RADIAL SHOCK WAVE THERAPY FOR CELLULITE Radial Shock Wave Therapy (RSWT) for Cellulite

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SUMMARY

Cellulite or 'orange-peel skin' can even be found in young adults who are overweight and/or have weak connective tissue. In older adults, these changes can be found in 80% to 90% of women to varying degrees. Different treatment approaches are available. In addition to different massage techniques, liposuction, subcision and topical preparations, physical methods like lasers, radiofrequency, ultrasound, and shock wave therapy are used. Radial shock wave therapy is a new method of treatment. Radial shock waves are high energy sound waves pneumatically created outside the body. They are directed into the tissue where they are disseminated in a radial (spherical) pattern. Thanks to this radial dissemination pattern the treatment is perceived to be very gentle. After the treatment is over, the tissue reacts to the shock wave with higher metabolic activity and this tones the epidermis. The acoustic waves also stimulate blood circulation and the production of collagen. The aim of our pilot study was to reduce the 'cottage cheese' look in the area of the upper thighs. To do this, comparable measurements were performed for 3 different types of treatments. Our research was able to show that the circumference of the upper thigh can be reduced significantly in individuals with cellulite. The appearance of cellullite can also be improved considerably.

INTRODUCTION

Cellulite, which is also called orange-peel skin, can develop even in young adults who are overweight and/or have weak connective tissue; with increasing age these changes can be seen in 80–90% of women to one degree or another.

Cellulite is not a pathological change – it is a purely cosmetic annoyance in the form of dimpling of the skin's surface. Due to weak connective tissue fibres, the septae in the subcutaneous tissue bulge out in the direction of the dermis/epidermis and are then visible on the surface of the skin as deformities and dimples that resemble cottage cheese (Fig. 1). The thighs and buttocks are most commonly affected, the upper arms, hips, abdomen and breasts less so. Cellulite occurs almost exclusively in women since men have a different type of connective tissue network in their fatty tissue. In addition to structural differences in the subcutaneous connective tissue septae [1], damage to the vascular network with a subsequent increase in pressure and oedema are also considered to be causes [2].

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There are many different approaches for treating cellulite. In addition to different massage techniques, other treatments include liposuction, subcision and topical preparations, physical methods, such as laser and radio frequency, as well as ultrasound and shock wave therapy. Radial shock wave therapy (RSWT) is a new treatment method. Radial shock waves are high-energy sound waves that are generated pneumatically outside the body. They are coupled through the skin near the pain zone to human tissue and they spread radially (spherically) from there. Thanks to this radial dissemination pattern the treatment is perceived to be very gentle. After the treatment the tissue reacts to the shock wave with increased metabolic activity [3] which tones the epidermis. The acoustic waves also stimulate blood circulation and the production of collagen [4]. The improved metabolism and circulation accelerate the removal of lymph.

The aim of our pilot study was to reduce the cottage cheese appearance of the upper thigh area. To do this, comparable measurements were performed for 3 different types of treatments.

MATERIALS AND METHODS

Shock wave therapy

The enPuls shock wave therapy system made by Zimmer MedizinSysteme GmbH (Neu-UIm, Germany) was used for the shock wave therapy. This is a system for electromagnetically producing and applying radial shock waves for physiotherapy and orthopaedics with a maximum penetration depth of 35 mm. The entire circumference of both thighs was treated. Two applicator heads were available for the therapy: one large (diameter 40 mm) and one small (diameter 25 mm).

To ensure that all the energy is transmitted, ultrasound gel (Sono Plus; Zimmer Medizintechnik, Neu-Ulm, Germany) was used as a coupling medium. A protective silicone cap was put on the applicator head to keep the hand piece clean. Different frequencies could be selected: 2 Hz, 5 Hz, 10 Hz and 16 Hz. The recommended frequencies were 10 Hz or 16 Hz, though the patient's response determined which was used. The shock wave can be emitted at four different energy levels – for our purposes levels II and III were recommended so that the therapy could be carried out with no pain. As a guideline, 2,500–4,000 shocks were administered per session.

During the treatment, the transducer head was always moved in the direction of the lymph flow. This enabled the pressure applied to the hand piece to be increased when moving towards the lymph nodes. The shock wave treatment was carried out 2–3 times a week for a total of 7 to 10 treatments over a period of 4 weeks. If values were missing for the final examination, the last observation carried forward (LOCF) method was used, that is, the last value available for a subject was used for the final evaluation.

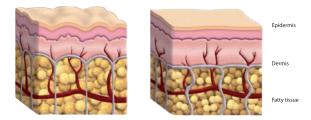


Fig. 1: Schematic cross-section through the skin of a woman depicting the connective tissue septae in subcutaneous fatty tissue left: with cellulite; right: skin with no cellulite.

Treatment groups

Three treatment groups were formed, for each of which the right and left thigh were compared for the study:

Group 1: Radial ballistic shock wave therapy with two different applicator heads; (25 mm and 40 mm in diameter)

Group 2: Combination of shock waves (40 mm applicator head) and topical substances, anti-cellulite gel (right leg) and anti-cellulite cream (left leg)

Group 3: Topical application of anti-cellulite gel (right leg) and anti-cellulite cream (left leg) only

For each subject a zone was defined on the lateral thigh where all measurements such as circumference, ultrasound imaging and surface profilometry, and photographs of the skin's surface, were taken. This zone was defined as the centre point of a straight line between the head of the femur and the lateral knee joint space.

Topical treatment

For the topical treatment, throughout the study in groups 2 and 3 an anti-cellulite gel (Beaute Pacifique, Denmark) was applied once daily to the right leg and an anti-cellulite cream (Alive, Israel) was applied to the left leg.

Documentation of findings

Before the first treatment and after the last treatment the following parameters were collected:

- Age
- Height, weight, BMI
- Body fat measured using impedance analysis
- Cellulite stage according to clinical criteria (stage 1 to 4 classified according to Nürnberger und Müller, Z Hautkr. 1979; 54: 47–57)
- Photo of the treated area
- Thigh diameter at the defined point
- Surface profile using fringe projection (triangulation)

- 20 MHz ultrasound scan of the skin to determine skin thickness and relative acoustic density
- Measurement of the microcirculation and oxygen saturation in the thigh using laser doppler and tissue spectrometry (02C, LEA Medizintechnik GmbH, Giessen)
- Questionnaire on side effects and subject satisfaction or self-rating of the treatment's success

RESULTS

There were 25 female subjects ranging in age from 27 to 66, whereby the majority of the subjects (20 subjects) were assigned to treatment group 2 (combination of shock waves and topical therapy). The different cellulite stages were classified by assessing the skin profile [5] using the following definitions:

Stage 0: Smooth skin, no cottage-cheese or orange-peel effect in the pinch test

Stage I: Smooth skin when lying down or standing up; orange-peel effect only seen during pinch test

Stage II: Smooth skin when lying down; cellulite visible when standing up and positive for cottage cheese look

Stage III: Visible when lying down and standing up

Three subjects (12%) were determined to have stage I cellulite;

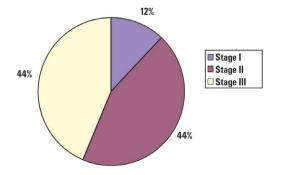
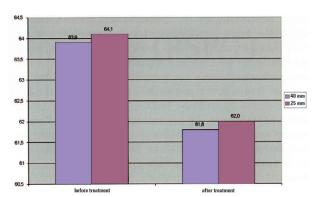


Fig. 2: Relative distribution of cellulite stages

there were 11 subjects (44%) each in stage II and stage III. The BMIs were between 20 and 31. The subjects' weight fluctuated from the start to end of treatment by no more than 1.3 kg. The subjects were told that they were not supposed to alter their lifestyles during the treatment period. The body fat test did not reveal any effect due to the treatment – for this parameter the value before and after treatment was constant, with a mean of 36%.

Treatment

On average 9.55 shock wave treatments were carried out. The frequency of the shock waves was between 10 and 16 Hz, the



treatments with an applicator head with a 40 mm diameter (blue) and an applicator head with a 25 mm diameter (red).

average energy level was III and an average of 2,646 shocks were administered per session.

Thigh circumference

To determine the thigh circumference for all of the subjects, a zone on the lateral thigh was defined as the centre of a straight line between the head of the femur and the lateral knee joint space. For the thighs that were treated with the 40 mm head (treatment groups 1 and 2), the thigh circumference could be reduced from an initial mean value of 63.9 cm (min. 51 cm, max. 73 cm) to 61.8 cm (min. 49 cm, max. 73 cm). For the thighs that were treated with the 25 mm head (treatment group 1), a reduction in the mean thigh circumference of 64.1 cm (min. 49 cm, max. 72 cm) to 62.0 cm (min. 48 cm, max. 72 cm) was achieved. For the subjects in group 3, who were treated with topical substances only, the thigh circumference at the defined site remained the same.

Ultrasound

The typical finding of hypoechoic areas in the subcutaneous tissue, known as 'fatty tissue hernias', was seen on the 20 MHz ultrasound for the subjects with stage 2 and stage 3 cellulite before the start of treatment. At the end of the treat ment the ultrasound image showed a reduction in the depth of these fatty tissue hernias and a reduction in the skin thickness on the left leg (-8%) and the right leg (-4.6%) for these individuals (Fig. 4). An increase in relative echogenicity was observed for the majority of the subjects. The thickness of the skin of subjects treated with topical substances only (group 3) stayed the same.

Surface measurements

Using the fringe projection method, the macro profile of the skin's surface was measured in the defined area on the lateral thigh while standing up for two subjects in each treatment

group. To do this, a system with 2 CCD cameras for detecting the projected fringe profile was used. The measured values were analysed using software specially modified by our measuring technology working group in MatLab (MathWorks Inc.). For the analysis we determined the value for the core roughness depth Rk, which indicates the mean roughness of the surface without taking into account the maximum (highest) and minimum (lowest) values. For both the shock wave treatment and the purely topical treatment a reduction in the core roughness depth was observed. This means that the skin surface was smoother in this area after being treated, regardless of the type of treatment (Fig. 5).

Changes to microcirculation

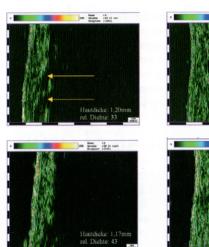
Changes to the microcirculation in the treated tissue were investigated using laser Doppler spectroscopy. For the subjects treated with shock waves (40 mm applicator head), the oxygen saturation (SO2) levels in the tissue increased immediately after the treatment. One hour after the treatment this effect could no longer be detected. Microcirculation (flow) dropped in most cases immediately after the treatment. An increase did not occur until after approximately 10 minutes' delay after the end of the treatment. This effect could also not be detected one hour after treatment.

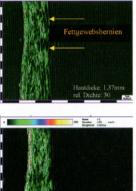
Side effects

Immediately following the shock wave therapy erythema was observed in the treated area. With all the treatment parameters the same, the erythema was more pronounced after treatment with the 40 mm applicator head and was observed for a longer period than with the 25 mm applicator head. The subjects' subjective perception was consistently described as positive. They described their skin as tauter and smoother, and the treatment as pleasant with a nice tingling feeling – a sign of the hyperaemic effect.

DISCUSSION

Cellulite is a skin change with a multifactorial aetiology. In addition to having connective tissue networks in the area of the





C: OS links nach 10 Behandlungen Therapiekopf Durchmesser 25 mm D: OS rechts nach 8 Behandlungen Therapiekopf Durchmesser 40 mm

Fig. 4: 20 MHz ultrasound of the left and right lateral thighs before treatment (A, B) and after 8 shock wave treatments (C, D). The arrows in A and B point to hypoechoic areas in the subcutaneous tissue, so-called fatty tissue hernias.

subcutaneous fatty tissue that are typical for women, according to the latest research hormonal factors, changes to microcirculation and the subsequent oedema and tissue hypoxia, as well as changes to the lipid metabolism [6] and inflammatory factors [7] are also thought to play a role.

While there are numerous topical and physical treatment methods available, there is little scientific evidence for their efficacy. The reason for this is that in many cases standardised, reproducible evaluation criteria are not used. Standardised photography and ultrasound imaging are currently considered the most important methods for quantifying cellulite [8]. Profilometry for depicting the topography of the skin's surface has been used for many years in cosmetology to establish the efficacy of wrinkle treatments [9].

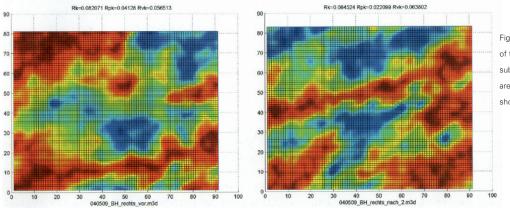


Fig. 5: Colour-coded illustration of the surface topography of a subject's thigh in the defined area A before and B after 8 shock wave treatments.