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Microneedling in Abdominal Scarring after DIEP-flap Breast Reconstruction to Improve Scar Quality: A Randomized Controlled Split Scar Trial

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Background: Deep inferior epigastric perforator (DIEP) flap breast reconstruction leads to large scars in the breast and abdominal region. Common symptoms related to abdominal scarring include changes in color, stiffness, thickness, and irregularity of the skin. The aim of this study was to examine whether microneedling improves the abdominal scar quality after DIEP-flap breast reconstruction.

Methods: A prospective randomized controlled within subject comparison design (N = 30) was used to study the effect of microneedling treatments on the abdominal scar, versus no treatment. Three electrically powered microneedling sessions were performed every 4 weeks on one side of the abdominal scar. Abdominal scar assessment was performed at baseline and 3-, 6-, and 9-month follow-up using the Patient and Observer Scar Assessment Scale (POSAS). Treated and untreated sides were compared using a *t* test or Wilcoxon signed-rank test in case the data were not normally distributed.

Results: Twenty-seven women completed the study. Microneedling treatment led to lower POSAS scores compared with the untreated scar side after the 3- and 9-month follow-up. At the 9-month follow-up, the POSAS total score (Mdn = 17, interquartile range = 18.3 versus Mdn = 21.4, interquartile range = 17.5) was statistically lower for the treated side compared with the untreated side, implying a better-appraised scar quality. The observer POSAS total score was statistically lower for the treated side compared with the untreated side.

Conclusions: Based on patient and observer ratings, overall abdominal scars after DIEP-flap surgery improve significantly after microneedling treatment. Scar symptoms reduce faster under the influence of microneedling treatment compared with no treatment. *(Plast Reconstr Surg Glob Open 2024; 12:e5487; doi: 10.1097/GOX.0000000000005487; Published online 24 January 2024.)*

INTRODUCTION

The deep inferior epigastric perforator (DIEP) flap has become the most widely used technique for autologous breast reconstruction for women after a mastectomy or prophylactic surgery.[1] Inevitably, the DIEP-flap breast reconstruction leads to large scars in the breast and abdominal region. Especially, the donor site scar on the abdomen leads to impaired physical and psychosocial well-being of the abdomen and overall satisfaction.[2,3] Common symptoms related to abdominal scarring include changes in color, stiffness, thickness, and irregularity of the skin.[4]

Although invasive surgery has its specific indications in scar treatment, demand for safe and less invasive treatment modalities to improve scar quality by stimulating the body's own regenerative mechanism, is increasing.[5,6] Available treatments, such as lasers or dermabrasion, are considered effective treatment options; however, when ablative, they result in significant damage to the epidermis, leading to prolonged healing times, which could result in side effects such as hyperpigmentation.[5–7] Microneedling is a nonablative minimally invasive scar treatment using

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small needles, also referred to as percutaneous collagen induction. Controlled microinjuries activate wound healing by reaching the papillary and reticular dermis in a purely mechanical way while minimally damaging the epidermis. The wound healing cascade is triggered by the body's own regenerating mechanism, normalizing the collagen production with a short down time and minimal side effects.[5–8]

Over the past years, microneedling has been recommended in several studies for the treatment of a broad range of skin conditions including various scars; however, there is a need for controlled studies.[5,9] The effect of microneedling on postsurgical scars has not previously been investigated in a controlled design, comparing treated versus untreated scar sides. The aim of this split scar study was, therefore, to examine whether microneedling improves the patient- and observer-reported abdominal scar quality after DIEP-flap breast reconstruction, comparing the treated and untreated scar side at 3-, 6-, and 9-month follow-up.

Takeaways

Question: What is the effect of microneedling on scar quality in abdominal scarring after DIEP-flap reconstruction?

Findings: In a split scar study (n = 30), microneedling was evaluated for its effect on abdominal scarring after DIEP-flap reconstruction. Microneedling led to lower POSAS scores at 3- and 9-month follow-up, indicating improved outcomes compared with the untreated side. Observers also reported lower scores for the treated side.

Meaning: Microneedling treatment significantly improves scar quality, with faster reduction of scar symptoms compared with no treatment.

METHODS

Trial Design

A prospective randomized controlled within subject comparison design was used to study the effect of three repetitive microneedling treatments on the abdominal scar after DIEP-flap surgery. The study was approved by the Dutch Research Ethics Committee (NL72993.091.20) and registered at trialregister.nl. All study participants provided written informed consent. A trained dermal clinician (K.E.) performed all microneedling treatments. After finishing the study, the women were offered to treat the untreated scar half with three microneedling treatments. This trial was reported according to the reporting items stated in the Consort statement.[10]

Setting, Participants and Recruitment

Women who had a DIEP-flap breast reconstruction in the past 18 months and at least 3 months ago were recruited from a university hospital (Radboud University Medical Center, Nijmegen, the Netherlands) and a teaching hospital in the Netherlands (Canisius-Wilhelmina Hospital CWZ, Nijmegen, the Netherlands). They were contacted by e-mail by an independent nurse specialist or plastic surgeon.

Women were asked if they had self-reported scar symptoms such as pain, itching, color, stiffness, thickness, or irregularity, and if they had a wish for improvement of the scar quality. Women who did were then asked if they were interested in participating in the microneedling study. Exclusion criteria were patients younger than 18 years of age, Fitzpatrick skin type greater than III, history of keloid scarring, patients who underwent (or were considering) other scar therapies, consideration to undergo surgical scar revision during the study or follow-up, pregnancy, and severe systemic diseases or skin lesions (like infections) near the abdominal scar. Exclusion criteria were checked by the treating dermal clinician, by phone before the first visit. All procedures were conducted in the outpatient clinic, department of plastic and reconstructive surgery, at the university hospital.

The Intervention

Microneedling treatments were carried out from October 2020 to March 2021. Microneedling was performed using an electrically-powered pen, the Dermapen 4, Australia, which has a disposable needle cartridge (16 needles) and adjustable depth and speed levels. Before treatment, the skin was cleaned with chlorhexidine 0.5% in alcohol 70%. Sodium chloride solution was applied to the scar for guiding the device; no anesthetic was applied.

The microneedling procedure consisted of three sessions, with a time interval of 4 weeks between the treatments.[8,11,12] The treatment settings (depth of needles, speed level, and the amount of passes) were determined by clinically visible uniform pin-point bleeding[7,8] and participant comfort. In each patient, treatment started more superficially with passes in the length of the scar at 1.5–1.75 mm, speed level 2. In a vibrating, stamp-like manner, the scar was treated diagonally and perpendicularly with 3-mm depth (ST, scar treatment setting of the Dermapen 4) to create pin-point bleeding (Fig. 1). Patients were instructed to apply a base cream (Cetomacrogol) to both sides of the scar starting the next day, at least once a day but as often as desired.

Outcomes

The primary outcome was the patient-reported abdominal scar quality at a 3-, 6- and 9-month follow-up after the last treatment, using the validated patient assessment scale of the POSAS 2.0. Scar characteristics: pain, itching, color, stiffness, thickness, irregularity, and overall opinion were assessed with a 10-point scoring system, with 1 point indicating "normal skin" and 10 points, "the worst imaginable scar." The calculated sum of the six first items comprises the POSAS total score, ranging between 6 and 60, where 60 corresponds to the maximum amount of scar symptoms.[13] The POSAS outcomes were divided into three categories: 1 = low score, no differences with normal skin: POSAS score 1; 2 = intermediate scores, minor differences with normal skin, POSAS scores 2 or 3; 3 = high scores, major differences with normal skin, POSAS item score of 4 or more.[4,14]

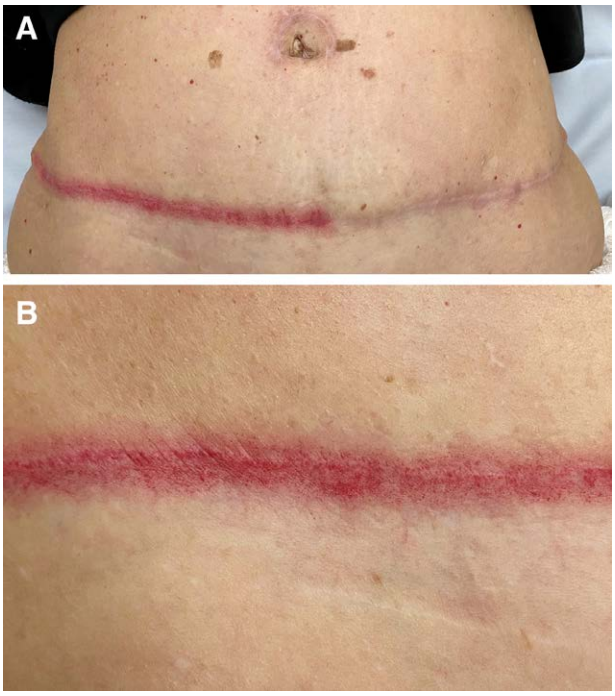

Fig. 1. A, A Photograph showing uniform pin-point bleeding after microneedling treatment of one scar half. B, A Photograph showing a close-up of uniform pin-point bleeding after microneedling treatment.

Secondary outcome measures were on-site clinical evaluation using the observer assessment scale of the POSAS (vascularity, pigmentation, thickness, surface area, relief, pliability, and overall opinion). Observer assessment was performed at baseline and at the 9-month follow-up.

A 5-day diary was kept after each treatment to monitor pain, itching, redness, peeling, or any other symptoms that occurred. Side effects were assessed with a numeric rating scale ranging from 1 to 10.

Sample Size

A sample size of 27 patients provided 80% power, with an alpha of 0.05 to detect a 30% difference in abdominal scar assessment between the treated and untreated side on the POSAS total score assessed by patients. Anticipating a 10% dropout rate, we aimed to include 30 patients in this study.

Randomization

At baseline, the scar was divided into two subareas that were randomly selected for the microneedling treatment and the untreated control side. The sequence was concealed using consecutively numbered, closed, nontransparent envelopes prepared by an independent nurse of the university hospital to ensure allocation concealment. The treating dermal clinician was blinded from the allocation sequence.

Blinding

On-site outcome evaluation was performed by blinded trained (on assessment of the POSAS on abdominal scars) research assistants at baseline and the 9-month follow-up. They were not involved in the treatments and did not know which side had been treated at the time of the assessment.

Statistics

An intention-to-treat analysis was performed, imputing missing data with the series mean in SPSS. Abdominal scar assessments for the treated and untreated sides were compared using a *t* test when data were normally distributed, or Wilcoxon signed-rank test in case the data were not normally distributed for the POSAS total scores at 3-, 6-, and 9-month follow-up. A Bonferroni adjustment was applied to reduce the chance of a type 1 error; results were considered significant at a *P* value of 0.01 or less.[15] The individual scar characteristics measured with separate POSAS items were analyzed using descriptive statistics. A sensitivity analysis was used to compare the POSAS total scores for scar maturation (≤ 1 year/ >1 year) at the initiation of treatment, to visualize the impact of scar maturation. A statistical analysis was performed using SPSS version 25.0 (IBM Corp., Armonk, N.Y.).

RESULTS

Patients were followed up between September 2021 and January 2022. Thirty patients were treated with three microneedling treatments; 27 patients completed all follow-up assessments. One patient dropped out immediately after the three treatments; the other two patients dropped out after the 6-month follow-up. (**See figure, Supplemental Digital Content 1,** the Consort 2010 flow diagram, which shows the number of women who where assessed for eligibility, the reasons for exclusion, and loss-to follow-up. **http://links.lww.com/PRSGO/C949**.)

Patients had a mean age of 51 (SD = 7.8) years. The median time since the DIEP reconstruction was 6.5 [interquartile range (IQR) = 11] months ago for patients entering the study (Table 1).

Table 1. Patient Characteristics

N = 30	Mean	± SD	Median	IQR
Age (y) *	51.4	(7.8)	52.5	(12)
BMI (kg/m²)	26.7	(3.2)	25.3	(4.7)
Time since DIEP (wk)	41	(24.2)	28.5	(49)
Time since DIEP (mo)	9	(5.5)	6.5	(11)

	n	%
Maturity of scar		
<6 months	15	50%
≥6 months	15	50%
Laterality		
Unilateral	16	53%
Bilateral	14	47%
Timing of reconstruction		
Direct	22	73%
Indirect	8	27%
History of breast cancer		
Breast cancer history	27	90%
Prophylactic surgery	3	10%

*Data normally distributed.

Table 2. POSAS Patient-reported Outcomes: Baseline, 3-, 6-, and 9-Month Follow-up

	Baseline ($n = 30$)				3-Month Follow-up ($n = 29$)				6-Month Follow-up ($n = 29$)				9-Month Follow-up ($n = 27$)			
	Untreated		Treated		Untreated		Treated		Untreated		Treated		Untreated		Treated	
	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)
Pain	2.5 (2.2)	1.0 (4.0)	2.5 (2.3)	1.0 (5.0)	2.2 (2.1)	1.0 (1.0)	1.4 (0.8)	1.0 (1.0)	1.7 (1.4)	1.0 (0.8)	1.3 (0.5)	1.0 (0.5)	1.7 (1.2)	1.0 (1.0)	1.7 (1.6)	1.0 (0.8)
Itch	3.0 (2.3)	2.0 (4.0)	3.0 (2.2)	2.0 (4.0)	1.7 (1.3)	1.0 (1.0)	1.4 (0.7)	1.0 (1.0)	1.7 (1.4)	1.0 (1.0)	1.6 (0.9)	1.0 (1.0)	1.8 (1.3)	1.0 (1.0)	1.5 (0.9)	1.0 (1.0)
Color	8.1 (1.3)*	8.0 (2.0)	7.9 (1.4)*	8.0 (5.0)	5.1 (2.2)*	5.0 (3.3)	5.0 (2.0)*	5.0 (3.0)	5.1 (2.0)*	5.0 (3.0)	5.1 (2.0)*	5.0 (3.3)	4.9 (2.4)*	4.9 (1.0)	4.4 (2.5)	4.0 (5.0)
Stiffness	7.4 (1.6)	8.0 (1.0)	7.3 (1.9)	8.0 (1.0)	4.6 (2.0)	5.0 (3.3)	3.6 (1.9)	3.8 (3.0)	5.0 (1.9)*	5.0 (2.0)	4.2 (2.0)*	4.1 (2.5)	4.3 (2.3)	4.3 (5.0)	3.8 (2.1)	3.0 (4.0)
Thickness	7.1 (2.0)	8.0 (1.0)	6.8 (2.1)	7.0 (2.0)	4.7 (2.1)	5.0 (4.0)	3.6 (2.0)	4.0 (3.3)	4.4 (2.3)*	4.4 (4.3)	4.1 (2.0)*	4.0 (3.3)	4.3 (2.2)*	4.2 (4.3)	3.7 (2.1)	3.0 (2.5)
Irregularity	7.0 (2.0)	8.0 (2.0)	7.0 (2.0)*	7.5 (3.0)	4.8 (2.2)*	4.9 (4.0)	3.8 (2.1)	3.4 (4.0)	4.7 (2.0)*	5.0 (3.0)	4.0 (1.7)*	4.0 (2.3)	4.4 (2.4)*	4.4 (5.0)	3.9 (2.1)	3.4 (4.0)
Overall opinion	7.2 (1.3)*	7.0 (1.0)	7.0 (1.4)*	7.0 (2.0)	5.2 (2.0)	5.0 (3.0)	4.8 (1.8)	5.0 (3.3)	5.2 (2.2)*	5.0 (3.0)	4.8 (2.0)*	4.8 (2.3)	5.1 (2.3)*	5.1 (4.0)	4.2 (2.2)*	4.0 (3.3)
Total score	35.2 (6.6)*	36.0 (7.5)	34.5 (7.9)*	34.0 (10.5)	23.1 (8.6)*	24.0 (12)	18.8 (7.5)*†	20.0 (12.8)	22.7 (7.6)*	22.7 (11.5)	20.1 (7.4)*‡	20.6 (12.0)	21.4 (9.3)*	21.4 (17.5)	18.9 (9.6)	17.0 (18.3)†

Note: N = 30 at baseline, missing data were replaced with mean. 1 = Normal skin; 10 = Worst imaginable scar or sensation. The calculated sum of the six first items comprises the POSAS total score, ranging between 6 and 60, where 60 corresponds to the maximum amount of scar symptoms.[15] Because data were imputed with mean, the median and IQR are not always a rounded number. Results were considered significant at $P \leq 0.01$.
*Data normally distributed: at 3-, 6-, and 9-month follow-up a paired sample *t* test was conducted to compare the untreated versus the treated scar site for the POSAS total scores, a Wilcoxon signed-rank test was conducted in case the data were not normally distributed.
‡$P \leq 0.05$.
†$P \leq 0.01$.

Patient-reported Abdominal Scar Quality

At baseline, there was no difference between both sides assessed with the POSAS patient assessment scale (<10%). The POSAS total score for the treated side was significantly lower compared with the untreated side after the 3- and 9-month follow-up, implying a better-appraised scar quality. At the 9-month follow-up, the median of the POSAS total score for the treated side was 17 (IQR = 18.3), compared with 21.4 (IQR = 17.5) for the untreated side, z = -2.1482, $P = 0.01$ (Table 2).

The sensitivity analysis, which compared the POSAS total scores for more mature (>1 year old) with unmature (≤1 year old) scars at the beginning of the treatment, showed similar differences between the treated and untreated sides of the scar. [**See figure, Supplemental Digital Content 2**, which displays the (A) sensitivity analysis of the POSAS total scores for the treated and untreated scar halves of patients who started microneedling treatment ≤ 1 year after surgery, versus (B) patients who started treatment >1 year of surgery. **http://links.lww.com/PRSGO/C950**.]

At the 9-month follow-up the POSAS overall opinion was 4.2 (SD = 2.2) for the treated side versus 5.1 (SD = 2.3) for the untreated side. All POSAS scar characteristics, except for pain, had a larger decrease in POSAS scores for the treated side compared with the untreated side during the last follow-up measurements at 9 months. Nonetheless, POSAS pain decreased more at the 3-month and 6-month follow-up for the treated side compared with the untreated side. POSAS items itch, stiffness, thickness, irregularity, and overall opinion showed the largest decrease at the 9-month follow-up for the treated side compared with the untreated side (Table 2).

Improvement from Baseline

At the 9-month follow-up, the POSAS total score improved 45% from baseline for the treated side (M = 34.5, SD = 7.9 to M = 18.9, SD = 9.6), compared with 39% improvement for the untreated side (M = 35.2, SD = 6.6 to M = 21.4, SD = 9.3). The POSAS overall opinion improved 40% from baseline for the treated side (M = 7.0, SD = 1.4 to M = 4.2, SD = 2.2) compared to 29% improvement of the untreated side (M = 35.2, SD = 6.6 to M = 5.1, SD = 2.3). In general, the previously established upward trend moderated at the following measurement moments (Fig. 2).

Impact on Low, Intermediate, and High Scores

Dividing POSAS outcomes into low, intermediate, and high categories, there were no differences between the two sides at baseline. Except for pain and itching, the vast majority of women reported high (POSAS ≥ 4) scores at baseline on the POSAS, indicating major differences between the scars and normal skin. (**See figure, supplemental Digital Content 3,** which displays low, intermediate, and high POSAS patient scores at baseline. **http://links.lww.com/PRSGO/C951**.)

Considering the shift in severity in terms of low, intermediate, or high POSAS scores, the scar characteristics

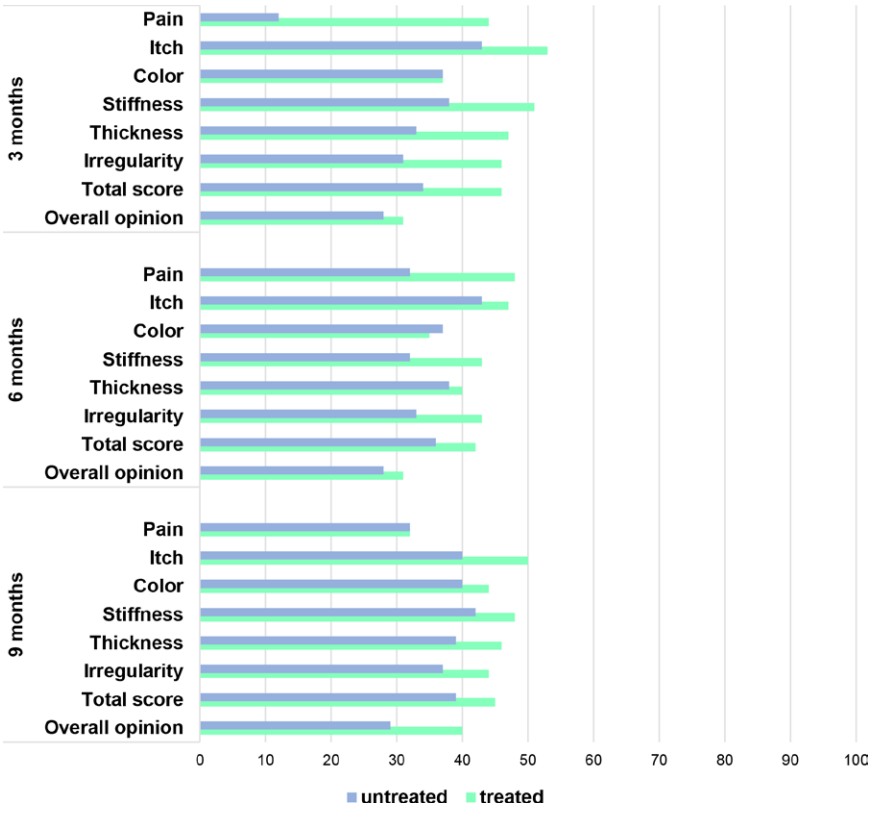

Fig. 2. Percentage improvement from baseline: POSAS patient-reported scar quality, treated side versus untreated side.

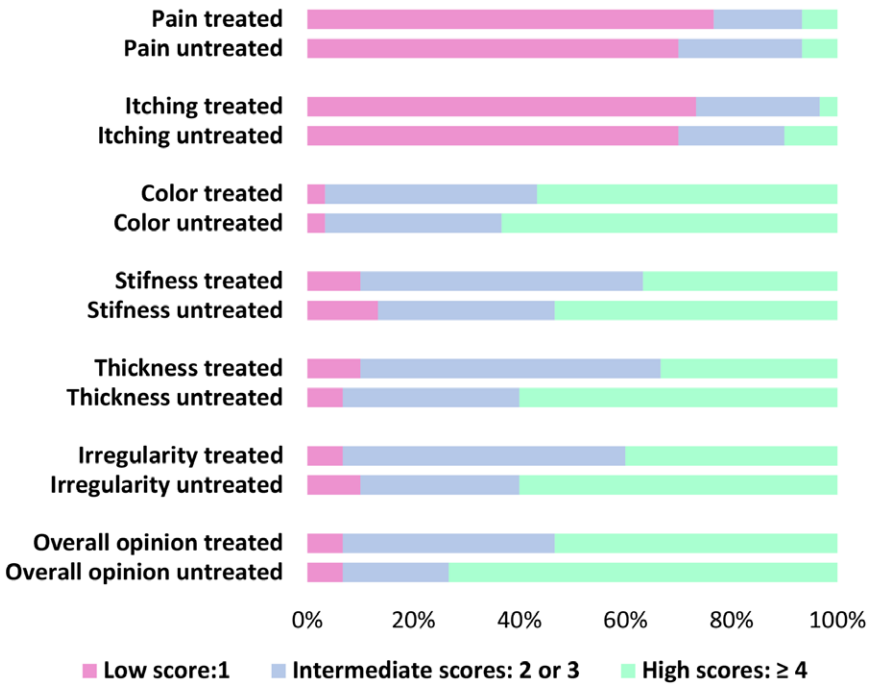

Fig. 3. Low, intermediate, and high POSAS patient scores at the 9-month follow-up. Note. 1 = Low score, no differences with normal skin: POSAS score 1; 2 = Intermediate scores, minor differences with normal skin: POSAS scores 2 or 3; 3 = High scores, major differences with normal skin: POSAS item score 4 or more. **See figure, Supplemental Digital Content 3** for baseline categories (**http://links.lww.com/PRSGO/C951**.)

Table 3. POSAS Observer-reported Outcomes: Baseline and 9-Month Follow-up

	Baseline (n = 30)				9-Month Follow-up (n = 27)			
	Untreated		Treated		Untreated		Treated	
	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)	Mean (*SD*)	Median (*IQR*)
Vascularity	4.7 (1.8)*	4.5 (3.0)	4.6 (1.9)	4.0 (3.0)	2.4 (1.0)	2.0 (0.6)	2.2 (0.9)	2.0 (0.6)
Pigmentation	2.6 (1.4)	2.0 (2.0)	2.7 (1.6)	3.0 (2.0)	2.7 (0.9)*	2.9 (1.0)	2.6 (0.9)	2.5 (1.0)
Thickness	3.1 (1.3)	3.0 (2.0)	3.1 (1.3)	3.0 (2.0)	2.5 (1.3)	2.2 (1.5)	2.3 (1.0)	2.0 (1.1)
Relief	3.6 (1.8)	3.0 (3.0)	3.6 (1.7)*	3.5 (3.0)	2.2 (1.0)	2.0 (1.5)	2.0 (0.9)	2.0 (0.8)
Pliability	3.9 (2.0)	3.0 (3.0)	4.0 (1.9)	3.5 (3.0)	2.8 (1.3)	2.4 (2.1)	2.3 (1.0)	2.0 (1.0)
Surface area	3.5 (1.2)	3.0 (1.0)	3.8 (1.5)	3.0 (2.0)	2.8 (1.2)	2.5 (1.3)	2.6 (1.3)	2.5 (1.0)
Overall opinion	5.2 (1.5)*	5.0 (2.0)	5.3 (1.3)	5.0 (2.0)	3.2 (1.3)*	3.0 (2.0)	2.9 (1.2)	3.0 (1.5)
Total score	21.4 (6.5)*	21.0 (8.8)	21.7 (6.6)*	21.5 (8.5)	15.3 (5.3)*	15.3 (9.3)	14.0 (4.4)*†	14.0 (6.4)

Note. n = 30 at baseline, missing data were replaced with mean.1 = Normal skin; 10 = Worst imaginable scar or sensation. The calculated sum of the six first items comprises the POSAS total score, ranging between 6 and 60, where 60 corresponds to the maximum amount of scar symptoms.[13] Since data were imputed with mean, the median and inter quartile range (IQR) are not always a rounded number.

*Data normally distributed: at 9-month follow-up, a paired sample *t* test was conducted to compare the untreated versus the treated scar site for the POSAS total scores. Results were considered significant at $P \leq 0.01$.

†$P \leq 0.01$.

stiffness, thickness, irregularity, and overall opinion had the largest shift from high to intermediate scores for the treated side compared with the untreated side (Fig. 3).

Side Effects

No adverse events have been reported. Expected side effects erythema (Mdn = 8.0, IQR = 1.5) and pain (Mdn = 4.2, IQR = 5.3) were the most reported symptoms on day one. Other side effects were rated 2 or less. On day 5, erythema (Mdn = 3, *IQR* = 2) and pain (Mdn = 1, IQR = 1) diminished considerably. Peeling increased somewhat within 5 days posttreatment (Mdn = 2, *IQR* = 3). Other expected side effects mentioned were irritated skin, mild edema, and minor bleeding.

Observer Scar Assessment

At baseline, there was no difference between both sides assessed with the POSAS observer assessment scale (<10%). At the 9-month follow-up, there was a significant difference in the POSAS total score for the treated side (M = 14.0, SD = 4.4) compared with the untreated side (M = 15.3, SD = 5.3) t (29) = -3.030, P = 0.005. POSAS item pliability showed the largest decrease at the 9-month follow-up for the treated side compared with the untreated side (Table 3).

DISCUSSION

This is the first randomized controlled observer blinded study researching the effect of microneedling on postsurgical scar quality of abdominal scars after DIEP-flap breast reconstruction. In our study, microneedling treatment led to statistically significant lower patient and observer scar assessment scores compared with the untreated scar side after the 3-, and 9-month follow-up, implying a better scar appraisal. No adverse events have been reported and expected side effects diminished fast.

Although the clinical effect of microneedling treatments seems subtle on the POSAS scores, for the treated side, we found larger decreases in major scar symptoms (≥4 POSAS) particularly for stiffness, thickness, irregularity and, overall opinion. Observers found improvement particularly on the pliability of the scar. The patient POSAS total score of the treated side, improved from baseline 34.5 (SD = 7.9) to 18.9 (SD = 9.6) at the 9-month follow-up (45%) (versus 39% improvement for the untreated side). The POSAS overall score improved from baseline 7.0 (SD = 1.4) to 4.2 (SD = 2.2) at the 9-month follow-up (40%) (compared with 29% improvement for the untreated side). The most recent (noncontrolled) trial on postsurgical scars showed an improvement of the POSAS total score after three microneedling treatments from baseline 23.7 (SD = 1.8) to 11.7 (SD = 1.0) at 16-week follow-up (50%).[16] A (noncontrolled) prospective microneedling study on different types of scars (acne, trauma, surgical) found an improvement of at least 50% of the treated scars after one to six treatments (average 2.5); however, this was not assessed with a validated scar assessment tool.[12] In a prospective (noncontrolled) burn scar study, the POSAS total scores improved from baseline 27 to 19 one year after treatment (30%).[17] Comparing the overall improvement from baseline of treated scars with other studies, we found similar results, however due to the lack of controlled studies, we cannot compare the differences found between treated and untreated scars. Thereby, without commonly used and clinically relevant cutoff points, the interpretation of the POSAS scores remains arbitrary.[14]

The found effects of microneedling on normalization on stiffness, relief, and thickness can be explained by the dermal reorganization, where formation of physiological collagen (type I) is induced instead of scar collagen (type III).[6,8] Cross-links are formed and collagenase breaks down inappropriately oriented fibers, which results in new, nontraumatized collagen with a normal lattice pattern rather than parallel bundles as in scar tissue.[6–8] Normalization of skin color can be explained by the synthesis of collagen, which improves the vital thickness of the epidermis reducing transparency of the skin, which was found in previous research on burn scars.[18]

For the majority of scar characteristics, the most substantial percentage of improvement from baseline was measured at the 3-month follow-up, and the previously established upward trend was moderated at the 6- and 9-month follow-up. However, for the POSAS overall opinion, the difference in effect between treated and untreated scar sides increased over months. Interestingly, at the 3-month follow-up, pain was decreased remarkably for the treated side compared with that for the untreated side; however, pain seemed to decrease equally over time for both sides after 9 months. This implies that scar symptoms, including pain, reduce faster under the influence of microneedling treatment compared with no treatment.

Based on current research, we gained insight into the effect of microneedling on scars after DIEP-flap breast reconstruction. The current study population is most likely representative for possible scar symptoms resulting after DIEP-flap breast reconstruction. The minimal occurrence of pain and itching of scarring in this study population is consistent with previous research (N = 248 women after DIEP-flap breast reconstruction), where we found that color, stiffness, thickness, and irregularity scored higher on the POSAS assessment scale.[4] From a biological perspective, it is plausible that effects found can be translated to other major postsurgical scars. In previous research, scars from a variety of etiologic sources were treated with microneedling, and no clinical differences were found between the different scars.[12]

Strengths and Limitations

In this study, a conscious decision was made to examine the effect of purely microneedling under standardized conditions, compared with no treatment. We intentionally aimed to investigate the effect of microneedling compared with natural maturation rather than another treatment. However, due to the impossibility of a placebo in the case of this study design examining microneedling, blinding of the patients was not possible. To mitigate this, we attempted to control for it by including blinded observers. Nonetheless, this approach could potentially introduce bias into the study. The standardization of three treatments may underestimate the possible effect of microneedling because from a clinical point of view, some scars needed more treatments. Also, no active intermediate or combination therapy was used, greater effects might be achieved in combination with using silicone gel,[11] noncultured skin cell supsension[19] vitamin A and C[20] or PRP.[21] We included participants with Fitzpatrick skin type III or less due to the limited prevalence of darker skin types within our clinic in the Netherlands. Therefore, we cannot make any statements regarding the effect of microneedling on Fitzpatrick skin types more than III.

Despite including a wide range of scar maturation, the sensitivity analysis indicates that the timing of microneedling initiation (≤ 1 year/ >1 year) does not affect the achievable effect. However recent (noncontrolled) research suggests that starting earlier in the maturation phase (6–7 weeks postoperatively) could potentially improve aesthetic results compared with treatments initiated late in the maturation phase.[16]

Patients were included with a wish for any improvement on their abdominal scar, resulting in a wide range of severity levels among the included scars. At baseline, patients rated their scar symptoms as major scar complaints (POSAS ≥ 4), whereas observers were more lenient in their assessment of the severity of scar characteristics. Improvement on a mild scar is more difficult to detect. Furthermore, a clinically meaningful improvement of two points on a 10-point scale on a specific scar characteristic may not be clearly visible in the overall POSAS total score. However, this can be important for the individual patient. This might lead to an underestimation of the effect of microneedling in this study. More significant and clinically relevant results might be found when investigating the effects on individual scar characteristics, needing a larger study population.

In addition, future research should investigate the number of treatments, interval between treatments, timing of initiation, the effect on Fitzpatrick skin types more than III, and the use of active intermediates to be able to study the clinical effect of microneedling in more detail. Future research is also necessary to determine a minimal clinical important change of the POSAS, using the recently adapted POSAS 3.0. Finally, our recommendation would be to compare microneedling with laser as a control group in a cost-effectiveness study, as recent research suggests that microneedling and laser can achieve comparable clinical effects.[22]

CONCLUSIONS

Based on patient and observer ratings, overall abdominal scars after DIEP-flap surgery improve significantly after microneedling treatment. In particular, stiff and thick scars, and overall scar appraisal seem to improve after microneedling treatment according to patient ratings. Scar symptoms, including pain, reduce faster under the influence of microneedling treatment compared to no treatment. Microneedling may occupy a niche for patients who desire minimally invasive scar treatments, while still attaining measurable results.

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DISCLOSURES

The authors have no financial interest to declare in relation to the content of this article. Dermapenworld and Dermapen Benelux loaned the Dermapen4 during the study and provided the necessary disposable needle cartridges and hygienic sleeves for the participants. Dermapenworld and Dermapen Benelux had no role in the study design, data collection, analysis and interpretation of data, writing, or the decision to submit the article for publication.

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REFERENCES

1. Healy C, Allen RJ. The evolution of perforator flap breast reconstruction: twenty years after the first DIEP flap. *J Reconstr Microsurg*. 2014;30:121–126.
2. Niddam J, Bosc R, Lange F, et al. DIEP flap for breast reconstruction: retrospective evaluation of patient satisfaction on abdominal results. *J Plast Reconstr Aesthet Surg*. 2014;67:789–796.
3. Everaars KE, de Laat EH, de Young-Afat D, et al. The impact of scars on satisfaction and Health-related Quality of Life after DIEP flap breast reconstruction. not yet published.
4. Everaars K, Tjin E, de Laat E, et al. Breast and abdominal scarring after DIEP flap breast reconstruction: an exploration of patient-reported scar quality. *J Plast Reconstr Aesthetic Surg*. 2022;75:1805–1812.
5. Atiyeh BS, Abou Ghanem O, Chahine FM. Percutaneous collagen induction (PCI) therapy for management of scars and photoaged skin—scientific evidence and review of the literature. *Aesthetic Plast Surg*. 2021;45:296–308.
6. Ramaut L, Hoeksema H, Pirayesh A, et al. Where do we stand now? A systematic review of the literature. *J Plast Reconstr Aesthet Surg*. 2018;71:1–14.
7. Alster TS, Graham PM. Microneedling: A review and practical guide. *Dermatologic surgery : official publication for American Society for Dermatologic Surgery [et al.]*. 2018;44:397–404.
8. Singh A, Yadav SM. Advances and widening horizons. *Indian Dermatol Online J*. 2016;7:244–254.
9. Iosifidis C, Goutos I. Percutaneous collagen induction (microneedling) for the management of non-atrophic scars: literature review. *Scars Burn Heal*. 2019;5:1–11.
10. CONSORT Group. Consolidated standards of reporting trials (CONSORT statement). Accessed December 7 2022.
11. Fabbrocini G, Marasca C, Ammad S, et al. Assessment of the combined efficacy of needling and the use of silicone gel in the treatment of C-section and other surgical hypertrophic scars and keloids. *Adv Skin Wound Care*. 2016;29:408–411.
12. Alster T, LI M. Microneedling of scars: a large prospective study with long-term follow-up. *Plast Reconstr Surg*. 2020;145:385–364.
13. Mundy L, Miller H, Klassen A, et al. Patient-reported outcome instruments for surgical and traumatic scars: a systematic review of their development, content, and psychometric validation. *Aestetic Plast Surg*. 2016;40:792–800.
14. Spronk I, Polinder S, Haagsma JA, et al. Patient-reported scar quality of adults after burn injuries: A five-year multicenter follow-up study. *Wound repair and regeneration: official publication of the Wound Healing Society [and] the European Tissue Repair Society*. 2019;27:406–414.
15. Pallant J. *SPSS Survival Manual, a Step by Step Guide to Data Analysis Using SPSS*. 4th ed. Allen & Unwin; 2011. Available at www.allenandunwin.com/spss
16. Claytor RB, Sheck CG, Chopra V. microneedling outcomes in early postsurgical scars. *Plast Reconstr Surg*. 2022;150:557e–561e.
17. Aust MC, Fernandes D, Kolokythas P, et al. Percutaneous collagen induction therapy: An alternative treatment for scars, wrinkles, and skin laxity. *Plast Reconstr Surg*. 2008;121:1421–1429.
18. Busch KH, Aliu A, Walezko N, et al. Medical needling: effect on skin erythema of hypertrophic burn scars. *Cureus*. 2018;10:e3260.
19. Busch KH, Bender R, Walezko N, et al. Combination of medical needling and non-cultured autologous skin cell transplantation (ReNovaCell) for repigmentation of hypopigmented burn scars. *Burns*. 2016;42:1556–1566.
20. Aust MC, Knobloch K, Reimers K, et al. Percutaneous collagen induction therapy: an alternative treatment for burn scars. *Burns*. 2010;36:836–843.
21. Schoenberg E, O'Connor M, Wang J, et al. Microneedling and PRP for acne scars: a new tool in our arsenal. *J Cosmet Dermatol*. 2020;19:112–114.
22. Nobari NN, Tabavar A, Sadeghi S, et al. A systematic review of the comparison between needling (RF-needling, meso-needling, and micro-needling) and ablative fractional lasers (CO2, erbium YAG) in the treatment of atrophic and hypertrophic scars. *Lasers Med Sci*. 2023;38:67.