CLINICAL REPORTS

Long-term improvement in the appearance of hypertrophic scars following a single treatment with acoustic subcision—A single center proof-of-concept study

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Abstract

Introduction and Objectives: Fibrosis, including hypertrophic scar formation, is a pathological condition characterized by excessive production and accumulation of collagen, and loss of tissue architecture, in response to wound healing. Alterations in the extracellular matrix (ECM) biomechanical properties may be important in modulating myofibroblasts and fibrosis formation. The acoustic subcision device uses rapid acoustic pulse technology to noninvasively improve the appearance of hypertrophic scars through both microdisruption of scar tissue matrix and downregulation of fibrotic fibroblasts leading to scar remodeling. The objective of this single-site proof-of-concept IRB-approved human clinical study was to evaluate the efficacy of acoustic subcision device for the improvement in the appearance of hypertrophic scars.

Method: Eleven hypertrophic scars in 10 participants were treated with a single 6-minute acoustic subcision application without anesthesia. Posttreatment adverse events (AEs) and tolerability were recorded. At 12 and 89 weeks posttreatment, scar heights and volumes were measured, and participant satisfaction questionnaires were completed. Finally, at the last visit the scar appearance was assessed by the Principal Investigator (PI) using the Mecott Modified Scar Scale (MMSS).

Results: Immediately following the acoustic subcision treatment, only mild, moderate erythema or pinpoint bleeding were noted. The treatment sessions were considered tolerable by all participants with an average pain score of 2.2 (on a 0–10 pain score with 10 being the worse possible pain). The 12- and 89-week assessments demonstrated mean height reductions of 46.3% and 56.8%, respectively from baseline. The differences in scar height were statistically significant (p < 0.01). The 12- and 89-week assessments demonstrated a mean volume reduction of 63.2% and 58.1% respectively from baseline. The differences in the scar volume were statistically significant (p < 0.001). The PI graded an average improvement of 33.7% in scar appearance using the MMSS, a statistically significant change (p < 0.001). Finally, >90% of participants reported satisfaction with the improvement in their scar.

Conclusion: This proof-of-concept study showed that a single noninvasive acoustic subcision treatment session can safely provide statistically significant improvement in the appearance of hypertrophic scars with minimal treatment pain and meaningful participant satisfaction. More work is needed on a larger number of scars to verify this finding. Further improvement in appearance is expected with multiple acoustic subcision treatments and/or treatments in combination with currently available options. Additional trials to verify this are planned.
INTRODUCTION

Fibrosis, in particular scar formation, is a pathological condition characterized by excessive production and accumulation of collagen, and loss of tissue architecture. Fibroblasts residing in connective tissues are responsible for extracellular matrix (ECM) homeostasis and repair. In response to tissue damage, they activate to become myofibroblasts which have organized contractile cytoskeletons and produce myriad proteins for ECM remodeling. However, persistent myofibroblasts (“fibrotic fibroblasts”) can lead to fibrosis with excessive collagen deposition and tissue stiffening.

In fibrotic disease progression, mechanical stresses in the surrounding microenvironment are a key mediator in the differentiation of myofibroblasts. Alterations in the ECM biomechanical properties, stiffness, in particular, may be an important therapeutic target that is able to modulate myofibroblast formation and fibrosis. Acoustic subcision has been shown to disrupt fibrotic structures in a time/dose-dependent manner using acoustic shockwave-induced shearing (see Figure 1).

Acoustic subcision device

The acoustic subcision device is an electrohydraulic (EH) high-intensity acoustic shockwave producing device using Soliton’s Rapid Acoustic Pulse (RAP) technology developed to improve the appearance of cellulite, a fibrotic condition. The acoustic subcision device as represented in Figure 2 is composed of three parts: the console, the handpiece, and a disposable cartridge. The console houses the power supply which provides high voltage to electrodes that are housed in the cartridge which can be replaced when the electrodes wear out. Additionally, the console contains a fluid management system that circulates saline through the cartridge for cooling. The cartridge is snapped in and out of the handpiece for quick replacement.

The acoustic subcision device was successfully used in a multi-center pivotal clinical trial to assess the safety and efficacy in treating participants with cellulite. Comparison of baseline and 12-week posttreatment photographs provided evidence that a single 45–60-minute treatment session improves the appearance of cellulite. There were no unexpected adverse events (AEs) or serious AEs reported. The acoustic subcision device has received FDA 510(k) clearance for indications to accelerate laser-based tattoo removal and to improve the appearance of cellulite.

The objective of this study is to evaluate the safety, efficacy, tolerability, and participant satisfaction of a...
noninvasive acoustic subcision treatment for the improvement in the appearance of fibrotic hypertrophic scars.

MATERIALS AND METHODS

The use of the acoustic subcision device in a single-center, prospective proof-of-concept study had been determined to present a nonsignificant risk in accordance with 21 CFR 812.3 for the intended use in this study by the overseeing Institutional Review Board (Advarra). The study also conformed to US Federal Policy for the Protection of Human Participants. The study is registered on Clinicaltrials.gov as NCT04016610.

Participants

Inclusion criteria for study participants included healthy male or female participants older than the age of 18 with a keloid or hypertrophic scar that was less than 5 years old; located on the chest, back, trunk or upper arms and legs; and easily delineated photographically. Key exclusion criteria included: participant having had scar treatments, including topical steroids, in the prior 12 months. Other exclusion criteria are listed in Table 1.

Treatment

Following completion of screening, enrollment and obtaining informed consent, a general past medical history and limited physical exam for each participant were completed. A specific medical history of the scar was taken including trigger, age, past treatments, and reoccurrence. At the baseline, 12- and 89-week visits physical measurements and photographs of the scar were obtained.

Acoustic subcision treatment was administered during a single office session. An acoustic coupling hydrogel pad and hydrogel were applied to the scar. No anesthesia or analgesics were given to the participant before, during or following the procedure. The acoustic subcision device provided rapid acoustic pulses at a rate of 50 Hz for a period of 6 minutes (2 minutes repeated up to three times as tolerated by participants). During the treatment, the treatment head was moved side-to-side by approximately 0.25 inches with a twisting motion. All treatments were administered by the Principal Investigator (PI) or the clinical site's nurses or technicians. Treatment areas were cleaned immediately posttreatment. No posttreatment dressings, compressions garments, or other care were needed.

Assessment

Immediately following treatment, the participants were evaluated for AEs. An assessment was made of the treatment area and recorded. Additionally, participants were asked to grade procedure pain on a 0-10 pain scale.

At 12- and 89-week postacoustic subcision treatment, improvement in the appearance of the participant’s scar was assessed by the change in the scar's height and volume measurements. Additionally, at 89-week the PI performed a direct and photographic evaluation of each participant's scar surface appearance, height, and color differences using the Mecott Modified Scar Scoring Scale (MMSS) as shown in Figure 3. Finally, the participants filled out a satisfaction questionnaire after viewing their before and after treatment scar photographs at the 12- and 89-week follow-ups. An additional satisfaction questionnaire with questions about the participants perception of discomfort, itching, color, tightness, flatness, softness, and size of their scar was filled out at the 89-week long-term follow-up only.

Statistical analysis

Where appropriate baseline, 12- and 89-week data were summarized using descriptive statistics, and significance testing using one-way analysis of variance (ANOVA) or t test (GraphPad Prism 9 for MacOS, Version 9.1.0 (216); GraphPad Software, www.graphpad.com).

RESULTS

Participants

Ten participants having 11 hypertrophic scars were enrolled in the clinical study and treated. While keloid scars were allowed in the inclusion criteria, none were encountered during the enrollment period in this primarily ethnically

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TABLE 1  Key exclusion criteria

| Prior scar treatments, including topical steroids, in the prior 12 months |
| Pregnant or planning to become pregnant during the duration of the study |
| Metal or plastic implants in the treatment area (vascular stent, or implants in the hips, knees, etc.) |
| Active electronic implants such as pacemakers, defibrillators, cochlear implants, nerve/brain stimulators, drug pump, etc. |
| Having a medical disorder that would hinder wound healing or immune response (no blood disorder, inflammatory disease, etc.) or coagulopathy(ies) and/or is on anticoagulant medication |
| Having a skin disorder (skin infections or rashes, extensive scarring, psoriasis, etc.) in the treatment area |
| Any surgical procedure in the prior 3 months, or planned during the duration of the study |
| A current smoker |
white practice population. At the 12-week follow-up, one participant was lost to follow-up. The volume measures were not recorded on a second participant. At the 89-week follow-up visit, one participant was lost to follow-up. There were an equal number of female and male participants having an average age (mean ± SD) of 55.6 ± 17.5 years. Table 2 provides a breakdown of demographics for the study participant population. The average scar age (mean ± SD) was 2.9 ± 1.0 years with a range of 2.2–3.6 years. Surgery was the source of all scars, and they were located on either the sternum (3), abdomen (3), or back (5). None of the scars had previous treatment. Table 3 provides a breakdown of baseline characteristics for the study scars.

Safety and toleration

All participants had expected AEs including mild erythema (90.9%); moderate erythema (9.1%); and mild pin-point bleeding (45.5%). All AEs observed were expected, and all resolved without intervention. No participant experienced unanticipated AEs or serious AEs.

The acoustic subcision procedure was reported tolerable to all participants (100%) and no participants requested that treatment be halted. On a 0–10 pain scale (0 equals to no pain, 10 equals to the worst pain possible) the average pain during the acoustic subcision treatment doses was 2.2 (range 0–6). Table 4 provides the results of the safety and toleration assessments.

### Improvement in the appearance of scars

Figure 4 provides a graph of the participant scar heights (mm) at baseline, 12- and 89-week. The mean height reduction for participant's scars at 12- and 89-week postsubcision treatment was 1.4 and 1.7 mm, respectively. This represented a 46.3% and 56.8% mean reduction from the baseline scar height. The differences in the scar height represented a statistically significant change from baseline to 12-week as well as baseline to 89-week as determined by ANOVA (mixed effects model) ($F[0.9847, 8.863] = 12.63^*, p = 0.0065$). There was no statistical difference between scar height from 12 to 89 weeks.

Finally, Table 5 summarizes the MMSS scores for the participant's scars at baseline and 89-week. The total MMSS score reduction (mean ± SD) from baseline was

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**Table 1:** Modified Scale.

| Category                | Score | Description                                           |
|-------------------------|-------|-------------------------------------------------------|
| Scar Surface Appearance | 1     | Surface appearance: Similar to normal skin.           |
|                         | 2     | Surface appearance: Slight mismatch (smoother or rougher than normal skin). |
|                         | 3     | Surface appearance: Noticeably rougher than normal skin. Shallow |
|                         | 4     | Surface appearance: Very rough compared to normal skin. Deep depressions and irregularities. Loss of normal architecture. |
| Scar Height             | 1     | No difference. Scar surface at the same plane of the normal skin. |
|                         | 2     | Slight difference. Smooth slope at the edge of the scar (positive or negative). |
|                         | 3     | Moderate difference. Defined slope at the edge of the scar (positive or negative). |
|                         | 4     | Extreme difference. Abrupt dropping at the edge of the scar (positive or negative). |
| Color Mismatch          | 1     | Color difference: Difficult to distinguish.           |
|                         | 2     | Color difference: Subtle but noticeable (Includes differences in pigmentation or erythema). |
|                         | 3     | Color difference: Moderate color difference. Easy to distinguish (Includes differences in pigmentation or erythema). |
|                         | 4     | Color difference: Major color difference. Prominent mismatch. (Include differences in pigmentation or erythema) |

*Each category is assigned a score from 1 to 4, for a total possible score of 3 to 12.*
2.9 ± 1.1. This represented a 33.7% mean reduction from the baseline MMSS score and was statistically significant \((p < 0.001, t\text{-}test, \text{two} \text{-} \text{tailed, paired})\).

Representative serial photographs at baseline, 12- and 89-week demonstrating improvement in the appearance of hypertrophic scars are shown in Figures 6–9.

**Participant satisfaction**

After viewing the baseline and 12-week posttreatment photos of their treated scars, 70% of participants agreed or strongly agreed with the statement “…the scar appears improved” and 70% of participants agreed or strongly agreed with the statement that “I feel there is good improvement in the appearance of my scar.” At 89-week posttreatment, the participant satisfaction improved with 100% and 90% of participants stating that they agree or strongly agree with those statements respectively (Table 6). Table 7 provides the results of the additional participant satisfaction survey questions asked at the 89-week long-term follow-up only.

**DISCUSSION**

At 89 weeks after a single 6-minute acoustic subcision treatment, there was a mean improvement in the scar appearance using the Mecott Modified Scar Scale of 33.7%, and a mean reduction of the measured scar height and volume of >55%. While the mean scar height and volume did not statistically improve from the 12-week...
follow-up to the 89-week follow-up (almost 2 years after a single treatment session), participant's satisfaction continued to improve. At 12 weeks 70% felt that there was “good improvement” in their scar, then by 89 weeks the percentage increased to 90%.

When surveyed at 89 weeks, 70%–100% of participants agreed or strongly agreed that their scars were less uncomfortable, itched less, pulled less, and were flatter, softer, and smaller than before treatment (see Table 7). These are meaningful clinical outcomes to the participants. These additional questions asked only at the 89-week follow-up brought the participant’s attention to these specific aspects of the long-term changes in their scars and this may have influenced their overall satisfaction responses.

In normal wound healing, myofibroblasts are required for tissue repair. However, in pathologic conditions, activated myofibroblasts become the critical effectors of fibrotic disorders. To repair, regenerate and restore homeostasis after injury, tissue-resident fibroblasts are activated and transform into myofibroblasts.2 In fibrotic disease progression, mechanical stresses in the surrounding microenvironment are a key mediator in the differentiation of myofibroblasts.2

The alteration in the ECM biomechanical properties, stiffness, in particular, may be an important therapeutic target that is able to modulate myofibroblast formation and fibrosis.2 Studies suggest that fibroblasts cultured on low stiffness substrates can maintain a normal phenotype. However, when cultured on high stiffness substrates they are activated to myofibroblasts.2 Importantly, when cultured on a low stiffness substrate, the myofibroblast activation was reversible. This suggests that the myofibroblast phenotype is not a permanent state but can be reversed by alterations in the matrix properties.2,10

The effects of mechanical stress on the extracellular environment in myofibroblast differentiation is well established.3 The authors hypothesize that the acoustic subcision technology causes microscopic disruption in the fibrotic scar matrix, thereby reducing a scar’s stiffness, abnormal appearance, and symptoms. By relieving mechanical stress in the microenvironment of the scar, we propose that the activated myofibroblasts are pushed back into a quiescent or apoptotic state, which leads to a reduction of fibrosis. The high pulse

![FIGURE 4 Scar height at baseline (Week 0), 12 and 89](image1)

![FIGURE 5 Scar volume at baseline (Week 0), 12 and 89](image2)
pressure and pulse rate of acoustic subcision allows noninvasive scar tissue disruption without cavitation damage or thermal degradation of surrounding tissue. Discomfort is minimal, in contrast to focused acoustic devices. All but one scar (which remained the same) in this series regressed in height and volume, again showing that the high-pressure pulses did not cause additional healthy tissue damage leading to increased scaring.

TABLE 5  Scar scores using Mecott Modified Scar Scale at baseline and 89-week

|               | Baseline       | 89-week        | Change |
|---------------|----------------|----------------|--------|
| Appearance    | 2.8 ± 0.8      | 3.0 ± 0.7      | 0.2 ± 0.9 |
| Height        | 3.0 ± 0.7      | 2.9 ± 0.6      | 0.1 ± 0.9 |
| Color mismatch| 2.9 ± 0.6      | 1.7 ± 0.5      | 1.2 ± 1.1 |
| Total score   | 8.6 ± 1.1      | 5.7 ± 0.9      | 2.9 ± 1.1 |
| Appearance    | 1.8 ± 0.6      | 1.8 ± 0.4      | 0.0 ± 0.2 |
| Height        | 2.2 ± 0.4      | 2.2 ± 0.4      | 0.0 ± 0.2 |
| Color mismatch| 2.2 ± 0.4      | 2.2 ± 0.4      | 0.0 ± 0.2 |
| Total score   | 5.7 ± 0.9      | 5.7 ± 0.9      | 0.0 ± 0.2 |

FIGURE 6  Images of Participant 1 showing (left to right) the scar at baseline, 12- and 89-week following a single 6-minute acoustic subcision treatment

FIGURE 7  Images of Participant 2 showing (left to right) the scar at baseline, 12- and 89-week following a single 6-minute acoustic subcision treatment

FIGURE 8  Images of Participant 7 showing (left to right) the scar at baseline, 12- and 89-week following a single 6-minute acoustic subcision treatment
It would be optimal to verify that the acoustic subcision treatment resulted in disruption of the fibrotic scar matrix through histologic examination. However, this was an initial proof-of-concept study in a small cohort of participants with the purpose of showing an improvement in the appearance of the scar as evidenced by a decrease in height and/or volume. All scars in this study were the result of surgical excision. Since the scars were at least 2 years old, it was felt that an invasive surgical biopsy to obtain histology from the treated area would cause reversion to an acute healing phase, and likely confound the observation of changes in the scar morphology and appearance. We intend to conduct an additional study in a separate cohort of participants with the purpose of obtaining pretreatment and posttreatment histology to verify disruption of the fibrotic scar matrix similar to that shown in Figure 1.

**Comparisons with other hypertrophic scar treatments**

Ogawa\textsuperscript{11} reported that randomized clinical trials show that intraleisional corticosteroids (triamcinolone acetonide TAC or ILK) can induce 50%–100% regression (in adults) of both hypertrophic scars and keloids. Associated side effects include injection-induced pain, systemic and local effects.

Haurani et al.\textsuperscript{13} conducted a prospective study on 24 patients with hypertrophic scars. They received intraleisional injections with 50 mg of 5-FU (50 mg/ml) and 10 mg of 1% lidocaine, once monthly for 10 consecutive months. A 65% reduction in scar volume was noted in all patients at the end of the treatment. Moreover, 86% of patients had partial or complete resolution of symptoms, which included pruritus, pain, and pressure.
Tanzi and Alster\textsuperscript{13} stated “Significant improvement in hypertrophic scars is generally noted within [2] PDL [585 nm pulsed dye laser] treatments.” Side effects include purpura and swelling, and patients should avoid sun exposure.

Acoustic subcision treatment results of >55% improvement in scar height and volume and a mean of 80% of participants reporting improvement in symptoms is similar to results seen with current common treatments discussed above. The advantage of acoustic subcision over these common treatments is that acoustic subcision is noninvasive, with only mild pain during treatment requiring no anesthetics, that results in significant improvement after a single treatment with clinically meaningful symptom reduction.

Hypertrophic scars can resolve over time without treatment. The scars in this study were 2.2–3.6 years old and had never been treated. Ten of 11 scars showed statistically significant improvement 12 weeks after a single acoustic subcision treatment ($p = 0.0025$ for height, $p = 0.0024$ for volume). The authors believe that this is unlikely to be a coincidental occurrence of spontaneous remission of all 10 scars within 3 months of treatment when all had been stable for at least 2 years.

Limitations of this study include a small sample size, lack of a control group, all white participants, a single treatment session, and no keloid, burn or contracture scars were enrolled. Future research is planned to include more diverse participants and scar types, additional treatments per participant, and some form of control cohort. An additional study is planned to collect punch biopsy samples preacoustic and postacoustic subcision treatment to obtain histology to document that human scar fibrosis is indeed disrupted by acoustic subcision treatment as hypothesized by the authors.

**CONCLUSION**

This proof-of-concept study showed that a single noninvasive acoustic subcision treatment session can safely provide statistically significant improvement in the appearance of hypertrophic scars with minimal treatment pain and meaningful participant satisfaction. More work is needed on a larger number of scars to verify this finding. Further improvement in appearance is expected with multiple acoustic subcision treatments and/or treatments in combination with currently available options. Additional trials to verify this are planned.

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