A Randomized, Controlled Clinical Study to Investigate the Safety and Efficacy of Acoustic Wave Therapy in Body Contouring

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BACKGROUND There is an increased demand for the reduction of localized adipose tissue by noninvasive methods.

OBJECTIVE The objective of this study was to determine the safety and efficacy of noninvasive lipolysis of excess adiposities overlying the lateral thigh region using acoustic wave therapy (AWT). This study incorporates 2 mechanical waves with varying properties in the same session: radial and planar AWT.

METHODS AND MATERIALS The treatment was performed using AWT on the lateral thigh areas of 15 female patients. The study was performed using the planar and radial pulse handpieces, with 8 sessions performed within 4 weeks. Follow-up visits were performed 1, 4, and 12 weeks after the last treatment.

RESULTS Reduction in both thigh circumference and subcutaneous fat layer thickness, measured through ultrasound, was observed.

CONCLUSION This study demonstrates that AWT is safe and efficacious for the treatment of localized adiposities in the saddlebag area. However, the results obtained were not statistically significant. Larger studies will be needed to further access the effects of AWT on thigh circumference reduction. Furthermore, the authors also found an improvement in the appearance of both cellulite and skin firmness after the treatments.

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The increased caloric intake and relatively sedentary lifestyle of the majority of the developed world have lead to the development of resistant fat deposits. This has increased the demand for both invasive and noninvasive fat reduction procedures. Because fat cells act as an energy reserve for women in pregnancy, this leads to a tendency in favoring lipogensis rather than lipolysis in females as compared with males.

Recent studies indicate that the combination of thickened subcutaneous adipose tissue (SAT) as well as blood and lymphatic flow impediment play important roles in the development of localized fat deposits and cellulite.[1] Lymph nodes act as cleaning stations for metabolic decomposition of products, foreign particles, and pathogenic agents; this includes proteins, fat, and various cells. As the lymphangion is driven by pumping muscle action, little muscle movement combined with large fat cells makes the system insufficient.[2] This slowing circulation is thought to stimulate lipogenesis resulting in the formation of adiposities, cellulite, and in more severe cases, lipedema.[3,4]

Ultrasound Technologies

Localized adiposities affect approximately 95% of women, yet effective and sustainable noninvasive body contouring treatments are still lacking.[1] More

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recently, ultrasound technology has been used in various body contouring and shaping treatments. Three distinct modalities that use ultrasound technology for body contouring have been reported. These include high-intensity focused ultrasound (HIFU), intense focused ultrasound, and acoustic wave therapy (AWT). High-intensity focused ultrasound technology functions by ablating SAT by producing molecular vibrations that increase tissue temperature and promote cell necrosis. At high frequencies, ultrasound energy is convergent, leaving the dermis and the surrounding tissue unaffected while resulting in lipolysis in the SAT. After the SAT has been ablated, macrophages gather in the treated area and phagocytose cellular debris such as extracellular lipids.[1,5] Intense focused ultrasound technology delivers ultrasound energy, which results in collagen stimulation, contraction, and remodeling.[6]

Acoustic Wave Therapy

Acoustic wave technology offers an alternative mechanism of action for the treatment of localized fat deposits in which high-intensity ultrasound waves disrupt the cellular membrane of adipocytes by causing shear stress and inducing lipolysis.[3] This study evaluates the safety and efficacy of AWT in the treatment of saddlebags in women. Saddlebags are localized adiposities that form on the hips or thighs. These localized deposits of fat are typically found in women as a result of the 4 to 5 billion additional fat cells as compared with men. In this study, AWT was applied in the thigh region of female subjects. Subsequently before and after photographs, changes in thigh circumference and fat layer thickness derived from ultrasound imaging were analyzed to determine the effectiveness of this treatment in reducing the volume and appearance of saddlebags.

Materials and Methods

In this study, the Cellactor SC1 (Storz Medical AG, Tägerwilen, Switzerland) was used to deliver acoustic waves to subject's skin using novel technology known as AWT. Acoustic wave therapy functions by propagating pressure pulses into subcutaneous tissue. This device is capable of delivering 2 sources of acoustic waves through 2 different applicators. The planar handpiece generates long planar acoustic pulses electromechanically. This is thought to have an effect on cells and their metabolism, ultimately resulting in an increased release of fat. The maximum energy level range is from 0.56 to 1.24 mJ/mm^2 with a pulse frequency of 4 Hz. The radial handpiece generates short, radial acoustic pulses pneumatically, activating blood, and lymphatic flow. The maximum energy range is from 2.6 to 5 bar with a frequency of 16 Hz. Unlike the planar applicator, which releases maximum energy approximately 10 mm beneath the skin surface, the radial applicator releases maximum acoustic intensity at the skin surface. Ultrasound coupling gel was applied during each treatment to ensure efficient transmission of energy and smooth movement of the applicators on the skin.

Fifteen subjects were treated for saddlebags with this device over the course of 4 months. All participants agreed to be treated on only 1 randomly chosen leg, allowing the untreated leg to serve as a control. Each subject received 8 treatments over the course of 4 weeks. Three follow-up visits occurred 1 week, 1 month, and 3 months after the final treatment. Each treatment consisted of 1,500 pulses delivered by the planar handpiece followed by 3,000 pulses delivered by the radial handpiece. Standardized digital photographs using the Nikon D70's single-lens reflex camera and thigh circumference measurements were taken before the first treatment and at each follow-up visit. Additionally, fat layer thickness was measured through ultrasound examination (Telemed Ltd., Vilnius, Lithuania) before the first treatment and at each follow-up visit. After the final treatment visit and at each subsequent follow-up visit, both subject and investigator assess the degree of improvement, if any. Inclusion criteria included healthy female subjects over the age of 18 years who had fat deposits in the outer thigh area. Patients with a body mass index of over 30 kg/m^2, systemic illnesses or who were undertaking a diet, weight reduction, or additional sports exercise program were excluded from the study. Institutional review board (IRB) approval was obtained by the Essex IRB.

Results

Subject and Investigator Evaluations

Both the physician investigators and the patients were asked to evaluate any visual improvement at the fourth visit, and then at the 1-, 4-, and 12-week follow-up visits. Gradual improvement was noted by both the investigator and the subjects up to the 4-week follow-up, with a slight decrease thereafter to the 12-week follow-up. At the fourth visit and 1, 4, and 12 weeks of follow-up, the investigator noted a mean improvement score (Table 1) of 0.3 ± 0.5, 1.3 ± 0.4, 2.3 ± 0.5, and 2.1 ± 0.7, respectively. Interestingly, the control side also saw a gradual increase in mean improvement scores by the investigators. At the fourth visit and the 1-, 4-, and 12-week follow-up, those scores had been 0.2 ± 0.4, 0.4 ± 0.5, 1.3 ± 0.5, and 1.7 ± 0.9, respectively. Although both the control and treated sides saw an increase in improvement scores, there remains a marked difference between the 2.

Ultrasound Imaging Analysis

Analysis of ultrasound imaging data measuring subcutaneous fat layer thickness reveals an overall decrease in thickness (Figure 1). Measurements taken before the first treatment indicate an average thickness of 1.4 ± 0.4 cm in both legs. Average thickness (n = 15) in the treated leg decreased in increments at the 1-, 4-, and 12-week follow-up by 1.3 ± 0.4 cm, 1.1 ± 0.3 cm, and 1.0 ± 0.3 cm, respectively. When comparing the mean values of a given week, a significant decrease between the treatment and control groups had first been found after 1 week of treatment. The treated thigh was on average 0.05 ± 0.7 cm thinner than the control's measurement at this point ($t(14) = 2.44$, $p = .029$). After 4 weeks, the mean thickness of the treated thigh was 0.15 ± 0.13 cm thinner than the thickness of the control group ($t(14) = 4.53$, $p < .0001$). After 12 weeks, the treated thigh had a mean thickness that was 0.27 ± 0.13 cm thinner than the control's mean thickness ($t(14) = 8.02$, $p < .0001$). Although the control side showed a decrease in fat layer thickness from 1.4 ± 0.4 cm at the baseline to 1.3 ± 0.3 cm at the 12-week follow-up visit, it was not statistically significant ($t(14) = 0.54$, $p = .59$). Comparably, the mean decrease observed between those 2 measurements in the treated group had been significant ($t(14) = 2.53$, $p = .017$).

TABLE 1. Improvement Scores Assessed by Investigator and Subjects

Improvement Score	*Improvement Percentage*	*Comment*
0	0–20	No improvement
1	21–40	Poor improvement
2	41–60	Good improvement
3	61–80	Very good improvement
4	81–100	Excellent improvement

Thigh Circumference Measurements

Average thigh circumference (Figure 2) taken at the baseline visit was 53.4 ± 4.8 cm in the control group and 53.4 ± 5.2 cm in the treatment group. When comparing the mean values of a given week, a significant decrease between the 2 groups was first found after 4 weeks of treatment. At 4 weeks, mean thigh circumference of the treated group was 0.42 ± 0.74 cm less than the mean circumference of the control group ($t(14) = 2.19$, $p = .046$). This same trend was observed again after 12 weeks of treatment where the mean circumference of the treated thigh was 1.10 ± 0.88 cm less than that of the control group ($t(14) = 4.83$, $p < .0001$). Mean circumference of the treated thigh measured at the 1-, 4-, and 12-week follow-up visits decreased from 53.4 ± 5.2 cm to 53.1 ± 5.1 cm, 52.7 ± 5.1 cm, and 51.7 ± 5.0 cm, respectively. Although the mean circumference of the control decreased from 53.4 ± 4.8 cm at baseline to 52.8 ± 4.8 cm at the 12-week follow-up visit, it was not statistically significant ($t(14) = 0.29$, $p = .77$). The mean decrease observed between those 2 measurements in the treatment group had not been statistically significant either ($t(14) = 0.91$, $p = .37$). Statistical analysis on the interaction between the application of treatment and the length of time had a significant effect on both adipose thickness and thigh circumference ($F_{(3,42)} = 18.98$, $p = .001$).

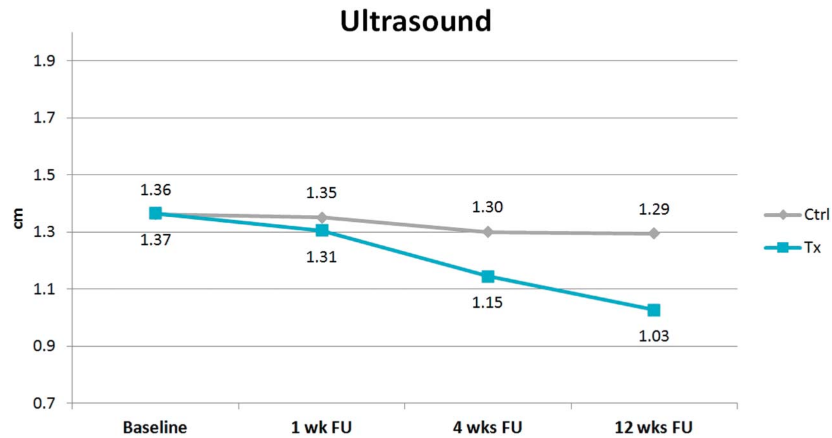

Figure 1. Ultrasound measurement of subcutaneous fat thickness.

Control

The control side showed a lower degree of improvement in all measurements. Furthermore subjects maintained an acceptable degree of weight fluctuation with no subjects losing or gaining a considerable amount of weight throughout the duration of the study.

Complications

Treatment was well tolerated by all subjects, with no serious adverse events reported. All patients developed mild erythema, lasting for a maximum of a few hours. Eight patients developed tenderness, resolving several hours after treatment, and 2 patients developed mild bruising that resolved spontaneously over the course of a few days without any treatment. Subjects reported that treatments were tolerated with minimal pain and little discomfort, with some patients reporting a pain level 1/10 while the rest rated it at 0/10. No pain medication or sedation was used or necessary for the treatments.

Discussion

Acoustic wave therapy has been used in urology for the disintegration of kidney stones and in the treatment of orthopedic conditions for over 25 years.[7] More recently, AWT has been found to strengthen connective tissue and improve skin elasticity. Studies examining its effects on the reduction of localized adiposity's and cellulite have shown promising results. Whereas other noninvasive technologies using ultrasound technology, such as HIFU, function by promoting cell necrosis, AWT emits short radial pulses that stimulate angiogenesis, and long planar pulses that result in cell membrane destruction by causing shear stress. Despite a small sample size (n = 15), an overall mean reduction of 1.7 cm in treatment side–thigh circumference was

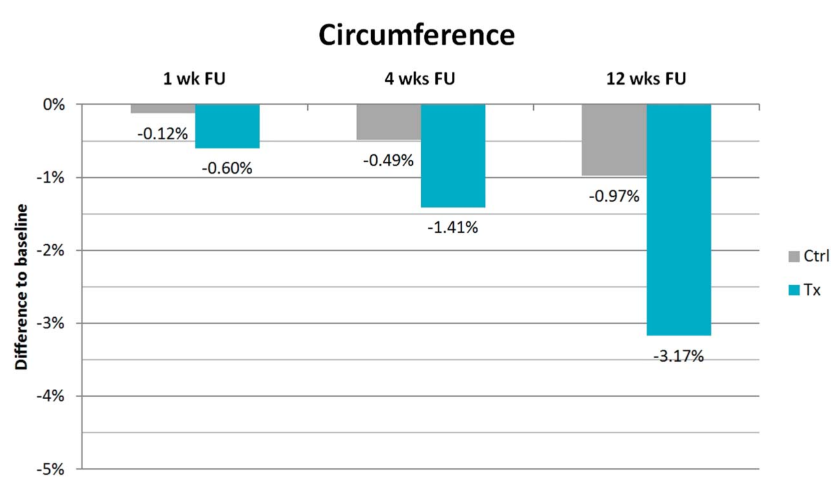

Figure 2. Thigh circumference reduction at 1, 4, and 12 weeks of follow-ups.

Figure 3. Before (left) and after (right) treatments of the saddlebag region. There is notable reduction of the saddlebag on the treated side.

found. Additionally, a mean reduction of 4 mm was found in the adipose layer on the treatment side. Control sides also showed a reduction of 0.6 cm and 1 mm in thigh circumference and fat layer thickness, respectively. Other studies, which have shown a similar improvement in control groups, have attributed this occurrence to a systemic treatment effect.[8] Patient and investigator rating and digital photography showed an improvement in the appearance and size reduction of saddlebags (Figure 3). Based on this study and the authors' experience, it is recommended that an average of 6 to 8 treatments spaced 3 to 4 days apart be performed for significant results and patient satisfaction. This can be tailed individually based on the patients' needs. More studies are needed to validate AWT as a viable non-invasive therapy for the treatment localized fat pads.

Conclusion

This study evaluated the safety and efficacy of AWT in body shaping, specifically the reduction of saddlebags in female subjects. A decrease in thigh circumference and decrease in fat layer thickness, accessed through ultrasound image, were the primary end points for this study. Secondary end points were a better long-term cosmetic appearance; this was evaluated using digital photography and patient and investigator ratings.

Acoustic wave therapy was found to be an effective treatment option in reducing localized adiposities in the thigh region. However, it is important to note that the results obtained were not statistically significant. An additional benefit of this treatment may be a sustained reduction in the appearance of cellulite. Improvement in overall appearance in addition to decreased thigh circumference and fat layer thickness continued to be seen until the final three-month follow-up, showing that AWT is not only a viable treatment option, but also a sustainable one. Other than mild redness, tenderness, and bruising, no serious side effects occurred during the course of this study. High patient satisfaction and investigator evaluations show that treatment with AWT is safe and effective in the treatment of saddlebags in female patients.

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