Translation

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Pilot study: Acoustic Wave Therapy (AWT) for Cellulite

The use of acoustic waves is gaining importance as a treatment in aesthetic medicine. The main indication for Acoustic Wave Therapy (AWT) is cellulite. Storz Medical AG, the leading company in shock wave research, has developed a cellulite therapy unit, the CELLACTOR SC1, which combines oscillating (rapid, steadily pulsing), radial pressure waves and planar acoustic waves for a broad spectrum of applications in aesthetic medicine. A pilot study at the Rosenpark Clinic in Darmstadt investigated the treatment results of just radial, just planar and combined treatment on 30 women with cellulite. The study found that the best results were achieved from the application of oscillating, radial pressure waves, in terms of both photographic evaluation and patient satisfaction. Based on these findings, the compact D-ACTOR 200 was developed as a purely radial unit with oscillating sound head specifically for the treatment of cellulite. In addition, the combination unit CELLACTOR SC1 is recommended for the treatment of further cosmetic indications, such as scars, stretch marks, body slimming and body shaping because the application of planar waves can be expected to bring about additional effects such as skin tightening, as well as more lasting results.

Background

Cellulite is a widespread problem among women. Most often it occurs at the thighs and in the gluteal region, rarely on the abdomen. Although many women suffer greatly from its psycho-social consequences, cellulite is not viewed as an illness but rather as a purely cosmetic problem.

The pathophysiology of cellulite is manifold, its formation quite complex. Normally only women are affected. Its basis is the special structure of female connective tissue. The septa of subcutaneous fatty tissue in women are often very taut and run perpendicular to the surface of the skin. As the fat cells in the subcutis increase in size, they are not held in place by the perpendicular septa, but rather press in the direction of the dermis/epidermis and are visible as dimples on the surface of the skin (cellulite). In addition to this, these often very taut, inelastic septa are largely incapable of accommodating the increase in volume in the subcutaneous connective tissue, thus causing further dimpling. In men, on the other hand, the septa run crosswise, which prevents the fat cells from extruding upwards and/or they are restrained better by the connective tissue.

Generally speaking, women have considerably more fat cells than men do, because they serve as an energy reservoir during pregnancy. Furthermore, hormonal fluctuations result in a shift of the lipometabolism toward lipogenesis. The enlarged or enlarging fat cells could also lead to increased pressure in the tissue, thus diminishing local microcirculation; this results in decreasing lipolysis. Thus the fat cells become further enlarged, and the cellulite increases – a vicious circle arises. Oedema and local inflammations also occur over time. As a result, advanced-stage cellulite displays typical fibrotic nodules.

Stage 0: No dimpling is seen when the skin is pinched.
Stage I: No spontaneous displays of alterations, pressure is required to show dimpling.
Stage II: Dimpling is visible when standing, but not while lying.
Stage III: Is characterised by skin alterations while both standing and lying.

Table in accordance with Nürnberger-Müller

The goal of treatment with acoustic waves is the stimulation of metabolic hindrances in subcutaneous fatty tissue or the improvement of local microcirculation in order to interrupt the vicious circle of insufficient supply, increasing pressure and reduced lipolysis. The procedure is also intended to lead to improved lymphatic drainage. Improved appearance of the skin and a reduction in dimpling are anticipated as a result.

Patients and Methods

The present study is a descriptive, prospective, single-centre study for which 30 patients, who had been recruited consecutively or from the customer files at the Rosenpark Clinic, were randomly assigned to one of the three treatment groups. Their cellulite was judged by a physician to correspond to Degrees I-III in stage distribution. Recruitment for the study was based on medical history. All of the patients were advised of the content and objectives of the study as well as of the advantages and side effects of the therapy and consented to participate. The minimum age for participation was 18. The following exclusion criteria were defined: serious cardiac or circulatory problems, regions of pain not clearly defined, untreated bleeding tendency or intake of a Vitamin K antagonist (e.g. Marcumar®), pacemaker, pregnancy and insufficiently treated arterial hypertension.

Study groups

The patients were assigned at random to one of the three groups.

1st group: Radial treatment in D-ACTOR mode only
Intention-to-treat Group n=11, Per-protocol Group n=11

2nd group: Planar treatment in C-ACTOR mode only
Intention-to-treat Group n=11, Per-protocol Group n=9 (2 participants dropped out because of scheduling conflicts)

3rd group: Combined CELLACTOR treatment comprising both D-ACTOR and C-ACTOR modes (radial and planar application)
Intention-to-treat Group n=8, Per-protocol Group n=7, incomplete documentation for one patient

Acoustic Wave AWT

The extracorporeal shock waves (ESWT) familiar from lithotripsy and pain therapy were specially modified to create acoustic waves for dermatological/cosmetic applications. Acoustic Wave Therapy (AWT) has a manifold effect on various types of cells and tissues. Improved metabolism and increased local circulation caused by the formation of new blood vessels (neovascularisation) and/or enhanced cell proliferation, among other things, are mechanisms of action of shock/pressure and/or acoustic waves.

CELLACTOR SC1

The CELLACTOR SC1, which was specially developed by STORZ MEDICAL AG of Tägerwilen, Switzerland for Acoustic Wave Therapy (AWT), was used in the study. The CELLACTOR SC1 is the only instrument currently on the market offering combined EPAT technology (Extracorporeal Pulse Activation Therapy). This instrument has two different systems and applicators and generates two physically different acoustic waves:

Fig. 1: STORZ MEDICAL CELLACTOR SC1; Planar acoustic waves and radial pressure waves.

Fig. 2: STORZ MEDICAL D-ACTOR 200; Oscillating radial pressure waves.

Fig. 3: Radial acoustic pressure wave applicator.

Fig. 4: Planar acoustic wave applicator.

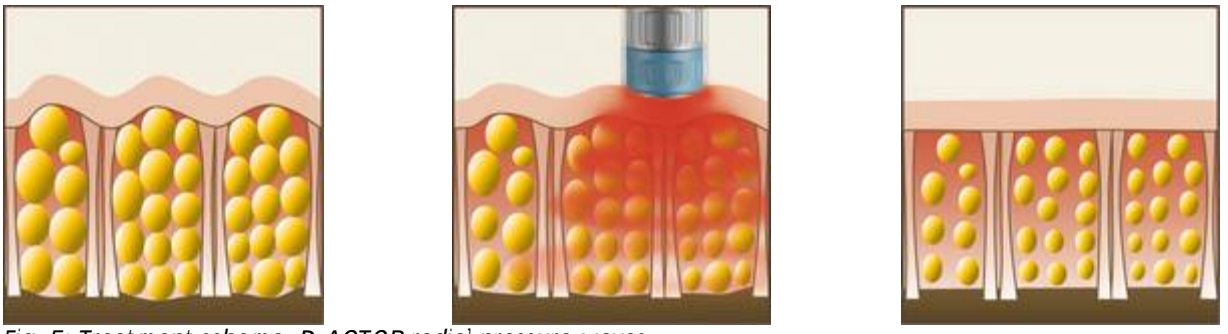

Fig. 5: Treatment scheme, D-ACTOR radial pressure waves

C-ACTOR (planar waves): The pulses are generated electromagnetically in a cylinder source with a parabolic reflector.
The adjustable energy range is 0.01 mJ/mm² - 0.38 mJ/mm².

D-ACTOR (radial wave): The pulses are generated ballistically by accelerating a projectile within the applicator using pressurised air. The maximum energy range is 1.4 bar to 5.0 bar.

Treatment
The patients were treated while lying down. In both therapy modes, the respective applicators were coupled to the treatment location with ultrasound gel in order to guarantee optimum energy transference.

The patients were treated either on the dorsal or ventral thigh in the gluteal region, depending on which area exhibited the more pronounced cellulite.

Treatment was carried out in the direction of manual lymph drainage. Activating the lymphatic system facilitates the removal of lymph-dependent substances (primarily extra-cellular fluid, lipometabolic products) from the intersitium, which is enhanced by manual lymphatic drainage massage in a centripetal direction.

Treatment parameters The treatment protocol prescribed 6 - 7 treatments at intervals of 2 - 7 days. The energy levels for the individual methods were adjusted according to the subjective sensation of the patient. The patients were expected to sense no pain, but definitely an immediate effect of the treatment.

The 11 patients in the first group (D-ACTOR, purely radial treatment) were on average 40 years old (26 - 51) and had an average BMI of 27 (19 - 44). During an average of 6.18 sessions (5 - 7), work proceeded with the following treatment parameters: an average of 1909 (1000 - 2000) radial pulses per session with a median energy of 2.95 bar (2.4 - 3.0) and a frequency of 15 Hz.

In the second group (C-ACTOR, purely planar treatment), the average age of the patients was 34 (31 - 53) and the average BMI was 23 (20 - 31). Two patients discontinued treatment due to scheduling problems. The remaining 9 patients were treated with the following parameters: during an average of 6.11 (5 - 7) sessions, 1000 pulses per session with an average energy of 0.34 mJ/mm².

A combined CELLACTOR treatment (C-ACTOR & D-ACTOR) was carried out on 8 patients in the third group. The average age was 40 (31 - 53); the average BMI was 23 (21 - 25). During an average of 6.375 sessions (6 - 7), an average of 2350 (2000 - 3000) radial pulses were applied per session with an average energy of 2.875 bar (2.6 - 3.0). Subsequently, an average of 1925 (1400 - 3000) planar pulses were applied per session with an average energy of 0.3475 mJ/mm² (0.32 - 0.38).

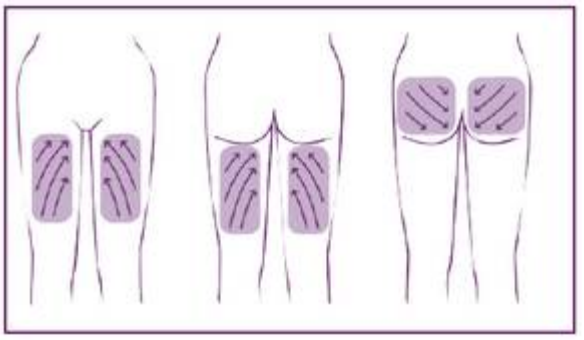

Fig. 6: Treatment directions in the direction of lymph flow.

Objective of the study

Previous investigations have shown that Acoustic Wave Therapy (AWT) improves the cosmetic appearance of the skin in that the waves stimulate both microcirculation and tissue metabolism. In particular, the stimulation of blood and lymph circulation in the subcutis exercises a favourable influence on cosmetic appearance, which then also leads to long-term improvement in the symptoms of cellulite.

The knowledge gained from application observations were anticipated to be reproduced in the present study. In addition, greater clarity was to be established regarding the differentiation of the individual methods with respect to the treatment of cellulite. The results of the singular radial therapy (D-ACTOR), the singular planar therapy (C-ACTOR) and the combination therapy were compared for this purpose. The following were defined as study endpoints: 1) visible improvement, documented with the aid of standardised photographs, 2) patient satisfaction and 3) skin elasticity three months after the end of treatment for each category, compared with the initial findings at the start of therapy.

Photos

Standardised photographs were taken before the beginning of treatment, after the last treatment and three months following the end of treatment in order to document cosmetic appearance.

The photos were then subsequently evaluated by seven individuals in accordance with the "blinded review" procedure. A scale of 0 - 10 was used (nonsignificant result 0.0 - 3.9, satisfactory result 4.0 - 5.9, optimum result 6.0 - 10).

Fig. 7: Treatment with planar acoustic waves, dorsal (C-ACTOR).

Fig. 8: Treatment with planar acoustic waves, ventral (C-ACTOR).

Fig. 9: Treatment with radial acoustic pressure waves (D-ACTOR).

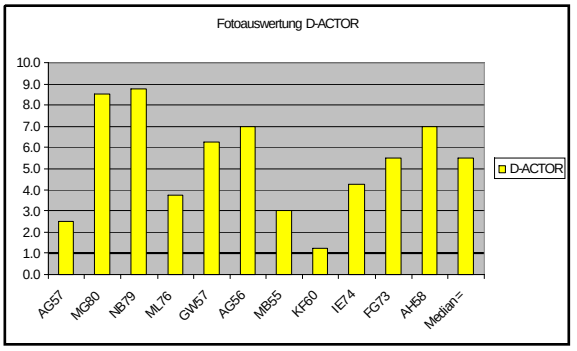

Fig. 10: Photo evaluation D-ACTOR

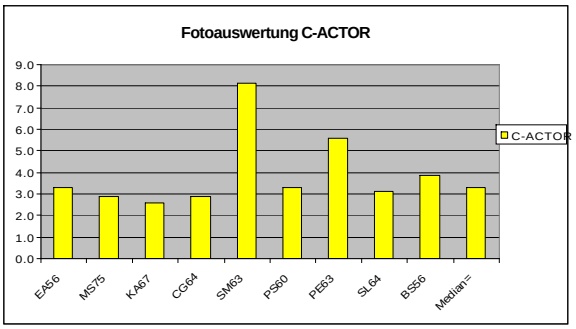

Fig. 11: Photo evaluation C-ACTOR

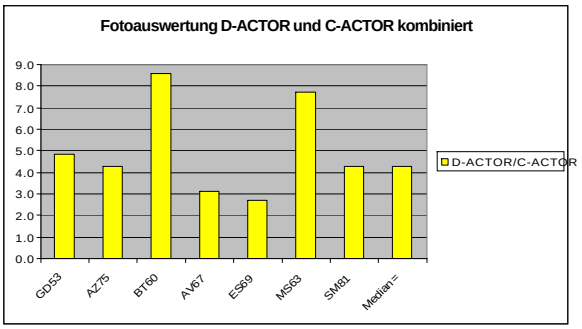

Fig. 12: Photo evaluation combined treatment

Patient satisfaction

The patients were surveyed at the end of the therapy with the aid of a questionnaire for the purpose of evaluating satisfaction with the new AWT methods. The participants provided information as to the point in time they detected an improvement of their cellulite and whether they would recommend the therapy to others.

They were also questioned about the following side effects: reddening, pain during and after the therapy, the emergence of spider-bursts, haematomas and other changes.

Skin elasticity

Prior to the first and last treatments, as well as at the 3-month follow-up, measurement was made of the elasticity of the dry skin at the treatment site. All measurements were taken with the patient lying down and at the same location. The Derma Lab of the Cortex Co. in Denmark was used for this purpose.

Results

1st group, D-ACTOR, radial pressure waves

The evaluation of the photographs of all 11 of the participants showed the best cosmetic results, with an average improvement of 5.5 (1.3 - 8.8) points. Five patients exhibited optimal results in the evaluation, three exhibited satisfactory results and three exhibited nonsignificant results.

The results are also reflected in patient satisfaction: 91% of the patients would recommend the pressure wave treatment to others. All 11 patients confirmed the subjective impression of improvement in their skin. The women noticed an improvement of the cellulite on average after 2.5 sessions of radial treatment. No side effects were described either during or after the treatment.

The data concerning skin elasticity were compiled completely for only eight participants in the first group. Here the average starting value prior to the first treatment was 11.58 MPa. This value dropped to an average of 10.03 MPa for the measurement prior to the final treatment. A slight increase, to an average of 10.08 MPa, was measured at the time of the three-month follow-up. As a whole, no significant change in skin elasticity was established.

2nd Group, C-ACTOR, planar acoustic waves

Nine of the eleven patients were available for evaluation. Here the median improvement of the photographically documented results was 3.3 (2.6 - 8.1) points. One patient exhibited optimal results in the evaluation, five exhibited satisfactory results and three exhibited nonsignificant results.

The planar treatment was judged to be worthy of recommendation to others by 44% of the participants. Fifty percent of the patients detected an improvement of their cellulite after an average of 3.8 treatments, 50% detected no improvement. No side effects were reported.

The measurement of skin elasticity revealed no significant change. The average starting value was 12.10 MPa, falling to an average of 10.81 MPa before the final treatment. A slight increase in skin elasticity, to an average of 12.11 MPa, was however established again at the time of the three-month follow-up.

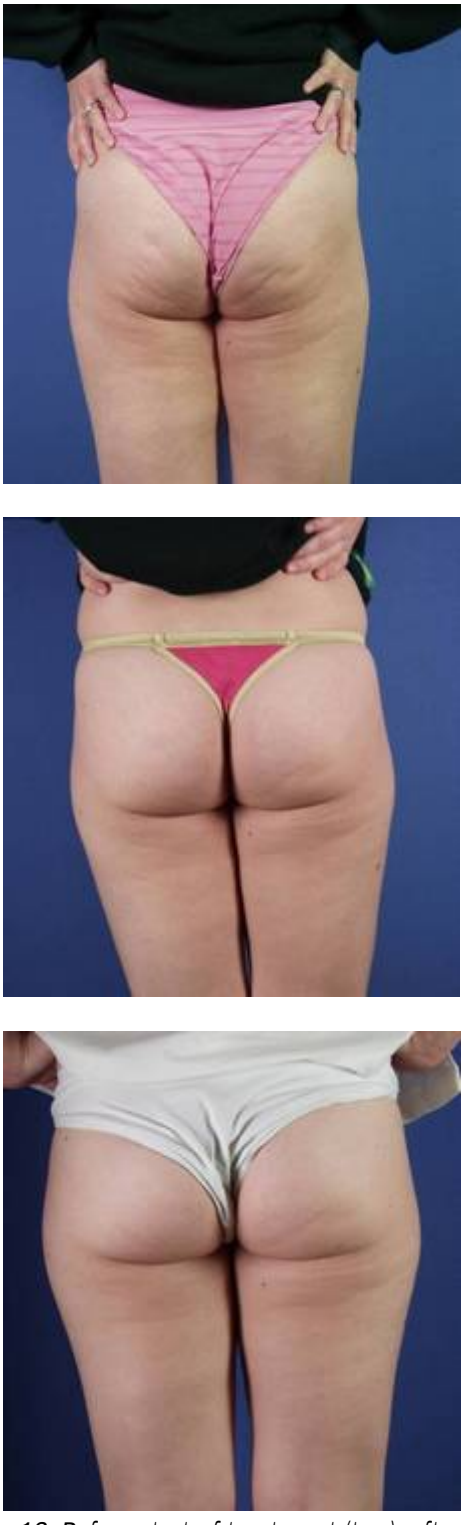

Figure 13: Before start of treatment (top), after 6 treatments over a 4-week period (centre), three months after end of treatment (bottom) – Example 1.

3rd group, combination treatment

7 patients were available for complete evaluation. The evaluation of the photographic documentation yielded an average improvement value of 4.3. Two of the patients exhibited optimum results in the evaluation, four exhibited satisfactory results and one exhibited nonsignificant results.

Seventy-five percent of the patients would recommend this combination therapy to others. Seven patients detected an improvement of their cellulite after an average of 3.6 treatments, one patient experienced no effect.

One patient reported a mild reddening of the skin after treatment; this was the sole side effect. Skin elasticity was measured completely for 5 participants.

The average initial value in the combination group was 10.33 MPa and rose to a value of 10.36 MPa prior to the last session. A further improvement in skin elasticity of an average of 10.85 MPa was measured at the three-month follow-up. A tendency towards improvement could be seen in the evaluation, but no significant increase could be established.

Discussion

Only a small sample of patients was studied in this pilot study. The average age in the group that received only planar treatment was considerably lower than in the other two groups. The BMI for the group that received only radial treatment tended towards the overweight range, whereas the other two groups exhibited normal weight on average. This may have had an influence on the treatment results, something which should be investigated in the context of larger studies. Among the younger women of normal weight in the planar therapy group, the result was perceived as being less convincing, even among the women themselves, whereas a majority of the women who were treated with radial waves sensed a pronounced result. For the combination treatment, the results fell in the middle between the two treatments. The combination of radial and planar waves thus did not lead to an enhancement of the effect. Radial waves proved to be the preferable strategy for the indication of cellulite because the results achieved from this method were the clearest in terms of both appearance and sensation, and were also the ones most clearly to be reproduced in the photographs. The benefit-risk ratio is here the highest; from the patient's point of view, the first effect that could be connected to the treatment appears on average as early as after one to two weeks.

Figure 14: Before start of treatment (left), after 6 treatments over a 4-week period (centre), three months after end of treatment (right) – Example 2

The results that can be seen and felt arise without the elasticity of the skin changing significantly in either direction. This factor therefore plays only a subordinate role at best and is not decisive for the success of cellulite treatment. This is in agreement with the pathogenetic idea that excessively weak connective tissue septa, with their anatomically unfavourable alignment, in conjunction with increasingly large fat cells, are a main cause of cellulite (although circulation disorders at the capillary and lymphatic vessel level are also involved but can be countered with acoustic waves). It is here as well as on the increased lipolysis that the effects of the acoustic waves, which are not limited to a restricted time frame but which can in fact still be documented as long as three months after the completion of the therapy, are felt. The changes are thus not simply of a temporary nature, as is the case with lymph drainage, for example, but rather effect a more lasting structural change in the tissue. The patients were instructed not to change their lifestyles and to continue to participate in sports and exercise to the same extent as previously. Despite these circumstances, the results turned out to be markedly different within the individual groups, thus suggesting a correlation with the procedures themselves.

AWT has proven itself in this pilot study to be practically free of side effects when used as directed.

Conclusion

AWT, in particular when used with radial waves, is an effective and very interesting treatment method for cellulite which did not produce any side effects among this particular group of patients. The pressure wave unit (D-ACTOR 200), which uses only radial waves, was developed by Storz Medical AG especially for the application of AWT in cases of cellulite.

The method has a great potential. Other concepts for different treatment parameters are currently being tested in view of long-term results.

Source: Translation of: "Pilotstudie Akustische Wellen Therapie (AWT) bei Cellulite"; G. Sattler, U. Pohl, K. Raegener; Published in: Ästhetische Dermatologie 02/2008