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ORIGINAL ARTICLE

Body shaping with acoustic wave therapy AWT®/EPAT®: Randomized, controlled study on 14 subjects

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Abstract

Introduction: Reduction of localised adiposities by non invasive means is a very frequent request among the female and male population. *Objective:* The objective of this study is to demonstrate the efficacy and safety of AWT®, combining two different mechanical waves, planar AWT and radial AWT during the same session, in volume reduction of saddle bags in women. *Methods:* Treatment was performed on the saddle bag areas of 14 female patients, with the CELLACTOR® SC1 (Storz Medical AG, Tägerwilen, Switzerland) using extracorporeal pulse activation technology, EPAT®. This device includes two handpieces, the C-ACTOR® and the D-ACTOR®. Within 4 weeks, eight AWT® treatment sessions have been performed with both applicators. Follow-up visits were performed 1, 4 and 12 weeks after the last treatment. *Results:* Measurements with the ultrasound system clearly demonstrate a significant diminution in the subcutaneous fat layer thickness and a reduction of the averaged circumference of thighs. *Conclusions:* This study, although performed on a small number of patients, tends to show the safety and efficacy of AWT® in treating localized fat areas in a non-invasive way. There is also an additional benefit for patients in reducing the cellulite appearance and improving the skin firmness at the same time by using AWT®.

Key Words: *Lipolysis, body shaping, fat depot reduction, acoustic wave therapy*

Introduction

Formation of diet and exercise resistant fat deposits

Reduction of localized adiposities by non invasive means is a frequent request among the male and female population. The combination of too high-calorie intake and lack of exercise cause many people to suffer from localized fat deposits. Sometimes, even if an adequate diet is started together with physical activities, these localized fat accumulations tend to persist.

The areas most frequently requested for loss of volume are abdomen, saddle bags, flanks, love handles, inner thighs and inner knees. In genetic terms, females have 21 to 22 billions fat cells, whereas males only have around 17 to 18 billions (1). This is due to the fact that the fat cells in females act as energy reserve during pregnancy. In addition to this, there is a sex-specific fat distribution within the organism: in females, the balance between lipogenesis and lipolysis is very much altered in favour of the former.

One reason for this phenomenon is the density of lipolysis-inhibiting receptors in fat cells. The density of these receptors in the female subcutaneous fat tissue is much higher than the density of lipolysis-stimulating receptors (2).

Aspects of microcirculation in tissue

Intrinsic movements of the smallest terminal vessels in the microvascular system are an elementary characteristic of micro angiodynamics and allow the blood flow through the vascular bed to be regulated. An accelerated blood flow and high vasomotor activity stimulate lipolysis, whereas a slower blood flow causes fat storage.

The main task of the lymph vessels in the tissue is to return substances that make up the lymphatic load from the interstice into the venous system.

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These substances, which can only be removed through the lymphatic system, include among others proteins and triglycerides. Water only acts as a transport medium. These large molecules are transported by lymph collectors. This lymphatic movement is driven by the pumping muscle action (3).

Reduced muscle movement and large fat cells cause an increasing insufficiency of the lymphatic as well as vascular system.

In brief, judging by recent findings it is assumed that there must be some correlation between blood and lymph circulation on the one hand and the formation of fat tissue on the other hand. Slow circulation causes lipogenesis, whereas fast circulation stimulates lipolysis, i.e. fat breakdown (4).

Acoustic Wave Therapy - AWT®

AWT® is a non-invasive technique using mechanical stimulation by acoustic waves. We have already demonstrated its efficacy in improving cellulite in a previous study (5). Patients only feel a vibrating sensation. A redness of the treated skin due to the increased blood circulation is typically seen even a couple of hours after the treatment.

The objective of this study is to demonstrate the efficacy and safety of AWT® during stimulation of metabolic activity in subcutaneous fat tissue by means of acoustic waves, in order to evaluate its effectiveness in reduction of the subcutaneous fat layer.

The study is designed to demonstrate the ability of volume reduction of saddle bags in women, combining two different mechanical, acoustic waves during the same session. The results are documented by multiple objective measurements methods: comparing the before and after pictures, circumference measurement of the thighs and fat layer thickness measurement by an ultrasound imaging system.

Finally, there have been placebo treatments performed with a reduced number of subjects as control group.

Material and Methods

The treatment was performed with the CELLACTOR® SC1 using extracorporeal pulse activation technology, EPAT®. This device is an acoustic wave generator which features two different treatment handpieces (Figure.1).

The C-ACTOR® handpiece is a high intensity electromagnetic system generating acoustic planar waves. These "high impact" acoustic waves have an effect on cells and their metabolism, among others the increase of cell wall permeability results in an increased release of fat, or triglycerides respectively (6) and regeneration of connective tissue (7). The

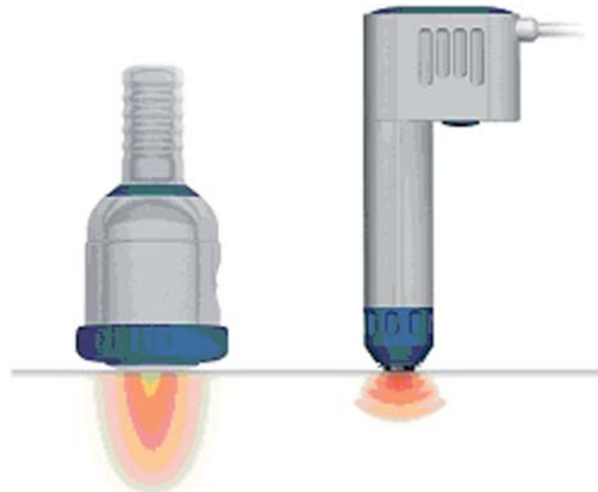

Figure 1. Wave form at C-ACTOR® handpiece (left) and D-ACTOR® handpiece (right).

D-ACTOR® handpiece is a vibrating massage system operated by compressed air generating "slow impact" acoustic radial waves, which stimulate the target tissue and activate the blood and lymphatic flow (Figure. 2). Additionally, ultrasound coupling gel is applied to the skin, in order to avoid energy loss through air inclusions at the handpieces/skin interface and to allow smooth gliding over the skin surface.

For the complete study 15 female patients were enrolled for the treatment of fat deposits on the lateral thighs, the so called saddle bags. This article reports the results with 14 patients which have reached third follow-up (12 weeks after the last treatment). As control group two randomly selected patients have been treated one-sided.

The study protocol specifies 8 AWT® treatment sessions within 4 weeks. One treatment comprises a combined application of both handpieces:

- C-ACTOR at energy level of 0.45 up to 1.24 mJ/mm^2, depending on sensitivity of the patient and at least 1500 pulses according to the size of the treated area.
- D-ACTOR at energy level of 3–4 bar and 3000 pulses.

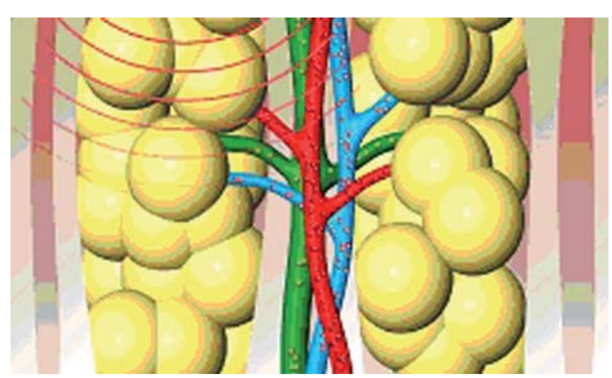

Figure 2. Activation of blood flow and lymphatic flow due to acoustic waves.

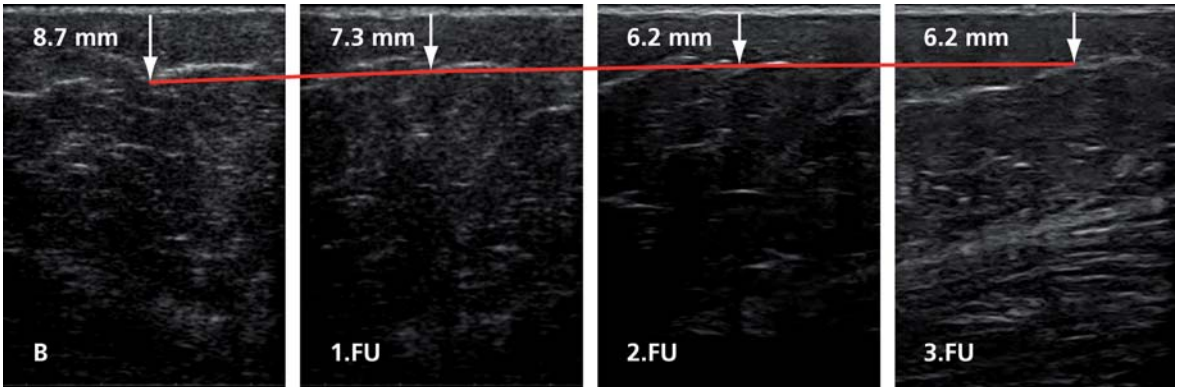

Figure 3. Ultrasound pictures of patient 202 left side: baseline (B), 1. FU, 2. FU, 3. FU. The thickness of the fat layer is reduced from 8.7 mm to 7.3 mm to 6.2 mm to 6.2 mm as shown in Fig. 5.

The study outcome is documented by the following parameters collected prior to the treatment and at the follow-up's (1, 4 and 12 weeks after the last treatment):

- fat thickness measured by ultrasound system (Echoblaster 128, Telemed Ltd, Vilnius, Lituania)
- thigh circumference measurements
- digital picture of the treated areas (Profect Full Body System, Profect Medical Technologies LLC, East Windsor, CT)
- patient satisfaction (questionnaire)

No anaesthesia was needed as the procedure is almost painless. Patients have only a vibrating sensation. A redness of the treated skin is typically seen, at maximum a couple of hours after the session. As expected, patients also noticed an improvement in skin texture and tightness.

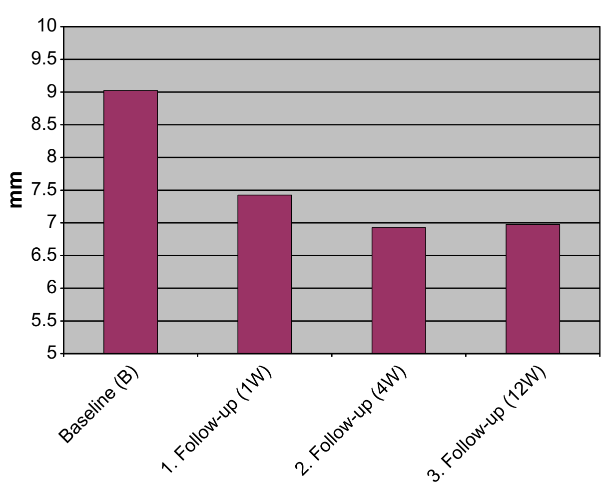

Figure 4. Fat layer thickness measured with ultrasound at the left leg of 14 patients prior to the treatment (B), 1. Follow-up, 2. Follow-up and 3. Follow-up. The mean value is deceasing significantly from 9.0 mm to 7.4 mm at 1. FU, to 6.9 mm at 2. FU, to 7.0 mm at 3. FU.

Results

Measurements with the ultrasound system clearly demonstrate a decrease of the subcutaneous fat layer thickness. An example of the ultrasound scan with the reduction of the fat layer thickness is shown in Figure. 3.

Prior to the treatment (B) the fat layer thickness is in an average over 14 patients at 9.0 mm and changes to 7.4 mm at the 1. FU, to 6.9 mm at the 2. FU and to 7.0 mm at the 3. FU. This is shown in Figure. 4.

The averaged value of the thigh circumference for all patients decreased from 60.0 cm before the treatment (B) to 58.8 cm at 1. FU, to 58.5 cm at 2. FU and to 58.2 cm at the 3. FU (see Figure. 5).

Statistical evaluation was performed with the software SigmaStat 3.5 (www.systat.com). The results are summarised in Tables 1 and 2. "Wilcoxon Signed Rank Tests" were performed between the values baseline (B) and Follow-ups (FU). The p-value of a particular test is given in parentheses. Before the statistical processing the values for left and right thigh were averaged for every single patient.

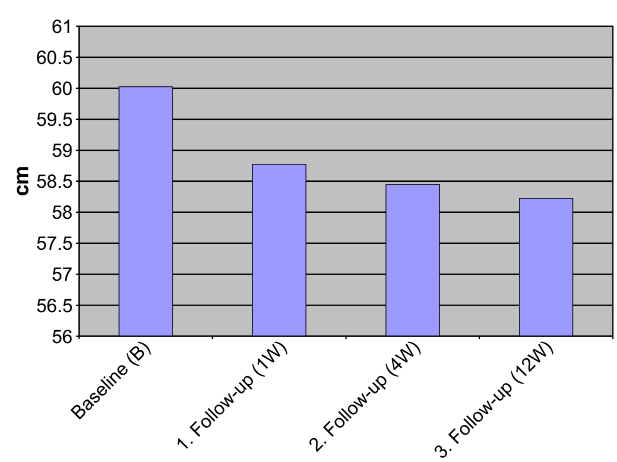

Figure 5. Circumference measured at thighs of 14 patients prior to the treatment (B) and during the 1. Follow-up, 2. Follow-up and the 3. Follow-up.

Table 1. Summary of the statistics the circumference of thighs and the thickness of the subcutaneous fat layer for different Follow-ups (FU) compared to the initial baseline (B). Wilcoxon Signed Rank tests were performed and the resulting p-value is given in parentheses. **All parameters of the fat layer thickness are statistically significant**.

	B	1. FU	2. FU	3. FU
Thighs circumference	60.0 cm	58.8 cm	58.5 cm	58.2 cm
Significance		*(0.068)*	*(0.002)*	*(0.007)*
Subcutaneous fat layer thickness	9.0 mm	7.4 mm	6.9 mm	7.0 mm
Significance		*(0.001)*	*(0.001)*	*(0.001)*

Thighs circumference

For the circumference of thighs, there is a statistically significant difference from baseline to 2. FU and 3. FU and a total reduction of 1.8 cm.

Subcutaneous fat layer thickness

Measurements with the ultrasound system clearly demonstrate a significant decrease of the subcutaneous fat layer thickness from 9 mm at baseline to 7 mm at the 3. FU.

Body weight

The averaged body weight decreases slightly from 62.6 kg before the treatment to 62.2 kg at the 1. FU and to 61.3 kg at the 3. FU. The body weight was not measured at the 2. FU. The decrease is not statistically significant.

Patient satisfaction at the 3. FU was very good to excellent for 12 (86%) out of the 14 patients (Figure. 7). There were no significant side effects observed except some minor bruising in two patients.

Control group

The two one-sided treated patients show a visible difference between the treated (Treatment) and non-treated side (Control). Nevertheless, due to the low number of untreated vs. treated patients' sides statistical evaluation is not possible. During the treatment period, one patient lost weight from 73.2 kg at the beginning to 64.8 kg at Follow-up 3. This effect is so strong, that it dominates the treatment effect. Therefore this patient is not considered for the comparison of treated versus non-treated side. The other patient (ID 206) had no change in body weight and the comparison of the fat layer thickness is shown in Figure. 8. The thickness is reduced in the non-treated side by 10% and in the treated side by 27%. The fat layer reduction in the non-treated leg is expected to be mainly due to a systemic effect which has been observed also in other scientific investigations (8, 9).

Table 2. Statistics for the body weight for different Follow-ups (FU) compared to the initial screening (B). Wilcoxon Signed Rank tests were performed and the resulting p-value is given in parentheses. The parameter change of body weight is statistically not significant.

	B	1. FU	3. FU
Body weight	62.6 kg	62.2 kg	61.3 kg
Significance		*(0.153)*	*(0.122)*

Discussion

In spite of the small number of patients evaluated, there is a significant level of improvement as documented by various quantitative and qualitative measurements. There is also an additional benefit for patients in reducing the cellulite appearance at the same time by using AWT. There were no side effects observed except some minor pain for few patients during therapy, slight skin reddening and minor bruising in two patients. The minor and temporary side effects also confirm the safety of AWT®.

Patient satisfaction after 8 treatments was very high with 64% for "excellent improvement", 21% for "very good improvement" and 15% for "good improvement" (Figure. 7).

Figure 6. Photograph of patient 202 prior to treatment (B) and at the 1. FU one week after the 8th treatment. The white line shows the shape "prior the treatments" in the 1. FU photograph. The circumference reduction in total was 9.7 cm.

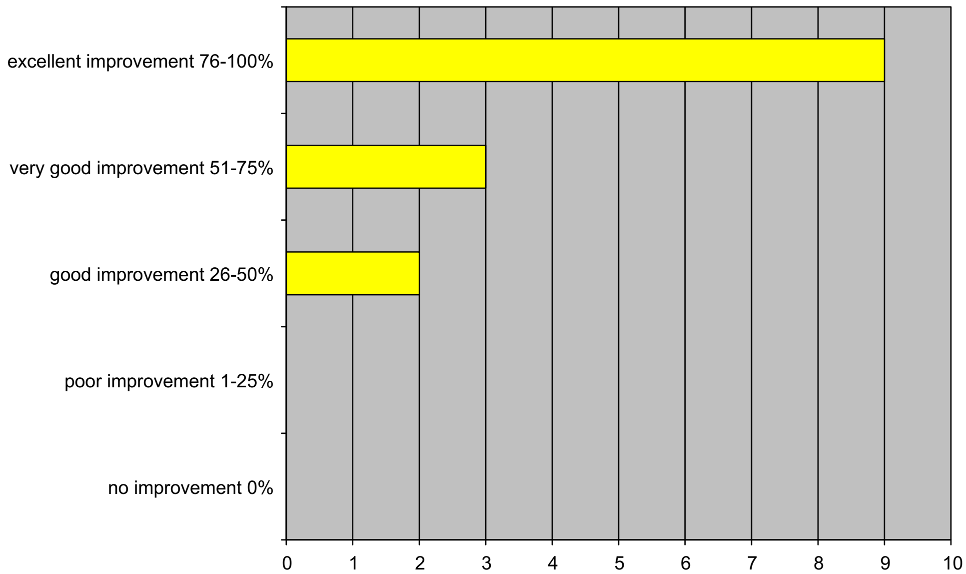

Figure 7. Patients were asked for their satisfaction with the AWT treatment on a scale from 0–100%. After the 3rd follow-up, 9(64%) out of 14 patients see an excellent improvement of the treated area.

The mean of the circumference of both legs has been reduced from 60.0 cm in the beginning to 58.8 cm at 1. FU to 58.5 cm at 2. FU and to 58.2 cm at 3. FU. This is an average reduction of 3.0% or 1.8 cm.

Measurements with the ultrasound system clearly demonstrate a significant decrease of the subcutaneous fat layer thickness with an average of 1.6 mm (17.7%) at 1. FU one week after the last treatment, 2.1 mm (23.3%) at 2. FU, four weeks later and 2.0 mm (22.2%) at 3. FU, 12 weeks later.

Conclusion

The body weight is slightly and not statistically decreased, therefore it cannot account for the statistical significant decrease in the circumference of thigh and the thickness of the subcutaneous fat layer. Therefore it is straightforward to conclude that these effects are due to the treatment with AWT.

This study, although performed on a small number of patients, tends to show the safety and efficacy of AWT in treating localised fat areas in a non-invasive way. AWT not only provides a localised volume reduction but also a skin texture improvement.

Disclosure of interests

M. A. Adatto and R. Adatto-Neilson are working at Skinpulse there is no conflict of interest. P. Novak, A. Krotz and G. Haller are employees of Storz Medical.

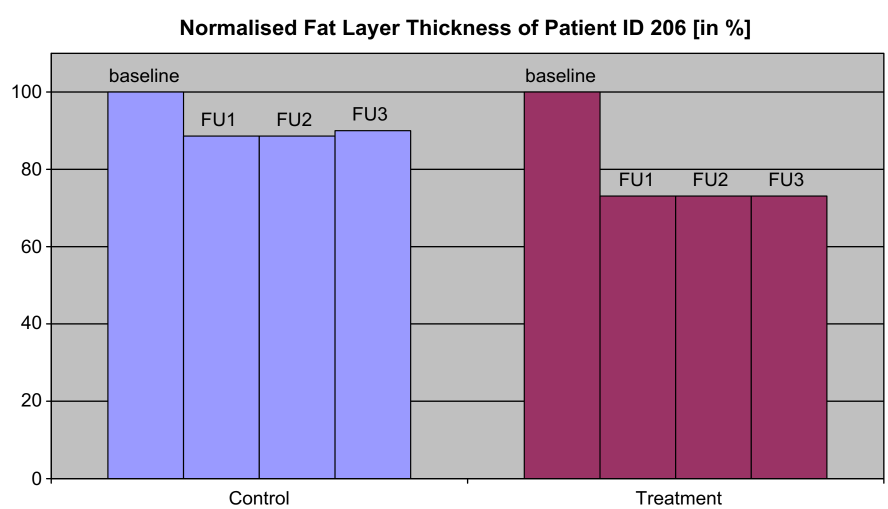

Figure 8. Fat layer thickness of patient ID 206. The data are normalised to compensate for baseline difference. The thickness of the non-treated side is reduced by 10% whereas the treated side shows a reduction of 27%.

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