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ORIGINAL ARTICLE NON-SURGICAL AESTHETIC

A 1-Year Follow-Up of Post-operative Scars After the Use of a 1210-nm Laser-Assisted Skin Healing (LASH) Technology: A Randomized Controlled Trial

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Abstract
Background Laser therapies are used prophylactically for excessive scar formation. The Laser-Assisted Skin Healing treatment induces a controlled heat stress that promotes tissue regeneration. This comparative trial is the first to evaluate the performance of a new automated 1210-nm laser system, compatible with all Fitzpatrick scale phototypes.
Methods Forty women undergoing bilateral breast reduction were enrolled in this double-blinded randomized controlled trial. The horizontal sutured incision of one breast was treated with the portable 1210-nm laser while in the operating theatre. The other breast was used as the study control. Objective measurements, subjective clinical assessments and safety evaluation were carried out over 1 year by both clinicians and patients.
Results Six weeks following surgery, better overall appearance and modified OSAS scores were reported for the laser-treated scars when compared to the control group ($p = 0.024$ and $p = 0.079$). This supports an early effect of the laser treatment during the inflammatory stage of the healing process. After a post-treatment period of 6 months, there continued to be a strong tendency in favour of the laser treatment based on the subjective scores and corroborated by the objective improvement of the treated scar volume ($p = 0.038$). At 1 year, the laser-treated scars continued to improve compared to the control ones in terms of volume ($p = 0.004$), surface ($p = 0.017$) and roughness ($p = 0.002$), and these comparatively better results were strengthened with the blind expression of patients' preference for their laser-treated scar ($p = 0.025$).
Conclusions This new 1210-nm laser treatment, used as a single session performed immediately after surgery, provides significant objective and subjective improvements in scar appearance. These data can be useful when preparing patients to undergo their surgical procedure.
Level of Evidence I 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 Surgical scar · Scar prevention · Laser · Laser-Assisted Skin Healing (LASH) · Heat shock protein (HSP) · Aesthetic surgery

Introduction

Every year, 234 million surgical interventions are performed worldwide [1]. Whatever the technique or the material, these surgical interventions invariably lead to scars with various degrees of aesthetic effects on the patient [2]. Numerous factors (specific anatomic location, genetic susceptibility, age, blood supply, infection, sun exposure, etc.) have been shown to potentially increase the risk of abnormal scar formation, even after minor surgery [3, 4]. Patients with non-Caucasian skin types, in particular, are known to be at very high risk for hypertrophic and keloid disorders [4–7]. According to the literature, 10–70% of surgical interventions are reported to lead to

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hypertrophic scars [5, 6]. To lower the aesthetic impact of surgical scars, many different strategies have been identified, such as silicone dressing, pressure therapy and compression devices [8–10]. According to the most recent guidelines, prevention of abnormal scar formation should always be a first priority [4, 9, 11–13]. The positive effects of early intervention, preventive measures with intensity adapted to the patients' needs and combined therapies are well recognized [4, 9–13].

During the past decade, laser therapy, with its broader application, has played a growing role in the field of scar prevention and treatment [8, 11, 14, 15]. In 2010, a new approach based on a preventive treatment of scars was developed with the Laser-Assisted Skin Healing (LASH) using an 810-nm laser diode [16]. Applied immediately after surgery, this device induces a controlled elevation of skin temperature which activates tissue regeneration through the overexpression of heat shock protein 70 (HSP70) [17]. These chaperone proteins are believed to shorten the inflammatory phase of the wound healing process and hasten scar maturation [18, 19]. An initial randomized clinical evaluation, assessing the efficacy of the device after abdominoplasty or breast reduction surgery, showed that the LASH can improve the appearance of surgical scars when compared to the control group [20]. Due to its 810-nm wavelength and to its possible absorption by melanin, this laser was exclusively dedicated for patients presenting with skin Fitzpatrick scale types I–IV.

Recently, the LASH device was improved with a 1210-nm laser diode, allowing its use on patients with all skin phototypes, including Fitzpatrick scale types V and VI. The objective of the present clinical trial was to assess the performance and safety of this new device when using it in conjunction with standard care compared to standard care alone. The "SLASH" study (Scar after Laser-Assisted Skin Healing) is a 1-year follow-up double-blinded randomized controlled study, undertaken on patients undergoing breast reduction, in which the laser treatment was applied immediately following the standardized surgical procedure.

Materials and Methods

This prospective double-blind randomized controlled trial was conducted at the University Hospital Center "La Conception" in Marseille (France), in accordance with Good Clinical Practice (GCP) guidelines, with the principles of the Declaration of Helsinki and with current French regulations. Study protocol and all documentation had approval from the French Ethics Committee (Comité de Protection des Personnes Sud Méditerranée I) and from the French Competent Authority (Agence Nationale de Sécurité du Médicament et des Produits de Santé) on May, 2013 (ANSM registration number 2013-A00279-36). All patients provided informed written consent prior to participation.

A sample size calculation was performed with a power goal of 0.8 and an alpha risk level of 0.05 based on a previous trial [21]. Forty women were enrolled by the four surgeons involved in this clinical investigation. Every Fitzpatrick scale phototype was accepted. All patients were scheduled for bilateral breast reduction (300–700 g by breast) using the conventional McKissock or Thorek techniques (with inverted-T scars). Exclusion criteria included any patient under the age of 18 years; current high-dose corticosteroid treatment; current photosensitizing treatment; any current additional systemic, topical or intralesional scar treatment other than those described in the protocol; current lactation or pregnancy; known history of keloid scarring; previous breast surgery; current malignancy; current bacterial or viral skin infection; systemic or autoimmune connective tissue disease; immunosuppressive condition; and any serious condition that might compromise the patient successful participation in this 12-month follow-up trial. There was no phototype exclusion criterion.

Surgical incisions of the bilateral breast reduction were sutured according to local standard procedures, using common surgical sutures (Monocryl™ Sutures, Ethicon™, Somerville, New Jersey, US) compatible with the laser use, according to laser manufacturer's instructions. The horizontal scar of one breast received laser treatment, while the other breast remained as a control (see Fig. 1). The treated and untreated breasts were randomly assigned through the

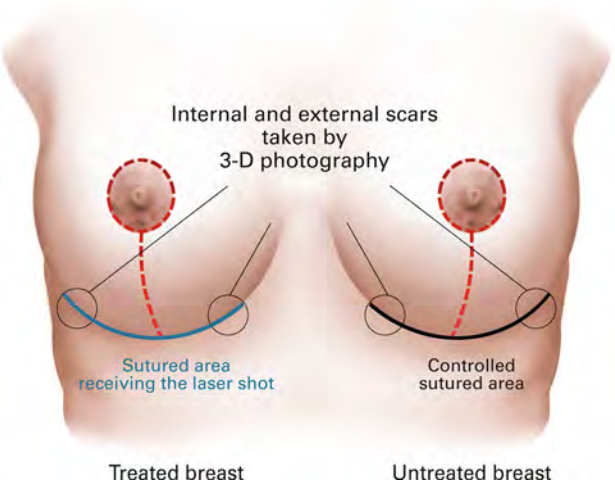

Fig. 1 Randomization of treated breast. The horizontal sutured incision of one breast was randomly allocated to the laser treatment, while the horizontal sutured incision of the other breast remained as the control

use of sealed envelopes. The randomization list was generated by an independent company.

The 1210-nm laser diode (UrgoTouch®, Laboratoires Urgo, Chenôve, France) is a secure, automated, portable laser providing a controlled elevation of skin temperature, due to its scar control system technology (see Fig. 2). The laser treatment (only one pass over the incision) was performed in the operating theatre, immediately after the placement of the intradermal sutures, when patients were still under general anaesthesia. The surgeon had previously received training on the use of the laser. The target cutaneous zone was secured by the application of safety strips including high technology microchips. These microchips authorise the laser shots and prevent any overdose. The sterile strips were positioned along the horizontal suture allocated to the treatment just before the laser shot. The laser shot duration is determined and controlled by the laser software itself, based on the patient's skin temperature detected by the embedded pyrometer of the device. This technology ensures the automatic discontinuation of the shot when the target skin temperature (53 ± 3 °C) has been reached, ensuring both reproducibility of the shots and patient safety. Neither preliminary parameter settings nor adjustments are required for the laser shot.

Aside from the laser treatment, both breasts received exactly the same care. According to recent guidelines [4, 11, 12] and local procedures, each breast was covered by a primary dressing providing a moist wound healing environment (UrgoTul®, Laboratoires Urgo, Chenôve, France). The dressings were changed on alternate days, and the sutured incisions were cleaned with saline solution. Patients were asked to wear a post-operative compression bra (Z-bra®, Medical Z, Chambray-Les-Tours, France) for 2 months after the surgery.

The primary objective of this clinical study was to evaluate the performance of the laser treatment on the cosmetic outcomes of the scars at 6 months and at follow-up at 1 year. Clinical assessments of all scars were conducted at 14 days (after suture removal) and 6 weeks, 3 months, 6 months and finally 1 year after surgery. In this double-blinded clinical study, neither the evaluating physicians nor the patients were informed of the allocation of the treatment before the end of the trial.

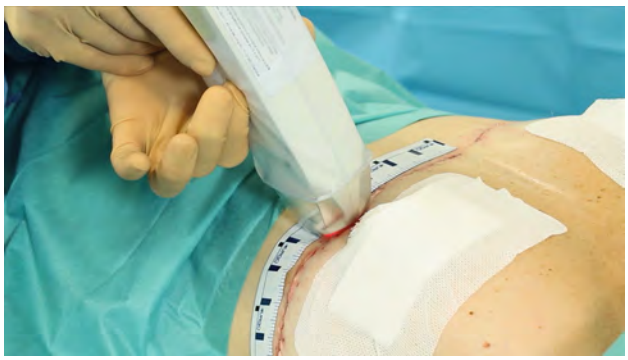

Fig. 2 Automated 1210-nm diode laser and its scar control system technology

Standardized two-dimensional (2D) photographs of each scar were taken at each visit by a blinded examiner at the Clinical Investigation Center (CIC) of the hospital. Two blinded physicians in the study separately examined all the photographs and expressed their overall opinion (OO) on the appearance of the scars, with a score from 1 (=similar appearance to healthy skin) to 10 (=worst possible appearance). In addition, physicians rated the scars using a modified Observer Scar Assessment Scale (mOSAS). The mOSAS investigates five scar features: vascularity, pigmentation, thickness, relief and surface area of the scar [21–23]. Each feature score ranged from 1 (=best, i.e., similar to normal skin) to 10 (=worst possible scar). The total score ranged from 5 to 50 (the lower, the better). These feature scales have been validated as reliable means of assessing scars [22, 23]. Patient's preference was also recorded at each evaluation, using a single-answer multiple choice questionnaire and an analogic visual evaluation scale (−100, absolute preference for the right breast scar; 0, no preference; +100, absolute preference for left breast scar).

To ensure objective analysis of the scar characteristics at 6 months and 1 year, three-dimensional (3D) calibrated photographs of internal and external sections of the scars were also obtained with a digital camera (3D LifeViz Micro™, Quantificare S.A., Sophia Antipolis, France). Volume, roughness and surface of the scar were then quantified by an independent company (Gredeco, Paris, France) using an image analysing software tool validated in scar assessment (Quantificare, Quantificare S.A., Sophia Antipolis, France) [24, 25]. Finally, to evaluate the safety for each patient, local adverse events and complications were reported if occurred.

SPSS v18.0 software (SPSS Inc., Chicago, IL) was used for statistical analysis. Nominal data were presented by their frequency. Mean values and standard deviations of continuous data were calculated. For the mOSAS score and the OO score, the mean value of the evaluations made by the two blinded physicians was used for analysis. Univariate analysis of variance (ANOVA) was used to compare the mOSAS scores and overall opinions of each group (laser and control). The Student's t test was used to compare the characteristics of the scar based on the analysis of the 3D photographs. The p value ≤ 0.05 was deemed to be statistically significant.

Results

Forty women had the incision of one breast treated with the 1210-nm diode laser at the time of the surgery. The mean duration of the laser treatment lasted 6.9 ± 2.5 min. The laser was rated by all the surgeons as very easy or easy to use. Demographic data of the treated patients are reported in Table 1. Patients' ages ranged from 18 to 71 years old (median age 45 years). The patients were in good health with a BMI that ranged from 18.6 to 29.4 kg/cm^2, with a median value of 24.4. There were few reported medical conditions, with no expected impact on wound healing (20% had hypertension, and there were no cases of diabetes), aside from the 22.5% of patients who reported that they were active smokers. Thirty patients had undergone previous surgery without any history of developing keloids or hypertrophic scarring. Thirty patients were Fitzpatrick's skin type III. Five, three and two patients were, respectively, typed II, IV and V–VI.

The mean weights of the breast reductions were similar in the treated and control groups (446.4 ± 129.1 vs. 446.5 ± 143.3 g), as were the mean lengths of the evaluated horizontal scars (19.7 ± 3.4 vs. 19.6 ± 3.4 cm). Postoperative care was also similar in both groups. Three patients were lost to follow-up at 6 months.

Subjective Outcomes Graded by the Blinded Physicians

Two-dimensional photographs of the control and laser-treated breast scars at 1-year follow-up are presented in Fig. 3. The analysis of the physicians' overall opinion (OO) on appearance of the scars, 14 days after the surgery and the laser treatment, revealed no significant difference between the treated scars and the controls (2.7 ± 0.7 vs. 2.8 ± 0.6), while the analysis of the appearance of the scars 6 weeks after the surgery revealed a significant difference between treated and untreated breasts favouring the laser-treated breasts ($p = 0.024$). The 1210-nm diode laser-treated scars demonstrated on average a better improvement of their overall appearance with a 2.5 ± 0.5 score compared to a 2.7 ± 0.5 score for the control sites. At 24 weeks, a similar difference was reported with a better OO score for the laser-treated scars (2.5 ± 0.7 vs. 2.8 ± 0.9; $p = 0.067$). At 1 year, the overall appearances of both treated and untreated scars had continued to improve, without a significant difference between the scores of the two groups.

Table 1 Demographic data of the treated patients

Age (years)—mean ± SD	45 ± 14
BMI (kg/cm^2)—mean ± SD	24.3 ± 2.3
Medical conditions—*n* (%)	
Surgical history	30 (75%)
Smoking	9 (22.5%)
Hypertension	8 (20%)
Cardiopathy	3 (7.5%)
Others	17 (42.5%)
Fitzpatrick's skin types—*n* (%)	
II	5 (12.5%)
III	30 (75%)
IV	3 (7.5%)
V–VI	2 (5%)

The analysis of the mOSAS scores at 6 weeks also revealed an improvement in the appearance of both laser-treated scars (from 13.3 ± 3.3 at week 2 to 12.2 ± 1.8 at week 6) and untreated scars (from 13.6 ± 3.1 to 12.7 ± 2.0). The laser-treated scars obtained on average better scores than the control scars, for overall score as well as for scores by parameter (vascularity, pigmentation, thickness, relief and surface), without reaching the level of significance ($p = 0.079$). The same tendency was reported at the 24-week evaluation, with a mean score of 12.5 ± 2.9 for the laser-treated scars compared to 13.7 ± 3.9 for the control ones ($p = 0.117$). At 1 year, the mOSAS scores of both the laser-treated and untreated scars have continued to improve and decreased in each group without a significant difference between them.

Objective Outcomes (Software Analysis of 3D-Photos)

Six months after the surgery and laser treatment, the measured volume of the scars was objectively improved in the laser group by 36% ($p = 0.038$) as compared to the control group. This result at an intermediate term of scar maturation persisted 1 year after the surgery with significant improvements in the characteristics of the laser-treated scars when compared to those of the control scars, in terms of volume (−29%; $p = 0.004$), roughness (−17%; $p = 0.002$) and surface (−11%; $p = 0.017$). Representative 3D photographs of the scars are provided in Fig. 4a, b.

Patients' Preference

The results of patients' preferences based on the blinded examination of their two scars are reported in Fig. 5. At each evaluation, a majority of the interviewed patients expressed a clear preference for one of their scars. At week 2, there was no difference between the rate of selection of the laser-treated and untreated scars. At week 6 and thereafter, patients with a pronounced preference showed a tendency to select the scar that had been treated. At 1 year, this preference for the laser-treated scar was statistically

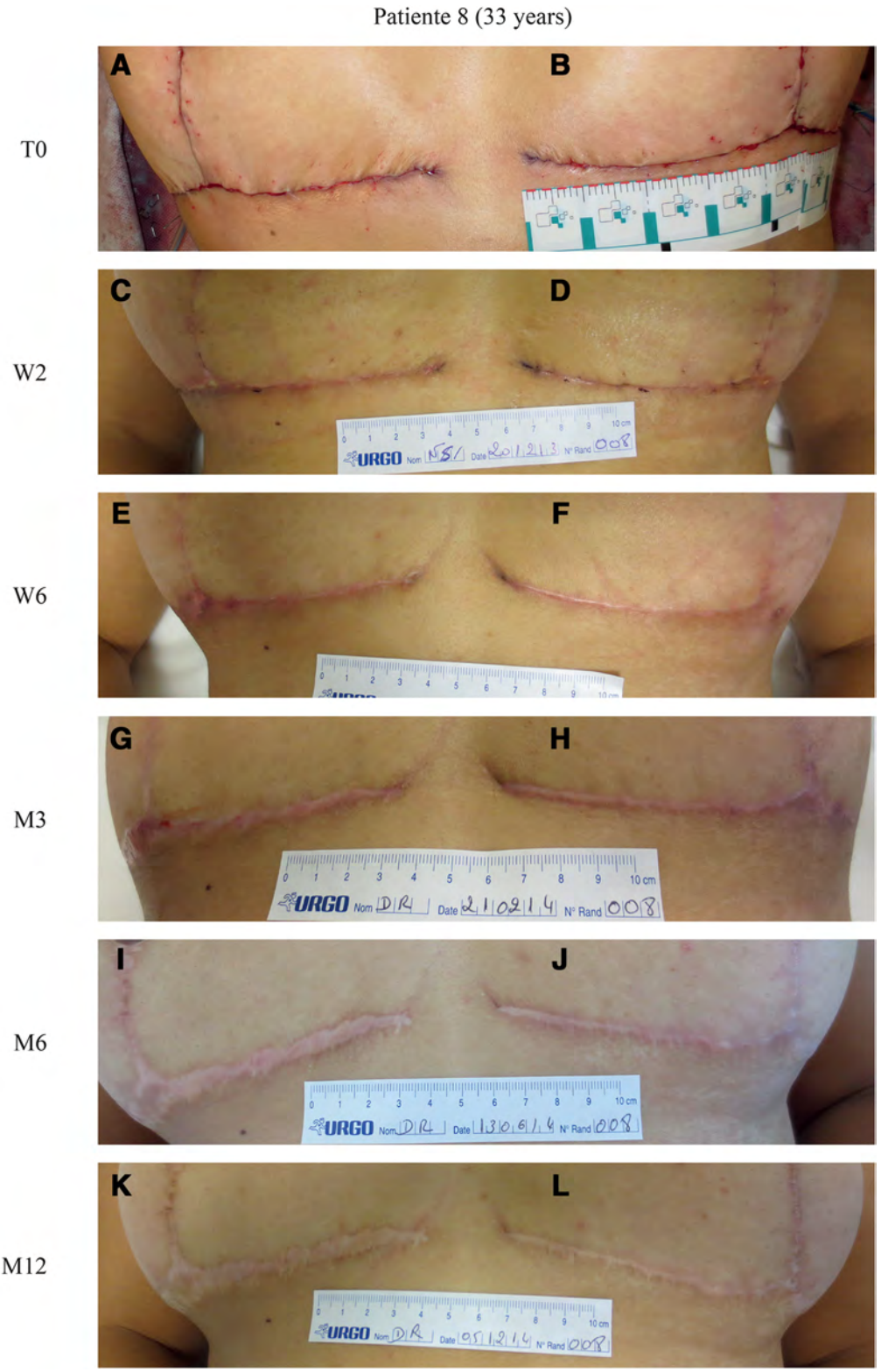

Fig. 3 One-year follow-up of the post-operative scars of patient number 8 (33 years old). Above are the representative 2D photographs of the control breast (**a**, **c**, **e**, **g**, **i**, **k**) and the laser-treated breast (**b**, **d**, **f**, **h**, **j**, **l**). The photographs were taken the day of the laser treatment (**a**, **b**) and then at 2 weeks (**c**, **d**), 6 weeks (**e**, **f**), 3 months (**g**, **h**), 6 months (**i**, **j**) and 1 year (**k**, **l**) following surgery

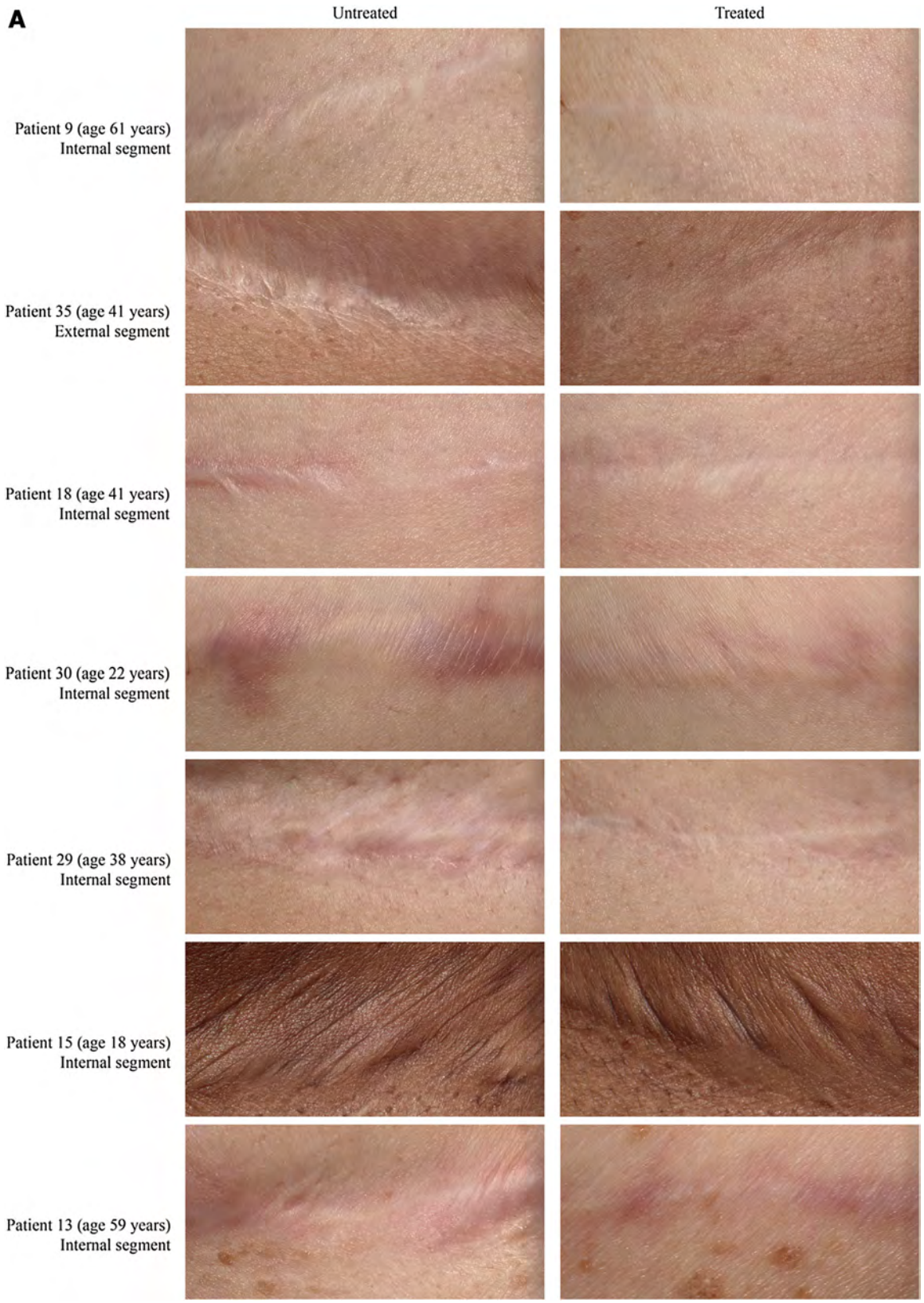

Fig. 4 **a** and **b** Representative 3D photographs of the horizontal scars provided for computer analysis. Above are external and internal segments of treated and control breasts of patients 1 year after the surgery

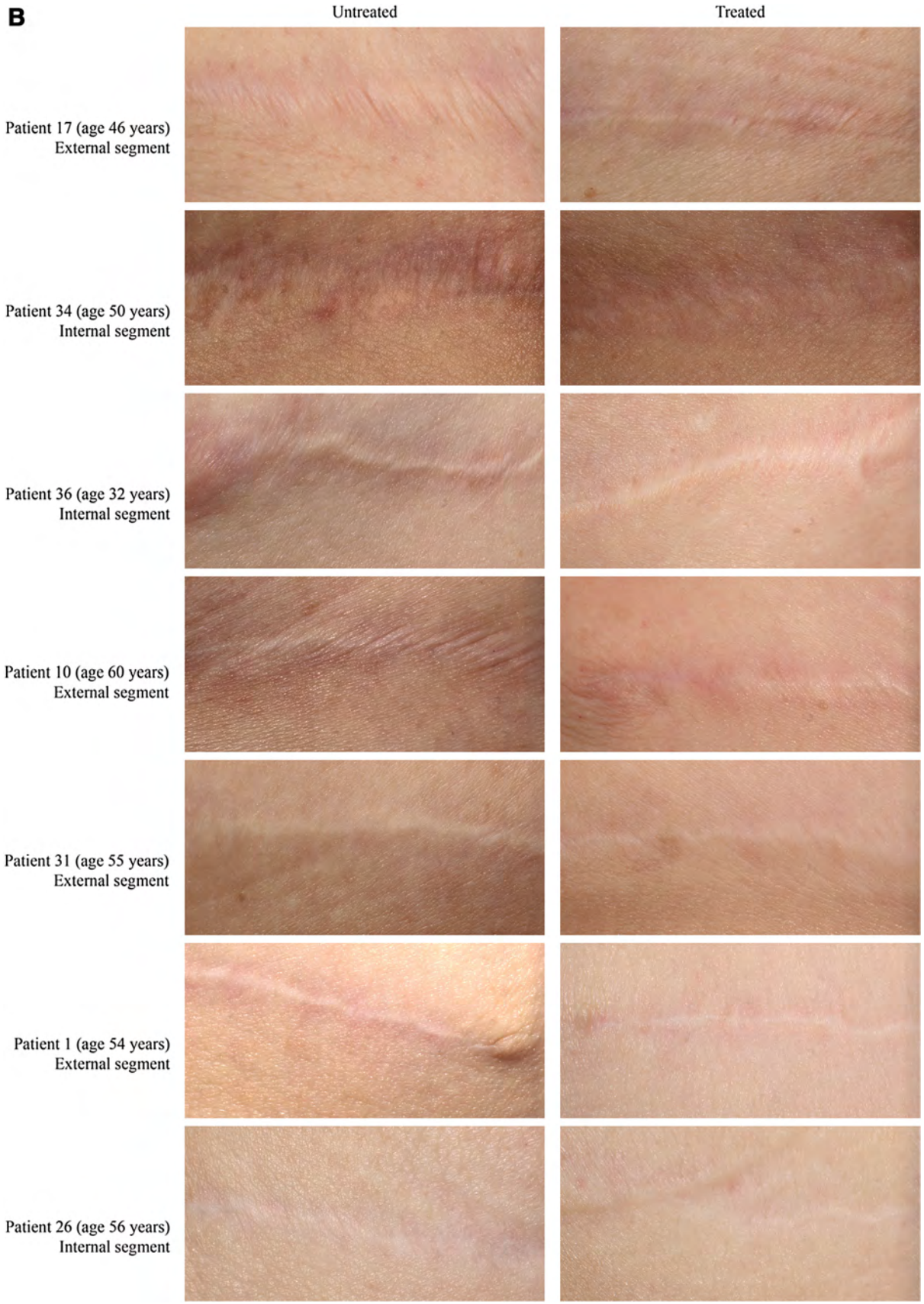

Fig. 4 continued

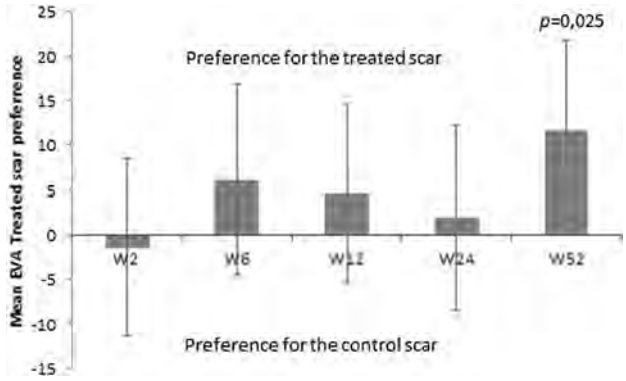

Fig. 5 Analogic visual evaluation of patient's preference. A positive EVA score reveals a preference for the laser-treated scar, a negative EVA score reveals a preference for the control scar and a null EVA score reveals no preference. *Error bars* indicates 95% confidence intervals

significant, with twice as many patients preferring their laser-treated scar as the number of patients preferring their control scar ($p = 0.024$). This result at 1 year was also confirmed by the analogic visual evaluation of patients' preference with a positive score of 11.7 in favour of the treated scars (95% confidence intervals 1.6–21.8; $p = 0.025$).

Safety

No adverse event was reported during this study. In particular, no adverse event or complication was observed in darker skin type patients. One complication occurred in patient no. 14 (phototype III), due to an unexpected failure of the device. This resulted in a surficial burn (second degree) that healed within 6 days, with no sequelae for the patient or pejorative evolution of its scar. The occurrence of this burn justified a temporary discontinuation of the trial during which an additional safety feature was integrated to the multiple security mechanisms of the device. No other complication was reported after resuming the clinical study.

Discussion

Improvement in the quality and cosmetic appearance of postsurgical scars using laser therapy has been demonstrated through comparative clinical trials with various levels of evidence [26]. Different lasers, such as the 585-nm [27–30] and 595-nm pulsed-dye lasers [29, 31–35], the 532-nm KTP laser [36], the 810-nm diode laser [20], the 1064-nm Nd:YAG laser [37], the non-ablative 1550-nm fractional laser [32, 35, 38, 39] and the ablative 10,600-nm carbon dioxide fractional laser [40, 41] have been assessed using different laser modalities. Some clinical trials have investigated single-laser sessions [20, 32, 40, 41], while others have experimented with multiple sessions [28, 30, 31, 39], occasionally with multiple laser passes during each session [33, 36, 41]. The laser treatments evaluated were performed or initiated immediately post-surgery [20, 40], after suture removal [27, 31, 36, 38, 41] or at a later date [28, 33, 37]. These different protocols make it difficult to compare the results of these clinical studies. To our knowledge, a general consensus has not yet been reached on an optimal wavelength or on the best laser parameters for the prevention of surgical scars, especially when all skin phototypes are considered [11, 29, 35, 39]. However, the authors of these publications agreed on the need for controlled heating or laser parameter adjustments depending on the specific characteristics of the treated patient to limit the occurrence of side effects [20, 28, 30, 34]. Laser settings are known to be very complex and tightly related to the risks of adverse events, notably in non-Caucasian populations who tend to be more prone to complications [10, 14, 15, 26]. Therefore, patients should always be treated cautiously [10, 14, 15, 26].

In this trial, the evaluated 1210-nm laser system is an automated device, designed to induce a controlled thermal stress that triggers HSP overexpression [17, 18, 42, 43]. The integrated software of the device determines the laser shot duration considering the specific skin characteristics of each patient, whatever the skin type may be. According to the results of this clinical study, based on both subjective assessments and objective measurements, the 1210-nm automated laser system provided improvements in the cosmetic outcomes of the scars. Six months after surgery, a better overall opinion of the treated scars ($p = 0.067$) and a lower mOSAS score ($p = 0.117$) were strengthened by a significant improvement in the volume of the treated scars ($p = 0.038$) as compared to the control scars. The 3D photograph analysis revealed an objective reduction of the laser-treated scars with a thinner, flatter and more normal appearance after 1 year. In the subset of dark skin type patients (Fitzpatrick scale types V–VI), the results also favoured the laser treatment, as the mean reductions of the scar volume and surface (respectively, 53 and 16%, as compared to the control scars), were in line with those observed in the set of treated patients, all skin type included (respectively, 29 and 11% as compared to the control scars). The corroboration of subjective results with objective measurements is important as subjective evaluations are still, to a certain extent, evaluator-dependent (inter-assessor variance), even when ratings are conducted in a blinded manner [44]. The subjective rating scales have been broadly introduced into clinical practice due to their free access and the minimal required training prior to use [45, 46]. Nonetheless, they present some weaknesses because these evaluations

may possess various degrees of reliability depending on the location, type, severity and age of the rated scars [44, 45, 47–50]. The lack of objective measurement is a legitimate limit of previous clinical trials evaluating laser therapies [28, 35], especially as today quantitative and reproducible assessments are facilitated by the development and validation of standardized techniques using 3D devices and computerized measurement software [24, 25, 44, 50, 51].

The patients' perspective is also essential when monitoring the changes over time in scar cosmetic appearance and determining the effectiveness of scar treatments. Godwin et al. [52] reported that 1 year after breast reduction surgery, the aesthetic outcome of the scar was the most frequent cause of dissatisfaction for both surgeons and patients. However, the majority of patients rated their surgery scars significantly higher than the professional graders [52, 53]. In another trial published in 2005, Celebiler et al. [54] revealed that of the three separate scars (peri-areolar, vertical and horizontal or infra-mammary scars) resulting from the inverted-T surgery, the infra-mammary scars received the least pleasing scores by the patients. In this clinical study, blindly choosing between their two horizontal scars, the majority of the patients with a marked preference favoured the treated scar at each evaluation, from week 6 to week 52 ($p = 0.024$). For scar evaluation, results at short term (inflammatory phase), intermediate term (6 months) and long term (1 year) are of equal importance. The follow-up duration of clinical trials assessing laser therapies is another limitation often stated in the literature [3, 13, 26]. The majority of the studies within this field of surgery were limited to a maximum follow-up period of 6 months [33, 35, 36, 38, 39] or less [27, 29–32, 34] while the majority of scars fade on average at approximately 7 months and their maturation is not complete before at least 1 year [3, 13, 26, 55]. Patients ideally wish to regain skin that appears as normal as soon as possible, but they also desire sustainable results. Their satisfaction with their scar embodies their appreciation of their surgery and can also have a significant impact on their long-term quality of life [56]. Paying attention to the psychological effects of scars on patients and providing them with realistic expectations of the final cosmetic result should be essential for all surgeons [57].

To minimize scar development, recent guidelines recommend the application of standards of care (skin tension release, moisturizing of the skin, sun protection) to newly formed incisions [4, 11]. Strategies should be adapted depending on the individual patient's scar risk factors and aesthetic concerns, with the use of combined therapies when necessary [4, 11]. In recent years, researchers have attempted to find the best treatment protocols for laser therapies and the best timing to perform or initiate laser treatments [4, 10, 28–30, 32, 37, 40]. In this clinical study, the preventive laser treatment was performed in the operating theatre on fresh incisions immediately following closure. The laser procedure took a minimum amount of time and was judged by the surgeons as easy to perform, without the need for prior parameter settings or any subsequent adjustment. An effective early intervention is consistent with the LASH technique mode of action [17, 18]. The heat shock induced by the 1210-nm laser is expected to act in a protective way, while the overexpressed heat shock proteins play a central role during the inflammatory phase, leading to controlled collagen production required for a normal wound healing process [3, 18, 19]. The results of this study suggest, given the automated 1210-nm diode laser procedure used, that a single treatment performed on the day of the surgery appears to be adequate to improve the cosmetic outcomes of surgical scars.

This study possessed some limitations as it was a single-centre trial in which only breast reduction scars were treated. Further investigations assessing the efficacy of laser treatments in a cohort of patients more explicitly at risk (e.g., patients with a prior history of hypertrophic scars or patients undergoing keloid resection) would be of great interest, as optimal preventive procedures in these patients are still sought.

Conclusions

This new automated 1210-nm laser treatment, performed immediately after surgery, provides significant objective and subjective improvements of the appearance of breast reduction scars, rated by both physicians and patients, at short- and long-term evaluations. These data can be useful when preparing patients for their impending surgery.

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Compliance with Ethical Standards

Conflicts of interest Z. Lemdjadi and S. Bohbot are employees of Laboratoires Urgo. Pr. D. Casanova and A. Alliez have received a speaker honorarium from the sponsor.

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