Editor's Choice

Effects of Preoperative Extracorporeal Shockwave Therapy on Scar Formation—A Pilot Study on 24 Subjects Undergoing Abdominoplasty Surgery

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Objectives: Extracorporeal shockwave therapy (ESWT) has been demonstrated as a feasible noninvasive method to improve wound healing. This effect was demonstrated to result from increased perfusion and angiogenesis due to systemic growth factor expression. We, therefore, hypothesized that preoperative ESWT reduces scar formation after surgery.

Methods: A prospective, controlled pilot study on 24 patients undergoing abdominoplasty was conducted and the efficacy of preoperative unfocused, low energy EWST was evaluated. The right and left half of the operative area were randomly allocated to ESWT or placebo treatment in intrapatient control design. At 6 and 12 weeks after surgery, scar formation was evaluated by 19 different scar parameters included in the patient, observer scar assessment, and the Vancouver scar scale.

Results: The overall rating of the Vancouver and POSAS scale with Mann–Whitney (MW) analysis revealed a clear trend favoring ESWT. At week 6, 7 of 19 parameters clearly favored ESWT ($MW > 0.53$). At week 12, 8 of 19 parameters clearly favored ESWT. The largest differences were observed in thickness and overall impression (Vancouver scar scale).

Conclusions: ESWT presumably reduces scar formation and postoperative symptoms after abdominoplasty surgery. Further studies are required to confirm ESWT efficacy with statistical significance. Lasers Surg. Med.

Key words: abdominoplasty; extracorporeal shockwave therapy; preoperative; scar improvement; wound healing

INTRODUCTION

Several experimental and clinical studies have demonstrated the efficacy of extracorporeal shockwave therapy (ESWT) as a feasible noninvasive method for the improvement of tissue repair and wound healing. Originally, ESWT was used as urological lithotripsy for the physical disintegration of urinary stones [1] but ESWT was soon extended to the field of orthopedic pathologies [2] and regenerative medicine, predominantly to enhance fracture healing [3,4].

In recent years, the efficacy of low energy, defocused ESWT in the treatment of delayed healing and chronic wounds has been investigated by experimental studies [5] as well as clinical trials. In these trials, unfocused, low energy ESWT was well-tolerated and improved tissue healing in patients with acute and chronic soft tissue wounds [6]. Likewise, a single defocused ESWT treatment significantly accelerated epithelialization of skin graft donor sites when applied immediately after skin graft harvest [7]. ESWT has further emerged as a feasible and safe approach for the treatment of deep partial thickness burns, thereby potentially preventing skin grafting and consecutive treatment such as burn scar contracture release [8]. ESWT additionally reduced the scar pain of burn patients after wound recovery [9]. Moreover, ESWT has been successfully applied for the treatment of chronic ulcers [10], diabetic foot ulceration [11,12], and decubital ulcers [13]. In these studies, no ESWT related toxicity, infection, or other safety concerns have occurred [7,8,10,11]. To our knowledge, no study exists that assessed ESWT efficacy on the reduction of scar formation before (elective) surgical intervention.

The underlying mechanism of ESWT efficacy for the improvement of wound healing relies on the increased release of systemic growth factors such as nitric oxide (NO), transforming growth factor β1 (TGF β1), vascular endothelial growth factor (VEGF), and bone morphogenetic protein

Abbreviations: BMI, Body mass index; BMP 2, Bone morphogenetic protein 2; ESWT, Extracorporeal shockwave therapy; MW, Mann–Whitney analysis; NO, Nitric oxide; POSAS, Patient and Observer Scar Assessment Scale; POSAS inv., Patient and Observer Scar Assessment Scale, investigator; POSAS pat., Patient and Observer Scar Assessment Scale, patient; TGF β1, Transforming growth factor β1; VEGF, Vascular endothelial growth factor.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJEForm for Disclosure of Potential Conflicts of Interest andnone were reported.

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2 (BMP 2) [14] that results in an angiogenic response [15,16] and improved perfusion [17]. Recent studies have suggested a predominant role of NO for the ESWT mediated increase of blood flow in the wound area [18]. Increased perfusion, as well as reduced inflammation and necrosis correlating with increased VEGF expression, seem to additionally contribute to the beneficial effects of ESWT in wound healing [19].

In the above-mentioned studies, ESWT was applied immediately after the surgical intervention. As the beneficial effect of ESWT on wound-healing results from a systemic expression and release of growth factors, it can be hypothesized that preoperative ESWT might be comparably effective. Indeed, in ischemia-challenged skin flaps in rats, an animal model that mimics the conditions of chronic wounds, preoperative ESWT enhanced skin flap survival [20] and neovascularization [21]. In abdominoplasty, ESWT could be easily applied on the operative skin area before surgery, thereby avoiding both the requirement of additional wound management and the increased risk of infection that might occur if ESWT is administered in the postoperative setting.

We, therefore, asked if preoperative ESWT reduces scar formation and postoperative symptoms such as itching and pain, both occurring after abdominoplasty surgery. To answer this question, we conducted a prospective, randomized, controlled pilot study on 24 patients undergoing abdominoplasty surgery in intrapatient control design and evaluated the efficacy and safety of preoperative ESWT.

MATERIALS AND METHODS

Study Design

The study was a prospective, randomized, double-blinded, controlled pilot trial conducted between August 2014 and October 2015 in Salzburg, Austria. The study duration for each patient was 4 months. ESWT was preoperatively applied 1 day before abdominoplasty surgery (visit 0) by plastic surgeon 1 (HT). At this visit, demographic and anamnestic data were obtained. The right and the left half of the operative area of the middle and ESWT was randomly allocated to ESWT or placebo treatment in intrapatient control design, meaning the patient was the control group himself. Randomization was established by the sponsor before the study. After surgery (visit 1), the primary outcome (reduction of scar formation), as well as the secondary outcome (patient reported side effects of scar formation such as itching and pain), was assessed after 6 weeks (visit 2) and after 12 weeks (visit 3) by blinded plastic surgeon 2 (ER). Adverse effects were documented at every study visit.

The study was performed in accordance with ICH-GCP guidelines and the ISO14155 standard as well as with the ethical principles laid down in the declaration of Helsinki. The study has been approved by the Ethical Committee (415-E/1730/12-2014). All patients provided written informed consent.

Participants

A total of 24 patients scheduled for abdominoplasty surgery were included. In addition to the indication for surgery, inclusion criteria comprised the age of 18 to 65 years and the provision of written informed consent. Exclusion criteria were current hematologic disorders, current treatment with anti-coagulatory medication, a history of active malignancy during the past 5 years and pregnancy.

Methods

Extracorporeal Shockwave Therapy. One day before abdominoplasty surgery, one ESWT treatment per patient was performed using the CELLACTOR® SC1 ESWT device and the C-ACTOR® handpiece with long standoff II (Storz Medical AG, Tägerwilen, Switzerland). For placebo treatment, a sham standoff II was used that completely absorbed the transmission of shockwave energy to the patient's body tissue (Fig. 1). During ESWT and placebo treatment, 50 impulses/cm^2 at a frequency of 4 Hz were applied to an area of approximately 5 cm along both sides of both planed surgical resection margins. One treatment area was around the lower incision, which was made from the left to the right anterior superior iliac spine across the lower

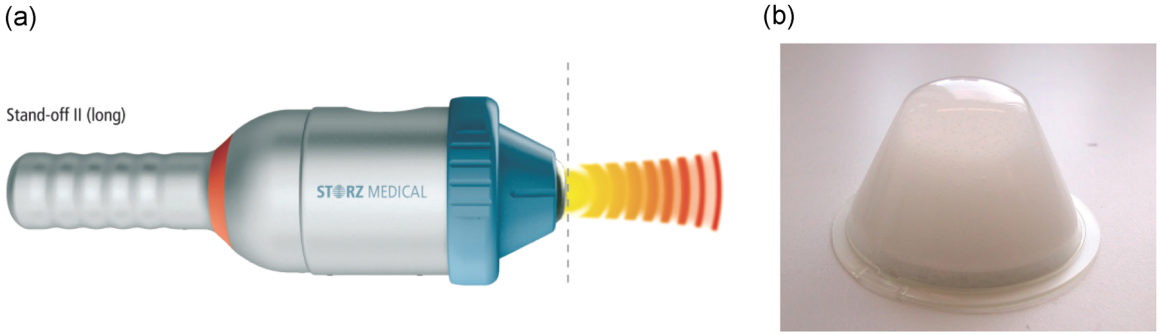

Fig. 1. Extracorporeal shock wave therapy handpieces for active (a) and placebo treatment (b). In our study, a C-ACTOR® handpiece with a long standoff (standoff II; Storz Medical AG, Tägerwilen, Switzerland) was applied (a). A sham standoff II that completely absorbs the transmission of shockwave was used for placebo treatment (b).

abdomen just above the pubic area, and the second one around the upper incision, which was approximately at the level of the umbilicus and dependent on the amount of access tissue. The maximum level of intensity was 0.25 mJ/mm^2, and the penetration depth was between 0 and 10 mm. Depending on the size of the operative area, treatment lasted up to 10 minutes and was performed without any anaesthesia.

Assessment of primary and secondary outcome parameters. Abdominoplasty surgery was performed identically in each patient according to Pitanguy's technique and by the same surgeon. A transverse lower abdominal incision was performed with the full undermining of a dermis fat flap over the muscle extending to the sternal and costal margins. Excessive tissue was excised and the umbilicus was repositioned. Incisions were closed in a layered fashion with subcutaneous Vicryl 2.0 and 3.0 interrupted sutures and a Monocryl 3.0 running suture for skin closure. Two closed suction drains were used in all cases. Postoperatively, the patient was placed in a modified Fowler's position and patients were required to wear an abdominal binder and avoid strenuous activities and heavy lifting for 6 weeks after surgery [22]. The operative area was photographed before and after surgery as well as after 6 and 12 weeks. Scar formation and symptoms were evaluated by the Patient and Observer Scar Assessment Scale, V2.0 (POSAS; [23,24]) assessing outcomes on a 10-point scale as well as by the Vancouver scar scale [25] (with 1 representing normal skin), assessing outcomes on a 3-point scale (with 0 representing normal skin), respectively. POSAS consists of an investigator—(POSAS inv.) and a patient-based evaluation (POSAS pat.). The parameters assessed by both scales comprised vascularity, pigmentation, thickness, surface, elasticity, and area as well as patient reported symptoms and outcomes such as pain, itching, colour, hardness, thickness, and surface.

Statistical Analysis

Because of the paired design of the study, data were nonparametrically analysed by the Mann–Whitney (MW) estimator [26]. The MW effect sizes were provided with two-sided 95% confidence intervals. The effect sizes were defined as follows: larger difference, inferiority; $MW \leq 0.44$; nonmarginal difference, inferiority: $MW \leq 0.47$; marginal difference: $MW = 0.48$–0.52; nonmarginal difference, superiority: $MW \geq 0.53$; larger difference, superiority; $MW \geq 0.56$. Values of p were based on the individual score values by means of a within-group MW test. Statistical significance was set at $p < 0.05$. The statistical analyses were performed using the software packages TESTIMATE (Version 6.5.14) and METASUB (Version 4.1) on high security PCs (HSPC) within a validated working environment at the department of "Clinical Research/Biometry" in the institute IDV Data Analysis and Study Planning under supervision of Volker W. Rahlfs, PhD, C. Stat. (RSS), with a "Certificate Biometry in Medicine GMDS" (idv-Datenanalyse und Versuchsplanung, Gauting, Germany).

RESULTS

Patient Characteristics

Patients were on average 36.6 (22–60) years old, and the majority of patients were female (83.3%). The mean body mass index (BMI) was 25.8 (21.3–29.3). A total of 54% of patients were smokers, and 29% suffered from the metabolic disease (thyroid hypofunction [5 of 24]; diabetes mellitus type 2 [2 of 24]). A history of scarring was inconspicuous in the majority of the patients (79%). During ESWT, a mean of 5671.42 (3300–8500) ESWT pulses were applied. The variation in the total number of ESWT pulsed applied depended on the extent of tissue which needed to be resected during abdominoplasty procedures as well as the individual weight and size of each patient. During abdominoplasty surgery, the mean weight of tissue resected was 1.19 kg (Table 1).

Primary and Secondary Outcomes

Scar formation on ESWT- and placebo-treated skin areas at weeks 6 and 12 after surgery were evaluated by the Vancouver scar scale and POSAS, as assessed by the investigator (POSAS inv.) and the patient (POSAS pat.). None of the comparisons reached statistical significance. However, nonparametric analysis by the MW estimator revealed a clear trend favouring ESWT treatment ($MW > 0.5$).

At week 6, seven analysed parameters out of 19 showed nonmarginal differences ($MW \geq 0.53$) in favour of ESWT (Fig. 2). These parameters comprised thickness (Vancouver, POSAS inv.), vascularity (POSAS inv.), elasticity (POSAS inv.), and area (POSAS inv.). The overall rating of the Vancouver and POSAS pat. both favoured ESWT. One parameter (vascularity, Vancouver) favoured the placebo. Larger differences ($MW \geq 0.56$) occurring at week 6 after surgery exclusively favoured ESWT (thickness [Vancouver, POSAS inv.]).

Likewise, at week 12, eight parameters out of 19 showed nonmarginal differences favouring ESWT (Fig. 3). These parameters were elasticity and thickness (both Vancouver), colour (POSAS pat.), pigmentation, thickness, and surface (POSAS inv.). The overall impression obtained by Vancouver and POSAS inv. favoured ESWT. Two parameters (vascularity, Vancouver; pain, POSAS pat.) favoured the placebo. Larger differences were observed in thickness and overall impression (Vancouver scar scale), both favouring ESWT (Fig. 3). Figure 4 exemplarily shows scar formation of a 45-year-old patient (BMI: 24.4 kg/m^2) at week 6 after surgery, illustrating the difference in scar formation of skin areas preoperatively treated by placebo (left) and ESWT (right).

No side effects were seen directly after treatment of during follow-up.

DISCUSSION

In the present pilot study, we demonstrated that preoperative ESWT presumably reduces scar formation

TABLE 1. Demographic, Anamnestic, and Clinical Characteristics of Patients

Variables	Total ($N = 24$)
Age, years (mean, range)	36 (22–60)
Sex, male, female	16.7% (4/24); 83.3% (20/24)
BMI, kg/m^2 (mean, range)	25.8 (21.3–29.3)
Smoking	54% (13/24)
Metabolic disease	29% (7/24)
Inconspicuous scar formation	79% (19/24)
Applied ESWT pulses, n (mean, range)	5671.42 (3300–8500)
Resected tissue, kg (mean, range)	1.19 (0.37–3.80)

BMI, body-mass-index; ESWT, extracorporeal shockwave therapy

and postoperative symptoms after surgery. Although none of the comparisons between placebo- and ESWT-treatment reached statistical significance, the obvious trend in favour of ESWT observed in the vast majority of scar variables is promising and justifies further analyses by sufficiently powered randomised clinical trials. In our study, no treatment-related toxicity, infection, or deterioration of any wound occurred.

Two general observations had led us to the hypothesis that ESWT before surgery might be equally effective in the reduction of scar formation and postoperative symptoms as ESWT performed immediately after surgery. First, preoperative ESWT clearly improved wound healing and neovascularization in the ischemia-challenged skin flap animal model [20,21]. Second, the beneficial effects of ESWT on wound healing have been shown to be based on rather systemic and long-lasting biological

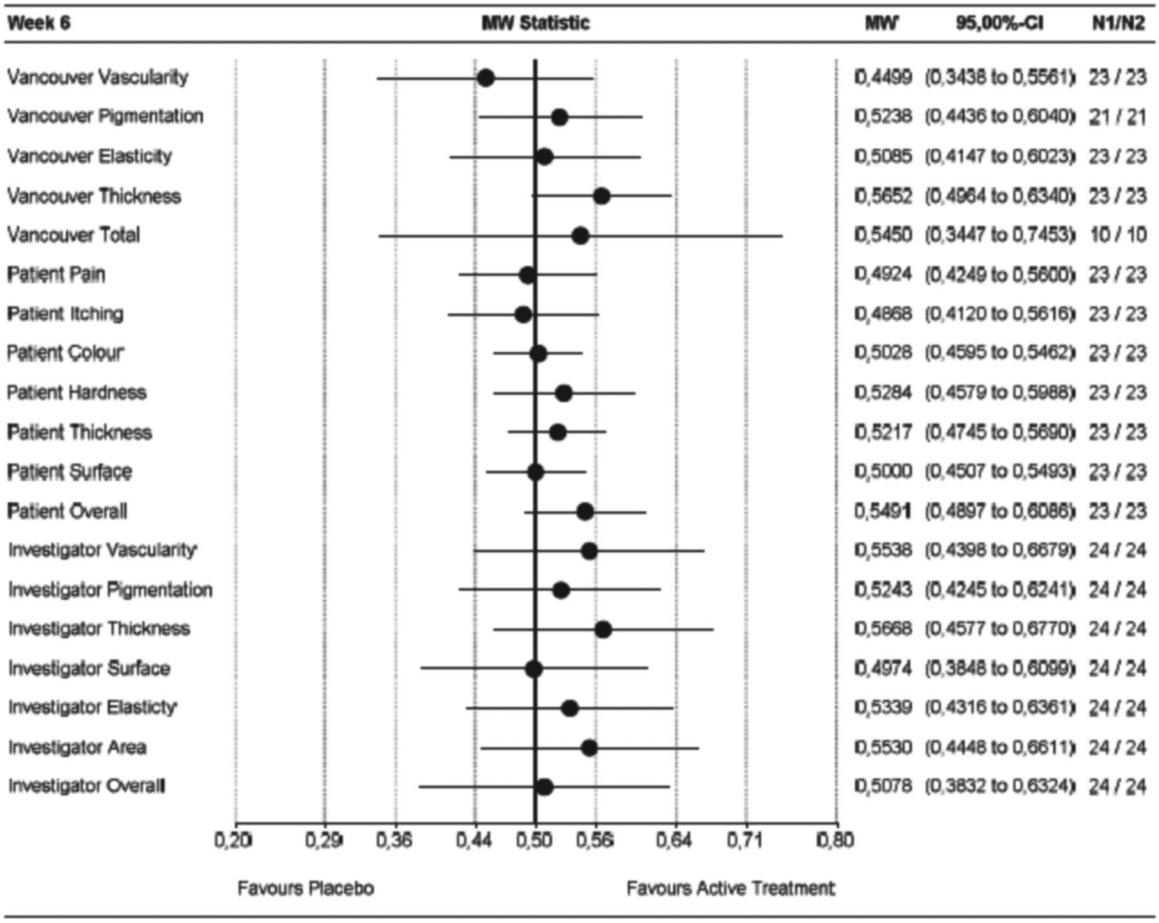

Fig. 2. Effect sizes of ESWT and placebo treatment at week 6 after abdominoplasty surgery. Parameters were assessed by the Vancouver scar scale and the POSAS, using a 3-point scale and 10-point scale, respectively. Data were nonparametrically analysed by the MW estimator. Sample sizes were 23 (Vancouver vascularity, elasticity, thickness), 21 (Vancouver pigmentation), 10 (Vancouver total), 23 (POSAS patient assessment), and 24 (POSAS investigator assessment). Data favouring the placebo (left; MW < 0.5) and active treatment (right; MW > 0.5) are presented with 95% confidence intervals. EWST, extracorporeal shock wave therapy; MW, Mann–Whitney; POSAS, patient and observer scar assessment scale.

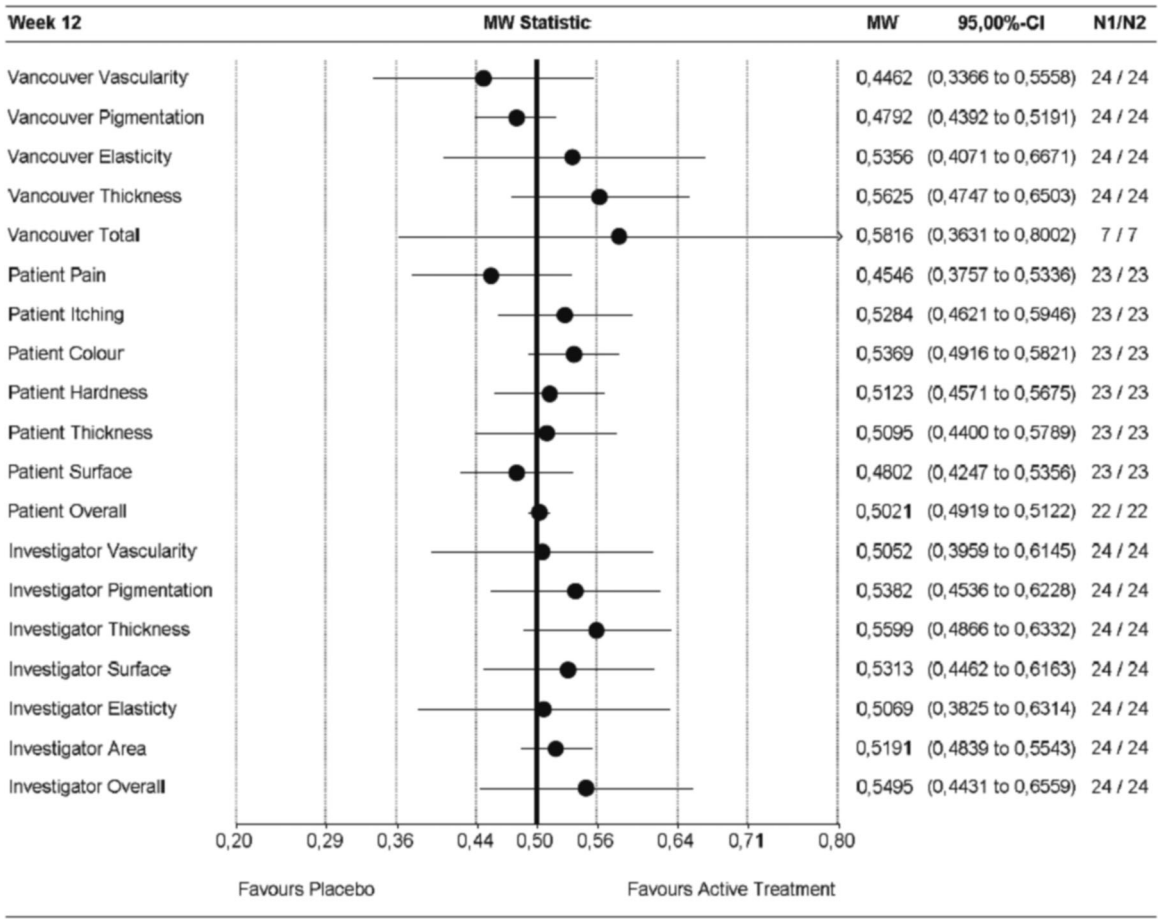

Fig. 3. Effect sizes of ESWT and placebo treatment at week 12 after abdominoplasty surgery. Parameters were assessed by the Vancouver scar scale and the POSAS using a 3-point and 10-point scale, respectively. Data were nonparametrically analysed by the MW estimator. Sample sizes were 24 (Vancouver vascularity, pigmentation, elasticity, thickness), 7 (Vancouver total), 23 (POSAS patient assessment pain, itching, colour, hardness, thickness, surface), 22 (POSAS patient overall assessment), and 24 (POSAS investigator assessment). Data favouring the placebo (left; $MW < 0.5$) and active treatment (right; $MW > 0.5$) are presented with 95% confidence intervals. EWST, extracorporeal shock wave therapy; MW, Mann–Whitney; POSAS, patient and observer scar assessment scale.

mechanisms that might improve wound healing independently from the time of ESWT application. The key event of these mechanisms seems to be an enhanced angiogenic response during tissue repair. NO levels are elevated after ESWT treatment by increased nonenzymatic and enzymatic [27] pathways, correlating with reduced necrosis and improved tissue perfusion. Moreover, the concentration of VEGF, a potent inducer of angiogenesis, is increased in ESWT treated wound tissue [15], and expression of the VEGF-receptor 2 has been shown to be upregulated after ESWT [16]. In animal models, the proangiogenic and anti-inflammatory response to ESWT correlated with the increased expression of the corresponding chemokines, cytokines, matrix metalloproteinases, hypoxia-inducible factors, and vascular remodelling kinase after 6 hours to 7 days after treatment [15,28]. Taken together, these observations suggest a potential systemic and long-lasting effect of ESWT that might be equally beneficial when applied pre- or post-operatively.

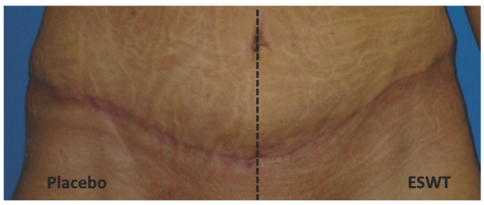

Fig. 4. Exemplary outcome (scar formation) of a 45 year old woman (body mass index: 24.4 kg/m^2) at week 6 after abdominoplasty surgery. The operative area was preoperatively treated by a placebo (left) and extracorporeal shock wave therapy (right).

If ESWT efficacy is based on the systemic expression and secretion of growth factors and cytokines,

the intrapatient control design of our study with placebo- and ESWT-treatment of the two halves of the same skin area intended for surgical cutting might have masked the differences between control and active treatment. Therefore, it might be assumed that another study design with patients allocated to either placebo or active treatment might have resulted in more substantial differences. Nevertheless, due to a significant variability in scar formation between patients, it may have been impossible to compare results.

In addition, the effects of ESWT have been shown to be more pronounced in cases of disturbed or delayed skin healing than in patients with normal regenerative capacity (unpublished observation). As the history of scar formation has been inconspicuous in almost 80% of patients, more pronounced effect sizes of ESWT could have been expected only in a minority of patients. According to the literature [29] and supported by our observations, all scar scales are of limited sensitivity and may only detect large differences between scars, which obviously hampers clinical assessment. A careful selection of patients with disturbed wound healing might, therefore, result in a more responsive and, accordingly, analysable patient population.

Moreover, the population of our study was quite heterogeneous with regard to demographic factors, BMI, smoking status, the presence of metabolic disease, and, importantly, the volume of tissue resected during abdominoplasty surgery. As all of these factors have been shown to affect wound healing [30], the heterogeneity of patients and the low sample size may have introduced bias. In particular, increased BMI has been shown to affect the outcome of abdominoplasty [31]. Another obvious limitation of our study is the low sample size. Accordingly, our results need to be confirmed in much larger study populations.

There is only limited data available on the efficacy of ESWT in wound healing before surgical intervention, and, to our knowledge, all of them were obtained in animal models for chronic wounds. Therefore, our pilot study was the first attempt to demonstrate the efficacy of preoperative ESWT in acute wound healing of human subjects. It is conceivable that the treatment parameters applied in our study require further optimization to gain full benefit. The maximum penetration depth of the applied shock waves was 10 mm, and patients received only one single ESWT treatment with 50 pulses/cm^2 on the day before surgery. Higher penetration depths, higher pulse counts per square centimetre, and repeated ESWT treatments before surgery might be required to stimulate lower cell layers of the skin to express substantially increased levels of proangiogenic growth factors.

However, most nonmarginal and all large differences between placebo and active treatment observed after 6 and 12 weeks favoured ESWT in our study. Although our results were statistically nonsignificant, we consider our data as promising. Preoperative ESWT on human subjects requires further optimization, and efficacy and safety will be tested in a large and sufficiently powered randomised clinical trial. The appropriate study design and statistical methods will be implemented in the study protocol to ensure accurate sensitivity.

CONCLUSION

In conclusion, the use of unfocused, low energy preoperative ESWT in the treatment of acute wounds is safe and presumably reduces scar formation and postoperative symptoms after abdominoplasty surgery. Further studies are now planned to optimise the protocols for preoperative ESWT treatment and to confirm ESWT efficacy with statistical significance.

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