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Extracorporal Shockwave therapy in aesthetic medicine

Aesthetic treatment with radial shockwaves transmits intense mechanical shockwaves into the tissue. The new shockwave system Z WavePro from Zimmer MedizinSysteme GmbH, Neu-Ulm, Germany, makes it possible to provide effective treatments for weak connective tissue, to tighten skin, to treat cellulite, and several other applications. Several studies have shown that the treatment improves blood circulation through the tissue, makes the epidermis firmer and significantly stimulates the formation of new collagen.

Fig 1: ZWavePro.
How it works

The stimulating effect of low-energy, defocused extracorporeal shock waves on the biological processes within the tissues they penetrate has been the focus of much research in recent years. The biological effect of being penetrated by a shock wave is becoming better understood. There are reports of biological responses that lead to the release of various substances (measured immunohistochemically), such as VEGF (vascular endothelial growth factor), eNOS (endothelial nitric oxide synthase) and PCNA (proliferating cell nuclear antigen) (Siems et al. 2005; Wang et al. 2006); also lesions of the cytoskeleton (Moosavi-Nejad 2006), changes in the mitochondria, endoplasmic reticulum and the nuclear membrane. Shock waves also stimulate blood circulation in the area of application and the patient’s metabolism; they also have an enormous antibacterial effect.

Scientific studies have shown that unfocused low-energy shock waves have a positive influence on the collagen structure of the skin and the body’s connective tissues. They improve blood circulation and metabolism of the body’s fat cells. The intense mechanical massage effect leads to a reduction of oedemas (not for use in fresh, highly inflammatory conditions), and to an improved elimination of toxins. It also stimulates the formation of collagen fibres. The skin becomes more elastic and, after just a few sessions, its firmness is not only noticeable but also visible.

Indications and contraindications

Cellulite (stages I-III), general skin tightening and increasing the skin’s elasticity, as well as for the following indications:

- weakness of the muscles and connective tissue
- stretch marks (striae)
- follow-up treatment for Cryolipolyse™ for skin tightening and/or to reduce fat cells
- in combination with radio frequency for skin tightening
- skin tightening following injection lipolysis
- follow-up treatment after injection lipolysis to reduce fat cells
- in combination with ultrasound for skin tightening and/or to reduce fat cells
- in combination with non-invasive laser treatment to reduce fat tissue
- functional scar treatment
- supporting lymphatic drainage with special programs
- lipoedema
- follow-up to liposuction for skin tightening and/or to reduce fat cells

In the following cases, treatment with shock waves is not recommended: vascular disorders in or in the vicinity of the treatment area; local infections in the treatment area; application to areas with malignant or benign tumours; direct application to cartilage surfaces or the small facet joints of the spine; direct application over implanted electronic devices, such as pacemakers, patient-controlled analgesia, etc.; application in areas where mechanical energy in the form of vibrations might lead to tissue damage, such as metal plates used to repair broken bones. Generally, treatments are not recommended for bleeding disorders or for therapies that result in a change in blood coagulation; in pregnancy; neurological diseases with vasomotion disorders in the treatment area; over body cavities filled with air, such as the chest; in children, especially in area of the epiphyseal joints. Caution is recommended in patients with sensory disturbances, with strong autonomic system disorders, or in patients under the influence of drugs and/or alcohol, as high circulatory stresses and inadequate treatment responses cannot be excluded. Persons receiving treatments that might
decrease and/or alter blood coagulation, or cause extended coagulation time (such as with aspirin), should consult their therapist regarding a possible suspension of this treatment, since the application of radial shock waves in these patients can increase the incidence of, or possibility of, haemorrhages and haematomas.

Course of treatment

The scope and course of the treatment is discussed with the patient. The patient is in a recumbent position and a gel or oil is applied to the treatment zone in order to introduce the acoustic sound waves into the body without energy loss. Open the lymphatic system, for example on the thigh, by first stimulating the lymph nodes in the groin with a low HZ and shock rate, then start the actual Z Wave™ treatment for 2-3 minutes, always working towards the lymph nodes. Apply cellulite reduction following treatment.

A cellulite session lasts about 30 minutes on average and is usually painless. Depending on the degree of cellulite, 6-10 sessions with a week between sessions may be required. In conjunction with acoustic wave therapy, 30 minutes per day of active exercise, a low fat diet, and 2-3 litres of liquids daily are recommended for faster elimination of the toxins that have been released.

Shockwave therapy with the Z Wave™-System can be delegated to trained assistants. Thanks to innovative, time-optimized treatment methods, the required time is approximately 30 minutes per session. A special room for this therapy is not absolutely necessary, since the compact system is portable. The device allows individual treatment programmes to be set for each patient. The innovative technology allows a compact design with no need for a compressor. The clear and modern colour display showing all parameters relevant for treatment and the modern touch operation are highly intuitive. Various, adjustable frequencies allow applications customized to the current condition of the person to be treated.
Treatment results

Excellent and reliable therapeutic results can be achieved for all the above-mentioned indications. Here are just a few examples:

Follow-up to Cryolipolysis™
For this indication, the fat reduction doubles in the first 4 weeks. The excess skin resulting from fat reduction or weight loss can be tightened using ZWave Pro. With this method of ZWave Body Contouring, the treatment zone becomes softer in the transitional areas and a better outcome for the patient can be achieved at an earlier point. The treatment success is visible and tangible for the patient and can be achieved much faster than without the ZWave Pro application.

Follow-up to injection lipolysis
Here, the combined method has a clear advantage over the method without ZWave Pro. The sound waves help to distribute the injection agent evenly across the tissue; additionally, the shock-wave therapy accelerates fat loss. Using Body Contouring, the ZWave therapy provides smooth transitions in the treated areas; the resulting excess skin is very well tightened. The treatment success is achieved faster.

Cellulite
Good and reproducible therapeutic results can also be achieved when treating cellulite. The surface structure is improved significantly, the skin is tightened and the extent of cellulite is reduced. Analysis of dietary habits and physical activity is also important in the cellulite treatment. Prior to starting therapy, the patient expectations should be discussed in detail. The treatment success is greatly increased by patient’s cooperation (diet, exercise).

Conclusions for clinical practice

The ZWave Pro system is suitable for many indications and can be used with patients of any age. The skin regains its natural elasticity and tonicity. The therapy has a positive effect on the body shape and reduces the scope of the treated area.

Fig. 3a-b: Appearance before (left) and after (right) Combination therapy with liposuction and ZWave Pro.
Extracorporeal shock wave therapy in aesthetic medicine

Patient satisfaction is generally high. However, a medical briefing, addressing patient expectations is also important, as with all aesthetic and cosmetic treatments. For specific indications, as for a cellulite treatment, the active cooperation of the patient is essential. A particularly high level of patient satisfaction can be seen in the case of combined treatments, such as liposuction, injection lipolysis, Cryolipolyse™ etc.

The long-term outcome depends on the weight, connective tissue, etc. of the individual patient. For some indications, the treatment results remain permanently visible, for others the patient may need a treatment package with 4-6 post-treatments per year. To achieve excellent treatment results, follow-up treatment is generally recommended.

Literature

Extracorporeal shock wave therapy in aesthetic medicine


Cryolipolysis and Radial Pulse Therapy

Jeffrey A. Hunt, D.O., R.V.S., discusses the efficacy and results of combined CoolSculpting® and ZWave therapy

Background Objective Cryolipolysis treatments are normally performed for 60 minutes followed by a vigorous massage. It takes a few weeks for the adipocytes to break down and begin absorbing. For this reason there is a 2-month wait before a second treatment can be carried out. The objective of this study was to combine weekly radial pulse therapy (using the ZWave system by Zimmer) to see whether it was possible to speed the rate of fat absorption to allow shorter treatment intervals.

Study Design In a randomized controlled study, five female patients were assigned to group A with CoolSculpting® and initial massage immediately followed by ZWave and then four ZWave treatments weekly. Another five female patients were assigned to group B with CoolSculpting® and initial massage only. Weekly weights and ultrasound measured fat thickness were assessed at baseline and at 1, 2, 3, 4, and 8 weeks.

Results The average fat reduction in both groups A and B were calculated on a weekly basis for 4 weeks and then at 8 weeks. Group A with ZWave treatment had over twice the fat reduction during each week, from week 1 to week 4, when compared with group B. Over 75% of the fat reduction achieved at 8 weeks was realised at the week 4 visit. The fat reduction of group B was slower and much more gradual. Patients were not placed on a diet and the weights for both groups were relatively stable. Weight loss was 12 lbs for group A and 15 lbs for group B at week 4. At week 8, weight loss was -15 lbs for group A and -25 lbs for group B.

Conclusions 3-minute radial pulse wave treatments immediately after cryolipolysis and weekly for 3 more weeks results in twice the rate of fat absorption. This should allow monthly CoolSculpting® treatments and body contouring results in half the time. Whether additional fat was destroyed was not determined by this study owing to its 2-month follow-up.

Cryolipolysis is a non-invasive, non-surgical method for the reduction of localized fat deposits. It is based on the principle that the fat cell has a lower freezing point than the surrounding tissue, and the process of cryolipolysis is achieved by freeze-thaw cycles. The process is carried out using specific cooling and heating devices, which are applied to the skin for a certain period of time. The fat cells are then damaged and released, and the body's natural processes take over to remove the damaged cells. The treated area is numbed with a topical anesthetic cream and a protective gel pad is placed over the area to be treated. The cooling device is then applied to the skin for a period of time, typically 1 to 2 hours. The device then warms up and this cycle is repeated, usually for a total of 30 to 45 minutes. The process is painless and the area is left numb for 30 minutes after treatment. The treated area may feel numb, hard, and swollen for a few weeks after the treatment. The treated area may also feel markedly softer and looser as the treated area thins out. The fat layer thickness was determined by use of MyLab five ultrasounds with a gel standoff. The thickest area of fat in the centre of the treated area was measured on each side of the abdomen. The ultrasound trans were blinded as to the patient groups. After each measurement the patients were treatment only.

methods

Ten patients were randomly assigned to one of two groups: one for radial pulse wave treatments, and the other for vigorous massage during the first intervals over 4 weeks.

Methods

Ten patients were randomly assigned to one of two groups: one for radial pulse wave treatments, and the other for vigorous massage during the first

areas for 3 minutes immediately after cryolipolysis and at weekly intervals over 4 weeks.

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Methods

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either weighed, or weighed and given a 3-minute radial pulse wave treatment. The radial pulse wave system used was the ZWave by Zimmer and settings were at 16 Hz and 90 mJ for 2500 pulses, which takes approximately 3 minutes.

**Results**

As described in the literature, the CoolSculpting® treatments were well-tolerated by the 10 subjects. There was minimal discomfort from adding the acoustic wave treatments initially, as it was comparable to the vigorous massage. As shown in Tables 1 and 2 the fat thickness was recorded for each patient at baseline and at 1, 2, 3, 4 and 8 weeks. The average fat reduction percentage was then plotted on a graph showing superior fat reduction with the combination treatment. 77% of the 8-week fat reduction was achieved at the 4-week level in group A.

**Discussion**

This study was designed to see whether there was a way to speed up fat absorption and shorten the interval between CoolSculpting® treatments. The combination treatment group appeared to also have less post-procedure discomfort, which may be reflected by faster resolution of the damaged adipocytes, and perhaps less inflammation. The authors believe there are multiple advantages to weekly radial pulse wave treatments. Weighing the patients weekly seems to make them less likely to gain weight. The shortened interval gives quicker results and more patient satisfaction. The authors believe this will result in more treatments being performed.

When multiple areas and repeated treatments are done, it is possible to get the WOW results that patients desire. It would be interesting to evaluate post-procedural pain on a weekly basis to see whether there is a clinically significant difference between the two protocols, which the authors believe there is based on patient comments. It would also be of value to follow and measure the fat reduction at the 3-month level to see if the combo treatment percentage of fat reduction is higher. Whether more radial wave pulses per treatment would result in further benefit has not been assessed.

**Conclusions**

The use of weekly radial pulse treatments as an adjunct to cryolipolysis causes fat reduction at twice the normal rate for the first 4 weeks. This allows cryolipolysis treatments on a monthly schedule and body contouring results in half the time. More studies need to be performed to pool data and see whether more fat per treatment is eliminated by combining cryolipolysis and radial pulse wave therapy.

CoolSculpting is a registered Trademark of ZELTIQ Aesthetics, Inc.

**References**


TABLE 1 Group A with ZWave

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AVG % Fat Reduction

|          | 0%  | 4%  | 8%  | 14% | 17% | 22% |

**Table 2 Group B without ZWave**

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AVG % Fat Reduction

|          | 0%  | 0%  | 3%  | 4%  | 6%  | 12% |
San Diego Plastic Surgeon Offers New Non-Invasive Cellulite Treatment

Z Wave by Zimmer Aesthetics Now Available at Moradi M.D.

San Diego CA (PRWEB) July 09, 2013 -- Dr. Amir Moradi and the staff of Moradi M.D. has recently added the Zwave by Zimmer Aesthetics to the body contouring department of his San Diego Plastic Surgery Practice, Moradi M.D.

Zwave uses high energy radial shockwaves in the reduction and improvement of Grade 1-3 cellulite (mild to moderate dimpling). During the treatment these radial waves are applied to the affected area. The surrounding tissue is affected and breaks occur in the grid of the molecules. This leads to a collapse of the gas bubbles within the fat structures (cavitation) and destabilizes the fat structures.

“We have found that the radial waves used during the Zwave treatment not only reduce cellulite, it also improves the overall structure and appearance of the skin.” -- Amir Moradi, M.D.

Cellulite is the herniation of fat within fibrous connective tissue that manifests itself as skin dimpling and nodularity, usually on the buttocks, legs, and abdomen. This usually start in women after puberty and rarely occurs in men.

The causes of cellulite include a slow down in the metabolism, physiology, rapid weight loss, hormonal changes, and genetic factors. Hormones play a dominant role in the formation of cellulite. Estrogen may be the important hormone to initiate and aggravate cellulite. There is also a genetic element in individual susceptibility to cellulite.

Those undergoing Zwave have experienced promising results in problem areas. The favorable results achieved through this comfortable, non-invasive procedure is what makes it a desirable option in body treatments. The affordable cost is another aspect that has drawn many for Zwave consultation at Moradi M.D.

Treatments are quick, lasting 20-30 minutes. A treatment series of 10 treatments performed twice a week is recommended for optimal outcome.

“The body sculpting market has long awaited something as promising as Zwave to treat cellulite. It is not only a stand alone procedure, we are using it in conjunction with our other body sculpting procedures. Many patients are also finding it beneficial post Lipo.” -- Amir Moradi, M.D.
The body contouring staff at Moradi M.D. has recently began coupling Zwave with other proven treatment modalities, both surgical and non surgical. Liposuction, Coolsculpting, Velashape and Exilis ELITE. Patients are now offered Zwave along with their body sculpting and skin tightening procedures to enhance the overall result.

San Diego Plastic Surgeon Dr. Moradi and his team at Moradi M.D., offer a large array of cosmetic services including; facial plastic surgery, dermal fillers and wrinkle reducers, laser treatments, body contouring and fat reduction, and medical grade skin care services and products. The physician and staff of Moradi M.D. pride themselves with providing patients with the utmost professional and personalized care. They strive to show their customers how they can look their best through affordable cosmetic enhancement and skin rejuvenation.

Dr. Amir Moradi, the founder of Moradi M.D., board certified in Facial Plastics and Reconstructive Surgery.

Contact Information
Lita Doody
Moradi M.D.
http://www.moradimd.com
760-726-6451
Online Web 2.0 Version
You can read the online version of this press release here.
**ABSTRACT**

In this case study of a unique instance, the effects of non-invasive generated shockwaves onto the skin and the underlying fat tissue of a cellulite-afflicted, 52-year-old woman were investigated. The treatment was applied at the lateral thighs once per week for a period of 10 weeks. Diagnostic high-resolution ultrasound (Esaote 25 Gold® device with 15–18 MHz linear probe), thermography (Thermo-Cell) and photography (Canon® camera) were performed before and after treatment. Changes to the subcutaneous fat were demonstrated using ultrasonography and thermography.

**CELLULITE** is a common topographical alteration in which the skin acquires an orange-peel or mattress appearance. In this condition, alterations occur to the adipose tissue and microcirculation that result from blood and lymphatic disturbances causing fibrosclerosis of the connective tissue. It is considered a non-inflammatory, degenerative phenomenon that provokes alterations to the hypodermis producing irregular undulations on the skin overlying affected areas. Cellulite is certainly not a serious condition from the medical point of view, but it does represent the most widespread and least tolerated aesthetic complaint among women. The condition is well-known as a result of intense publicity campaigns in the mass media and cosmetics industry, targeted at increasing the market for cosmetic creams, electro-medical equipment, and therapeutic fantasies that often lack a scientific basis, although they do sometimes improve the aesthetic aspect of the problem. A few treatments supported by some evidence are available today, such as mechanical therapy with suction, bipolar radiofrequency, carboxytherapy, mesotherapy, and recommendation of exercise and weight-loss, for example. Shockwaves applied locally to the skin with cellulite may be an effective non-invasive therapy combined with any of the other treatments.

**High Energy Radial Shockwave Therapy (HERST)**

Shockwaves transmit mechanical energy from the place of generation to distant areas. They display a single, mainly positive pressure pulse of large amplitude that is followed by comparatively small tensile wave components. When using shockwaves for therapy, effects that make the pressure pulse even steeper as a result of non-linearities in the propagation medium, as well as phenomena such as refraction and diffraction at acoustic interfaces, must be taken into consideration. The fact that shockwaves selectively effect acoustical interfaces
(connecting two media, each with a different density, e.g. oil/water) and pass through homogenous elastic tissue without damage to the majority of the area is medically important. Unfocused extracorporeal shockwaves radially spread with an energy flow density per pulse smaller than 0.1 mJ/mm², which decrease the power by one third for every centimeter that penetrates into the tissue.

**Biological effects of HERST**

The stimulating effect of defocused extracorporeal-generated shockwaves on biological processes within the tissues reached has increasingly become the centre of interest over the last few years. The biological mechanism of action after a shockwave is still unknown to a large extent. Biological reactions of liberation of different agents (measured by immunohistochemistry) such as vascular endothelial growth factor (VEGF), endothelial nitric oxide synthase (eNOS), and proliferating cell nuclear antigen (PCNA) have been reported. On the subcellular level, the damages are the increase of permeability of the cell membrane, lesions of the cytoskeleton, and changes to the mitochondria, endoplasmatic reticulum, and nuclear membrane of the cell that may lead to apoptosis. Shockwaves are also effective as a means of increasing local blood circulation and metabolism, as well as having a high antibacterial effect.

**Pathophysiology of cellulite**

Nobody can deny that the term ‘cellulitis’ has been misused, because in medicine the suffix ‘itis’ refers to an inflammation or infection. Therefore, ‘cellulitis’ might refer to any inflammation of the cells involved. In cellulite, there is no inflammation or infection, but perhaps an alteration of interstitial tissues. There was a time when cellulite was thought to be a mere increase of fat in subcutaneous tissues associated with an altered lymphatic and venous flow, and lymphatic stasis. Furthermore, there was a deeply rooted notion that cellulite was closely related to the specific stasis subsequent to hypotonia or venous and lymphatic disease. It was therefore assumed that a previous varicose disease should exist for cellulite to appear. In fact, this is infrequently true. Most often, the interstitial...
Incipient cellulite, recognised by an orange peel appearance, represents focally enlarged fibro-sclerotic strands partitioning the hypodermis and limiting the out-pouching of fat lobules. In contrast, fully developed cellulite recognised by a dimpled skin surface represents subjugation of the hypertrophic response of the hypodermal connective tissue strands when the resistance is overcome by progressive fat accumulation (in subjects with high body mass indices) forming papillae adipose that protrude into the lower reticular dermis.

Materials and methods
A healthy woman, aged 52 years with Fitzpatrick skin type III and cellulite degree III agreed to have the skin at her right thigh treated with HERST over 10 sessions, and with no treatment at the contra-lateral thigh. The giving of informed consent was required to perform the treatment. The patient was asked to continue with her usual daily routine, without undergoing a specific exercise regimen. Changes in subcutaneous fat where evaluated using diagnostic high-resolution ultrasound (Esaote 25 Gold® device with 15-18 MHz linear probe) and liquid crystal contact thermography (LCCT) (Thermo-Cell).

Exclusion criteria related to health status included:

■ Disease of the skin
Thrombosis or post-thrombosis syndrome
Known melanoma or chemotherapy
Anti-coagulation therapy
Cortisone-therapy
Known metabolic disorder (e.g. diabetes mellitus, hypercholesterolaemia)
Inflammation within treatment area
Other simultaneous treatment of cellulite.

High-resolution ultrasound
The high-resolution ultrasound was carried out at the beginning and at the end of the study. It is an image-producing and non-invasive diagnostic tool, which is able to give an exact representation of the structure and quality of the subcutis, and therefore the result of cellulite therapy can be evaluated precisely.

Liquid crystal contact thermography
LCCT measures minor differences in skin temperature. In this study, LCCT was used to detect a change in micro-perfusion of the surrounding tissue treated with HERST.

Application technique and device parameters
The low-energy defocused HERST was produced by electromagnetic means with the ZWave® device (Figure 2), with the energy flow density per shot set at 0.02 mJ/mm². The treatment was applied to the right lateral thigh, once per week for a period of 10 weeks. Over a surface area of 120 cm² of skin, 3700 shots were applied homogeneously at 16 Hz and 120 mJ. The control area was the left thigh. At the end of the treatment period (equivalent to 37 000 shots), a questionnaire was completed with regard to tolerance (pain and side-effects) and the subjective outcomes of cellulite.

Results and discussion

Impact of HERST on remodelling subcutaneous fat
In addition to tightening the skin and improving its quality, an ideal therapy of cellulite should ensure a reduction to the subcutaneous fat. In one study, the hypothesis was stated that low-energy defocused HERST treatment (12 sessions) is effective in treating cellulite through the remodelling of subcutaneous adipose tissue. This effect can be corroborated by the subjective comments of the patient (in which improvement as a result of treatment may have a latent period of 2-6 months), as well as studying the superficial adipose tissue using high-frequency ultrasound (indirect signs of subcutaneous remodelling) and LCCT (indirect signs of increased perfusion). The present prospective design study (low-energy, HERST, 10 therapy sessions) supports this hypothesis.

A remodelling in the subcutis can be seen using high-resolution ultrasound. In the pre-treatment echography it is possible to see typical macro-nodules of cellulite degree III, in both the areolar and lamellar layers of the subcutaneous adipose tissue (Figure 3). The superficial fascia is unfolded and hyperechogenicity of the subcutis is shown. In the post-treatment echography, an improvement to the area (without nodules), increased homogenisation of the echogenicity and linear superficial fascia can be seen, all of which are typical of...
Shockwave Therapy to treat Cellulite

Before (left) and after (right) treatment with HERST therapy

Cellulite degree I (Figure 4). Hyperaemia was clearly visible with LCCT at the site of HERST treatment, starting immediately thereafter and lasting for a number of days. In the pretreated thigh, it is possible to see areas with a low perfusion (black in colour) typical of macro-nodular cellulite degree III. (Figure 5). In the post-treated thigh, it is possible to see areas with a low perfusion (black in colour) typical of well-perfused areas, all typical proof of cellulite degree I (Figure 6).

Conclusions
The encouraging results obtained in this study reveal that HERST is an interesting non-invasive therapy for cellulite, not only by strengthening the skin’s scaffolding fabric, but also by remodelling the subcutaneous fat tissue. Further studies should investigate whether parameters such as the patient’s age (adolescent, adult or elderly females), body composition (obesity), and the stage of cellulite have an influence on the outcomes of HERST.

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Combination of Shockwave Therapy with Cold and Heat in Cellulite Treatment

SHOCK WAVE THERAPY OF CELLULITE: COMPARISON BETWEEN THE COMBINATION PRE-COOLING VERSUS PREVIOUS TISSUE WARMING

KLAUS FRITZ1, 2, MELTEN-ÖNDER1, 3, GEORGE-SORIN TIPLICA2

SCHLÜSSELWÖRTER
Cellulite, Bodycontouring, radiale Stoßwellentherapie, ZWave, Diathermie, Micro 5, Cryo 6 Derma, Kaltlufttherapiegerät, Gewebsmodellierung.

ZUSAMMENFASSUNG
Ziel dieser Anwenderstudie war, die Wirkung einer radialen Stoßwellenbehandlung in Kombination mit einer Vorkühlung des Gewebes durch Kaltluft oder der Vorerwärmung des Gewebes durch Diathermie auf das Hautgewebe zu analysieren und diese Ergebnisse miteinander zu vergleichen.


KEY WORDS
Cellulite, body contouring, radial shock wave therapy, ZWave, diathermia, Micro 5, Cryo 6 derma, cool-air-therapy-device, tissue modelling

SUMMARY
Aim of this study was to evaluate the effect of radial shock wave treatment in combination with tissue a pre-cooling with cold air or a prewarming of tissue through diathermia and to analyse and compare the results on skin tissue.

Material and methods: 10 voluntary probands with cellulite grade I and III, classified after the NuernbergerMueller-Scale took part in this study. The results of the two combination therapies where compared 4 months upon completion of the study. Before classical treatment with radial shockwave therapy Zwave, one side of the treatable tissue area was treated with the Cryo 6 Derma skin cooling system and the other side with the Micro 5 Microwave Diathermy unit. The findings – before and 4 months after the last treatment – where fotodocumented, the circumferences of the thighs measured and the skin contour was assessed by the three doctors on the basis of a modified score, which is also used for assessment of wrinkles (Shoshani, Westerink).

Results: 4 months after the first treatment with radial shockwave therapy, the group treated before with diathermy, showed a far better improvement between the two combination therapies. Radial shockwave therapy itself, was effective in both compared treatments.

Conclusion and Discussion: Two different combined shockwave treatments where conducted and compared with each other: pre-cooling vs. pre-warming. The individual results of this study showed, that radial shockwave therapy is effective in the treatment of cellulite and the effectiveness can even be increased, if the tissue is pre-treated with diathermy.

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Combination of Shockwave Therapy with Cold and Heat in Cellulite Treatment

EINLEITUNG

Shock waves were introduced approximately 20 years ago to disintegrate kidney stones. This procedure subsequently has been used in orthopedics and traumatology to treat various insertional tendinopathies and delayed unions of fractures. (1,2) In recent years shock waves are used as a noninvasive treatment alternative for cellulitis (3). Cellulite is an aesthetically disturbing skin problem mainly on thighs and buttocks, that affects 85-98% post adolescent women showing an “orange peel” aspect characterized by a dimpled skin surface. (4,5). Cellulite is a disorder in which adipose tissue extends through the dermis, producing a dimpling in the affected areas. Nürnberger et al graded cellulite by inspection (6). Despite being just a cosmetic concern many affected patients have negative psychosocial emotions and look for treatments to improve their appearance. It has been demonstrated that shockwaves can have many biological effects, can caused the release of several mediators and increase the local circulation as well as the production of collagen (7,8). Although this treatment claims to be able to improve cellulite appearance, the long term improvement still has to be reviewed. Other technical approaches like cooling down the tissue as cryolipolysis or heating the tissue like in Radiofrequency or laser lipolysis also have shown improvements in cellulite and body contouring . So the objective of this pilot study was to evaluate if a combination of shock wave treatment with pre cooling or heating might further improve the results. And to compare both combinations.

METHOD

10 female volunteers aged 40 to 63 years (mean : 51 ) with cellulite level 1-3 were treated in the Dermatology and Laser Centrum in Landau Germany in 2011. Cellulite was classified according to the Nürnberger –Müller scale. Full verbal and written informed consent was obtained from the patients. Before and after treatment weight, circumference of upper legs and photographs were evaluated. For shockwave the device “enPuls” (Zimmer Medizin Systeme GmbH) was used. 2000 unfocused shock wave pulses of 12 Mpa pressure at a frequency of 10 Hz were applied 3 times a week, allowing a penetration depth of 0-35mm.

Pre treatment one side additionally was heated up with microwave using the Zimmer microwave device heating the skin up to 40 °C for 10 minutes positioned 10 cm over the skin (Figure 1) On the opposite site the skin was cooled for 10 minutes down to 20 C using the Cryo6 -level 2-3 before shock wave treatment. (figure2). The temperature was monitored with an infrared non contact thermometer.

The purpose of the preheating phase was to obtain a clinically effective temperature of 39–40°C. Photographs were taken at baseline, at the end of the treatment course. Circumference measurements of thighs were taken according to a standardized measurement method. Circumference was measured by the independent evaluators. Additionally, the investigators were asked to record and immediately report any adverse or unexpected effects .All of the patients underwent four treatment sessions at 3-week intervals. For a total of 12 sessions (3 months)

RESULTS

Both treatment approaches were very well tolerated without any side effect, few patients experienced mild pain due to the mechanical pressure of the shock waves. Immediate
Combination of Shockwave Therapy with Cold and Heat in Cellulite Treatment

Effects were an erythema in 36% of the participants. No patients experienced burns or skin injuries. At 3-month follow-up, participants in the first treatment group (heating group) received better scores (Figure 1, photo 1). The average reduction in thigh was 4.3 cm or – 7% with heating (61.4 to 57.3 cm) and of 2 cm or – 3.3% (61.4 to 59.4 cm) with cryo.

**DISCUSSION**

Cellulite represents an important social problem for women. The pathophysiology of cellulite involves changes in the subcutaneous adipose layer and the extracellular matrix. Cellular mechanisms of cellulite are not fully understood. However, it is accepted that changes include enhanced lipogenesis, decreased lipolysis, and increased lipid storage within the adipocytes as well as changes in the dermal architecture and a parallel formation of fibrous septae allowing the protrusion of adipose tissues tissue.

Shock waves are transmitted through the surface of the skin and spread radially into the tissue. Christ et al. used extracorporeal acoustic pulses in 59 female cases and showed the improved skin elasticity values. Ultrasound evaluation also confirmed increased density of collagen in the dermis and subcutis.

Kunzi Rapp and Fritz et al. used shockwave treatment in 25 cellulite patients and in their study with two different applicators (small 25 mm versus large 40 mm) were compared and the results were evaluated with 20 MHZ diagnostic ultrasound. They observed better results with the large applicator and recommended this treatment as promising in cellulite level 1-2. In their randomized shockwave trial, Knobloch et al. focused on the importance of daily gluteal strength training in females suffering from cellulite.

Radiofrequency (RF) appears to be more established and clinically proven. RF energy generates heat, which causes a controlled thermal dermal injury.

Nonablative skin resurfacing technologies share a common method of inducing thermal dermal injury while preserving epidermal integrity. Immediate heat-induced changes in collagen structure and long-term dermal collagen remodeling are believed to induce tissue tightening. Several reports have demonstrated the efficacy of RF treatments for middle and lower face laxity.

Cryolipolysis on the other hand has been shown to be effective in melting fat deposits and by a mild inflammation results in tightening. However, cryolipolysis applies cooling down to 3°C on skin surface for 45 min combined with a suction by vacuum, which is significantly more intense than the 10 minutes of cooling that we had used.

Heating by microwave achieves a similar effect like RF and remight result in similar tissue reaction as known from RF. Combination treatments of shockwave and microwave is a new noninvasive procedure for reducing subcutaneous fat volume and fibrous cellulite. When used on the skin and underlying fat, probable cause a remodeling of the collagen fibers, improving the orange peel appearance. The addition of heating to shock wave added value to the clinical outcomes. Although the method and devices are different from our study, cooling may have effects on body contouring, this is why we examined the pre- treatment with air cooling.

Cryolipolysis, on the other hand, is a noninvasive method used for the localized destruction of subcutaneous adipocytes. Ferraro et al. used the combination of shockwave and cryolipolysis and showed that the action of Ice-Shock Lipolysis is a safe, effective, and well-tolerated noninvasive procedure for body contouring. In particular, the authors believe that this could be an ideal alternative to liposuction for patients who require only small or moderate amounts of adipose tissue and cellulite removal or are not suitable candidates for surgical approaches to body contouring and they discussed the synergistic effects of cooling and shock waves.
This is a first study comparing heat and cold devices and combined with shock therapy.

In our study with pre-heating we obtained better results – 7% compared – 3.3%.

This new preliminary study supports the observation that the combination of heating can produce significantly better results than shock waves only in Cellulite 1-3 level. This treatment can be used as monotherapy and as well before and post liposuction procedures to obtain better results.

CORRESPONDENCE

Financial Disclosure:
Dr Fritz has received the devices by the company Zimmer to perform the treatments for the study. There was no funding of the study. Prof. Meltem Önder has not received any financial or other support.

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Figure: Evaluation of Reduction in Thigh Measurements with cooling(Cryo6) and Heating(Microwave)
RESULTS OF SHOCKWAVE THERAPY FOR BODY CONTOURING IN CELLULITE
COMPARISON OF LARGE VERSUS SMALL HEAD APPLICATORS

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Key words

Cellulite, Shockwave therapy, small / large applicator, Body Contouring

Abstracts

Background

Cellulite is a widespread problem for females. Shockwave therapy (SWT) is beneficial in terms of improved skin elasticity in published clinical data. The present study investigates the effects of shock waves on cellulite afflicted skin using two different size head applicators.

Methods

Cellulite classification were made according to Nürnberger-Müller scale, in 25 female subjects (Ages 25-50). Shockwave, with small head applicator (25 mm) and large head applicator (39 mm) were applied contra laterally and the results were compared. SWT was applied onto the skin at the lateral thigh 3 times a week for a period of 4 weeks. Frequency was 10 Hz / 16 Hz and number of pulses in area were 1500-2000. Before and after treatment; weight, circumference of upper legs, photographs were evaluated. 20 MHz diagnostic ultrasound was also used to be able to evaluate the treatment efficacy.

Results

Better results were obtained in reduction of circumference with 39 mm applicator. Diagnostic ultrasound with 20 MHz showed more homogenous tissue appearance and increase of tissue density with 39 mm applicator.

Discussion

The result of this study suggests that SWT is effective in treating cellulite through the remodeling of skin collagen. Large (39 mm) head applicator is more effective than small (25 mm) applicator. Shockwave therapy may effect by helping lymphatic drainage. It’s massage effect causes revascularition. SWT may become one of the noninvasive optimizing therapy for clinical management in females suffering cellulite.

Cellulite is aesthetically disturbing skin problem of thighs and buttocks that affects 85-98% post adolescent women. “Orange peel” aspect characterized by a dimpled skin surface. (1, 2, 3, 4) Cellulite is uncommon in men, the majority of affected men also suffer androgen deficiency, cirrhosis. (5) Cellulite also called as liposclerosis, panniculopathy and gynoid lipodystrophy. Nürnberger graded and formulated to evaluate of cellulite by inspection. (Table 1)

Surface of skin is smooth in normal healthy skin. The women skin is thinner than the skin of men. On the other hand, skin of women with cellulite, the septa of subcutaneous connective tissue is thin that results in formation of large fat cells chambers. The pathophysiology of cellulite related with the septa of the subcutaneous connective tissue. The fat cell chambers herniate into the surface and cause dimpling formation. In subjects with high body mass indexes have progressive fat accumulation.
Although, it is only a cosmetic concern, many affected patients have negative psycho social emotions and would like to have better appearance. There are various cosmetic procedures and devices to reduce unwanted local subcutaneous fat. Exercise and weight loss are important factors. Invasive methods are surgically lipectomy or liposuction. Semi-invasive methods include cellulipolysis; injection lipolysis; laser lipolysis and cryolipolysis. Non invasive body contouring methods compose of creams (caffeine, retinol); mesotherapy; mechanical massage; vacuum or pressure; bipolar radiofrequency (RF); infrared (IR) heat; ultrasound or shock waves. (3,4,6)

Shock wave therapy (SWT) is a local painless therapy method for cellulite. High energetic sound pressure waves are transmitted through the surface of the skin and spread radially into the tissue effecting a large and deep treatment area.

Unfocused low pressure acoustic waves are created by an electromagnetic projectile mechanism.

The electromagnetic energy creates a ballistic motion of the applicator. Shockwaves have been used in medicine in urology in renal stone treatment aiming to destroy the targeted areas. (7,8)

Shock waves are used in orthopedic patients with tennis elbow, calcaneal spur and golf arm. (9,10)

It can be also used for wound healing and ulcer treatments. (11,12,13)

It has been demonstrated that SWT has biological effects and are caused to release of several mediators and increase local circulation. (14,15) The accustic waves stimulate blood circulation as well as the production of collagen.

Increased concentrations of serum malandialdehyde and plasma proteins in cellulite patients are shown.

After SWT treatment, these serum concentrations decreased. SWT stimulates angiogenesis and promotes tissue revascularization. (15,16)

In our study we aimed to show the efficacy of SWT and compare the different head applicators in cellulite treatment. Effects of SWT on cellulite type were also investigated.

Methods
This study took place in Landau Dermatology and Laser Centrum in Germany in 2011.

25, non-pregnant female, of age between 20 and 50 years having cellulite parameters were selected to participate in the study. Cellulite classification was made according to Nürnberger-Müller scale. (1,2)

Each participants signed informed consent form. Before and after treatment; weight, circumference of upper legs, photographs were evaluated. 20 MHz diagnostic ultrasound was used to be able to evaluate and show the treatment effect.

We used “Z Wave” device. (Zimmer MedizinSysteme GmbH)

Two different applicator heads (small (25 mm) and large (39 mm)) were compared contralateral applications (Figure 1 a, b). Energy is chosen according to the sensitivity of patients (10 Hz-16 Hz). The ultrasound gel is used for transmission of the energy. Treatment was performed along the ways of lymphatic drainage (Figure 2). Number of pulses in area were between 1500-2000. The sessions were 3 times a week and 4 week period (Table 2).

Results
This treatment was very well tolerated without side effect and pain. There was only temporary erythema with 39 mm therapy head applicator in one case.

Circumference evaluation showed that with 39 mm applicator head had better results (Figure 3).

Clinical evaluation showed smoothening in threatening area with 39 mm applicator.

Tightening of skin were evaluated and cellulite scores were reduced (Figures 4a, 4b, 5a, 5b, 6a, 6b). Diagnostic 20 MHz ultrasound showed that after 12 session with 39 mm applicator of SWT, in increase in tissue density and there was more homogenous tissue appearance. (Figure 7, 8)

Discussion
Shockwaves are presented by a single, positive pressure pulse of large amplitude. High energy extra corporeal generated shockwaves is mechanical energy transformed by piezo effect. The pressure waves transmitted through the surface of the skin and spread radially into the tissue.
These waves were first used for kidney and urethral stone fragmentation (7, 8). This noninvasive method is also used for musculoskeletal diseases such as tennis elbow, golf arm, tendinopathia and pseudoarthritis (9,10). Chronic skin ulcers and burnings respond positively to shockwave therapy as well (11). Sparsa showed positive effects on ulcus curulis by increasing local blood circulation (13). Gerdesmeyer focused on may have a antimicrobial effects (17). Shockwaves are effective to increase local blood circulation and metabolism (Table 3).

The biologic action is reported as liberation of different agents such as vascular endothelial growth factors, endothelial nitric oxide synthahase or proliferating cell nuclear antigen. Angehrn questioned the shockwave treatment in treating cellulite by remodeling collagen within the skin. In subjects with high body mass indexes have progressive fat accumulation.

In vivo measurements in 21 female patients with lipedema and cellulite parameters were carried out before and after therapy including manual lymph drainage and compression as main shock wave therapy (SWT). The results of this study suggest that low energy of SWT is effective in treating cellulite through the remodeling skin collagen (18).

Oxidative stress parameters of blood serum and biomechanic skin properties/smoothening of dermis and hypodermis surface were evaluated in Siems study (16). SWT improved significantly the biomechanic skin properties leading to smoothening of dermis and hypodermis surface. It is concluded as a release of lipid peroxidation (LPO) products from edematous dermis is an important sclerosis-preventing effect of SWT (11). Christ used extracorporeal acoustic pulses in 59 female cases. Skin elasticity values gradually improved. This study confirmed the effects of acoustic wave therapy on biologic tissue, including stimulation of microcirculation. Ultrasound evaluation also confirmed density of collagen in the dermis and subcutis. In this study postmenopausal women between 40 and 65 years of ages were respond better. In this study is recommended a combination of healthier nutrition, sufficient intake of water, increase body activity (19). This therapy is a safe for body shaping. Kuhn investigated effects of shockwaves in cellulite affected 50 year old woman. From untreated contralateral area and from treated area skin samples were taken for histopathological evaluation. Any damage to the treated skin area in particular no mechanical destruction could be demonstrated. However induction of neocollagen and elastin was observed. The dermis thickness increased (20).

Similarly, in our study an increase of tissue density is seen with 20 MHz ultrasound evaluation after 12 session with 39 mm head applicator. There was also more homogenous tissue appearance as well. SWT treated cellulite case was evaluated with high frequency high resolution ultrasound in Kuhn study as well. It is noticed that increased collagen content after treatment. This result supports our study. In this study increased thickness of the dermis particularly collagen and elastin is confirmed by histologically. Amazing amount of neocollagen and neoelelasin supports the effects of shockwaves after 4 sessions.

Shockwave is a non invasive method. Christ evaluated skin appearance with photographs and ultrasound. No clinical side effects were observed except minimal pain in 3 of 59 patients. This pain was related 2 days before menstrual period. During these days the applied energy was reduced. None of our cases pain observed. During the therapy only slight redness of skin were seen.

The effectiveness of massaging device has been showed by Lucassen (21) the result lasted only 1.5 months. However in Christ study with pulse activation in cellulite, improvement of skin elasticity was evaluated after 6 months follow up and the result lasted 6.5 months. They recommended this treatment for more older age group especially with a long history of cellulite.

On the other hand in our study cellulite level 1 and 2 responded better. The treatment had no sufficient effect in cellulite level 3-4. Cutis laxa; adipositas and lymphodema need more sessions. Knobloch focused on their randomized shockwave trial importance of daily gluteal strength training in females suffering cellulite (22). Negatively affected microcirculation may result in intracellular oedema and reduced lymphatic drainage in cellulite cases. Adatto investigated the effects of acoustic wave and extracorporal pulse activation in controlled randomized study. Volume of depression and elevations and roughness parameters were evaluated with 3D images. At the 3 month follow up, while the treated legs maintained improvement, the untreated legs matched the improvement of treated legs, suggesting a systemic treatment effect. It is theorized that the acoustic wave stimulation may have resulted in improvement lymph drainage and microcirculation within the tissue (23).
Better lymphatic drainage resulted in less edema. Tissue tightening is related with increased tissue density. Initiation of new collagen causes more homogenous tissue appearance. Treatment should be performed along the ways of lymphatic drainage. Activation of lymph nodes before treatment might improve the drainage. The massage effect of device may stimulate fibroblast and initiate the lypolysis. Release of growth factors from tissue and increase of revascularization are the main effect (17, 23, 24).

Our study demonstrates that SWT is promising in cellulite level 1-2, persisting fat deposits. It may be combined with endermology and lypolysis. It can be used pre and post liposucction or laserlipolysis.

Acknowledgements

The author have no conflicts of interest to report. This study supported by Zimmer MedizinSysteme GmbH, Germany in terms of using their device for the study.

Table 1: Cellulite Grading (Nürnberg - Müller scale)

<table>
<thead>
<tr>
<th>Definition</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>No dimpling while standing and lying, pinch test reveals “folds and furrows”, no mattress-like appearance</td>
<td>0</td>
</tr>
<tr>
<td>No dimpling while standing or lying, pinch test reveals the mattress-like appearance</td>
<td>1</td>
</tr>
<tr>
<td>Dimpling spontaneously when standing</td>
<td>2</td>
</tr>
<tr>
<td>Dimpling spontaneously positive standing and lying down</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 2: Shock wave application adjustments

<table>
<thead>
<tr>
<th>Wave</th>
<th>unfocused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure</td>
<td>12 MPa</td>
</tr>
<tr>
<td>Rise time</td>
<td>1000 msec</td>
</tr>
<tr>
<td>Penetration depth</td>
<td>0-35 mm</td>
</tr>
<tr>
<td>No of pulses</td>
<td>2000/cm²</td>
</tr>
<tr>
<td>Frequency</td>
<td>10 Hz</td>
</tr>
<tr>
<td>No of sessions</td>
<td>3/weeks</td>
</tr>
<tr>
<td>No of treatment</td>
<td>12 sessions</td>
</tr>
<tr>
<td>Group1/2</td>
<td>25 mm / 39 mm applicator heads</td>
</tr>
</tbody>
</table>


Table 3: Possible Mechanism of Action of Shock Waves

<table>
<thead>
<tr>
<th>Shockwaves Effect</th>
<th>Decrease Cellulite Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical massage</td>
<td>Improvement in lymph circulation</td>
</tr>
<tr>
<td></td>
<td>Decrease in fat cells oedema</td>
</tr>
<tr>
<td></td>
<td>Increase in leakage of membrane</td>
</tr>
<tr>
<td>Increase local blood flow</td>
<td>Improvement of metabolism</td>
</tr>
<tr>
<td></td>
<td>Anti-oxidative effect</td>
</tr>
<tr>
<td></td>
<td>Less fibrosklerotic effect</td>
</tr>
<tr>
<td>Increased dermal connective tissue growth,</td>
<td>Firmer skin and less bulging</td>
</tr>
<tr>
<td>release of growth hormones</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1a, 1b: Shockwave device and application heads
Figure 2: Application Method

Figure 3: Reduction of Circumference with 39 mm and 25 mm head applicators

Comparison between 25 mm and 39 mm applicator head circumference before and after shock wave sessions

Study by Dr. Fritz, Germany
Results of Shockwave Therapy for Body Contouring in Cellulite

Figure 4a, 4b: Before and after Treatment

Figure 5a, 5b: Before and after Treatment

Figure 6a, 6b: Before and after Treatment

Figure 7, 8: 20 MHz Diagnostic
Results of Shockwave Therapy for Body Contouring in Cellulite

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Efficacy and safety of shockwaves combined with microwaves in the treatment against cellulite

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Abstract

The successful use of shockwave as Acoustic Wave Therapy (AWT) or EPAT (Extracorporeal Pulse Activating Therapy) in non-invasive treatment of cellulite is well documented. This study focused on efficacy and safety of shockwaves complemented with microwave radiation. Thighs of six women suffering from cellulite in stages II and III were treated 10 times within 4 weeks with ballistic generated shockwave (ZWave, Zimmer, Germany). Reverse sides of thighs were heated by microwave during AWT. Increase of echo density as well as improvement of collagen structure could be shown by Ultrasound documentation within the follow-up. Although efficacy of shockwave treatment is not significant enhanced by supplemented heating, an excellent subjective feeling is verified by all test subjects.

Keywords Cellulite, AWT, microwave, ZWave

Introduction

Orange peel skin affects 80 percent of women suffering from these unaesthetic dimples on their thighs, belly, buttocks and upper arms. The demand for effective but non-invasive methods against cellulite continuously increases. Cellulite can be treated more effectively since the causes for its development are understood. As the septa of women run almost perpendicular to the surface of the skin, enlarged fatty cells push upwards towards the skin surface, causing the feared typical orange peel appearance phenomenon known as cellulite. Consequences are metabolic changes occurring in microcirculation of blood and lymph (1-8). Extracorporeal shockwave lithotripsy (ESWL) has been successfully used since 1980 in medicine for the disintegration of kidney stones (9,10) and extracorporeal Shockwave Therapy (ESWT) for the treatment of orthopaedic conditions of tendon and muscle disorders since 1992 (11-13). There are various physical-technical processes and methods of generating acoustic wave: electrohydraulic (14), electromagnetic, piezoelectric (15) and ballistic principle. The living tissue cells respond to mechanical stimuli induced by acoustic waves with cellular processes like growth, cell migration and protein synthesis. Subsequent biochemical reactions as stimulation of metabolism, blood and lymph circulation as well as mobilizing of fat deposits have been shown to reduce fatty acid level (16-18). Moreover, orientation of collagen fibers is reorganized (19). The successful use of shockwave as Acoustic Wave Therapy (AWT) or EPAT (Extracorporeal Pulse Activating Therapy) in treatment of cellulite is well documented (20). The present study investigates the efficacy and safety of ballistically generated shockwaves (ZWave, Zimmer MedizinSysteme GmbH, Germany) in combination with microwave radiation for the treatment and reduction of cellulite.

Material and methods

Six females aged 25 – 55 with cellulite (stage 2-3, Nürnberger and Müller (4)) were treated with the shockwave system ZWave (Zimmer, Germany). Electromagnetically generated acoustic waves were applied with a maximal penetration depth of 35 millimeters. A contact gel as coupling medium ensured the complete energy transfer. Frequencies between 10 and 16 Hz were selected with a total of 2500 (+/-) impulses and energy level averaged between 1 and 2. Thighs of test subjects were treated for 4 weeks a total of ten times. Therapy was performed in accordance with the principles of manual lymph drainage. Right thighs of patients were attended additively with microwaves in the area requiring treatment. Warming of the tissue was achieved by microwaves (unpulsed, averaged 75 Watt) for 7 to 10 minutes. The following parameters were measured at baseline: age, weight [kg], size [cm], BMI [kg/m²], body fat by impedance analysis [%], degree of cellulite [second and third stadium], circumference of both thighs in specified areas left/right [cm], photographic documentation of treated areas, 20 MHz ultrasound measurement of the skin and documentation of volunteers subjective perception. During each treatment a range of different parameters were...
monitored: age, weight [kg], size [cm], BMI [kg/m²], body fat [%], circumference of both thighs in specified areas left/right [cm], and the documentation of probands subjective perception. In every fifth treatment photographic documentation of treated regions was carried out. After the last treatment measurement data of the following parameters were recorded: age, weight [kg], size [cm], BMI [kg/m²], body fat by impedance analysis [%], degree of cellulite [second and third stadium], circumference of both thighs in specified areas left/right [cm], photographic documentation of treated areas, 20 MHz ultrasound measurement of the skin, and documentation of volunteers subjective perception. During screening, patients completed also a questionnaire covering: demographics, medical background and potential contraindications to therapy. Satisfaction of test persons as well as clinical evaluation concerning the success of the treatment by the attending physician was requested by a structured questionnaire.

Development of temperature distribution in tissue caused by microwaves:

To a depth of one centimeter tissue is warmed up to 40°C in the focus of microwave radiation, corresponding to the thickness of the subcutaneous fat layer (Study Dr. Klaus Fritz, Landau: Stoßwelle). Temperature in underlying tissue reaches 33 °C, but at least 28°C at a depth of 30 millimeter.

Results

Defined areas in the thighs of six female patients diagnosed cellulite stage 2 (n=4) to 3 (n=2) were treated 10 times with shock waves. Tissue of one side was also heated with microwave radiation. Frequencies between 10 and 19 Hz were selected with an energy level of II to III and 2500 to 4500 shocks. Pulsed microwaves intensity of 75 Watt was applied for 7 to 10 minutes with a distance of 10 centimeter to the skin.

Circumference of the thigh, body fat, BMI

In defined areas of lateral thighs treatment with additional microwave higher circumference reduction (0.16 percent) was attained (fig. 1; table 1, not significant). Changes in levels of body fat (averaged 4.25 %) varied individual in follow up independently from stage of cellulite (fig. 2). No significant changes in BMI (fig. 3) or body weight (fig. 4) were monitored.

Photographical and ultrasound documentation

Relief in defined areas has slightly improved by shock wave treatment both with respectively without heating of tissue at the end of treatment series (fig. 5). At the end of treatment period increased echo density and improved structure of collagen could be shown for shockwaves combined with microwave by ultrasound imaging during course of treatment (fig. 6, 7). However, for all test subjects ultrasonic measurements demonstrably confirmed the increase of echo density as well as the improvement of collagen structure in the presence of tissue heating in the treated area. Average reduction of circumference of 1.68 percent could be obtained without significant differences comparing both procedures (shock waves combined with microwaves: 1.84 percent).

Side effects

During treatment subjective perception of the participants were characterized as positive. No side effects were observed. Heating of treated tissue was perceived mainly as more pleasant. Following the therapy, subjective impressions of skin were smoother and former in areas treated with microwaves.

Subjective perception

This pilot study shows that the treatment has no side effects and is well tolerated by the patients. Subjective perception perceived from patients as more pleasant in the warmed side of thighs. Also skin was described smoother and former already directly after the treatment combined with microwave. The beneficial effect is felt short-term and could not be verified by photographic documentation during the course of treatment.
Efficacy and Safety of Shockwaves combined with microwaves in the treatment against cellulite

Discussion

The study’s findings show that combination of AWT with microwave is just as efficient treating cellulite as shock wave alone as other studies shown recently. Subjective impressions are more pleasant for shock waves applied in warmed tissue. In contrast to recently described findings, no side effects were determined (21, 22). Ultrasound measurement as a safe, sensitive and accurate method (23, 24) demonstrates significantly increased elasticity of the connective tissue and improves the tightening of the skin. Application of shock waves activates blood circulation, metabolism, neovascularization and production of collagen (25). Lymph draining is accelerated by improved metabolism and circulation. Regardless of the type generating the shock waves similar effects were demonstrated already in several studies. Shock waves generated by linear arranged piezoelectric crystals are focused into tissue by a curved handpiece. By the use of different silicone cones, energy of sound waves can be delivered to a depth of approximately 50 mm below the surface of the tissue (Richard Wolf GmbH, Knittlingen, Germany). Another option to generate shock waves is the principle used in pneumatic hammer: A projectile in the handpiece accelerates a pneumatic pulse to a very high speed for transmission into the area to be treated (26; Storz Medical AG, Tägerwil, Switzerland). In addition to increased elasticity of tissue and the reduction of cellulite, the reduction of circumference can be achieved by AWT (2 cm). All these techniques generating shockwaves are already being used successfully, but also have limitations. The more dimples are present, the more capacity of appliances are recommended to achieve sufficient significant results due to micro-traumas. The combination of shock wave therapy with further applications as heating, cryolipolysis (27), massage (28), infrared, vibration, radiofrequency or vacuum provide opportunities to overcome the limiting factor of AWT.

Conclusion

This pilot study of the shock wave combined with simultaneous heating of the area against cellulite shows that the treatment has no side effects and is well tolerated by the patients. Subjective perception perceived from patients as more pleasant in the warmed side of thighs. Also skin was described smoother and former already directly after the treatment combined with microwave. The beneficial effect is felt short-term and could not be verified by photographic documentation during the course of treatment. For all test subjects ultrasonic measurements demonstrably confirmed however the increase of echo density as well as the improvement of structure of collagen in the presence of tissue heating in the treated area. Average reduction of circumference of 1.68 percent could be obtained without significant differences comparing both procedures (shock waves combined with microwaves: 1.84 percent). Further investigations should be continued based on reproducible, defined and standardized high quality evaluation criteria from the outset like determination of skin thickness, monitoring of ultrasonic density and profilometry. These data will provide statistically significant information about the influence of tissue warming on the success of shock wave therapy against cellulite.

References

17. Delius M, Uebelhe F, Guo L. Anwendung von Stoßwellen für den Transfer von Molekülen in Zellen; Biomedizinische Technik; Band 47 (Teil 1); 2002:382-385.
Legends of Figures and Tables

Figure 1: Reduction of circumference at the end of 10 treatment series with shock waves in percent (+/- microwaves; without microwaves: blue, with microwaves: red)

Figure 2: Changes of body fat (mean values in percent) in course of treatment period

Figure 3: Difference of BMI (in percent) from beginning to end of treatment series

Figure 4: Difference of weight (in percent) from beginning to end of treatment series

Figure 5a: Photo documentation: HA; first treatment session (shockwave: left thigh, shockwave + microwave: right thigh)

Figure 5b: Photo documentation: HA; fifth treatment session (shockwave: left thigh, shockwave + microwave: right thigh)

Figure 5c: Photo documentation: HA; tenth treatment session (shockwave: left thigh, shockwave + microwave: right thigh)

Figure 6a: Ultrasound documentation DermaScan 20 MHz: RK, before treatment series

Figure 6b: Ultrasound documentation DermaScan 20 MHz: RK, at the end of treatment series; improvement of tissue structure, well-defined and smooth border with the subcutis, visible reduction of cellulite

Figure 7a: Ultrasound documentation DermaScan 20 MHz: HA, before treatment series

Figure 7b: Ultrasound documentation DermaScan 20 MHz: HA, at the end of treatment series; improvement of tissue structure, well-defined and smooth border with the subcutis, visible reduction of cellulite

Table 1: Average reduction of circumference [%] in AWT-treated areas of thighs at the end of 10 treatment series with/without additional microwave heating.
Figures and Tables

Figure 1

Figure 2

Figure 3
Efficacy and Safety of Shockwaves combined with microwaves in the treatment against cellulite

Figure 3

Fig. 5a-c

Fig. 6a + b

Fig. 7a + b
<table>
<thead>
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<th>Reduction circumference [%]</th>
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<th>RSWT + MW</th>
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<td>ES</td>
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<tr>
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<td>HA</td>
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<td>Han</td>
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<td>0</td>
</tr>
<tr>
<td><strong>Mean value</strong></td>
<td><strong>-1,68</strong></td>
<td><strong>-1,84</strong></td>
</tr>
</tbody>
</table>

Table 1
**Kasuistik**

**Stoßwellentherapie bei Cellulite**

**Nebenwirkungsfrei und angenehm schmerzarm**

Dr. med. Markus Steinert, Biberach a.d. Riß, erläutert die Verwendung von Stoßwellen zur Therapie der Cellulite. Dabei zeigt sich, dass der Einsatz von Stoßwellen den Oberschenkelliumfang deutlich reduziert und die Haut straffer und glatter wird.


**In Stufe II und III schmerzfreie Therapie**

Die Stoßwelle kann in vier verschiedene Energietupfen abgegeben werden; hier wurden die Stufen II bis ins Bein bewegungsempfindlich empfinden, sodass die Therapie schmerzfrei durchgeführt werden konnte. Als Richtwert galten pro Behandlungssitzung 2.500 bis 4.000 abgegebene Stöße. Die Behandlung sollte immer in Richtung der Lymphablöschung erfolgen. Dabei kann der Druck auf das Hautstück erhöht werden, wenn in Richtung der Lymphknoten behandelt wird. Zu zusätzlichen topischen Therapien wurde während der Studienzeit von einer Probandin nach der Therapie bestimmt, Stadium II bei einer Probandin (6 Prozent) bestimmt, Stadium III bei zehn Probandinnen (39 Prozent) und Stadium II bei zehn Probandinnen (35 Prozent).

Die Stoßwellentherapie erfolgte nun zweizeitig: einmal täglich ein Anti-Cellulite- Gel unter dem mittleren Gewicht von 73,9 kg reduziert. Das Körpergewicht betrug im Mittel 64,1 cm (Minimum 49 cm, Maximum 73 cm) erzielt werden. Bei der rechten Körperseite, die mit dem 25-mm-Kopf behandelt wurde, konnte der Oberschenkelumfang von anfangs mittleren 63,9 cm (Minimum 51 cm, Maximum 73 cm) auf 63,2 cm (Minimum 49 cm, Maximum 73 cm) reduziert werden. Bei der rechten Körperseite, die mit dem 25-mm-Kopf behandelt wurde, konnte die Neovaskularisation der Vitale Zone am lateralen Oberschenkel auch die Mitte einer Geraden zwischen Femurkopf und lateralem Kniegelenktipus definiert. Bei der linken Körperseite, die mit dem 40-mm-Kopf behandelt wurde, konnte die Neovaskularisation der Vitale Zone am lateralen Oberschenkel umfangs von anfangs mittleren 63,9 cm (Minimum 51 cm, Maximum 73 cm) auf 63,2 cm (Minimum 49 cm, Maximum 73 cm) erzielt werden.

**Empfinden der Probanden bestimmt Auswahl der Frequenz**


Bei der linken Körperseite, die mit dem 40-mm-Kopf behandelt wurde, konnte die Neovaskularisation der Vitale Zone am lateralen Oberschenkel umfangs von anfangs mittleren 63,9 cm (Minimum 51 cm, Maximum 73 cm) auf 63,2 cm (Minimum 49 cm, Maximum 73 cm) reduziert werden. Bei der rechten Körperseite, die mit dem 25-mm-Kopf behandelt wurde, konnte die Neovaskularisation der Vitale Zone am lateralen Oberschenkel umfangs von anfangs mittleren 63,9 cm (Minimum 51 cm, Maximum 73 cm) auf 63,2 cm (Minimum 49 cm, Maximum 73 cm) reduziert werden. Bei der linken Körperseite, die mit dem 40-mm-Kopf behandelt wurde, konnte die Neovaskularisation der Vitale Zone am lateralen Oberschenkel umfangs von anfangs mittleren 63,9 cm (Minimum 51 cm, Maximum 73 cm) auf 63,2 cm (Minimum 49 cm, Maximum 73 cm) reduziert werden. Bei der rechten Körperseite, die mit dem 25-mm-Kopf behandelt wurde, konnte die Neovaskularisation der Vitale Zone am lateralen Oberschenkel umfangs von anfangs mittleren 63,9 cm (Minimum 51 cm, Maximum 73 cm) auf 63,2 cm (Minimum 49 cm, Maximum 73 cm) erzielt werden.

**Subjektives Empfinden durchweg positiv**

KEY WORDS: Cellulite, cottage-cheese skin, shock wave therapy

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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Radial Shock Wave Therapy (RSWT) for Cellulite

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-Ulm, 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 Nürberger 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 (O2C, 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; 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 average energy level was III and an average of 2,648 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 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].
"Extracorporeal shock wave bodycontouring comparison of 25 mm versus 40 mm application head"

**Introduction**
The application of shock wave therapy in humans has been primarily to disintegrate kidney stones, induce neovascularization to promote tissue regeneration, and dissolve calcified tendonitis and lateral epicondylitis. There are no studies available yet describing the efficiency of shock waves for cellulite treatment. We treated patients with cellulite and uneven contours of the upper legs in order to find out if shock wave treatments allow to improve body contours.

**Materials and methods**
A total of 10 female patients with cellulite stage 1 to 3 and connective tissue weakness were treated for 10 sessions within 3 weeks on the outer and inner thigh areas and the gluteal region in a split body study starting with 1500 – 2000 pulses/treatment area in Cellulite grade 1, 2500 pulses in grade 2 and 3000 pulses in grade 3 using a 25 mm applicator on the right side and a 40 mm applicator on the left side with a shock wave device manufactured by Zimmer (Germany).

**Results**
The reduction in circumference on the 25 mm head (right side) was 0 -1 cm at the end of the 8 sessions, the reduction on the 40 mm applicator side was 2.5 cm in average. The contours were significantly more smoothened with the larger 40 mm hand piece than with the 25 mm, cellulite and firmness improved in pinch tests.

**Discussion**
The mechanism behind this effect is not yet fully understood. It has been shown that shock waves stimulate the early expression of angiogenesis-related growth factors, including endothelial nitric oxide synthase (eNOS), vascular endothelial growth factor (VEGF), and proliferating cell nuclear antigen (PCNA), contributing to induced vascularization and improving blood supply, with increased cell proliferation and tissue regeneration and repair.
Shockwave treatment for cellulite
Shockwave treatment for cellulite

The search for an appropriate treatment for cellulite has been going on for decades. This paper presents the use of shock waves in cellulite therapy. Results show that the use of shock waves distinctly reduces thigh circumference and renders the skin firmer and smoother.
**Introduction**

In cellulite, weak connective tissue fibres cause bulging of the septa of the subcutaneous adipose tissue – primarily in the thighs, upper arms, hips, buttocks, and abdomen. This causes dimpling of the skin surface. Cellulite is found almost exclusively in women since men have a different connective tissue structure in adipose tissue. In overweight persons and/or those with weak connective tissue, cellulite can already manifest in young adulthood; with increasing age, varying degrees of cellulite are found in 80 to 90 percent of women.

Radial shock wave therapy (RSWT) is a new treatment method. Radial shock waves are high-energy acoustic waves that are pneumatically generated outside of the body. They are applied to human tissue via the skin surface near the affected area, and they then spread radially (spherically. This radial spreading makes the treatment feel particularly comfortable. After treatment, the tissue around the affected area reacts to the shock wave with increased metabolic activity. The epidermis becomes tighter as a result. In addition, the acoustic waves stimulate circulation, neovascularisation, and the production of collagen. The improved metabolism and circulation speed the drainage of lymphatic fluid.

**Method**

The Z-Wave shock wave therapy system (Zimmer MedizinSysteme GmbH, Neu-Ulm, Germany) was used for shock wave treatment. The same system is used in physical therapy and orthopaedics under the name enPuls.

Two applicator heads, a large one (40 mm diameter) and a small one (25 mm diameter), were available for therapy. The left side of the body was always treated with the large head and the right side with the small head.

Ultrasound gel (Sono Plus) was used as a coupling medium to ensure complete energy transmission. To avoid soiling of the handpiece, a protective silicone cap was applied to the applicator head.

Different frequencies were available: The recommended frequencies were 10 Hz and 16 Hz, and their selection was determined by the sensation that each patient reported.

The shock wave can be emitted at four different energy levels – levels II and III were recommended here for pain-free therapy.

For each treatment session, 2500 to 4000 shocks were recommended.
The treatment should always be applied in the direction of lymph flow. The pressure on the handpiece could be increased when moving in the direction of lymph nodes. As an additional topical treatment, an anti-cellulite gel (Beaute Pacifique, Denmark) was applied once daily throughout the study period.

Results were supplemented with photo and ultrasound documentation. If the final examination results of a particular volunteer were missing, we used the "last observation carried forward" (LOCF) method, in which the last value available for that patient was used in the final analysis.

Results

Eighteen women with cellulite in stages I, II, and III volunteered for this study.

The stages were identified by evaluating the skin surface relief on the buttocks and thighs using the following system:

Stage 0
Smooth skin, no mattress phenomenon, and no orange peel effect in the pinch test.

Stage I:
Smooth skin when lying and standing; orange peel effect only triggered by so-called pinch test.

Stage II:
Smooth skin when lying; cellulite exhibited when standing and positive mattress phenomenon.

Stage III:
Cellulite exhibited when lying and standing

Stage I was identified in one patient (6%), stage II in 7 patients (39%), and stage III in 10 patients (55%).

Shock wave therapy was performed 2-3 times per week, with a total of 10 treatments administered in a period of 4 weeks. The patients were asked not to change their usual lifestyle during the treatment period.

The patients' average body weight was 74.1 kg at the start of therapy and dropped to an average weight of 73.9 kg in the course of treatment.

Body fat measurements showed no effect of the treatment – their value stayed unchanged at 36% before and after treatment.
For the thigh circumference measurement, a zone at the lateral thigh was defined in all patients; this zone was in the centre of a straight line between the femoral head and the lateral knee joint line.

On the left side of the body, which was treated with the 40 mm head, the thigh circumference was reduced from an initial average of 63.9 cm (minimum 51 cm, maximum 73 cm) to 63.2 cm (minimum 49 cm, maximum 73 cm).

On the right side, which was treated with the 25 mm head, the average thigh circumference was reduced from 64.1 cm (minimum 49 cm, maximum 72 cm) to 63.4 cm (minimum 48 cm, maximum 72 cm).

When the data of the patients with stage II or III cellulite were analyzed, the reduction of thigh circumference was somewhat greater for stage III than for stage II.

The patients consistently reported a positive subjective experience. They reported firmer and smoother skin, and the therapy was experienced as pleasant with an agreeable tingling sensation, which is suggestive of a hyperaemic effect.

From the physician’s perspective, deeper dimples were still present, but the skin appeared much firmer.

**Discussion**

Initial investigations have shown that thigh circumference can be significantly reduced by shock wave therapy in patients with cellulite. The appearance of cellulite can be noticeably improved as well. In patients with stage III cellulite, slightly more changes can be expected than in those with milder forms of cellulite. No difference in effect was shown for the different applicator heads.

The patients subjectively experienced the skin as firmer and smoother. Deep dimples are unlikely to completely disappear.

In summary, shock wave therapy offers a new form of cellulite treatment that is free of side effects and very well accepted by patients.