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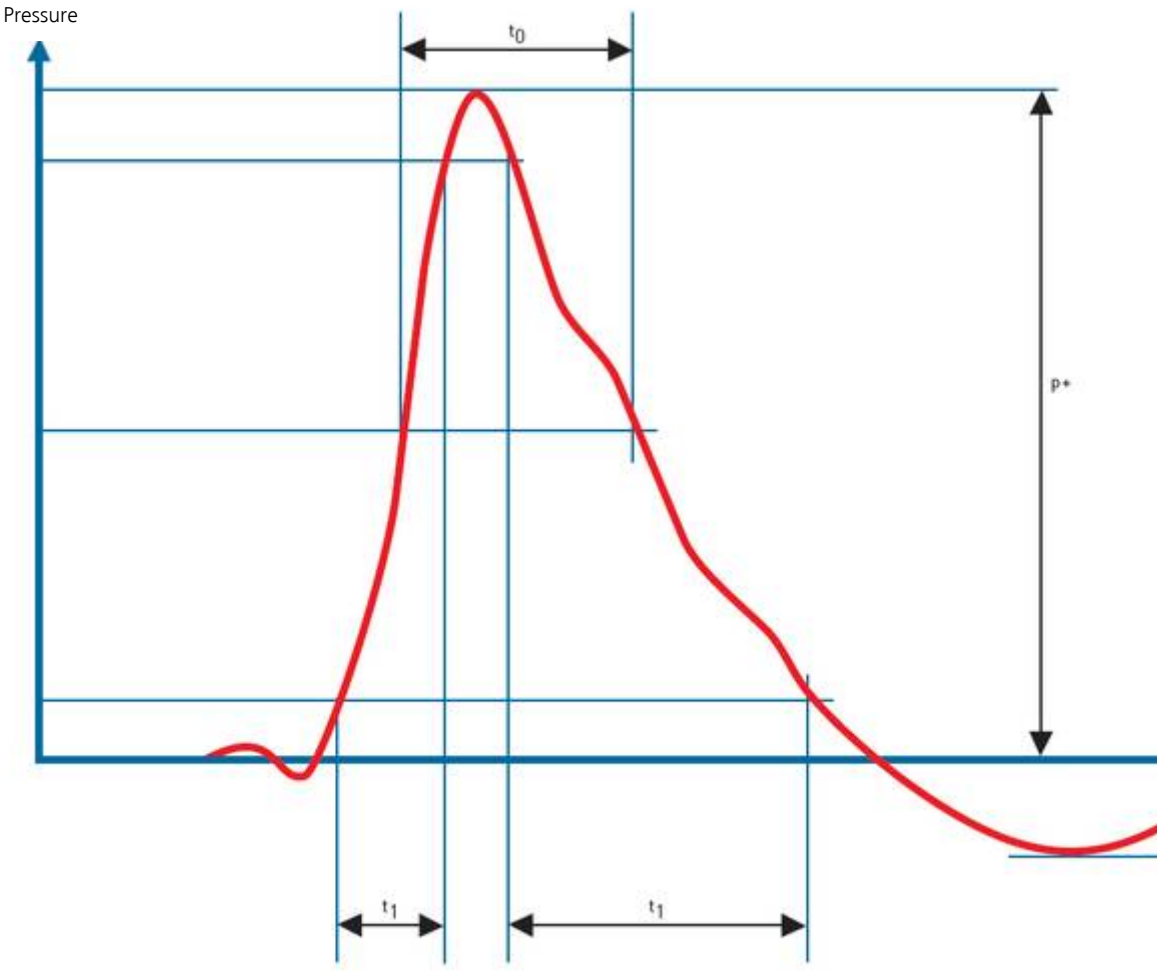

# Effects of Shock Wave Therapy on pathological changes in subcutaneous adipose tissue. A pilot study

Introduction Cellulite, which occurs in all women in Western countries, describes typical changes in the subcutaneous tissue, primarily in the thighs and gluteal region. By compressing the skin with the so-called "pinch" test, the diagnosis of "cellulite" can be tentatively classified: If "orange peel" skin is seen, this is physiological and can be treated as a normal cosmetic problem. If substantially more serious changes to the surface of the skin are seen, often called the "mattress phenomenon", this should be considered a pathological change in the adipose tissue (2). (Figure 1)

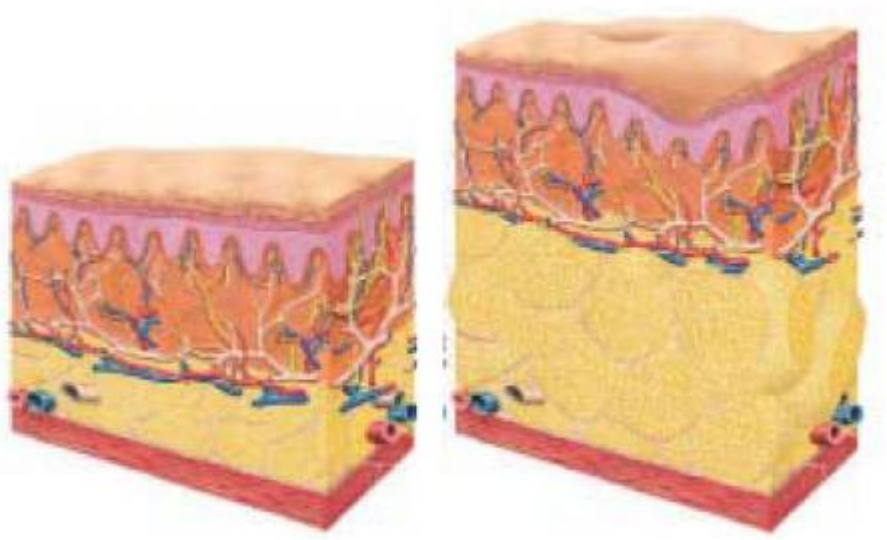

*Figure 1*

1) Normal skin and subcutis: epidermis, cristae cutis, epidermal papillae, superficial dermis, arterial and venous loops of the subpapillary plexus, lower corium layer, adipose tissue.

b) Cellulite stage IV: Epidermal indentations due to retraction of sclerotic connective tissue bundles in the dermis. The adipose cells have combined to form macronodules that can be palpated as "nodes".

Regardless of the stage of diagnosis, cellulite involves significant cosmetic and psychological components. Many affected women suffer from the appearance of their legs and the accompanying reduction in quality of life.
The wide variety of cosmetic body care products to treat this "condition" have not delivered on promises of long-term success (10). Device-based cosmetic methods for firming the skin and muscles can currently be divided into four areas: Mechanical systems, such as sub-pressure massage, micromassage; DC and AC electrical systems, such as iontophoresis; thermal treatments, such as heat/cold devices or infrared devices; and the increasingly popular light treatment with a soft laser (11). The acute mechanism of these methods always involves an increase in skin circulation with metabolic activation, leading to a fresher skin appearance. However, use of device-based cosmetic methods only leads to long-term success if the patient follows general lifestyle concepts including a healthy diet, sufficient physical activity and a positive attitude (11).

**Objective of the pilot study** Shock Wave Therapy represents a new therapeutic method for treating the type of tissue described above. The effects of acoustic waves on the microcirculation of female subcutaneous adipose tissue, particularly the stimulation of blood and lymph circulation, were investigated for the first time. It is assumed that a relationship exists between blood and lymph circulation and the structure of adipose tissue. Slow circulation leads to lipid biosynthesis, while rapid circulation leads to lipolysis (2). Adipose tissue is highly-vascularised, with one capillary per adipocyte. In view of the fact that shock waves with high pressure amplitudes increase membrane permeability (12, 13), we postulated that the exchange of blood lipids would be stimulated.
The biomechanical effects of shock waves can lead to adiabatic deformations at the acoustic bordering surfaces of tissue (14), which could lead to strengthening of connective tissue and a more balanced skin surface for the indication in question.

**Introduction to shock wave physics** Shock waves are acoustic waves that are characterized by high pressure amplitudes in comparison with surrounding pressure (9, 15, 16). Medical shock waves are created outside of the body and applied to targeted points within the body without injuring the body's surface. In the beginning, shock waves were primarily a focus of interest due to their successful use in disintegrating kidney stones. Due to their exceptional success in the field of kidney stone therapy, shock waves were later used to resolve calcifications in the shoulder or tendon insertions (9). This revealed a new mechanism of shock waves: the initiation of healing processes due to improved metabolism and increased circulation (17, 18, 19). (Figure 2).

Modern impulse wave sources create electromagnetic shock waves outside the body, use a water pillow as a transmission medium and are applied to biological tissue using gel. The shock waves radiate outward in accordance with the laws of acoustics/optics. If acoustic properties such as density or wave speed change at bordering surfaces, the outward radiation of the waves also changes. Shock waves are transmitted, reflected, refracted and scattered.

The characteristics of shock waves differ from those of ultrasound. Ultrasound places a high-frequency alternating load on tissue in the frequency range of several megahertz that leads to heating and tissue damage at high amplitudes (9, 17, 18, 19).
The effects of shock waves are partially due to the forward direction of their force effects, with impulse transmission at bordering surfaces. Among other things, this causes biomechanical effects such as contraction of lymphatic vessels.

**Materials and methodology** The DermaSelect shock wave device manufactured by Storz Medical AG (Tägerwilen, Switzerland) was used. A modified form of the device is also in use for orthopaedic indications including calcaneal tendinosis, lateral and medial humeral epicondylitis, heel spurs or pseudoarthroses.
For use in dermatology, the therapy head was built in a variable form to allow the focus point to be in a water pillow, resulting in a divergent shock wave front that can be applied to the therapy zone in a way that is gentle on skin. The energy can be adjusted among 20 levels based on the subjective pain felt by patients.

The pilot study began in June 2003 on the left leg of study participants and ended on September 5, 2003. The study was then continued on November 1, 2004, and ended on March 30, 2005. The pilot study was created as a side-to-side comparison: The participants were asked to note and document any individual

differences between their treated and untreated legs. The number of participants was set at 20. The duration of treatment lasted a total of three weeks and two shock wave sessions were performed each week.
To determine therapeutic success, digital photographs were made at the first and last shock wave session for a before/after comparison.
Volume and circumference measurements were performed with a perometer. The measurement system consists of a light frame that can scan the entire leg without physical contact, recording both the circumference and volumetric data. This system was previously used primarily for compression hose measurements and is now being increasingly used by lymph specialists for monitoring the clinical course of complex physical drainage therapy. The weight of the participants was also measured and their personal life situations were recorded at the first consultation.

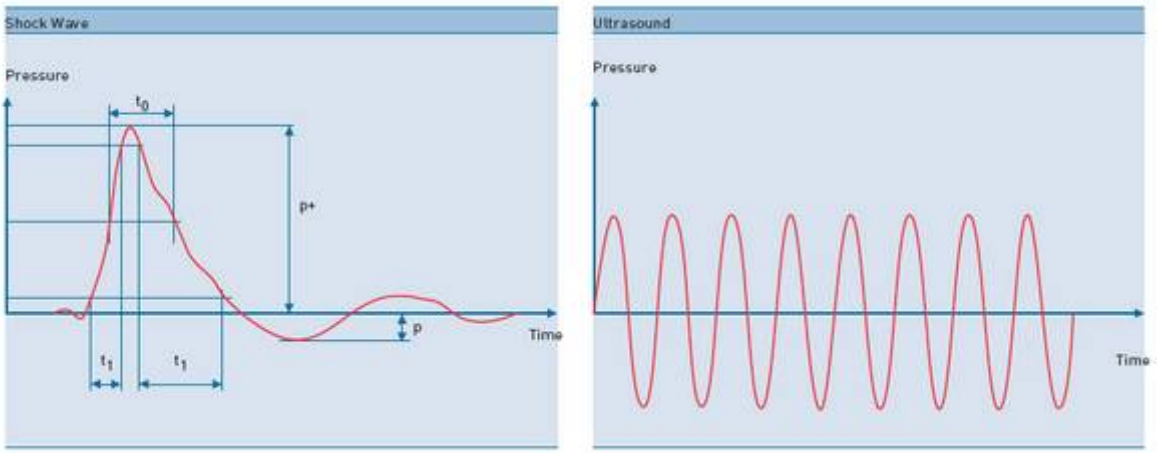


*Figure 2:*

Time/pressure profile of a shock wave. The increase to peak pressure ($p_+$) takes place in a few nanoseconds. Peak pressures are at approximately 10-150 megapascals. Ultrasound is a periodic wave with limited duration. © Storz Medical AG, 2004, Dr. O. Wess

Diagnostic criteria Participants were between the ages of 19 to 56 (average age 37.25 years old) with an average BMI (Body Mass Index) of 29.18 (minimum BMI of 20 to maximum BMI of 41.6). All participants had severe cellulite measured with a pinch test. The following exclusion criteria were defined: venous disease, vein surgery in the last two months, cardiac disease, joint disease, pregnancy and breast-feeding mothers.

Therapy course Based on the study design, six treatments were performed with two post-treatment examinations at 14 days after the last therapy unit. The shock wave sessions were performed between 7 and 12 AM where possible. As treatment in the morning was not possible for some participants due to occupational conflicts, these participants were treated at the same time every evening. Treatment conditions were constant, although the treatment room had a temperature of up to 36° during the hot summer of 2003. The temperature in the treatment room then normalized in the winter. The treatment course was documented using digital photographs of the participants and standardized CRFs (Case Report Forms). Circumference and volume measurements of the treated and non-treated leg were performed with a perometer before and directly after shock wave treatment. Shock wave treatment was performed on each leg; the left leg was treated in the summer and the right leg was treated in the winter. The shock wave treatment lasted approximately 15 minutes.
A total of 2,400 impulses were applied to the femoral adipose regions (anterior, posterior, lateral) using circular movements of the therapy head based on the directions used in lymph massage. The shock wave energy was adjusted based on the subjective effects reported by the participants: The therapy was not allowed to become painful, but the shock waves were applied at a level at which the participants felt a significant effect.

Results All patients tolerated the new therapy method using shock waves extremely well. Subjective impressions of the treated leg and photographic analyses showed a significant improvement in skin surface for more than 70 percent of patients. Patients were particularly sensitive two to three days prior to menstruation; in these cases, the applied energy had to be reduced by half. One patient left the study for occupational reasons. For two patients, skin irritation in the form of significant erythema was seen after therapy. No other side effects were observed. In general shock wave treatment led to a significant improvement in skin surface appearance, circumference and elasticity ("firmness") of the treated thigh. We observed both a significant reduction in thigh volume and a reduction in thigh circumference of 2 cm on average. One woman reported a reduced circumference in the treated leg that corresponded to a new clothing size.
In contrast to other known methods for cellulite treatment, these results provide optimistic data with regard to long-term or permanent effects of shock wave treatment. The patients who came for treatment on the other leg approximately four months after the first round of treatment showed no changes in the achieved positive effects from the first treatment: The circumference, volume and skin elasticity remained nearly constant four months later. This means that therapeutic success can be considered long-term or even permanent. Additional follow-up studies are necessary to support these results.

## Case studies

*Figure 3:* Female patient, 38 years old, 67 kg, pronounced weak connective tissue, six therapy units, before / after

*Figure 4*: Female patient, 36 years old, weak connective tissue, six therapy units, before / after

*Figure 5*: Female patient, 25 years old, 81 kg, pathological adipose tissue distribution with epidermal indentations, six therapy units, before / after

The course of therapy with regard to lymph volume was much more successful in the summer than in the winter: The volume of the treated leg was reduced by 10.25 percent (7 percent in the control leg), while the relative volume reduction in the treated leg was 4 percent in the winter (3.8 percent in the control leg).

Subjective evaluation of the new therapy method was extremely positive after treatment was completed. The following answers were given in response to the question "Did you observe changes after shock wave treatment?":

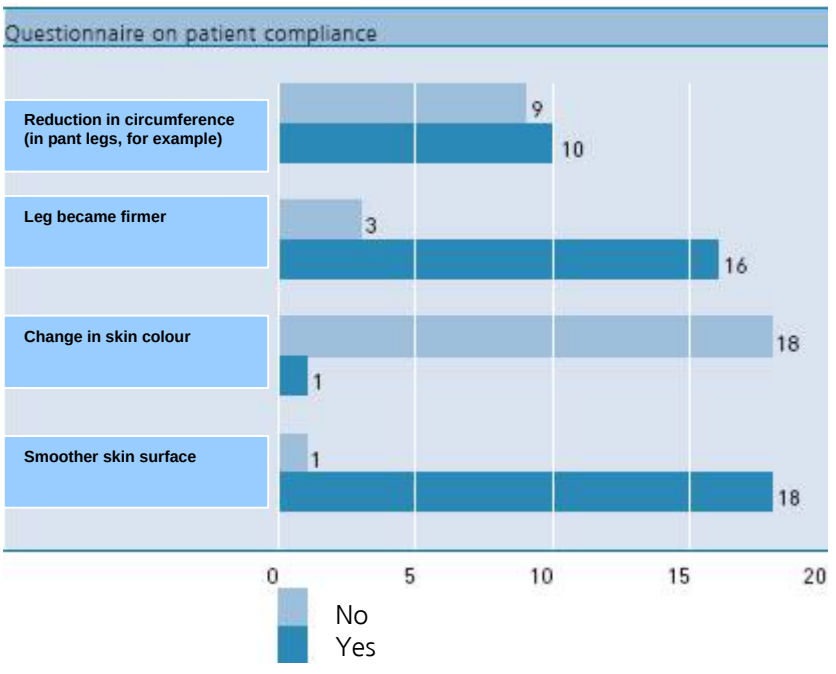


*Figure 6*

**Treatment follow-up** Treatment success was recorded with circumference and volume measurements in the treated and untreated legs in the first, second and third week after initiation of therapy using a perometer.

**Volume**
The treated leg lost an average of *203 ml* per week. This corresponds to a reduction in leg volume of *6.1%* during the period of observation.

**Total volume: Control leg** The non-treated leg (control leg) lost an average of *330.55 ml* per week. This corresponds to a reduction in volume of the placebo leg of *6.59%* during the period of observation.

**Total volume change, summer vs. winter**

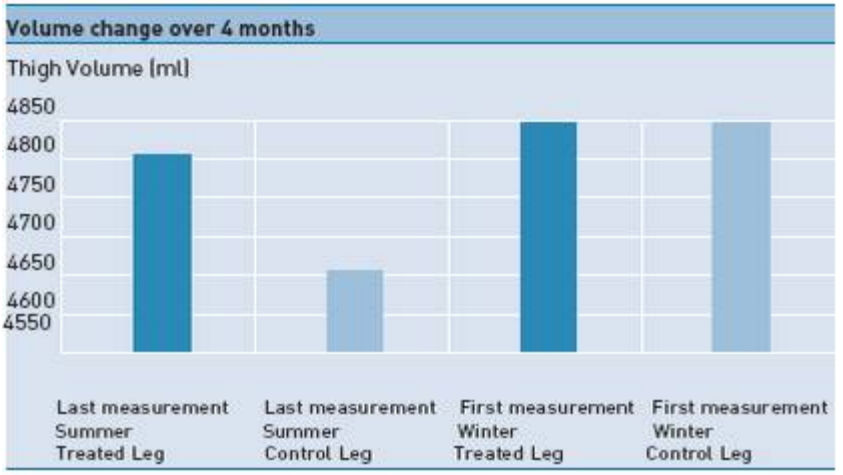


*Figure 7*

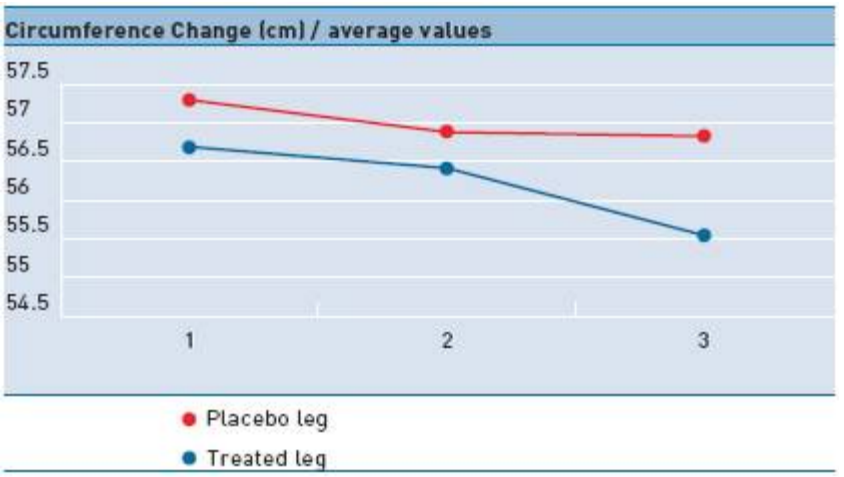


*Figure 8*

Circumference was reduced by 2.65 cm in the treated leg. Weight did not change substantially during the two periods of observation.

**Discussion** One of the reasons for the effects of Shock Wave Therapy is the helpful effect of the surrounding temperature for lymph volume. The optimum VAR (venoarterial reflex) is at 34° to 35°C. The arteriolar musculature shows increased contraction capabilities due to the manual effects of shock waves on lymphatic tissue (2, 19).
Over a long-term observation period, the average leg volume of the leg treated in the summer remained constant from the beginning of therapy to November. In contrast, the placebo leg had reached its original volume at the first measurement in the winter. This indicates that Shock Wave Therapy stimulates microcirculation for a positive effect on lymph volume in female subcutaneous adipose tissue, leading to positive long-term improvement in tissue. This also confirms recent scientific developments that show a correlation between blood and lymph circulation and the structure of adipose tissue. Slow circulation results in lipid biosynthesis, whereas rapid circulation stimulated by shock waves leads to lipolysis (2).
The observed firming of connective tissue could be due to the forces exerted by the shock wave at tissue borders, as connective tissue can regenerate extremely rapidly through mitotic cell division and the formation of new fibres. Defects in various organs also often heal with connective scar tissue (2).

**Summary** Shock Wave Therapy represents a successful, new therapeutic method for a disease that has been resistant to therapy and that causes a significant amount of suffering. These initial results provide evidence of permanent and successful treatment. The described sets of measurements indicate a permanent improvement in affected tissue from shock wave application which can mobilize microcirculation, improve lymph drainage and strengthen connective tissue. In summary, the pilot study showed that shock wave therapy could represent the first successful therapy approach for cellulite.

Source: Tanslation of: Braun, Martin T., Wroblewska, Katharina K, Daser, Andrea; „Effekte der Stosswellentherapie bei pathologischen Veränderungen des subkutanen Fettgewebes. Eine Pilotstudie."; Ästhetische Dermatologie 04/2004