EFFICACY AND SAFETY OF AWT IN ANTI-CELLULITE TREATMENT

Markus Steinert, Alexander Krotz and **Pavel Novak** discuss a small study on the use of Acoustic Wave Therapy to reduce the appearance of cellulite and improve the skin's overall function

DR MARKUS STEINERT is Dermatologist, Laserklinik Dr Steinert, Biberach, Germany; **ALEXANDER KROTZ** is Shock Wave Therapist, Konstanz, Germany; and **DR PAVEL NOVAK** is Director of Product Development, Tägerwilen, Switzerland

email: info@hautdoc.de; www.dres-steinert.de; www.sportheilpraxis-konstanz.de

KEYWORDS
acoustic wave therapy, cellulite, skin elasticity, skin thickness, non-invasive treatment

ABSTRACT
Full title
Investigating the efficacy and safety of Acoustic Wave Therapy in anti-cellulite treatment

This clinical evaluation shows how to use Acoustic Wave Therapy (AWT) for the temporary reduction of cellulite. Fifteen female patients with an average age of 35 years were treated with the D-ACTOR 200® (Storz Medical AG) twice per week for a total of eight treatments. Weight and circumference were measured at screening before (V) and after (ZW) the treatments, as well as at the follow-up examination (FU) 4 weeks after the last session. The degree of cellulite was determined by the aesthetic practitioner using a modified Hexsel Scale, referred to as the Cellulite Severity Scale (CSS). Additionally, skin elasticity and Young's Modulus, a measure of how easy it is to deform the skin from its normal state, were measured in the treated area. The results show that the degree of cellulite – assessed using the CSS – showed a significant improvement from baseline to follow-up. Also, skin elasticity showed a statistically significant difference between V, ZW, and FU.

CELLULITE REFERS TO THE MATTRESS (OR ORANGE PEEL) phenomenon of the skin, and affects a huge percentage of women of all ethnicities. Cellulite is a non-inflammatory degenerative process, but not a disease; it is a modification of connective tissue caused by biological factors, mostly occurring in females (a small percentage of men may develop cellulite). One of the main negative consequences of cellulite, from a psychological point of view, is low self-esteem.

The aetiology of cellulite is complex. Cellulite is caused by the specific structure of the collagen fibre bundles; the fat cell chambers with the surrounding fibre bundles project straight upwards into the dermis. This is most common in females, while the male subcutis is held together by tangential fibre bundles. The growing fat cells between the septa cause the dimpling effect and reduce the blood and lymphatic microcirculation. This could be the reason for intracellular oedema and reduced lymphatic drainage, resulting in an increased storage of fat[1]. This leads to alterations of adipose tissue and microcirculation, causing fibrosis of the connective tissue, and results in the well-known mattress/dimpling aspect on the surface of the skin[2,3]. ▷

> “Cellulite refers to the mattress (or orange peel) phenomenon of the skin, and affects a huge percentage of women of all ethnicities.”

▷ In this clinical evaluation, Acoustic Wave Therapy (AWT) is used for the temporary reduction of cellulite (i.e. the results can last for 1 year or more, but are dependent on lifestyle factors and genetics). It is known that metabolism and circulation are stimulated by the use of acoustic waves in dermatological and cosmetic applications. Proven mechanisms of action of pressure waves are neovascularisation, growth of new blood vessels, and increased cell proliferation[4]. The side-effects of acoustic pressure waves are low. At most, mild pain and skin reddening can be expected during the treatment[5,6].

The objective of this clinical evaluation was to demonstrate the efficacy and safety of AWT in anti-cellulite treatment. To achieve this, a number of measures, such as thigh circumference measurements, high-resolution ultrasound, viscoelasticity and photographic evaluation, were included.

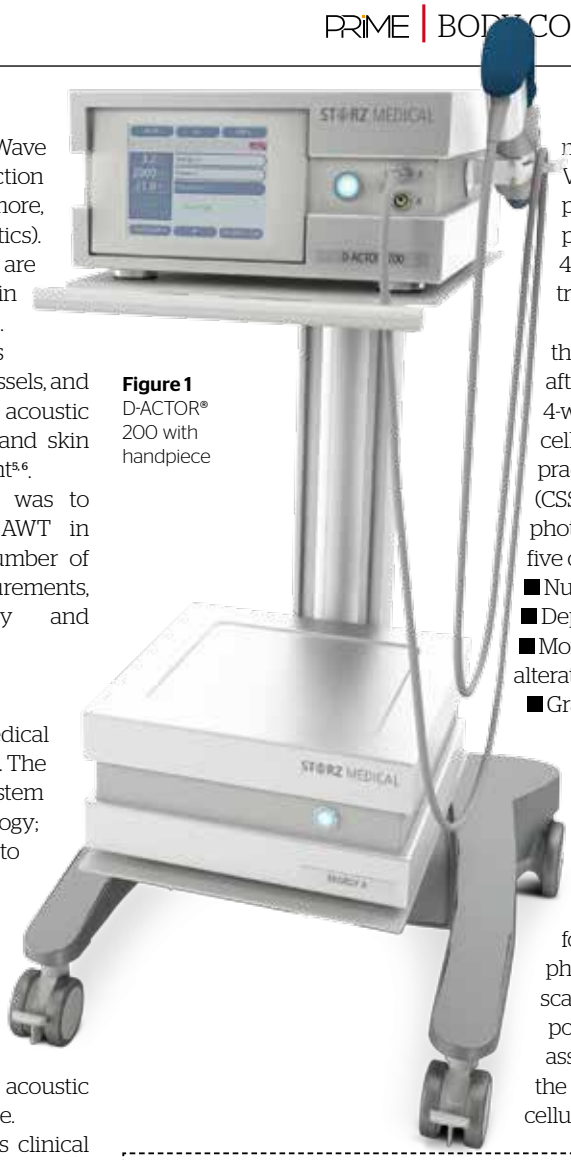


Figure 1 D-ACTOR® 200 with handpiece

Materials and methods

For the treatment, the D-ACTOR® 200 (Storz Medical AG, Tägerwilen, Switzerland) was used (*Figure 1*). The D-ACTOR® 200 is a vibrating massage system (Extracorporeal Pulse Activation Technology; EPAT), which operates with compressed air to perform AWT on targeted tissue. The system comprises a control unit, a pneumatically-driven handpiece with multiple types of transmitters, and a pressurised air source. The pulses are generated by ballistic impact by accelerating a projectile with pressurised air, which strikes the vibration transmitter. The generated vibrations—the radial acoustic waves—propagate directly into the treated tissue.

Two different handpieces were used in this clinical evaluation, the D-ACTOR handpiece with CERAma-x® transmitter and the V-ACTOR® handpiece.

During screening, patients completed a questionnaire covering demographics, medical background and potential contraindications to therapy. Each patient signed an informed consent explaining the risks and benefits of the procedure. All 15 patients were female, eight of whom were under 40 years of age, and seven aged 40 years and over. The main inclusion criterion for the study was cellulite; exclusion criteria were contraindications to treatment, such as haemophilia, anticoagulants, thrombosis, tumour diseases, pregnancy, and cortisone therapy.

> “The D-ACTOR® 200 is a vibrating massage system, which operates with compressed air to perform AWT on targeted tissue.”

Each thigh was partitioned into three areas: front side, rear side and buttocks. The treatment was performed with the CERAma-x transmitter, applying a total of 24 000 pulses at 2.6–4.6 bar and 18 Hz, depending on the pain intensity tolerated by the patient. Additionally, a massage was performed with the V-ACTOR, applying a total of 20 000 pulses at 2.6–3.6 bar and 35 Hz. The patients were treated twice per week for 4 weeks, receiving a total of eight treatments.

The weight and circumference of both thighs were measured at screening (V), after the treatment period (ZW), and at the 4-week follow-up visit (FU). The degree of cellulite was determined by the aesthetic practitioner using the Cellulite Severity Scale (CSS) introduced by Hexsel[7]. CSS is a photonumeric cellulite severity scale with five criteria:

- Number of evident depressions
- Depth of depressions
- Morphological appearance of skin surface alterations
- Grade of laxity, flaccidity, or sagging skin
- The classification scale originally described by Nürnberger and Müller.

Treatment progress was documented through a series of photographs covering all treated areas. For each patient one area at baseline, after the treatment period and at follow-up was selected, and four independent experts assessed the photographs according to a modified Hexsel scale. The modification was necessary, as point E of the Hexsel scale can only be assessed by palpation in direct contact with the patient. The scale ranges from 0 (no cellulite) to 12 points (maximum cellulite). ▷

Figure 2 Cellulite Severity Scale (CSS)

The CSS is determined by the therapist at the three time points. Friedman's Test showed a significant reduction of cellulite from baseline to follow-up.

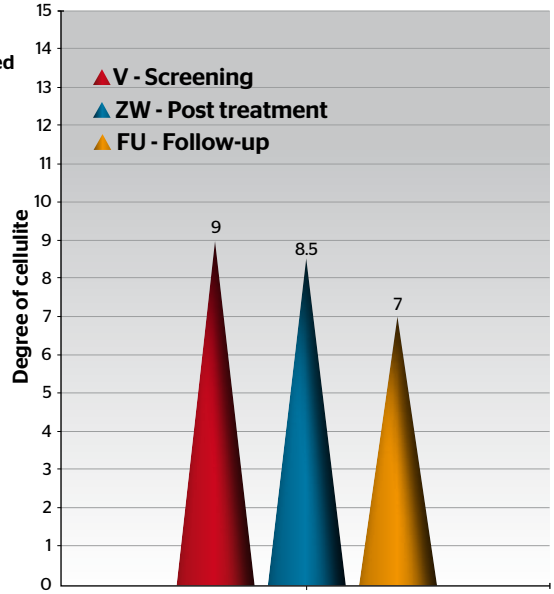
FRIEDMAN TEST:
15 out of 15

CHI-SQUARE =
11.773 with 2 degrees of freedom (*P*=0.003)

STUDENT-NEWMAN-KEULS METHOD:
V vs FU: Difference of ranks: 16; q = 4.276; signficance: yes

V vs ZW: Difference of ranks: 6.5; q = 2.457; significance: no

ZW vs FU: Difference of ranks: 9.5; q = 3.591; significance: yes



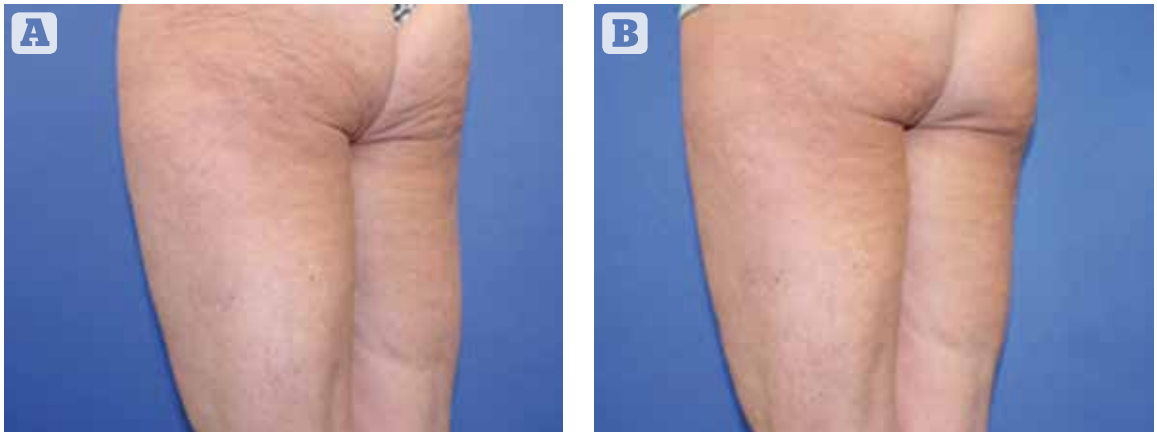


Figure 3 Photographic documentation. (A) Patient 7KC is shown at the initial screening and (B) at the follow-up visit. The modified Hexsel Scale was reduced from the 8.2 average value to 5

▷ In addition, skin elasticity was measured at a defined spot within the treated area. The DermaScan® (Cortex Technology, Denmark) device is a 20 MHz ultrasound system delivering high resolution images with a height of 12.1 mm and a penetration depth of only a few millimetres (*Figure 4*). The velocity of sound was set to 1580 m/s, which is the generally accepted average velocity for skin tissue.

The settings for all measurements of all patients were constant in order to obtain comparable images. These images enabled the definition of a contour line at the skin surface and an additional line at the 'rear side' of the skin, possibly imaging the interface between the epidermis and the dermis.

Cellulite shows its characteristics in an irregularly formed interface[8], resulting in a long contour line. By dividing the area between the two contour lines by the height of the image, it was possible to calculate a well-defined skin thickness..

The DermaLab® (Cortex Technology, Denmark) device is based on suction applied to the skin's surface with a diameter of 1 cm. It measures the 'negative' pressure needed to suck the skin by 1.5 mm into the circular device. When the suction is shut off, the skin relaxes and the time required to retract to the original state is measured. With the known geometry of the sensor and the skin thickness measured with the ultrasound system, it is possible to calculate a parameter called Young's Modulus (*E*), which is a measure of elasticity, equal to the ratio of the stress acting on a substance to the strain produced – in this case, the substance being the skin.

> "The DermaScan® device is a 20 MHz ultrasound system delivering high resolution images with a height of 12.1 mm and a penetration depth of only a few millimetres."

Assessment

To assess the behaviour of the skin, it is also important to consider the change from the deformed state to the normal state. This is carried out through a combination of the elevation and retraction phase, and the parameter thus defined is referred to as viscoelasticity. According to Cortex Technology, an effective treatment would result in a higher viscoelasticity value.

Statistical analyses were performed using the SigmaStat 3.5 software (www.systat.com). As the number of patients was rather small, median values are used and the 25% and 75% quartiles are given in brackets. Non-parametric tests were used throughout the entire analysis process. For the estimation of effect sizes, Cohen's d mean and standard deviations were used. ▷

Figure 4 Length of the contour lines (mm)

The length of the contour line for three time steps is determined on the basis of the ultrasound images. See *Figure 5*: Line 1 is the length of the skin surface. Line 2 corresponds to the length of the interface between epidermis and dermis. The Friedman Test showed a significant decrease

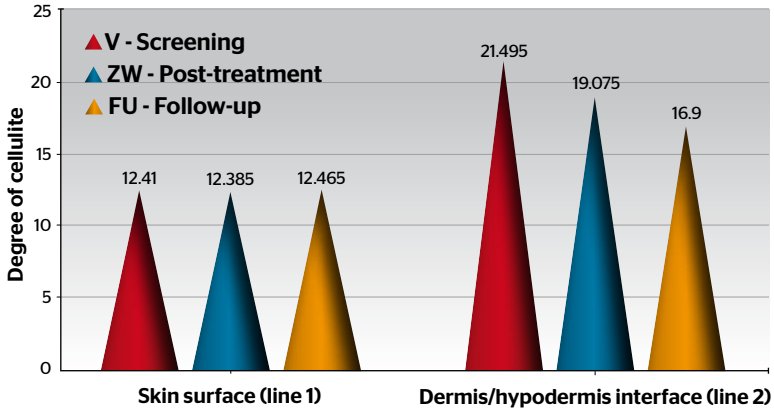
FRIEDMAN TEST:
14 out of 15

CHI-SQUARE =
7000 with 2 degrees of freedom (*P*=0.030)

STUDENT-NEWMAN-KEULS METHOD:
V vs FU: Difference of ranks: 13; q = 3.474; signficance: yes

V vs ZW: Difference of ranks: 2; q = 0.756; significance: no

ZW vs FU: Difference of ranks: 11; q = 4.158; significance: yes



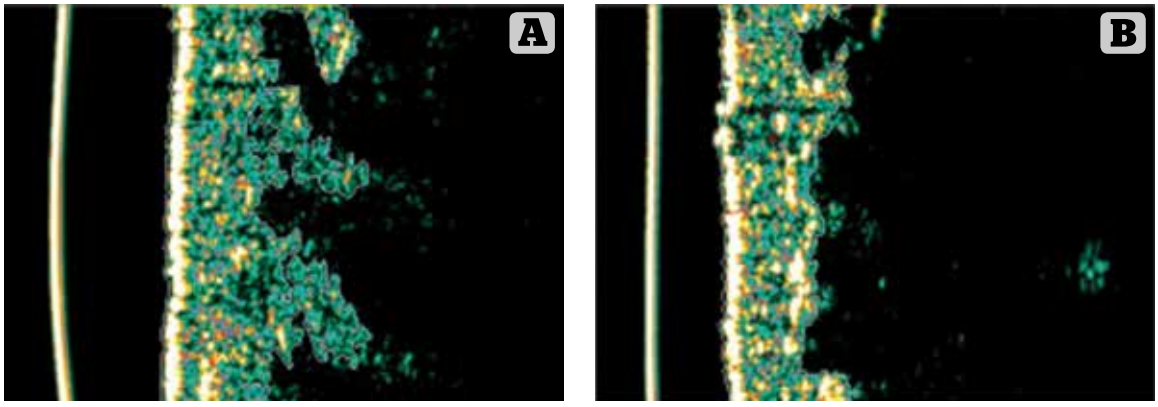


Figure 5 High resolution ultrasound images with a height of 12.1 mm and a penetration depth of a few cm of the skin obtained at the front side of the right thigh. (A) Image at baseline. The long contour line resulting from the dark notches that penetrate into the epidermis is clearly visible. This is a manifestation of cellulite. (B) The dark notches are drastically reduced at the follow-up visit

▷ Results

This clinical evaluation included 15 female patients. The average age was 35 years (29; 50). The average body mass index (BMI) was 22.3 (20.9; 25.9) at the start of the study, and showed a slight increase to 22.4 after the treatment period, and to 22.5 at the follow-up visit.

The average circumference of both the left and right thigh decreased from 55.8 cm (51.8; 57.8) at baseline to 54.8 cm (50.8; 56.8) after the treatment period and to 53.1 cm (50.6; 56.5) at the follow-up visit.

> **“This clinical evaluation included 15 female patients. The average circumference of both the left and right thigh decreased from 55.8 cm to 53.1 cm at the follow-up visit.”**

The degree of cellulite, determined by the aesthetic practitioner on the basis of the CSS, showed a significant decrease from 9 (6; 11) at baseline to 8.5 (6; 10) after the treatment period, and to 7 (4.3; 8) at follow-up (*Figure 2*). The photographic documentation was evaluated by four different experts using the modified Hexsel Scale (CSS).

The ratings of the four experts and the therapist at baseline were compared in order to see whether they coincide in their estimation of cellulite. This comparison is done using Kendall's coefficient of concordance (Kendall's W). It is 1 for a total overlap of the results, 0 for total disagreement and 1/m for random agreement, m being the number of evaluators. The overall W for all patients at baseline was 0.833, which indicates a high correspondence. With m=5 (four experts plus the aesthetic practitioner) and the degree of freedom df=14, one can calculate a highly significant difference between the results of the evaluators and a random concordance.

In the evaluation of the DermaScan data, only 14 out of 15 patients were considered, as the baseline values of one patient were missing. As seen in *Figure 4*, the contour line of the skin surface (line 1) remained constant over the entire case report. The contour line of the back of the thighs (line 2) decreased from the baseline value of 21.495 mm (17.19; 24.24) to 19.075 mm (18.28; 24.84) after the treatment, and to 16.9 mm (15.81; 19.33) at the follow-up measurement. The Friedman test as a test for repeated measures analysis of variance on ranks showed a statistically significant difference (P=0.03). The Student-Newman-Keuls Method identified differences between baseline and FU, and ZW and FU. The skin thickness measurement showed no significant change over the entire case report: baseline 1.7 mm (1.49; 1.91); ZW 1.72 mm (1.51; 1.87); and FU 1.68 mm (1.41; 1.79).

In the data received using the DermaLab measure, one baseline data set was missing (14 out of 15). The raw data for Young's Modulus were corrected using the skin thickness achieved from the DermaScan measure. For two patients, post-treatment values were missing and were replaced with the last value carried forward method.

Young's Modulus data showed an upward trend; however, they scatter strongly and there is no significant change. Baseline: 1.28 MPa (0.85; 2.02), ZW: 1.51 MPa (1.20; 1.85), FU: 1.93 MPa (1.57; 3.05). The viscoelasticity increased from 0.61 MPa to 0.99 MPa, showing that the skin was tighter and stronger.

Viscoelasticity increased from the baseline value of 0.61 MPa (0.32; 1.29) to 0.90 MPa (0.18; 1.69) after the treatment sessions, and up to 0.99 MPa (0.71; 1.59) at the ▷

Figure 6 Young's Modulus and Viscoelasticity

Young's Modulus (Ymod) [MPa] is shown in blue. It increased, but data scattered strongly and statistical evaluation showed no significance. The same holds for the viscoelasticity (VE) [MPa] values shown in red. Increasing median values, but no significance owing to strong data scattering

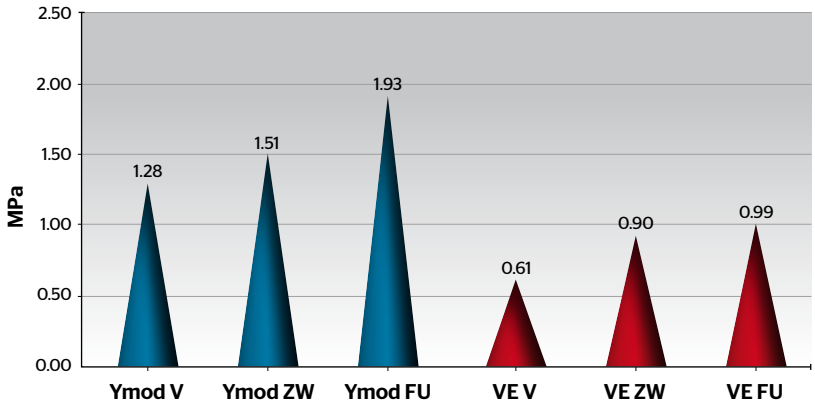


Table 1 Effect sizes (estimate)

	Cohen's d
Contour line	0.63
Young's Modulus	0.44
Viscoelasticity	0.41

Effect sizes were estimated using Cohen's d. d = 0.2 indicates a small effect and d = 0.8 a strong effect, the best effect is seen in the contour line, while Young's Modulus and viscoelasticity experience only an average effect

▷ follow-up. Again, the data scatter strongly and the statistical evaluation showed no significant change.

Effect sizes using Cohen's d were estimated for the contour line, Young's Modulus and viscoelasticity. Results are summarised in *Table 1*. Young's Modulus and viscoelasticity showed a nearly average size and the contour line an average-to-strong treatment effect.

Discussion

This clinical evaluation was designed to evaluate the efficacy and safety of AWT in anti-cellulite treatment. Treatment success was measured using a variety of methods.

The circumference of the thighs decreased from 55.8 cm to 53.1 cm. As the BMI remained constant, this reduction is a clear sign of an effective treatment with AWT. According to the evaluation of the results with the CSS scale, four experts using photo-documentation and the aesthetic practitioner evaluating the patients, found a consistent and clear treatment effect. The DermaScan device enabled the measurement of two parameters: skin thickness, which remained constant over the entire treatment process, and the length of the contour line, which showed a rather strong treatment effect and decreased significantly.

> "Anti-cellulite treatment with AWT significantly alters the structure of the dermis–hypodermis interface."

The DermaLab measurement strongly delivered scattered data and a nearly average treatment effect. There is no statistical significance as the number of patients was too small. The spatial high resolution of the DermaScan enabled detection of changes in the sub-millimetre range (*Figure 5*). The AWT treatment changes the substructure at the interface between the dermis tissue and the adipose tissue. *Figure 4* shows that, on average, the dermis-hypodermis contour length decreases as a result of treatment. The 'smoothing' of the dermis-hypodermis interface indicates an improvement towards a cellulite-free appearance.

A study by Adatto et al[5] showed a reduction of the fat layer

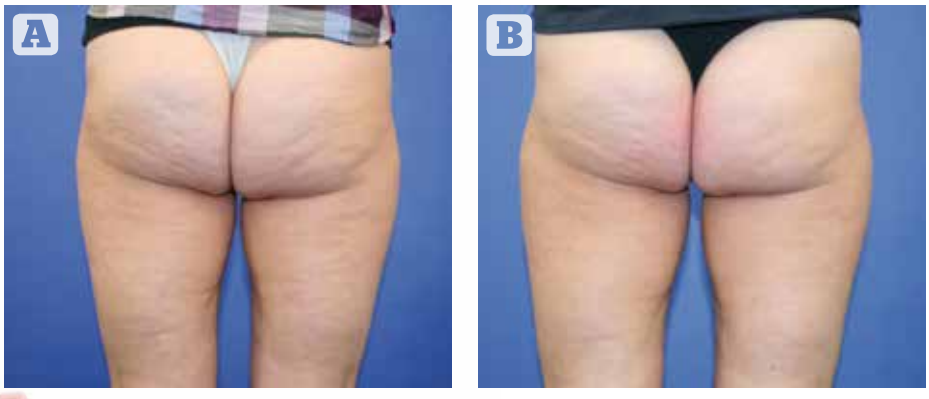


Figure 7 Photographic documentation. (A) Patient is shown at the initial screening and (B) at the follow-up visit.

thickness and of the cellulite appearance. The circumference of both legs had been reduced from 60cm to 58.2cm at 12-week follow-up. Measurements with the ultrasound system demonstrate a significant decrease of the subcutaneous fat layer thickness with an average of 2mm (22.2%) at 12-week follow-up. The minor and temporary side-effects confirm the safety of AWT. Only minimal side-effects, such as redness and swelling, were apparent in this study. The authors are currently working on follow-up studies.

Conclusions

Anti-cellulite treatment with AWT significantly alters the structure of the dermis-hypodermis interface. High resolution ultrasound and the DermaLab suction apparatus provide valuable information with regard to the condition of the skin, and can be used as objective measures to monitor the progress achieved with AWT. AWT and the applied measurement devices are safe to use and showed minimal side-effects in this study.

▶ ***Declaration of interest*** *The authors Dr Pavel Novak and Alexander Krotz are employees of Storz Medical AG. Dr Markus Steinert has been supported by Storz Medical AG.*

Key points

- Acoustic Wave Therapy is a non-invasive, painless treatment methdology for the appearance of cellulite
- Cellulite is caused by the specific structure of the collagen fibre bundles; the fat cell chambers with the surrounding fibre bundles project straight upwards into the dermis
- The objective of this clinical evaluation was to demonstrate the efficacy and safety of AWT in anti-cellulite treatment
- A number of assessment measures – thigh circumference measurements, high-resolution ultrasound, viscoelasticity and photographic evaluation – were included
- Anti-cellulite treatment with Acoustic Wave Therapy significantly alters the structure of the dermis-hypodermis interface

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