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ORIGINAL ARTICLE BODY CONTOURING

Photobiomodulation Improved the First Stages of Wound Healing Process After Abdominoplasty: An Experimental, Double-Blinded, Non-randomized Clinical Trial

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Abstract

Background Photobiomodulation is widely studied for its potential benefits in the wound healing process. Numerous scientific studies have highlighted its effect on various phases of wound repair, but clinical validations are few. This comparative trial aims to evaluate the influence of photobiomodulation on the post-abdominoplasty healing process.

Methods Seventeen Caucasian women (aged 18–55) who underwent an abdominoplasty were enrolled in this double-blinded, controlled clinical trial. The postoperative scars were divided into two areas; the right side of the scars was treated with ten sessions of photobiomodulation (consisting in three types of wavelengths). The other part of the scars was used as control and did not receive any additional treatment. Clinical assessments of both parts of the scars were scheduled at 1, 6 and 12 months postoperative.

Results Within six months following surgery, significantly improved quality of the scars on the treated side compared with the untreated side was reported by patients and experienced professionals according to Vancouver Scar Scale, Patient and Observer Scar Assessment Scale ($p < 0.05$) and standardized photographs ($p < 0.05$). At 1 year of follow-up, patients observed no differences between the treated and untreated sides of the scars. This suggests that photobiomodulation appears to play an early role in the wound healing process, accelerating the first stages of cicatrization.

Conclusion This study statistically validates the positive impact of photobiomodulation treatment on the first stages of the postoperative healing process. Carried out on Caucasians participants only, this study should, however, be performed on a more heterogeneous population to definitively confirm these effects on an international population.

Clinical trial registry Registro Brasileiro de ensaios clínicos: http://www.ensaiosclinicos.gov.br,Trial RBR-49PK78.

Level of Evidence II This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Wound healing · Photobiomodulation · Phototherapy · Abdominoplasty · Surgical scar

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Introduction

Surgical procedures often lead to post-traumatic lesions or non-esthetic scars: principal causes of patient and surgeon dissatisfaction. Photobiomodulation plays a growing role in the treatment and prevention of post-surgical scars, and the positive effects on human skin of this large family of technologies are constantly being highlighted through the implementation of clinical investigations [1–6].

Although there is still research to be done to fully understand the mechanism of action of the technology; two primary pathways have been well documented: The enzyme cytochrome C oxidase has been identified as a major player in the intracellular pathway, whereas other molecules such as growth factors are activated by the extracellular pathway [7–10]. Many studies have reported the effects of low-dose photobiomodulation on different mechanisms involved in the wound healing process. Depending on the illumination setting, this form of phototherapy can promote reduction in inflammatory cell production, the promotion of dermal cell proliferation and migration, the stimulation of collagen synthesis, angiogenesis or granulation [11–15]. Researchers have also demonstrated that similar effects could be achieved with different types of illumination sources under the appropriate conditions of wavelengths, doses, working distance and irradiance [16–18].

The aims of the present study were to assess the clinical effect of photobiomodulation on the post-surgical wound healing process and to analyze its influence on the stages of cicatrization to understand at what stage it is better to apply it. This clinical investigation compared the treated with the untreated side of the scar of patients who have undergone an abdominoplasty using scar assessment scales, standardized photographs and simple subjective questionnaires over a 1-year follow-up period.

Materials and Methods

This experimental, prospective, double-blinded, controlled and non-randomized trial, registered under the trial number RBR-49PK78, was conducted at the plastic surgery division of a public hospital. All procedures performed in this trial were in accordance with the principles of the Declaration of Helsinki (1996) for human experimentation and were approved by the ethical committee of the institution in 2013.

All participants had previously contracted the hospital to undergo an abdominoplasty and provided informed and written consent before participating in this trial.

Participants

Based on two previous similar studies [19, 20], a sample size of 17 patients totaling 34 observations (each patient was her own control) was determined to detect a difference of at least two points in the scales and to consider improvement in the scars with a 80% power and a significance level of 5%. (Remark: six additional patients were enrolled in this clinical investigation to counterbalance dropouts.)

Twenty-three Caucasian female patients aged 18–55, with BMI between 20 and 30 kg/m^2 and with bilateral and symmetrical scarring after abdominoplasty, were recruited by the plastic surgery division and enrolled in this trial between January 2014 and July 2016.

Exclusion criteria were as follows: patients with liposuction; patients with dermatitis or with supra-umbilical striae or tattoos, which can make evaluation of the final scar more difficult; patients with known history of keloid scarring or any medical condition that could impair wound healing; patients who suffered dehiscence, seromas, infections or flap necrosis within or around the scar; patients who underwent any corrective surgery on the scar; or patients who became pregnant in the postoperative period. Patients were also excluded if they were tobacco and/or alcohol users, if they received chemotherapy or radiotherapy, if they were receiving corticosteroids or if they were using any topical or systemic treatment to improve wound healing.

Experimental Design

Surgical interventions were carried out by four residents, and all details that could influence healing were collected during surgery. To avoid variation in the technique, a single surgeon (main author) performed the suturing in a standardized procedure. Poliglecaprone-25 3-0 and 4-0 suture (Monocryl^{TM}, Ethicon. Johnson & Johnson, USA) was used, a simple and a continuous intradermic suture, for the subcutaneous and dermic plane, respectively. The scar was finally covered with antibiotic cream and gauze.

Photobiomodulation treatments began 48 h after surgery and were performed every other day, for ten sessions. To ensure blinding, patients kept their eyes covered during the illuminations and two LED (light emitted diode) devices were used. The first device, providing the treatment, was applied on the right side, while the second device was used on the left side of the scar emitting a simple illumination without any treatment, so neither the patients nor professional had information on the treated and untreated sides. Device characteristics and irradiation parameters are summarized in Table 1.

During treatment, the patient was lying in dorsal decubitus, in a room without artificial or natural illumination, and a paperboard separator was positioned in the midline to avoid cross-illuminations.

Follow-up examinations were scheduled for 1 month, 6 months and 1 year post-surgery.

The Vancouver Scar Scale (VSS) and Patient and Observer Scar Assessment Scale (POSAS) were applied at 1 and 6 months post-surgery by two independent plastic surgeons (with more than 20 years of experience), blinded for the treated side. The evaluation was always performed on a marked area of 2 cm^2, localized at 5 cm from the midline to the treated and to the untreated sides (Fig. 1). VSS evaluates four variables (pigmentation, vascularity, pliability and height) to give a total score ranking from 0 to 13, where 0 corresponds to a normal skin [19]. POSAS is composed by two numeric scales: One is completed by the clinician (OSAS: Observer Scar Assessment Scale) and the other one by the patient herself (PSAS: Patient Scar Assessment Scale). OSAS evaluates five characteristics (vascularization, pigmentation, thickness, relief and pliability), to give a total score ranking from 5 to 50, where 5 corresponds to a normal skin [19]. PSAS evaluates six variables (pain, itching, color, stiff, thickness and irregularity) to give a total score ranking from 6 to 60, where 6 represents a normal skin without symptoms [19].

Standardized photographs were taken at 1 and 6 months post-surgery. Digital images of the scar were standardized in a natural light-free environment with controlled lighting, using a dichroic light bulb 50 W and 5400 K temperature of white light, placed at 70 cm from the half line scar on a tripod in exact 45° angle in relation to the skin surface.

A special device was created that ensured the camera placement at a distance of 10 cm between the lens and the scar and allowed a lateral illumination. For all the images captured, the same camera (Panasonic LUMIX® DMC-FZ62) and image format.RAW eliminating all color filters were used. The photographs were always in a centralized area on each side, at 5 cm from the midline (Fig. 2).

Two methods were used to analyze the photographs:

Table 1 Device characteristics and irradiation parameters

Device	LUXePro, ISC, Switzerland
Wavelengths (nm)	520, 590, 645
Irradiances (mW/cm^2)	15.5, 3, 12
Treatment duration (min)	15
Working distance (cm)	5
Energy density per treatment (J/cm^2)	10

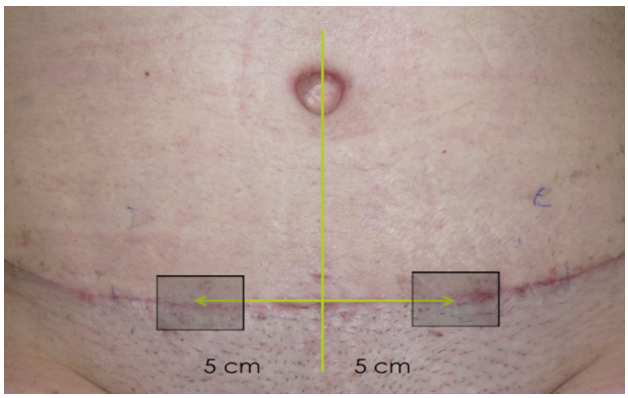


Fig. 1 Application areas of the scar assessment scales

- Two plastic surgeons were directed to assign a score of 1 or 2 to indicate their preference in favor of the most esthetic scar by comparing two standardized images. They first compared two images on the same side (1 = 1 month, 2 = 6 months). They then compared the images taken after 6-month follow-up of the treated side and the untreated side (1 = treated side, 2 = untreated side). The images were observed on a single PC with maximum brightness and no change in contrast or color.
- To quantitatively and objectively compare the treated with the untreated sides, the areas of the scar at 1 and 6 months post-surgery were quantified using the software Image J 1.52a.

Remark: Only 56 of the 68 standardized photographs could be analyzed due to the poor quality of some of them.

One year after the surgical intervention, patients were asked to complete a questionnaire by e-mail evaluating the esthetic and the sensitivity results of both scar sides. To assess the quality of the scar, patients were directed to assign a score on each side of their scar according to the following scale: 1 = very good, 2 = good, 3 = regular, 4 = bad and 5 = very bad. In the same way, participants were asked to assign a sensitivity score: 1 = normal and similar to other parts of the body, 2 = hyposensitive, less sensation or numbness and 3 = hypersensitivity or more sensation than in other parts of the body.

Statistical Analysis

Statistical analysis was performed using GraphPad Prism 7.00 for Windows (GraphPad Software, La Jolla, CA, USA) and XLSTAT 2018.3 [Data Analysis and Statistical Solution for Microsoft Excel. Addinsoft, Paris, France (2018)].

Data collected over the first 6 months were analyzed as follows.

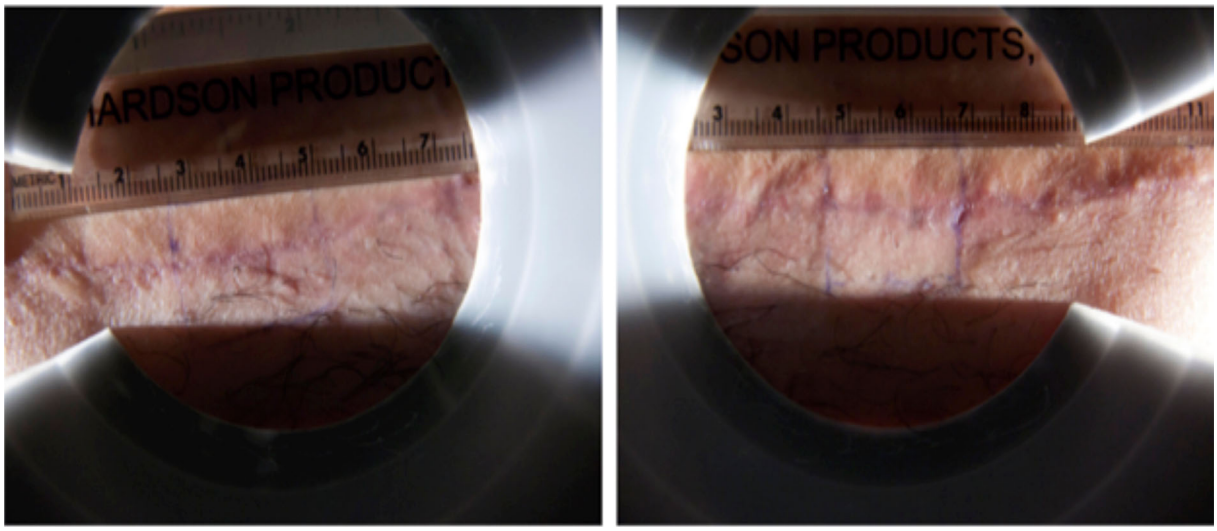


Fig. 2 Standardized photographs results on the treated and the untreated sides

All variables recorded on the treated and untreated side at the first and the sixth month of follow-up, from VSS, PSAS, OSAS scales and scar areas, were tested using a two-way repeated measure ANOVA (condition * time effects).

The underlying assumptions of ANOVA were checked using Skewness–Kurtosis coefficients (normality of distribution), residual normal probability plot (homogeneity of distribution) and a linear regression analysis in order to evaluate the influence of independent variables (age, time of surgery, BMI, quality of the skin) on the collected data.

Contingency analyses (Cohen's kappa and Chi-square tests) were performed to process data from the visual analysis of the standardized photographs taken by two different observers.

Data from the one-year follow-up questionnaire were tested by Wilcoxon signed-rank test to compare the sensitivity of the skin and the quality of the scars of the treated side with the untreated side at 1 year postoperative.

The tests were considered significant when p value was < 0.05.

Results

Participants

Twenty-three women underwent abdominoplasty at the plastic surgery division of the public hospital. Six participants were withdrawn from study: One participant became pregnant at 5 months postoperative; one participant did not complete the LED sessions; one participant missed scheduled visits; one participant declined to participate in the trial 2 months after surgery; one participant suffered dehiscence of the scar; and one participant requested a revision surgery at 5 months post-surgery. Data from 17 patients were finally used in statistical analyses evaluating the effect of photobiomodulation treatment at 1 and 6 months post-surgery. Out of these participants, 11 agreed to complete the follow-up questionnaire at 1 year post-surgery. Clinical features and patient characteristics are detailed in Table 2.

Table 2 Clinical features and patient characteristics

Characteristics	*N*	%
Female	17	100
Age (years)	35.7 (27–52)	–
Caucasian	17	100
Surgical time (min)	189.52 (150–230)	–
BMI (kg/m^2)	26.1 (22.4–28.4)	–
Surgeons' opinion about the skin quality		
Good	10	59
Bad	7	41
Very bad	0	0
Surgeons' opinion about flap tension		
Without tension	0	0
Mild tension	0	0
Moderate tension	13	76
High tension	4	24
Complications during surgery	0	0
Follow-up of 6 months	17	100
Follow-up of 12 months	11	65

Follow-Up Examinations at 1 and 6 Months Post-Surgery

Scar Assessment Scales

Data are presented in Table 3.

Two professionals applying VSS and OSAS scales analyzed the quality of the scar.

Regarding the VSS scale, the quality of the scars was significantly better on the treated side in comparison with the untreated side at 1 and 6 months post-surgery ($F = 9.80$, $p = 0.0065$). However, even if the quality of scar tended to improve over time and was always better on the treated side, neither the factor *time* ($F = 1.50$ $p = 0.2383$) nor their interaction (time * treatment) ($F = 0.24$, $p = 0.63$) seemed to be significant.

The scores obtained with the OSAS lead to the same observations. The cosmetic outcomes were better on the treated side compared with the untreated side at the first and the sixth month post-abdominoplasty ($F = 11.82$, $p = 0.0034$) but neither time ($F = 0.43$, $p = 0.52$) nor the interaction ($F = 1.08$, $p = 0.31$) seemed to be significant.

Linear regression analysis demonstrated that none of the independent variables (age, BMI, surgeon's opinion about the quality of the skin and surgical time) affected the results obtained (p values > 0.1).

The results of the patients' evaluations (PSAS) also showed significantly better cosmetic outcomes on the treated side at 1 and 6 months post-surgery ($F = 10.74$, $p = 0.0047$). However, neither time ($F = 0.5938$, $p = 0.45$) nor the interaction ($F = 2.195$, $p = 0.16$) seemed to be significant.

Standardized Photographs

Two different evaluators performed the standardized photographs assessment and compared the treated with the untreated side of the scar at the sixth month. The concordance between the assessments of evaluators 1 and 2 could be qualified as almost perfect (Kappa concordance index = 0.851). Both evaluators noted a better esthetic result of the scar on the treated side 57.1%, compared with the untreated side 35.7% of the cases (Chi-square = 10.37, $p = 0.001$).

When analyzing the evolution between the first and the sixth month post-surgery, the concordances were moderate to almost perfect (from 0.533 to 0.851) and evaluators agreed to prefer the scar at 6 months post-surgery in 57.1% of the cases.

Standardized photographs taken at 1 and 6 months post-surgery were also analyzed with the software Image J 1.52a to more objectively compare the area of treated scars with the untreated ones. Data and examples of the software contouring are presented in Fig. 3 and Table 4. The area of the scars was significantly smaller on the treated side in comparison with the untreated side at 1 and 6 months post-surgery ($F = 12.17$, $p = 0.0040$). However, even if the area of scar tended to reduce over time and was always smaller on the treated side, neither the factor *time* ($F = 1.716$ $p = 0.2128$) nor their interaction ($F = 0.395$, $p = 0.5406$) seemed to be significant.

One-Year Follow-Up Questionnaire

The 1-year follow-up questionnaire was completed by 11 participants by e-mail. Data are presented in Tables 5 and 6 and were tested by Wilcoxon signed-rank tests. Regarding the quality and the sensitivity of the scar, patients did not notice a statistically difference between the treated and untreated sides ($p = 0.071$ and $p = 0.109$, respectively). No patient assigned a bad or very poor quality of their scars on any side.

Adverse Events

No side effects related to the photobiomodulation treatment were reported in this clinical investigation.

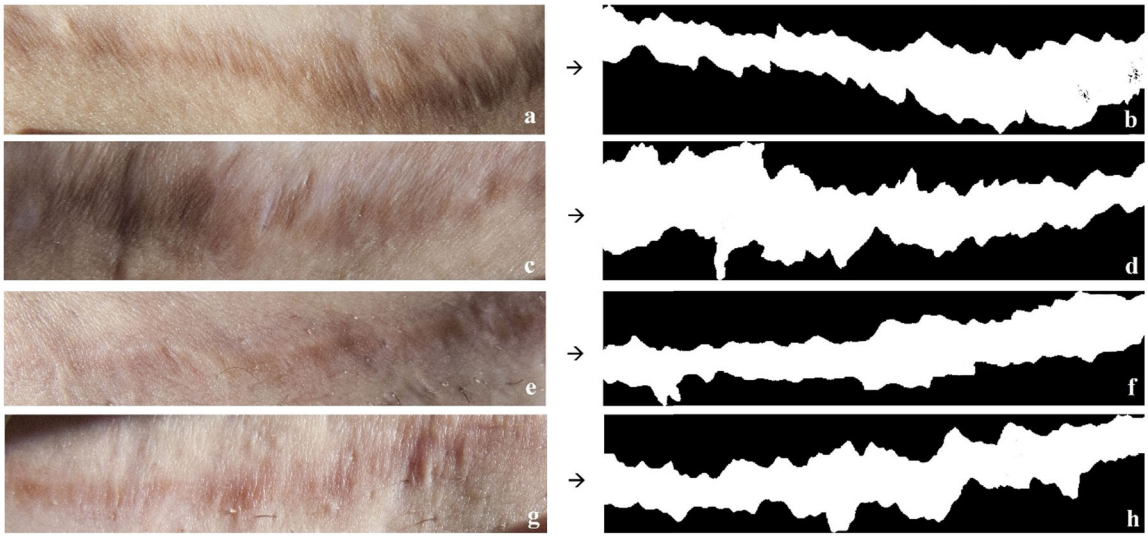
Discussion

The objective of this study was to evaluate the effects of photobiomodulation on the post-surgical healing process. All participants enrolled in this clinical investigation

Table 3 Scar assessment scale scores

	Treated side at 1 month ($n = 17$)	Untreated side at 1 month ($n = 17$)	Treated side at 6 months ($n = 17$)	Untreated side at 6 months ($n = 17$)
VSS	2.71 (0.52)	4.38 (0.50)	2.32 (0.53)	3.68 (0.69)
OSAS	8.53 (0.79)	11.12 (0.98)	8.56 (0.78)	10.03 (0.93)
PSAS	11.94 (1.69)	13.24 (1.78)	10.24 (1.09)	12.18 (1.29)

Values are mean (SEM)



Standardized photographs of the treated (a) and untreated (c) side of the patient 7; Surfaces of healing area analyzed by the software ImageJ for the treated (b) (area= 405239 px) and untreated (d) side (area= 587831 px) of the patient 7; Standardized photographs of the treated (e) and untreated (g) side of the patient 9; Surfaces of healing area analyzed by the software ImageJ for the treated (f) (area= 451885 px) and untreated (h) side (area= 457155 px) of the patient 9.

Fig. 3 Examples of ImageJ software contouring of standardized photographs taken at 6 months post-surgery

Table 4 Areas of the contour of scars

	Treated side at 1 month (n = 14)	Untreated side at 1 month (n = 14)	Treated side at 6 months (n = 14)	Untreated side at 6 months (n = 14)
Areas in pixels	376,157 (30,626)	425,093 (22,574)	362,306 (31,919)	400,930 (29,050)

Values are mean (SEM)

Table 5 Proportions of patients' perception of the quality of the scar at 1-year follow-up on both sides

	Treated			Total
	Very good	Good	Regular	
Untreated				
Very good	0.100	0.000	0.000	0.100
Good	0.200	0.300	0.000	0.500
Regular	0.000	0.100	0.300	0.400
Total	0.300	0.400	0.300	1.000

Table 6 Proportions of patients' perception of the sensitivity of the scar at 1-year follow-up on both sides

	Treated			Total
	Normal	Hyposensitive	Hypersensitive	
Untreated				
Normal	0.545	0.091	0.000	0.636
Hyposensitive	0.091	0.091	0.000	0.182
Hypersensitive	0.000	0.091	0.091	0.182
Total	0.636	0.273	0.091	1.000

underwent an abdominoplasty. The choice to focus on this type of surgery was essentially based on two points: Firstly, the technique of the abdominoplasty used in this study results in a large-size scar that allows each patient to be her own control with photobiomodulation applied on one side of the scar. Secondly, abdominoplasty is one of the most common esthetic surgical procedures with a high rate of complications including wound-related complications [21], and it was therefore interesting to evaluate the benefits of photobiomodulation on this type of surgery.

In this clinical trial, we evaluated the impact of ten sessions of photobiomodulation on the post-surgical healing process and demonstrated that the quality of the scar was better on the treated side compared with the untreated side at 1 and 6 months post-surgery. Although the results were mostly obtained with subjective scales, the strength of the latter seems well verified. Indeed, these results were significantly observed with all the different scar assessment scales used in this study and confirmed by more objective criteria using a software quantification. Moreover, the results involved the opinion of professionals but also reflect

the opinion of patients. Otherwise, the observers' assessment scales, VSS and OSAS, which have been applied by two professionals with more than 20 years of experience, have excellent inter-class reliability.

Even if the quality of the scar tends to improve more quickly on the treated side, the statistical analysis did not really validate definitively an accelerating effect of the healing rate. This implies that photobiomodulation had an overall effect, but does not allow us to conclude that it significantly accelerated healing between the first and the sixth month post-surgery. Furthermore, patients did not report any difference of scar quality between treated and untreated sides. To statistically validate these results and optimize the duration of the treatment effects, it would be interesting to follow the healing more regularly in the first 12 months postoperative.

There are many scales to assess the quality of scars. The Vancouver Scar Scale and its modified version, the Manchester Scar Scale, the Hamilton Scale, the Patient and Observer Scar Assessment Scale, Matching Assessment of Scars and Photographs, the Stony Brook Scar Evaluation Scale (SBSES), the University of North Carolina "4P" Scar Scale and the Visual Analog Scale and Dermatology Life Quality Index are among the best known scar assessment scales [22, 23]. All these scales have their own characteristics and evaluate different criteria taking into account or not the scar description and comorbidities. There is currently no real standard to select the optimized scale according to the type of studied scar.

To facilitate the comparisons of the results obtained in this trial with other treatment methods or type of surgeries, the selection of the assessment scales used in this clinical investigation was in line with a recent review considering VSS and POSAS as the most used in published clinical trials [24].

This made it possible to verify that the order of magnitude of the data obtained with the two scales was in agreement with the already published articles evaluating post-surgical or post-traumatic scars.

For comparison purposes, Bianchi et al. [25] used the POSAS to evaluate the outcome of the healing process of post-traumatic and surgical facial scars that were treated with self-drying silicone gel. After 2 months, the PSAS mean scores were 12.86 in the treated group and 12.35 in the untreated one. The OSAS scores were 11.39 and 10.03, respectively.

In 2018, Fleisher et al. [26] evaluated patient satisfaction and patient and physician assessment of scar appearance after Cesarean skin closure with suture versus staples. The scores were assessed at a median of 46 days postoperatively. In this study, depending on the condition tested the PSAS scores varied from 15 to 20 and the OSAS scores from 12 to 13.

Casanova et al. [5] evaluated the performance of a new automated 1210-nm laser system and observed an OSAS median score decreasing from 13.3 at week 2 to 12.2 at week 6 on the treated scars and from 13.6 to 12.7 on the untreated scars.

Matiasek et al. [27] studied 45 patients who underwent abdominoplasty or mastectomy with transverse rectus abdominis muscle (TRAM) flap reconstruction and who were given both a standard postoperative wound dressing on one wound side and an octenidine-based hydrogel with transparent film dressing, covered with standard postoperative dressing on the other side. They especially evaluated the scars with the VSS scale used at 3, 6 and 12 months postoperatively and found a lower score on the treated side at all time points: at 3 months: 2.50 versus 4.25; at 6 months: 1.75 versus 2.96; and at 12 months: 0.86 versus 1.92.

If these publications did not study the same type of scars or evaluated them at slightly different timings, they allow to validate the order of magnitude of the values obtained in the present clinical study and show that the efficacy of photobiomodulation is largely comparable to that obtained with previously validated treatments.

To perform a statistically valid study with good power on a small sample size, the inclusion and exclusion criteria had to be really selective. This constraint does not allow validating the effects of the treatment on a non-Caucasian population with different health conditions. The positive effects obtained in this study therefore suggest that it would be interesting to test the treatment on a more substantial number of patients as well as on a larger population.

Finally, this clinical trial was not randomized and only the right side of the different scars was submitted to photobiomodulation. Nevertheless, we considered that there were no differences between the treated and untreated sides because the patient and surgery always were the same and only one surgeon carried out the skin sutures.

Conclusion

In this clinical investigation, photobiomodulation had an overall beneficial effect on the quality of the scar of Caucasian patients at the first and the sixth month post-surgery. The quality of the scar was actually improved on the treated side in comparison with the untreated side according to all the different assessment tools used in this trial. At 1 year of follow-up, no differences between treated and untreated side of the scar were noticed by the participants, which suggests that LED therapy seems to be a promising technology to accelerate the first stages of the wound healing process. Nevertheless, studies on more heteroclite groups and with closer follow-up visits should be

considered to definitively validate this trend on an international population. Furthermore, it would be very interesting to carry out additional in vivo or clinical studies with histological examinations to better determine the impact of photobiomodulation on the quality of tissue during the healing process.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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