

ACOUSTIC WAVE TREATMENT FOR CELLULITE - A NEW APPROACH

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Keywords: acoustic wave therapy, shock wave therapy, cellulite, subcutaneous adipose tissue

Abbreviations: AWT – acoustic wave treatment, ESWT - extracorporeal shock wave treatment

ABSTRACT

Background and Objectives:

Cellulite is a biological caused modification of the female connective tissue. In extracorporeal shock wave therapy pulses are penetrating into the tissue without causing a thermal effect or micro lesions, but leading to a stimulation of tissue metabolism and blood circulation, inducing a natural repair process with cell activation and stem cells proliferation. Only a limited number of studies on cellulite exist with extreme differences in opinion. Recently ESWT treatment showed evidence of remodeling of collagen within the dermis and of stimulating microcirculation in fatty tissue.

Study Design and Methods:

The study was designed to assess the efficacy of acoustic wave treatment by comparison of treated vs. untreated side (upper-leg and buttock).

11 female patients with a BMI less than 30 and an age over 18 years were included. One thigh and bottom were treated and then compared to the other untreated side. Treatments were performed with the Acoustic Wave Module D-Actor® 50 (radial pulse). 6 treatments were given every 7 days. The applicator Ø 20 mm was used at 3 bar respectively the maximal tolerated pressure, 10 Hz, 20.000 pulses applied for the upper leg and buttock (10 areas), in a centripetal direction of treatment.

Documentation was done before and 1, 4, 12 weeks after last treatment by standardized photo documentation, relaxed and with contraction of muscle, measurement of body weight and circumference of the thigh (defined middle), pinch test (defined middle upper leg) and evaluation of hormonal status and lifestyle (exercise, sports, diets).

The efficacy of AWT was evaluated before and 1, 4, 12 weeks after last treatment. Patients rated the improvement of cellulite (skin surface, texture of tissue, difference treated vs. untreated side), overall satisfaction and acceptance. The therapist assessed improvement of cellulite (skin surface, texture of tissue, difference treated vs. untreated side), side effects (erythema, hematoma, pain) and photo documentation treated vs. untreated side, before vs. after treatment. A blinded investigator evaluated the results using photo documentation right vs. left leg, before vs. after treatment in a frontal, lateral, dorsal relaxed and contracted view.

Results:

Patients rated the improvement of cellulite at the treated side with 27,3% at 4 and 12 weeks after the last treatment. In comparison the rating of therapist was 34,1% at 4 and 31,2% at 12 weeks after the last treatment. The blinded investigator could verify an improvement of cellulite at 4 weeks in 18,2% at the posterior thigh at and at the bottom in 36,4% of patients and at 12 weeks in 66,7% of patients at the posterior thigh as well as the bottom.

No side effects were seen. The comparison of the circumference of the upper leg treated vs. untreated side showed a significant decrease on the treated side with a p-value of 0,091 even though a general loss of body weight was seen. There was no significant difference in the pinch test.

Conclusion:

Radial acoustic waves are effective and safe to treat cellulite. No side effects were seen. The effect of treatment begins delayed and is first seen after 5 treatments. The improvement of cellulite increases continual up to 3 months. Patients' satisfaction and acceptance is high. Preliminary results assume that higher pressure in treatments needs less applied pulses; results are better and faster visible.

1. Introduction

1.1. Background and Objectives

Cellulite is no disease, it is a biological caused modification of the female connective tissue. The so-called orange peel syndrome or cellulite describes the mattress phenomenon of the skin, which affects more than 80% of women of all ethnics. This appearance leads “only” to an aesthetic problem, but is a cause of concern for many women worldwide.

The physical structure of the skin is different dependent on gender. The septa of women’s connective tissue are running parallel contrary to the men’s which are crossed (**Fig. 1**). In addition women have more fat cells about 21 – 22 billion, whereas men only 17 – 18 billion.

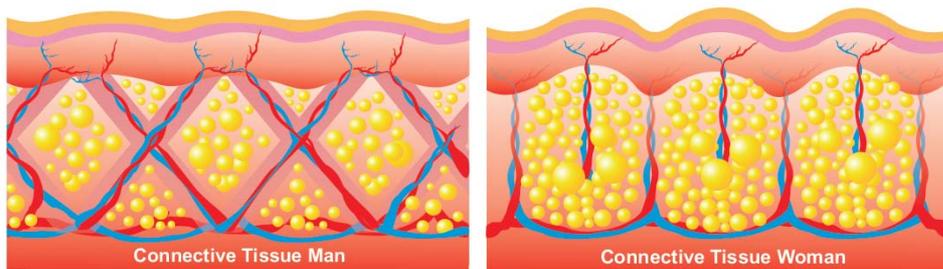


Fig. 1: Comparison of connective tissue of men and women

The enlarging of fat cells between the septa not only causes the dimpling effect, but also reduces microcirculation of blood and lymph. If microcirculation is decreasing, fat is stored more and more (**Fig. 2**). Less elasticity of skin through aging also worsens the dimpling effect. This is a vicious cycle and the reason for ineffectiveness of sport and diets. In addition the connective tissue often becomes weaker with age and the ‘mattress’ appearance is in fact more visible.

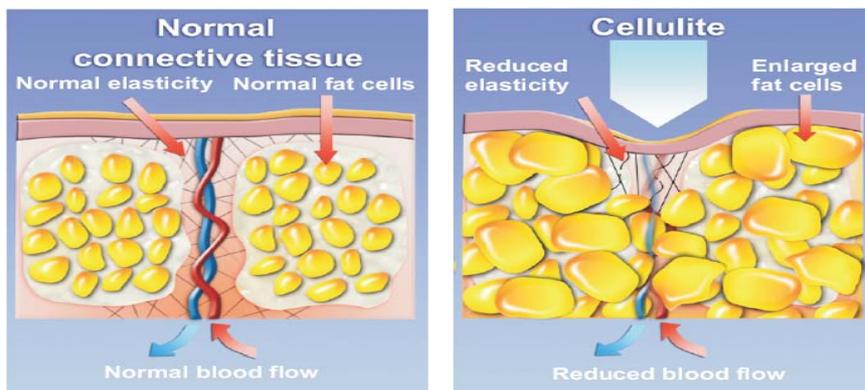


Fig. 2: Relation of normal connective tissue, blood flow and fat cells and cellulite affected tissue

A variety of different therapies for treating cellulite with different devices are on the market, non invasive and invasive, as creams, mesotherapy, endermology, ultrasound, radiofrequency, up to laser lipolysis procedures.

Acoustic wave technology is a new approach to improve the appearance of cellulite. In acoustic wave treatment pulses are penetrating into the tissue leading to a stimulation of tissue metabolism and blood circulation, inducing a natural repair process with cell activation and stem cells proliferation.

Up to now only a limited number of studies on cellulite treatment exist with extreme differences in opinion [5]. Recently AWT which is an extracorporeal shock wave treatment (ESWT) showed evidence of remodeling of collagen within the dermis [1] and of stimulating microcirculation in fatty tissue [2].

1.2. Technology & Mechanism

Acoustic waves are pneumatically generated pressure waves. These waves are similar, but softer than the extracorporeal shock waves which are used in urology for lithotripsy for more than 20 years now. Compared to these shock waves the acoustic waves are longer and not focused (radial). They penetrate up to 25 mm into the skin without thermal effect and reach the subcutaneous fat. The radial acoustic waves are proven in orthopedic treatments like tennis elbows and activation of muscle and connective tissue.

The pressure differences stimulate the tissue metabolism and the blood circulation which lead to a natural repair process with cell activation and stem cells proliferation. These variations are even enhanced by reflection especially at indurate (fibrotic) tissue [3] [4].

Radial pulses (acoustic wave) are pneumatic with a penetration depth of 25 mm (**Fig. 3**).

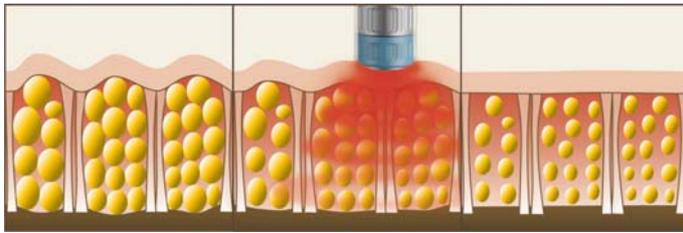


Fig.3: Simulation of therapy with Acoustic Waves

2. Material and Methods

2.1. Study Design

The study was designed to assess the efficacy of acoustic wave treatment by comparison of treated vs. untreated side (upper-leg and buttock). This was thought to be a good way to exclude all other interacting factors beside acoustic waves, which could as well influence the appearance of cellulite.

11 female patients with a BMI less than 30 and an age over 18 years were included. Exclusion criteria were acute inflammation of the treated area, intake of blood dissolvent drugs, performed liposuction or body lift within the last 5 years or pre-treatments with endermology and other body contouring devices within the last 6 months and others. One thigh and bottom were treated and then compared to the other untreated side.

Treatments were performed with the Acoustic Wave Module. A thin layer of ultrasound gel was applied to the treatment area first. The handpiece which emits the radial acoustic waves was moved with slight pressure and in skin contact towards the lymph nodes and backwards without pressure, which means in a centripetal direction of treatment

6 treatments were given every 7 days. The applicator with a 20 mm spot size was used at 3 bar respectively the maximal tolerated pressure, and at 10 Hz, 20.000 pulses were applied for the upper leg and buttock (10 areas).

Documentation was done before and 1, 4, 12 weeks after last treatment by standardized photo documentation, relaxed and with contraction of muscle, measurement of body weight and circumference of the thigh (defined middle), pinch test (defined middle upper leg) and evaluation of hormonal status and lifestyle (exercise, sports, diets).

The efficacy of AWT was evaluated before and 1, 4, 12 weeks after last treatment. Patients rated the improvement of cellulite in terms of skin surface, texture of tissue, difference treated vs. untreated side, as well as overall satisfaction and acceptance of the AWT. The therapist also assessed improvement of cellulite in terms of skin surface, texture of tissue, difference treated vs. untreated side, as well as side effects of AWT (erythema, hematoma, pain) and photo documentation treated vs. untreated side and before vs. after treatment. A blinded investigator evaluated the results using photo documentation right vs. left leg, before vs. after treatment in a frontal, lateral, dorsal relaxed and contracted view.

3. Results

Patients rated the improvement of cellulite at the treated side with 27,3% at 4 and 12 weeks after the last treatment. The rating of patients differed from the rating of therapist, because patients could not evaluate their back entirely easy and therefore could not estimate the improvement of the back side as well as the front side.

In comparison the therapist saw an improvement of cellulite between 25 and 50% for all patients, especially in view of tightening of the skin. The rating of the therapist was 34,1% at 4 and 31,2% at 12 weeks after the last treatment. (**Fig. 4**)

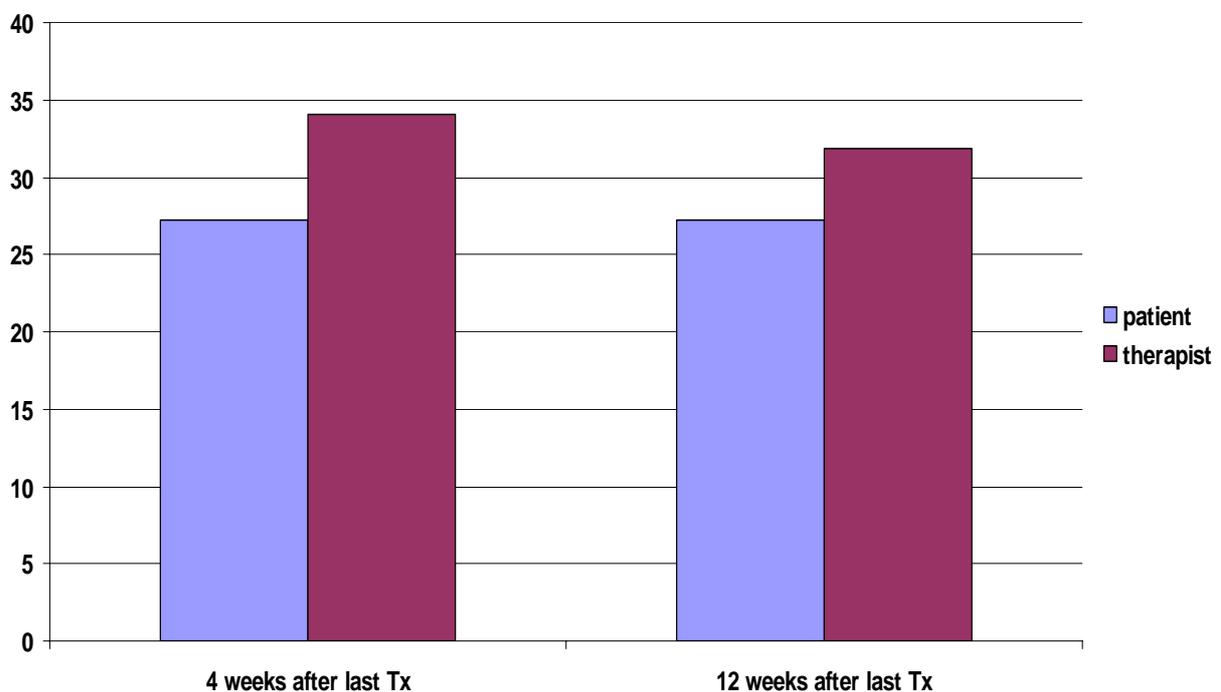


Fig. 4: Results -percentage of the average improvement rated by patient vs. therapist at 4 and 12 weeks after last treatment

The blinded investigator could verify an improvement of cellulite at 4 weeks in 18,2% at the posterior thigh at and at the bottom in 36,4% of patients and at 12 weeks in 66,7% of patients at the posterior thigh as well as the bottom (**Fig. 5 & 6**). Significantly the blinded investigator could identify the treated side in 54,5% (6 out of 11 patients) by evaluation of the

standardized photos only, which is important as the improvement of the cellulite is seen less on the pictures as in nature.

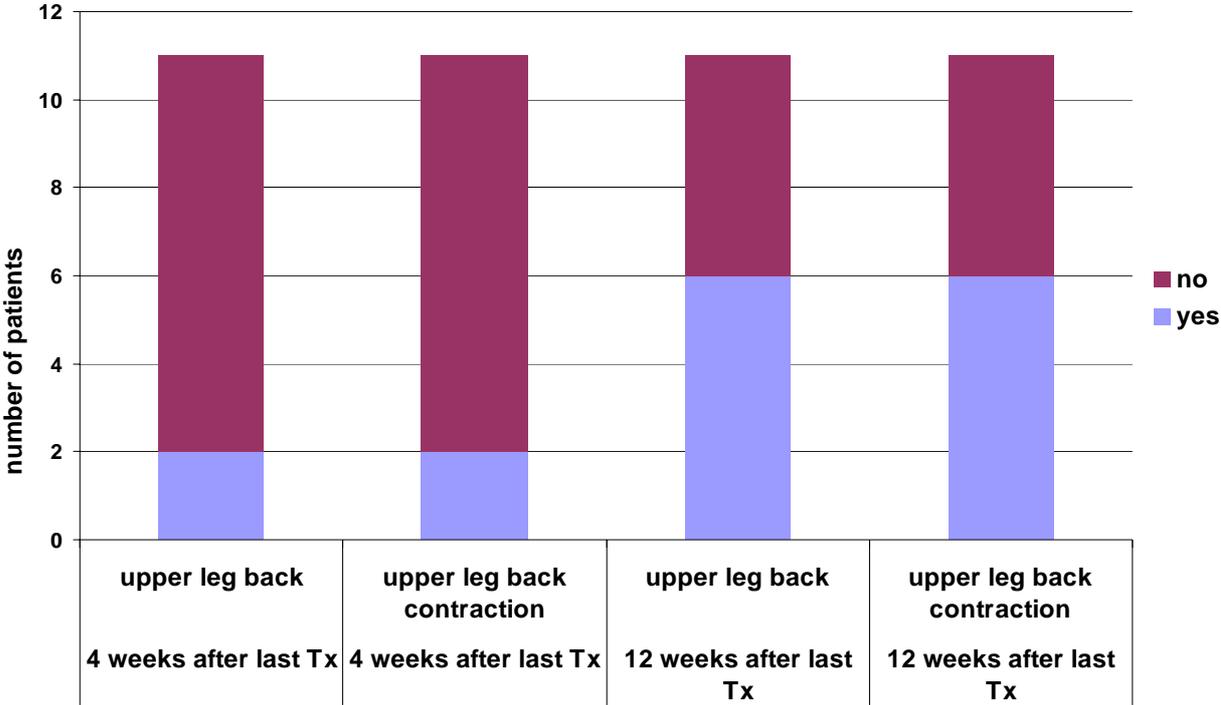


Fig. 5: Results blinded investigator improvement yes/no - posterior thigh relaxed and with muscle contraction

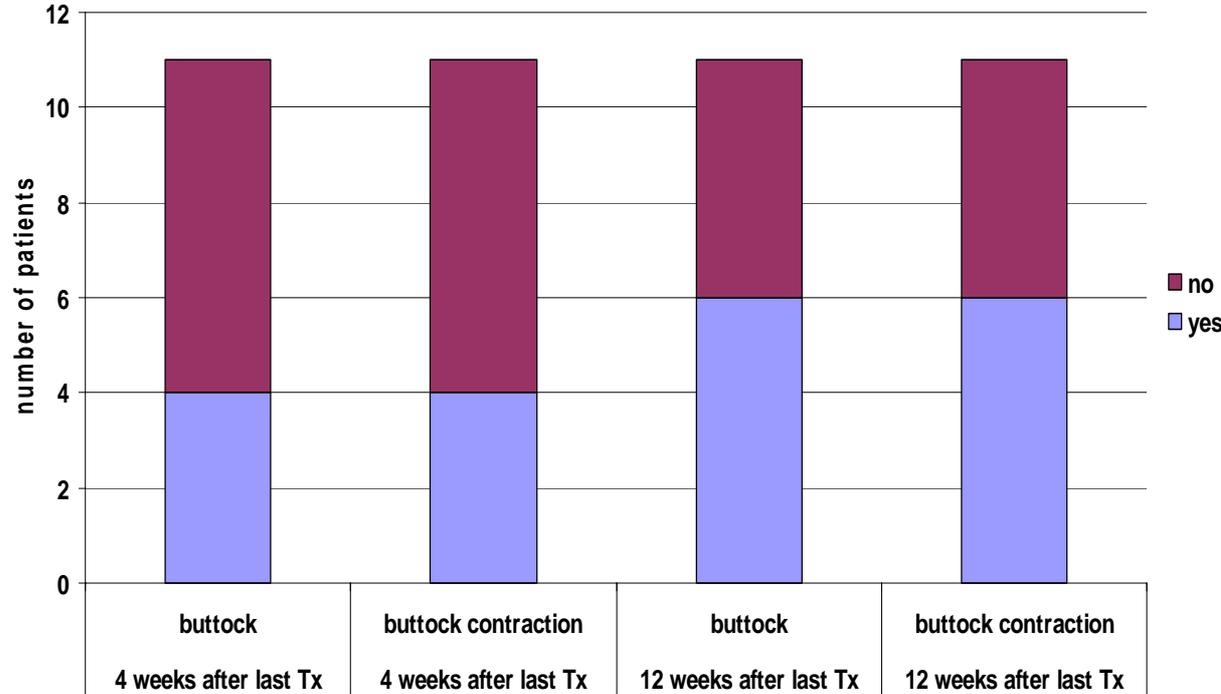


Fig. 6: Results blinded investigator improvement yes/no - bottom relaxed and with muscle contraction

No side effects were seen. The comparison of the circumference of the upper leg treated vs. untreated side showed a significant decrease on the treated side (**Fig. 7**) with a p-value of 0,091 even though a general loss of body weight was seen. There was no significant difference in the pinch test (**Tab. 1**).

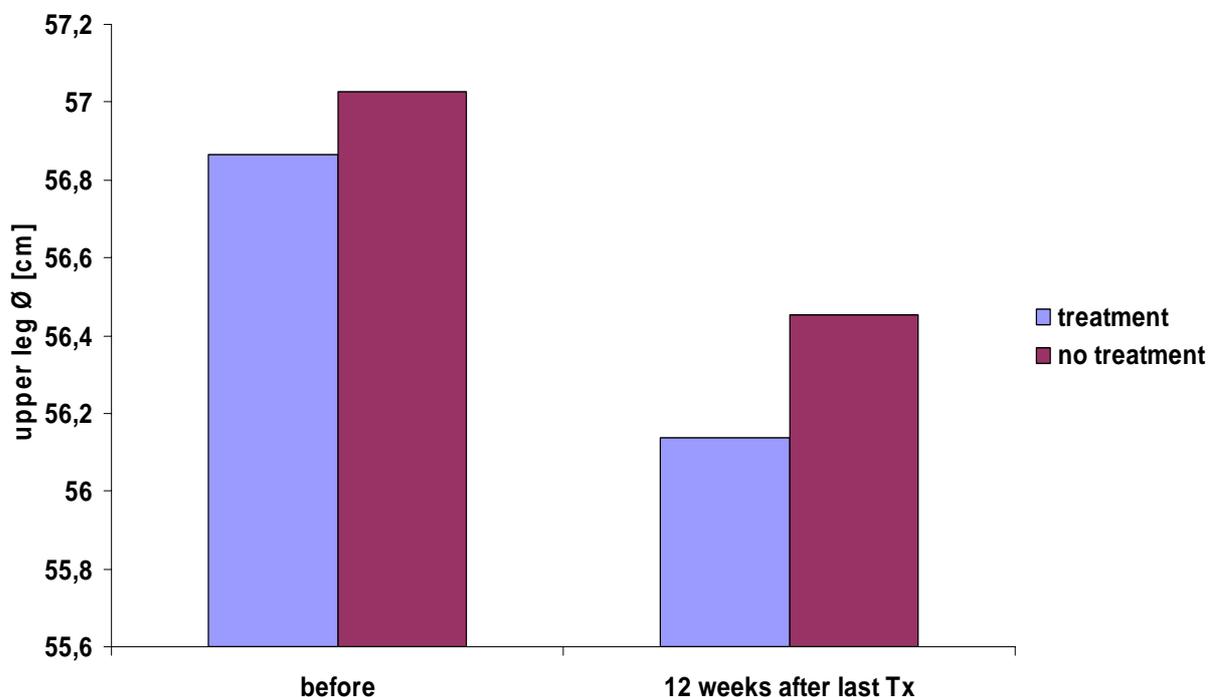


Fig 7: Average measurement of the circumference of the upper leg (treated vs untreated side) before and at 12 weeks after last Tx

		pre Tx	post Tx	p-value	
body weight	kg	67,6	66,06	0,054	
upper leg Ø	cm	56,56	56,14	0,091	treated
pinch test	cm	3,77	4,05	0,245	treated
upper leg Ø	cm	57,03	56,45	0,221	untreated
pinch test	cm	3,75	4,04	0,250	untreated

Tab. 1: Average results 12 weeks after last Tx (n=11)

Interestingly beside that the therapist could also notify an improvement of the untreated side. This would indicate that the reaction is not localized to the treated area only.



Fig. 8: Radial AWT- treatment vs. no treatment: before and 12 weeks after last Tx of the right side with muscle contraction, patient number 2, 40a – BMI 19,6



Fig. 9: Radial AWT- treatment vs. no treatment: before and 12 weeks after last Tx of the right side with muscle contraction, patient number 5 - 39 a - BMI 23,56

Further experiences of AWT besides this study showed, that in general 8 treatments are necessary to get an even better result compared to the study. We recommend an interval of 7 days or maximum 3 treatments in 2 weeks, shorter intervals are less effective. When patients could tolerate a higher pressure in the treatment the results were better and faster to see. Our experience also showed that in AWT compared to endermology less treatments are necessary to reach the same effect and the result lasts longer.

4. Conclusion

Radial Acoustic Waves are effective and safe to treat cellulite. No side effects were seen. The effect of treatment begins delayed and sometimes not before 5 treatments. The improvement of cellulite increases continual up to 3 months. Patients' satisfaction and acceptance is high. Preliminary results assume that higher pressure in treatments needs less applied pulses. Results are better and faster visible.

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