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FINAL REPORT

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Introduction

Background and justification for the design of the clinical investigation

With the exponential rise in the number of surgical weight loss procedures being performed, so too has risen the number of body contouring procedures performed by plastic surgeons. Comparing data from 2000 to 2017, the number of brachioplasties performed for arm rejuvenation in the United States has increased from 338 to 18,033. Since its original description, the brachioplasty procedure has evolved through a multitude of technical modifications, all of which have been aimed at improving outcomes with regard to scar and contour. Different authors who have written on the subject advocate different approaches, but most agree that postoperative scarring is the most common issue that arises in patient complaints postoperatively.

There exists a wide variety of treatment options to improve the outcome of post-brachioplasty scarring and there is a consensus that the quality of wound healing is related to the outcome.

Among the various options for wound healing, electric fields in the form of direct microcurrents to wounds have been reported to result in a reduction in healing time, inflammation and pain. However, the delivery systems used on patients are often bulky, with limited clinical data reported. The majority of studies concerning electrical stimulation showed a significant improvement in wound area reduction or accelerated wound healing compared to the standard of care or sham therapy as well as improved local perfusion.

To date, no study mentioned objective measurements of scar parameters, results of scar scales or PROMs for the long-term outcome of this intervention. The aim of this study is to investigate whether the outcomes of patients with brachioplasty scars treated with standard wound care, hydration and microcurrent therapy differ significantly from the outcomes of patients who received the same treatment except for the microcurrent therapy.

Description of the investigational medicinal product and its intended purpose

Micro current therapy is a therapy to treat humans / animals using electric current with amperages flowing in the µA range. The device offers 2 treatment methods: manual treatment, which requires manual input corresponding to the mentioned parameters, and automatic treatment which, depending on the clinical picture and the currently measured resistance between the electrodes, allows the device to automatically change the mentioned parameters. In accordance with the different disease patterns automatic treatment consists of a chronological sequence of treatments with different parameters. For this study we use an automatic treatment with predefined settings. This automatic programme consists of a variation of 20 different frequency settings during 17 minutes. This programme is repeated one time which leads to a total treatment time of 34 minutes. The intensity setting for the treatment is between 200 and 350 µA. The treatment is applied 5x per week in the first 6 weeks and 1 – 2 x per week in the following 6 weeks. The treatment is stopped after three months. Four electrodes are placed according to the below mentioned schedule.

The B-E-St microcurrent device is developed to treat humans/animals with low amperage in the range of µA. For this purpose the device is equipped with 4 treatment channels: A1, A2, B1 and B2.

Channels A and B (A1, A2 and B1, B2) are galvanically separated so that no current can flow from A to B resp. inversely. Subchannels 1,2 are not isolated galvanically, though they are operated in time division multiplexing so it's actually a time-dependent galvanic isolation. When channel A1 is active, current flows e.g. from A1+ to A1- while A2+ and A2- are in a high impedance state. Meaning charge carriers that are moving in the pathway of A1 when A1 is active are not influenced by A2. Subsequently A2 is activated and A1 is in a high-impedance state. The same goes for channels B1 and B2.

By using a channel processor that is allocated to each of the main channels A and B, a pulse repetition with an adjustable impulse frequency, definable amperage and direction can be set for channels A and B. The pulse repetition can be divided into 3 areas: one with rising pulse amplitude, one with constant pulse amplitude and one with falling pulse amplitude. The duration of the three areas is adjustable.

Typical values for the areas are: 0.5 seconds until the pulse amplitude reaches the set maximum value, 2 seconds for holding this maximum value and 0 seconds to reset the pulse amplitude to 0. This envelope shape (rise, hold, fall) applies to both subchannels 1 and 2 at a time. Only an amperage and a pulse frequency can be set for both subchannels. The current direction can however be set for each subchannel separately. The chosen current is toggled between the subchannels with the pulse repetition.

After the envelope comes another fourth, unalterable area that outputs a measurement current. This area lasts for 400msec.

Treatment takes place exclusively with current impulses, when necessary with alternating polarity. The recommended amperage of this device for treatment is usually the value of the pulse amplitude in the "hold" area.

Method

Objective of the Clinical Investigation

Primary Objective: The patient-reported outcomes registered with Patient Scar Assessment Scale of the microcurrent treated site differ significantly from the non-treated site.

Secondary Objective(s): The results of subjective observer-reported outcomes, QOL questionnaires and objective outcome measures of redness and pliability of the microcurrent treated site differ significantly from the non-treated site.

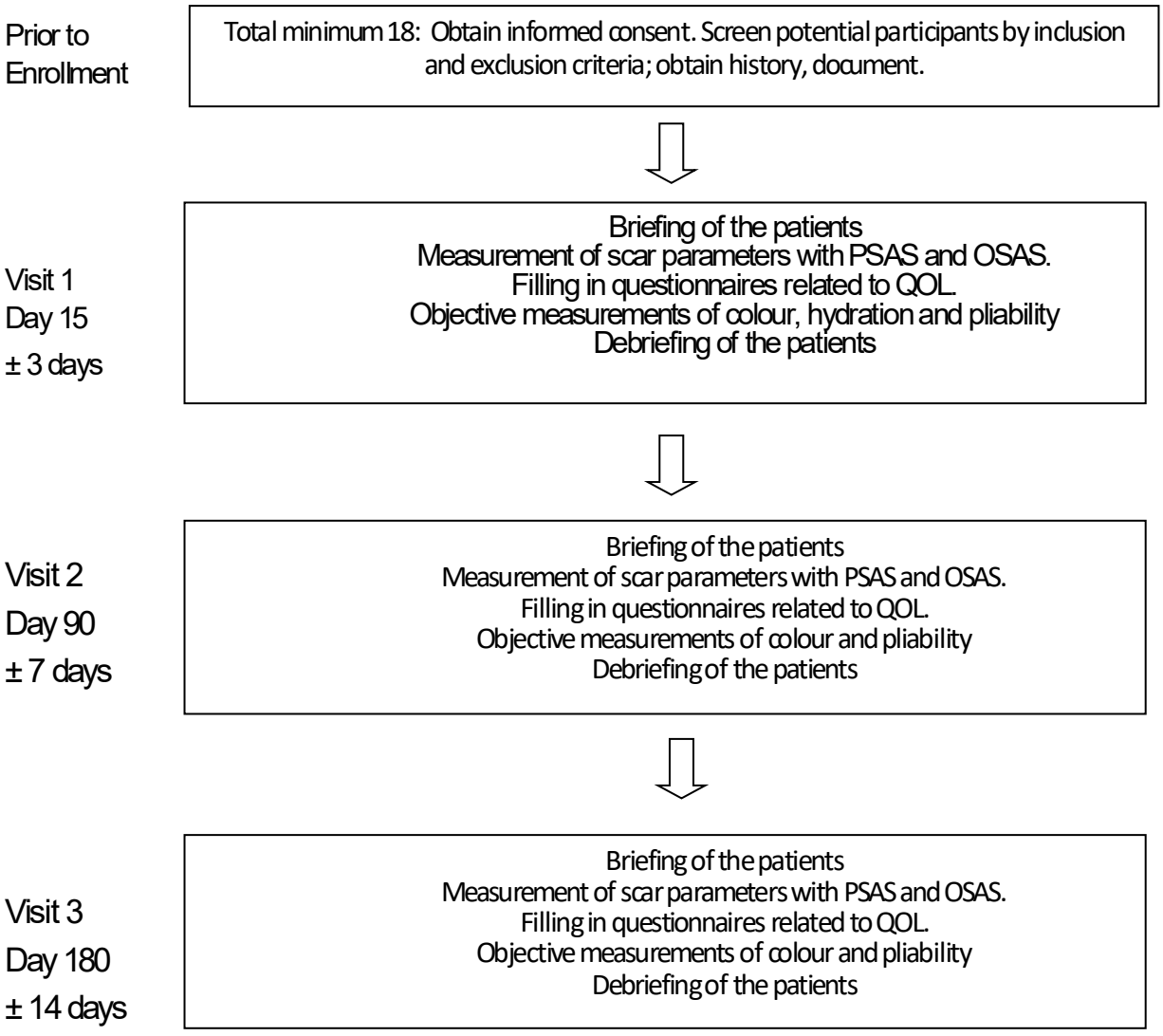
Design of the Clinical Investigation

This study is a prospective, single centre two-arm randomized controlled study with a minimum of 18 patients and a maximum of 20 patients. The study will take place at OSCARE, Van Roiestraat 18, B-2170 Merksem (Antwerpen), Belgium.

The scar on the contralateral arm serves as a comparator.

Methods and timing for assessing, recording, and analysing variables

Schematic of Study Design:



Inclusion criteria for subject selection

- The subjects must be between 18 and 75 years old.
- Having received surgical treatment, more specific bilateral brachioplasty.

Exclusion criteria for subject selection

- Subjects who have an implanted or other electrical stimulatory device such as pacemakers, or any other implanted electronic nerve, muscle or tissue stimulation.
- Subjects with implanted hearing aids.
- Subjects with a history of seizures, epilepsy.
- Women who are pregnant at the time of enrolment
- Central neurological conditions
- Peripheral paralysis
- Patients with diabetes mellitus
- Subjects unable to give informed consent

Results

Adverse effects

One patient developed an infection in the axilla of the arm that received the intervention. Measurements could still take place since the measurements were performed on the lower third of the scar, closer to the elbow. However, a general swelling of the upper arm was noticed, Which could have influenced the measurements.

One other patient showed skin irritation after 5 weeks of treatment. The treatment was temporary postponed for 5 days and restarted afterwards.

No further problems occurred.

Demographics

To date 20 patients are enrolled in the study, of which 16 patients have completed all the assessments. Four drop-outs were recorded. The descriptive characteristics of these patients are found in Table 1.

Table 1: Descriptive characteristics of the subjects.

Mean age	41 years ±12 years
Mean scar age	1 month
Gender	20 female
Ethnicity	16 Caucasian – 4 North African

POSAS Patient

The Patient Scale contains six questions applying to pain, itching, colour, pliability, thickness and relief.

Each of the six items on both scales has a 10-point score, with 10 indicating the worst imaginable scar or sensation. The lowest score is '1', and corresponds to the situation of normal skin (normal pigmentation, no itching etc.).

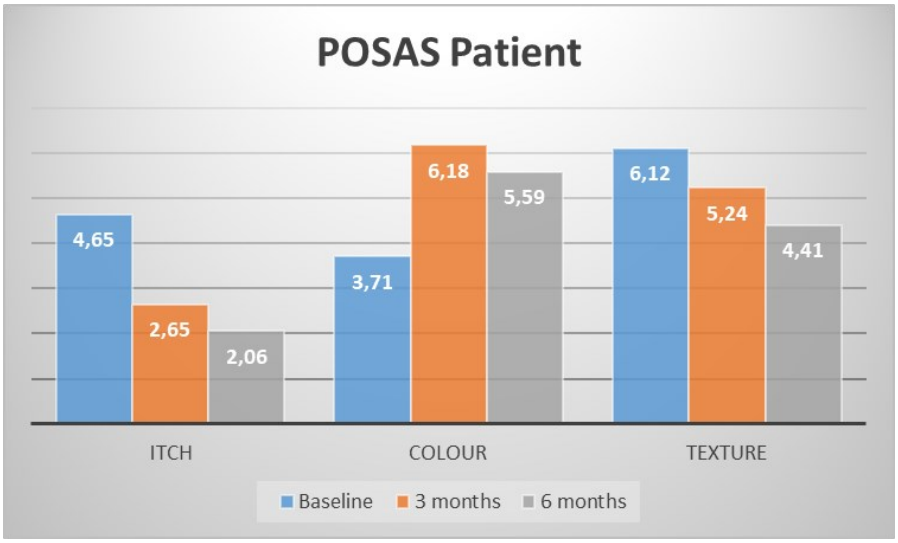
The Patient Scale POSAS contains the following questions:
1. Has the scar been painful the past few weeks?
2. Has the scar been itching the past few weeks?
3. Is the scar colour different from the colour of your normal skin at present?
4. Is the stiffness of the scar different from your normal skin at present?
5. Is the thickness of the scar different from your normal skin at present?
6. Is the scar more irregular than your normal skin at present?

Besides these six questions, the patient is asked to provide an Overall Opinion regarding scar quality. At the end the "Total Sum of Scores" is calculated by adding up all six items.

Following parameters have shown to be statistically significantly altered:

- **Itch** showed a statistically significant improvement after 3 months ($p = .029$) and after 6 months ($p = .009$) and has decreased from 4.65 at baseline to 2.06 after 6 months.
- **Colour** showed a statistically significant increase after 3 months ($p < .001$) and after 6 months ($p < .001$) and has increased from 3.71 at baseline to 5.59 after 6 months.
- **Texture** showed a statistically significant improvement after 3 months ($p = .043$) and after 6 months ($p = .017$) has decreased from 6.12 at baseline to 4.41 after 6 months.
- A trend towards improvement, however not statistically significant, was also seen for **Pain**, which has decreased from 2.65 at baseline to 1.94 after 6 months ($p > .05$) and **Sum of Scores**, which has decreased from 25.33 at baseline to 21.94 after 6 months ($p > .05$).

Table 2: Statistically significant results of the POSAS Patient in the intervention group.



We observed no statistically significant differences between the intervention group and the control group for any of the POSAS patient items.

POSAS Observer

In the POSAS observers rate vascularity, pigmentation, pliability, thickness, relief and surface area. The directions for use of the different parameters of the Observer Scale POSAS are as follows (all parameters should be compared to normal skin at a comparable anatomical site whenever possible):

Vascularity: Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas.

Pigmentation: Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity.

Thickness: Average distance between the subcuticular-dermal border and the epidermal surface of the scar.

Relief or Texture: The extent to which surface irregularities are present (preferably compared with adjacent normal skin).

Pliability: Suppleness of the scar tested by wrinkling the scar between the thumb and index finger.

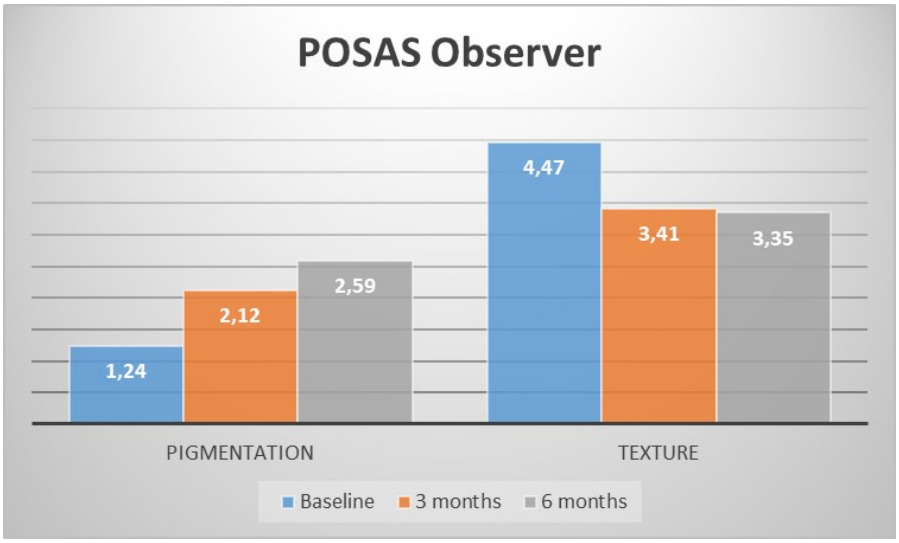
Surface area: Surface area of the scar in relation to the original wound area.

The **Overall Opinion** is assessed as well and the **Total Sum of Scores** is calculated by adding up all six items.

Following parameters have shown to be statistically significantly altered.

- **Pigmentation** showed a statistically significant decline after 3 months ($p = .009$) and after 6 months ($p = .002$) and has increased from 1.24 at baseline to 2,59 after 6 months.
- **Texture** showed a statistically significant improvement after 3 months ($p = .034$) and after 6 months ($p = .030$) and has decreased from 4.47 at baseline to 3.35 after 6 months.
- A trend towards improvement, however not statistically significant, was also seen for **Pliability**, which has decreased from 4.94 at baseline to 4.08 after 6 months ($p > .05$).

Table 3: Statistically significant results for the POSAS observer of the intervention group.



We observed no statistically significant differences between the intervention group and the control group for any of the POSAS observer items.

Colorimetry, hydration and elasticity

The colour is measured using a Mexameter® which results in a melanin index computed from the results of red and infrared wavelengths and an erythema index calculated from the results of green and red wavelengths.

Hydration is measured with the Corneometer® of which the measuring principle is based on the capacitance method. The hydration values vary between 0 and 120 AU. The hydration measurements were carried out mainly to investigate possible correlations between erythema and hydration and between elasticity and hydration.

Elasticity is measured with the Cutometer®. The measuring principle is based on the suction method. Negative pressure is created in the device and the skin is drawn into the aperture of the probe and released again after a defined time. Inside the probe the penetration depth is determined by a non-contact optical measuring system. The Cutometer® measures the vertical deformation of the skin in millimetres.

When comparing the intervention group (group 0) with the control group (group 1) there were no significant differences between the groups for erythema, pigmentation and elasticity.

For erythema, a trend towards improvement was visible for both groups, however not statistically significant. The control group seems to perform better than the intervention group, however this was not confirmed by statistical significance. Below you can find a graphical representation of the results for erythema.

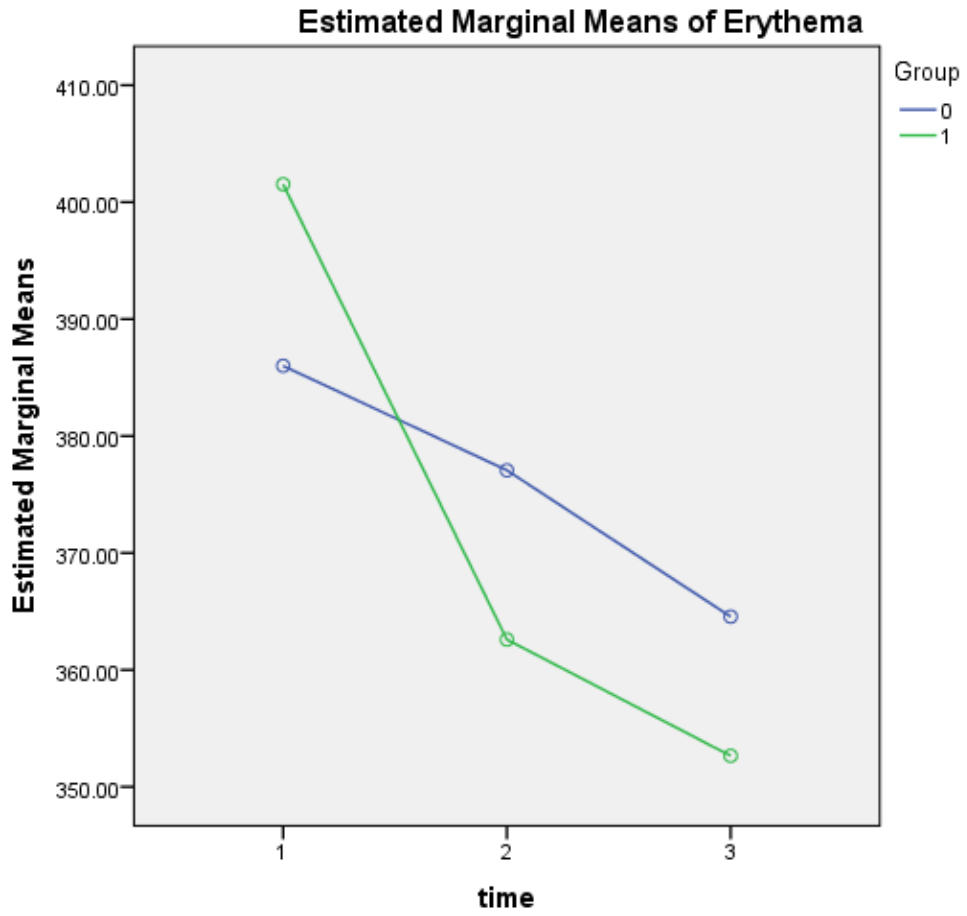


Fig 1: Graphical representation of the results for erythema

For **Pigmentation,** a statistically significant difference was found for both groups over time ($p < .0005$) and after 3 months and after 6 months ($p < .0005$ and $p = .001$). Looking at the group results separately, a statistically significant decrease was observed over time as well for the intervention group ($p = .008$) as for the control group ($p = .001$). Below you can find a graphical representation of the results for pigmentation.

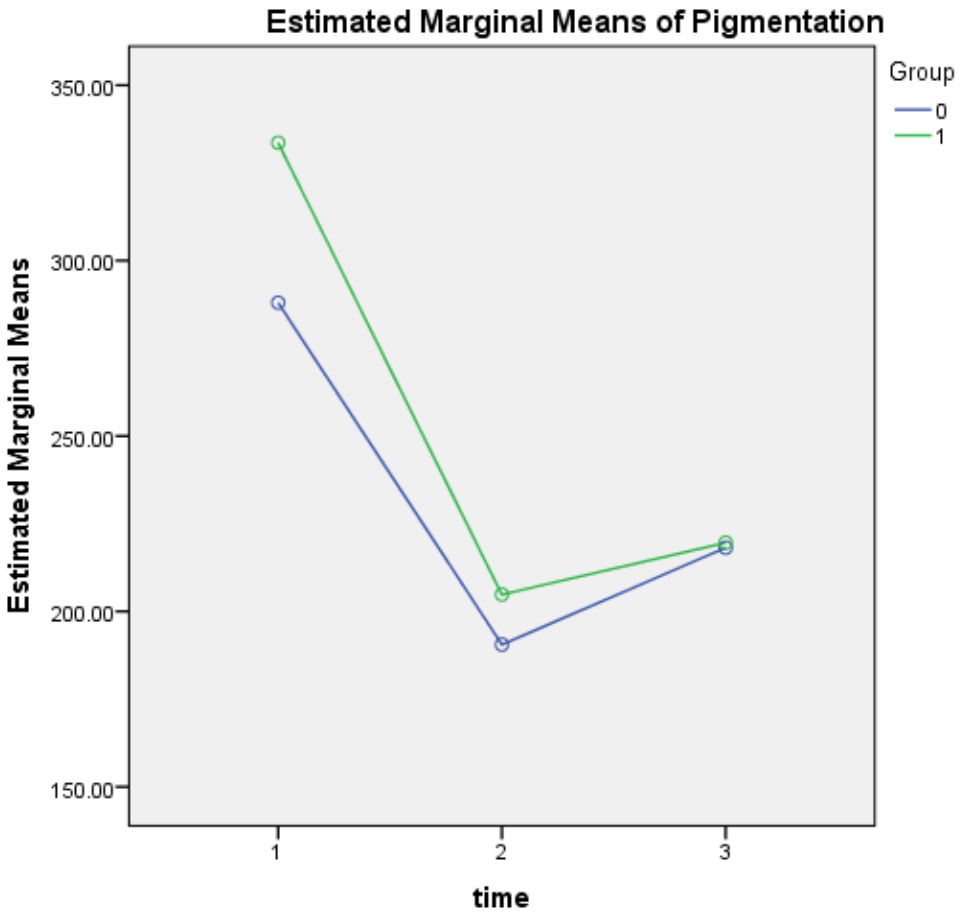


Fig 2: Graphical representation for the results on pigmentation

The **hydration** measurements showed a small improvement after 3 months for both groups (p > .05). After 6 months the results showed another small improvement for the intervention group (p > .05); but a decline for the control group (p = .091). Both results were not statistically significant. For hydration there was a statistically significant difference between the groups after 6 months (p = .045) in favour of the intervention group. Below you can find a graphical representation of the results for hydration.

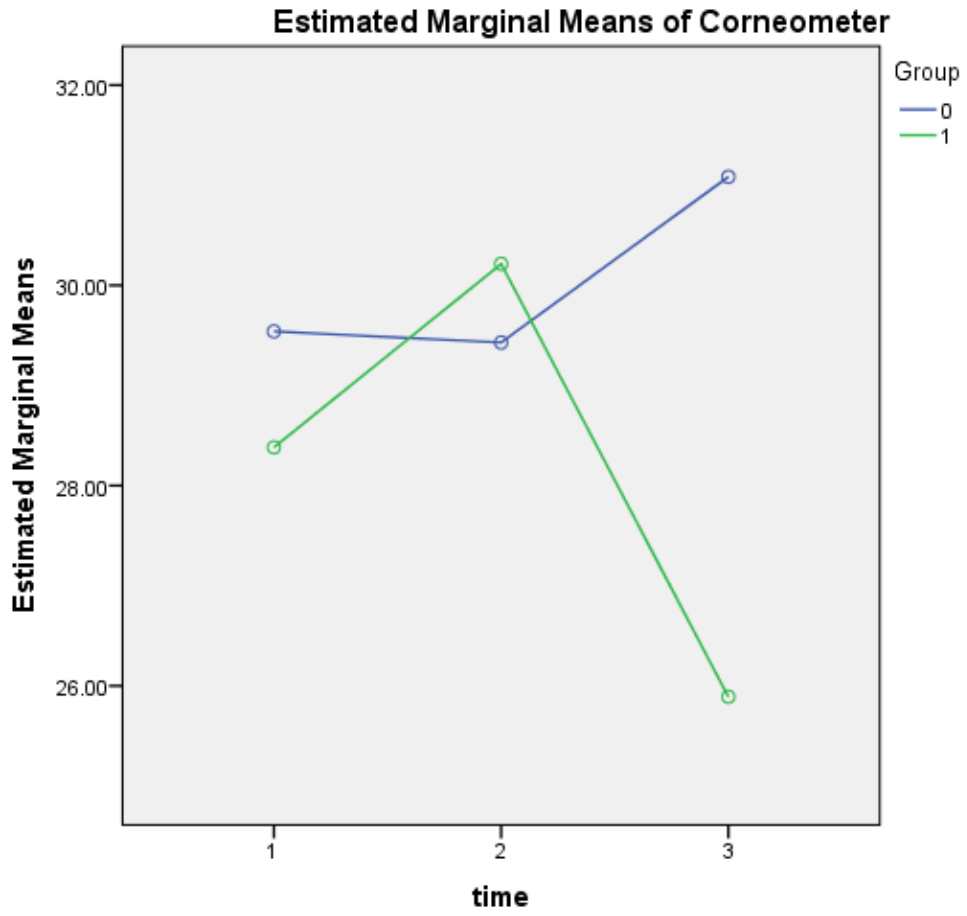


Fig 3: Graphical representation of the results for hydration.

For **elasticity**, measured with Cutometer®, we observed an improvement over time for the intervention group and a decline for the control group. There was a statistically significant group difference after 3 months (p = .043), which did not show anymore after 6 months, although the difference in absolute numbers was still the same. The improvement of the intervention group over time was not statistically significant, but it did show a trend towards a better performance of the intervention group. Below you can find a graphical representation of the results for elasticity.

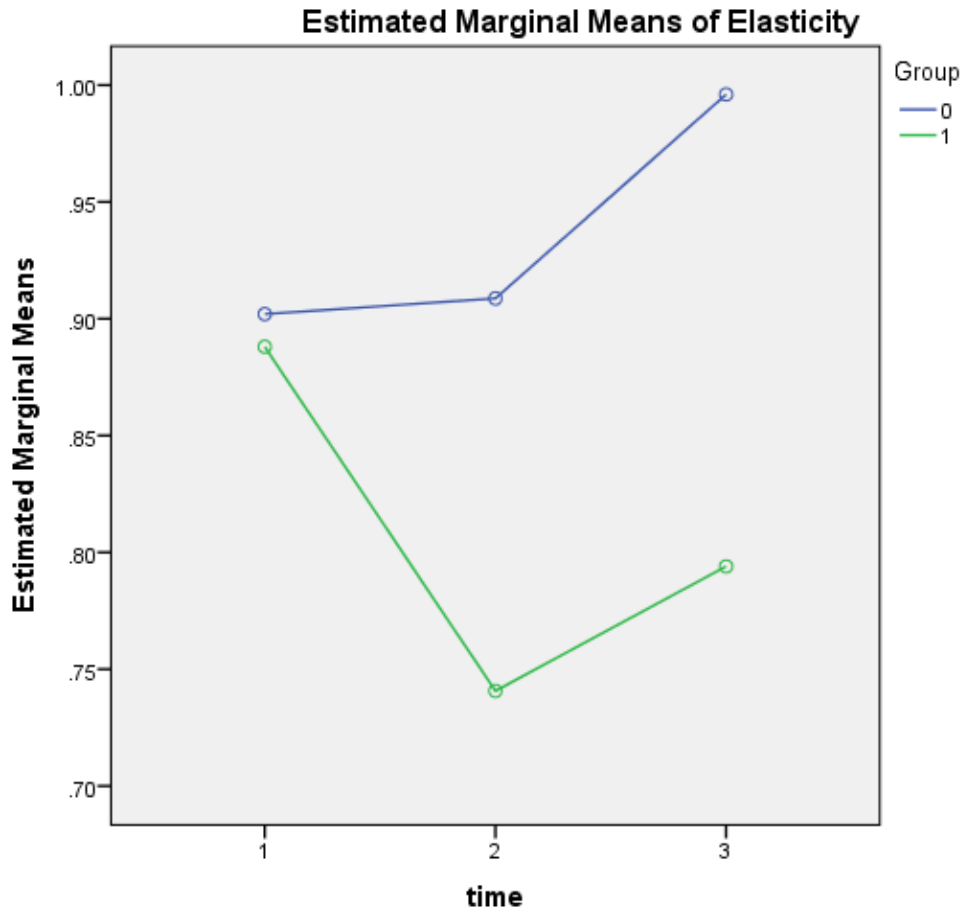


Fig 4: Graphical representation of the results for elasticity.

There was a statistically significant correlation between the hydration values and the elasticity values after 3 months ($r = 0.48$, $p = .012$). Patients with significant higher hydration values in the treated arm also showed higher elasticity values in favour of the treated arm. The significant correlations are marked in green in the table below.

Table 4: Correlations between hydration and elasticity after 3 months.

ID	Hydration difference	Elasticity difference
1	9.07	0.3
2	11.52	0.18
3	9.08	-0.68
4	2.59	0.31
5	14.24	0.07
6	-9.26	-0.80
9	7.40	0.24
10	9.94	0.03
11	1.01	0.11
12	26.80	0.90
13	-10.10	-0.91
14	7.80	0.92
15	-30.80	-0.93
16	12.80	0.04
17	14.23	0.13
19	-7.66	0.02
20	7.76	-0.01

Discussion

The **POSAS** results showed significant improvements for **itch, colour and texture.**

Itch is generally upregulated immediately after surgery and normalizes again between 3 and 6 months after surgery.

The improvement of texture can be attributed to the **normal evolution** of the healing process, which was confirmed by the lack of statistically significant differences between the groups.

Colour seemed to decline over time, which was not in line with the objective measurements. It is possible that patients perceived the redness to become more prominent, since they expected it would decrease sooner after surgery.

For the **objective measurements**, a curious finding was the significant improvement of pigmentation, already after 3 months. This can be attributed to the fact that patients were asked not to wash the arm until the first follow-up visit to the surgeon, when the baseline measurements were carried out. At that time traces of Isobetadine® were still present. This could have influenced the melanin index of the Mexameter®. Therefore it is our opinion that the pigmentation results are not relevant.

For **elasticity**, a trend towards a better performance of the intervention group was observed, however not statistically significant. These results were supported by a **positive correlation** between the **hydration** values **and** the **elasticity** results. This could indicate that **sufficient hydration of the scar is mandatory** for a beneficial result from the microcurrent treatment.

Most of the results showed a trend towards an improvement after 3 months, with a status quo or a setback after 6 months. This could be due to the short period of treatment, which was only administered for 6 weeks. We therefore suggest investigating the effects of microcurrent therapy with a treatment period of at least 3 months.

A sample of only 20 patients is also too small to generalize these results. A larger comparative trial with longer follow-up must be initiated before we can draw any firm conclusions.

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