scar.
- **Conclusion:** The results suggest that patients treated with the soft silicone dressing experienced greater and more rapid improvements compared with non-treated patients. These results concur with those of previous studies. The fact that Mepiform is self-adhesive and causes limited damage to the stratum corneum on removal gives it an added value compared with non-adhesive silicone gel dressings.
- **Declaration of interest:** This study was supported by Mölnlycke Health Care AB, Gothenburg, Sweden.

postoperative scarring; hypertrophic scar; self-adhesive soft silicone dressing

A variety of techniques are used in the management of hypertrophic scars. However, the evidence base for many treatments is poor, and some may have only a placebo benefit.¹ This may be in part due to the difficulty in assessing the efficacy of treatment methods as scars have a natural tendency to improve over time.¹

A study design with randomisation, an adequate control group and long-term follow-up is therefore required to facilitate conclusions about efficacy. The aim of this open randomised controlled one-year clinical investigation was to compare the efficacy of a self-adherent soft silicone dressing (Mepiform, Mölnlycke Health Care AB, Gothenburg, Sweden) with no treatment in patients with hypertrophic scars following plastic surgery.

Method

Participants

The participants were recruited from patients having elective surgery for burns or plastic surgery at the Special Sciences Institute, Department of Plastic Surgery, Madrid, Spain. Eligible patients were adults aged 18 years or older with postoperative scarring

who were attending the outpatient clinic. According to Mustoe,¹ such procedures have a high incidence of hypertrophic scarring.

Patients were excluded from the study if they:

- Suffered from an underlying disease judged by the investigator to possibly interfere with the treatment of the hypertrophic scar (for example, cancer)
- Had a known hypersensitivity to the product used in the study
- Were unable to comply with the study procedures and/or attend the clinic for follow-up visits
- Had any type of keloid scar as treatment for minor keloid scars requires a combination of silicone dressings and intralesional corticosteroids, while major keloids can be treated with antihistamine and, in some cases, radiation.¹

Study design

The study was performed in accordance with the ethical principles set forth in the Declaration of Helsinki. Written informed consent was obtained from all patients participating in the study. Since this was an explorative pilot study it was determined that 12 would be a suitable number of patients.

Participants were randomly allocated to one of

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Table 1. Patient demographics

Patient	Treatment	Physical examination	Underlying diseases	Other major surgery	Type of scar	Time since surgery	Previous treatment of scar
1	Mepiform	Normal	None	Bilateral breast reduction	Postop breast	1 month	None
2	Control	Normal	None	None	Postop breast	2 months	Pressure garment
3	Mepiform	Normal	None	None	Postop breast	2 months	Topical cream
4	Control	Normal	None	None	Postop breast	3 weeks	Topical cream
5	Control	Normal	CA mammae	Mastoidectomy	Postop breast	3 weeks	None
6	Mepiform	Normal	None	None	Postop breast	2 weeks	None
7*	Mepiform	Normal	None	None	Postop breast	1 month	Topical cream
8	Control	Normal	None	Breast reduction	Postop breast	1 month	None
10**	Control	Morbid obesity, abdominoplasty, legs lifting	None	Gastroplasty	Postop right leg	1 month	Pressure garment
11**	Mepiform	Morbid obesity, abdominoplasty, legs lifting	None	Gastroplasty	Postop left leg	1 month	Pressure garment
12	Mepiform	Normal	None	Bilateral breast reduction	Postop breast	2 months	None

*Patient 7 discontinued for personal reasons two months after the start of the study
 **Patient 10 and 11 was the same patient
 Patient 9 withdrew consent after randomisation and never enrolled

the two treatment options by a predetermined computer-generated randomisation list.

Blinding was not possible as this was a dressing versus no dressing study, therefore an open design was used. In addition, at our clinic patients with hypertrophic scars do not normally receive any treatment during the first year after surgery as options such as silicone gel sheeting have only recently become available.

Interventions

Participants were randomised either to treatment with the self-adherent soft silicone dressing or no treatment. They were advised to use the dressing for about 23 hours per day and to reapply the same sheet until adherence was judged to be insufficient, or for a maximum of one week.

Endpoints

Participants were evaluated at baseline, monthly up to six months and after 12 months.

The primary objective was to evaluate improve-

ments in scar characteristics according to the Vancouver Scar Scale,² which includes the following parameters:

- Pigmentation
- Height
- Pliability
- Vascularity.

Other endpoints were:

- Photographs of the scar taken at baseline and after 12 months
- Participants' views on the condition of the scar (smooth, dry, moist, hard, itchy and pain) at baseline and at each follow-up visit
- Participants' and investigators' assessment of overall dressing performance after 12 months
- Adverse events noted at each follow-up visit.

Statistical methods

In this exploratory investigation the sample size was not calculated based on a predefined power to detect a significant difference for the primary endpoint. The aim was rather to obtain information to serve as

a base for designing future confirmative investigations. The results are presented in a descriptive manner without calculation of p values.

Results

Participants

Eleven female patients (six in the treatment and five in the control group) were randomised and enrolled into the study. In the dressing group the mean age was 28.8 years (range 20–43) and in the control group it was 29.4 years (range 22–40). Other demographic data are given in Table 1. Nine had had breast surgery and two lower abdominal-glutealplasty due to obesity. Treatment was initiated between two weeks and two months after surgery. Ten participants completed the 12-month investigation; one in the treatment group discontinued the study due to personal reasons.

Efficacy

During the study period all scars, including those in the control group, improved according to the Vancouver Scar Scale. However, as seen in Fig 1, the improvement was greater in the treatment group; individual patient results at baseline and 12-month follow-up are given in Table 2. Most improvement in pigmentation, height, pliability and vascularity took place in the period up to the six-month follow-up visit. The further improvement up to the 12-month follow-up visit was similar in the two groups.

Fig 2 shows scars in one participant before (a) and after (b) 12 months of treatment.

At baseline three participants in each group judged their scars to be 'hard'. After six months all those in the dressing group judged their scars to be 'smooth', while two in the control group still considered their scars to be 'hard'.

The doctor's assessment of overall dressing performance was 'very good' or 'good' in all participants, while participants' own assessments were 'very good' or 'good' in four out of five cases.

Safety

One adverse event was reported during the study. The participant experienced a local skin reaction at the site of the scar and discontinued dressing use. After one month her skin had returned to its normal condition and she resumed the treatment; the skin reaction did not reappear.

Discussion

Each year in the developed world 100 million people acquire scars, some of which cause considerable problems.³ Global figures are unknown but doubtless much higher. People with abnormal skin scarring may face physical, aesthetic, psychological and social consequences that may be associated with substantial emotional and financial costs. Those who undergo plastic surgery for aesthetic reasons

Fig 1. Vancouver Scar Scale results: pigmentation, height, pliability and vascularity

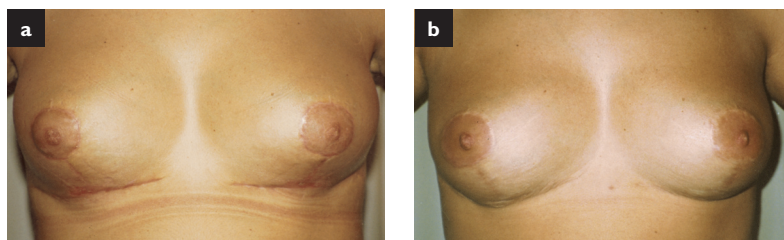
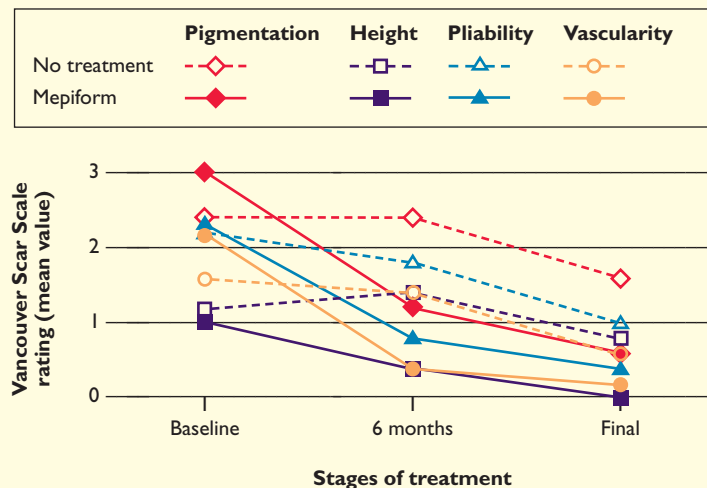


Fig 2. One participant's scar before (a) and after (b) 12 months' treatment

may be particularly sensitive to disfiguring scars.

Skin repair results in a broad spectrum of scar types, ranging from a fine line to a variety of abnormal scars such as widespread scars, atrophic scars, scar contractures, hypertrophic scars and keloid scars. Raised scars are described as hypertrophic or keloid. Linear hypertrophic scars are red, raised, sometimes itchy and confined to the border of the original surgical incision. Scars may increase in size rapidly for three to six months and then, after a static phase, begin to regress. They generally mature to have an elevated, slightly rope-like appearance, with an increased width. The full maturation process may take up to two years.

Accurate scar assessment is essential for diagnosis and for starting, monitoring and evaluating a therapeutic strategy for scar management. The severity of scars is often judged by eye but can be assessed quantitatively with a scar assessment guide such as the Vancouver Scar Scale.² A standardised colour photograph of the scar lesion provides a reference with which to evaluate the effectiveness of treatment. Due to the natural tendency for scars to improve over time it is important in clinical trials to have a control group, allocate participants to treatment or control group by proper randomisation,

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Table 2. Vancouver Scar Scale data: individual patient data recorded at baseline and last visit (12 months)

Patient no.	Treatment	Visit no.	Pigmentation	Height (mm)	Pliability	Vascularity	Pressure therapy
1	Mepiform	1	3	1	3	2	No
		8	0	0	1	0	No
2	Control	1	3	1	3	2	No
		8	2	1	1	0	No
3	Mepiform	1	3	1	1	2	No
		8	1	0	1	0	No
4	Control	1	0	1	1	0	No
		8	2	1	1	1	No
5	Control	1	3	1	2	2	No
		8	2	1	1	2	No
6	Mepiform	1	3	1	2	2	No
		8	0	0	0	0	No
7	Mepiform	1	3	1	3	3	No
		5	2	1	2	2	No
8	Control	1	3	2	3	2	No
		8	1	0	1	0	No
10	Control	1	3	1	2	2	Yes
		8	1	1	1	0	Yes
11	Mepiform	1	3	1	2	2	Yes
		8	0	0	0	0	Yes
12	Mepiform	1	3	1	3	2	No
		8	2	0	0	1	No

Pigmentation: 0 = normal; 1 = hypopigmented; 2 = mixed; 3 = hyperpigmented
 Height: 0 = flat/normal; 1 = <2mm; 2 = 2-5mm; 3 = >5mm
 Pliability: 0 = normal; 1 = supple/flexible; 2 = yielding to pressure; 3 = firm/inflexible; 4 = banding/rope-like; 5 = contracture
 Vascularity: 0 = normal; 1 = pink; 2 = red; 3 = purple
 Visit 1 = baseline; visit 8 = 12 months (data for the other patient visits can be obtained direct from the author)

and to follow up participants for a year or more.

An international advisory panel has recently issued international clinical recommendations on scar management.¹ The group reported a qualitative overview of more than 300 published references using standard methods of appraisal.

For prevention, the panel recommends silicone gel sheeting as the first-line option. Its use should begin soon after surgical closure, when the incision has fully epithelialised, and be continued for at least one month. Silicone gel sheets should be worn for a minimum of 12 hours daily, and if possible for 24 hours per day, with twice-daily washing.

For management of linear hypertrophic scars the panel recommends that silicone gel sheeting should be used as first-line therapy, in line with results from randomised controlled trials. If the scar is resistant to silicone therapy, or is severe and pruritic, further management with corticosteroid injections is indicated.¹ If silicone gel sheeting, pressure garments and intralesional corticosteroid injections are not successful after 12 months of conservative therapy, surgical excision with postoperative application of silicone gel sheeting should be considered.¹

Conclusion

The strengths of this exploratory investigation are the randomisation procedure, the control group and the one-year follow-up period.

There are two major limitations: the small sample size gives a low power to detect significant differences between the treatment and the control groups, and the open design increases the risk of bias in the assessments of scar characteristics.

However, the results of this study are in line with those of clinical trials with other silicone gel sheetings and in accordance with the results of other clinical studies on Mepiform.⁴⁻⁷

The fact that the study dressing is self-adherent gives it an added value as it may also be used in patients in whom the adhesive tapes used to secure non-adhesive silicone gel sheets causes discomfort and skin irritation.⁸

Mepiform has been shown to cause less damage to the stratum corneum of the skin upon repeated removal than other adhesive dressings.⁹

In conclusion, we consider that the soft silicone dressing should be explored as a first-line prophylaxis, and applied as soon as possible after surgical closure. ■