

Improvement in Skin Elasticity in the Treatment of Cellulite and Connective Tissue Weakness by Means of Extracorporeal Pulse Activation Therapy



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BACKGROUND: Extracorporeal pulse activation therapy (EPAT), also called extracorporeal acoustic wave therapy, seeks to achieve effective and long-lasting improvement of age-related connective tissue weakness in the extremities, especially in the treatment of unsightly cosmetic skin defects referred to as cellulite.

OBJECTIVE: The objective of this study was to stimulate metabolic activity in subcutaneous fat tissue by means of EPAT in order to evaluate its effectiveness in enhancing connective tissue firmness and improving skin texture and structure.

METHODS: Fifty-nine women with advanced cellulite were divided into 2 groups; one group of 15 patients received planar acoustic wave treatment for 6 therapy sessions within 3 weeks; a second group of 44 patients received 8 therapy sessions within 4 weeks. Changes in connective tissue were evaluated using the DermaScan C ultrasound system (Cortex Technology, Hadsund, Denmark). Skin elasticity measurements were performed using the DermaLab system (Cortex Technology). Photographs of treated areas were taken at each therapy session and at follow-up sessions.

RESULTS: Skin elasticity values gradually improved over the course of EPAT therapy and revealed a 73% increase at the end of therapy. At 3- and 6-month follow-ups, skin elasticity had even improved by 95% and 105%, respectively. Side effects included minor pain for 3 patients during therapy and slight skin reddening.

CONCLUSIONS: This study confirmed the effects of acoustic wave therapy on biologic tissue, including stimulation of microcirculation and improvement of cell permeability. Ultrasound evaluation demonstrated increased density and firmness in the network of collagen/elastic fibers in the dermis and subcutis. Treatment was most effective in older patients with a long history of cellulite. (*Aesthetic Surg J* 2008;28:538–544.)

Cellulite is caused by an increase in fat deposits on the buttocks and thighs and by skin aging caused by thinning collagen layers. It typically affects women, owing to their genetic predisposition to the disorder. Women have 21 to 22 billion fat cells, whereas men have only about 17 to 18 billion. Female fat tissue stores fat more easily and quickly than male tissue, because the accumulated fat cells in females act as energy reserve during pregnancies.^{1,2}

The main cause of cellulitis is to be found in the structure and condition of the connective tissue. In the female thigh, arched and almost perpendicular collagen fiber bundles run through the subcutis. These structures determine the skin texture at the interface between the corium and subcutis. If one pinches the skin between the thumb and index finger (the so-called pinch test), the fat cell chambers bulge out and produce the typical orange peel appearance.^{1,3} In all, female skin is more elastic than male skin.

The fact that skin—and female skin in particular—is hormonally influenced explains why skin aging in women accelerates when the hormonal milieu changes, as occurs, for example, during pregnancy. Estrogens in the epidermis stimulate cytogenesis and the production of collagen fibers.⁴ The number of elastic skin fibers declines and their structure changes. The epidermal tissue becomes weaker while the subcutaneous tissue gradually hardens.^{1,3,4}

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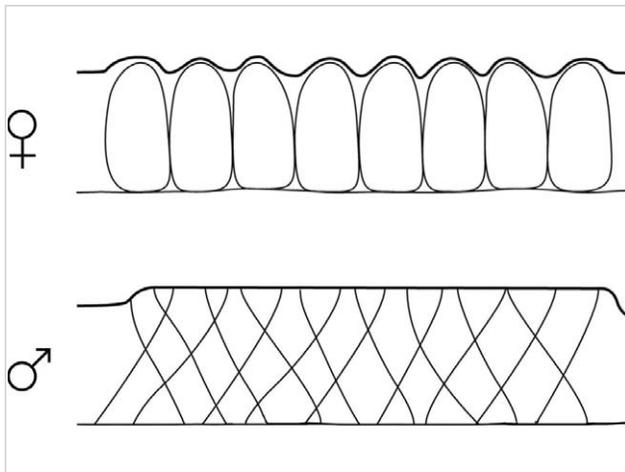


Figure 1. When compared to the fiber orientation in male skin, the structure of the subcutaneous fat tissue in the female thigh clearly explains why the “orange peel” appearance revealed by the pinch test occurs only in women.

Moreover, skin aging gradually weakens the skin’s natural defense mechanisms. Because of the influence of oxygen radicals, protein molecules increasingly accumulate in the skin. However, free radicals are not only produced in response to external stimuli, such as sunlight or ozone, but also accumulate in the tissue as a result of factors such as smoking, stress, an unhealthy diet, or excess weight.

Another factor to be considered is the blood circulation in the skin, which determines the transport of oxygen and nutrients and the migration of immune cells. For example, sitting or reclining for long periods seriously affects lymphatic drainage. This leads to increased fat deposits and causes the skin to gradually develop the distinctive orange peel appearance of cellulite.^{1,5}

Cellulite can develop from a cosmetic deficit into a medical problem in the form of lipedema. At this advanced stage of cellulite, the lymphatic vascular system is no longer able to return a sufficient amount of protein and lipid molecules from the interstitial space into the venous blood system. The high concentration of plasma proteins and lipids and their secondary degradation products in the interstice causes fibrosis and alters tissue properties.

METHODS

Patient Groups

A total of 59 female patients with advanced cellulite (stage 2 to 3, revealed by pinch test) and age-related connective tissue weakness were divided into 2 groups who underwent slightly different treatment regimens. The age, weight, and body mass index (BMI) of all patients were recorded before treatment. Because preliminary studies had indicated that extracorporeal pulse activation therapy (EPAT) had no significant effect on patients’ weight, this parameter was not recorded after completion of the therapy. Group A consisted of 15 patients with a mean age of 44.58 years (range, 33-59

years) and a mean BMI of 24.39 (range, 18.2-30) who underwent planar acoustic wave treatment for 6 therapy sessions within 3 weeks. Group B consisted of 44 patients with a mean age of 45.47 years (range, 21-63 yrs) and a mean BMI of 25.34 (range, 16.2-40) who underwent planar acoustic wave treatment for 8 therapy sessions within 4 weeks.

Inclusion criteria for both groups were the following: more than 20 years of age, with stage 2 or 3 cellulite, according to the Nurnberger-Muller scale, and an ability to both read and comprehend the informed consent form.

Exclusion criteria for both groups were determined through an anamneses questionnaire and confirmed by the responsible physician. They included the following: pregnant/breastfeeding; anamnesis of phlebitis or deep venous thrombosis in leg; inflammation in therapy region; lipoplasty or endermology in therapy region less than 6 months before the study; serious cardiovascular problems; implanted cardiac pacemakers not approved for shock wave therapy; diffuse pain areas; and the use of vitamin K antagonists (phenprocoumon).

Extracorporeal Pulse Activation Therapy

Extracorporeal acoustic pulses are characterized by high pressure amplitudes, short pressure rise times, and short and asymmetric pulse characteristics. They transmit energy from the point of generation to the therapy regions and have been shown to cause cell activation, improve metabolism, and release messenger substances.⁶

In order to ensure optimal transmission efficacy, the acoustic waves are generated extracorporeally in water (ie, in a medium with acoustic properties that are similar to those of human tissue).

Therapy System

Treatment was performed with the planar handpiece, the C-Actor, of the CELLACTOR SC1 (Storz Medical AG, Tägerwil, Switzerland). This applicator includes an electromagnetic acoustic wave source with a coupling membrane that is applied to the skin of the female patient. Ultrasound gel is used between the applicator and skin in order to avoid energy loss through an air layer on the surface of the skin.

Treatment

Groups A and B were treated at the Utoquai Clinic for Aesthetic Plastic Surgery in Zurich, Switzerland, between December 2005 and April 2006. After completion of preliminary examinations, extracorporeal acoustic waves generated by means of the EPAT system were applied to the outer and inner thigh areas and to the gluteal region. The number of applied pulses per patient and therapy session was identical in both groups.

The gluteal and femoral therapy regions selected before the treatment were treated with 800 pulses using the handpiece at an average energy level of 0.25 mJ/mm², which means that a total of 3200 pulses were applied per patient. Each treated therapy region was approximately 10

× 20 cm. Treatment was performed by “scanning” the therapy region with the applicator; that is, by moving the applicator both horizontally and vertically over the therapy region to ensure uniform tissue treatment.

Evaluation Methods

Skin structure. Changes in the connective tissue structure in the corium and at the interface with the subcutis were identified by using the DermaScan C ultrasound system (Cortex Technology, Hadsund, Denmark). The 20-MHz ultrasound transducer offers a 60 × 130 μm resolution and a 10-mm penetration depth. Echo-free structures are displayed as black regions in the ultrasound image. Connective tissue structures appear in green, red, or yellow.

The basic requirement for the measurement and analysis of ultrasound images is that all images are produced with the same system and by using identical amplification settings. Because the ultrasound reflection intensity is related to the relative density of the targeted tissue, it also provides information on the arrangement of the collagen and elastic fibers. The color scale indicates the intensity of ultrasound reflection; white indicates the highest reflection, and black indicates the lowest reflection.

The ultrasound images were blinded on the basis of the manufacturer’s image coding per patient and rated by a group of 4 independent reviewers according to the following criteria: 1 = weak structure; 2 = medium structure; and 3 = firm structure. The images were inserted into a PowerPoint presentation (Microsoft, Redmond, WA) and submitted to the reviewers in arbitrary order.

Skin elasticity. Measurements conducted in this study were performed with the DermaLab system (Cortex Technology). This system is designed to determine the modulus of elasticity. For this purpose, the skin is sucked into the probe cavity (approximately 10 mm) to a reproducible level by applying a vacuum. The measured values are in the region of 2 to 15 MPa (megaPascals). High MPa values indicate that a higher vacuum strength was required to lift the skin, which reflects a greater level of skin firmness. The measuring accuracy specified by the manufacturer is ± 2%. Measurements were always performed before each therapy session and at the same skin location and marked with a special body marker.

Values in the medical literature were investigated for comparison with the measurements in our observation series; however, there were few examples and these differed significantly between each other. The lack of standardized measurement methods for the determination of mechanical skin properties has frequently been criticized.⁷ Only measurement values obtained with the same measurement system in which the stress applied and the tensile speed remain unchanged, can be accurately compared.

Skin appearance. Photographs were taken of the treated body regions at each therapy and follow-up session.

RESULTS

Changes in Skin Elasticity

In group A, as demonstrated in Figure 2, skin elasticity increased continuously. Skin elasticity increased by 45% ($P < .004$) and by 75% at 3-month follow-up ($P < .004$). The differences between the mean values were highly significant.

For group B, skin elasticity results measured at the end of the therapy revealed a 73% increase ($P < .001$; Figure 3). At the 3- and 6-month follow-ups, skin elasticity had improved by 95% and 105%, respectively ($P < .001$).

By contrast, the improvement in skin properties achieved with chemical skin care products (creams or lotions) generally ranges between 12% and 25% and may reach just over 30% in individual cases. According to Voss and Schlippe,² an improvement of more than 40% is to be considered an exceptional result.

Skin Structure

Analysis and evaluation of ultrasound images. The result of the objective visual evaluation by independent reviewers is summarized in Figure 4. The evaluation revealed an upward trend in the visually determined skin tissue density values, which had significantly increased from baseline.

Figure 5 is a DermaScan image of cellulite skin in 54-year-old female patient. Before therapy (Figure 5,A), the interface between the corium and the subcutis appears as a broken, irregular line; the black structures

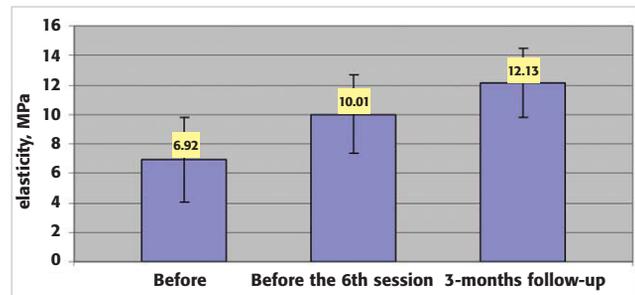


Figure 2. Wilcoxon signed rank test: group A, 6 therapy sessions, 3-months follow-up after last therapy session. N = 14 out of a total of 15 subjects. The measurement values of 1 patient had to be excluded from the statistics because of nonparticipation in one of the therapy sessions.

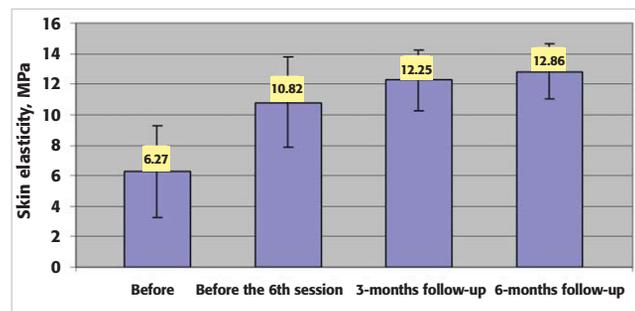


Figure 3. Wilcoxon signed rank test: group B, 8 therapy sessions, 6-month follow-up after the last therapy session. N = 42 out of a total of 44 subjects. Two patients had to be excluded from the group because of the lack of treatment data.

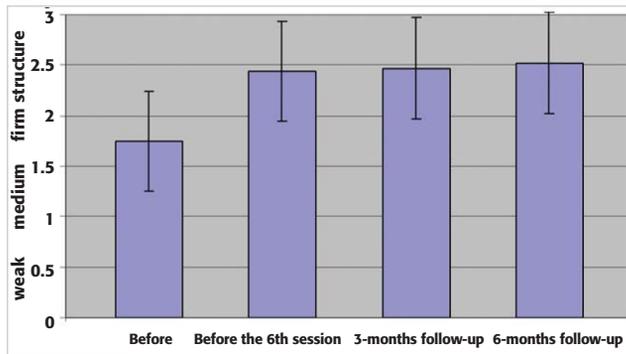


Figure 4. Evaluation of score ratings of DermaScan ultrasound images, including follow-up examinations.

are fat cells and lymphatic fluid. After therapy (Figure 5,B), the skin tissue has become measurably more compact, indicating a strengthening of the connective tissue. Echo-free interspaces (black) have been reduced. By contrast, Figure 6 includes typical images of women without cellulite.

Cosmetic Evaluation

Figure 7 illustrates a representative case before, immediately after, and 3 months after 6 EPAT treatment sessions.

Side Effects

Acoustic waves have only minimal side effects, such as minor pain during therapy or slight skin reddening. This was confirmed in 95% of the subjects treated.² During the investigations, no clinical side effects were observed except for minimal pain in 3 of 59 patients. This minimal pain was observed 2 to 3 days before the menstrual period of the female patients. During these 2 to 3 days, the applied energy level was reduced.

DISCUSSION

EPAT makes use of low-intensity acoustic waves and pulses. It relies on long-term positive experience and on

reports in the scientific literature confirming the effectiveness of shock wave therapy. This noninvasive therapy method has been successfully used in urology for more than 25 years and has also proven its efficacy in the treatment of orthopedic disorders. In the validation of the side effects of this therapy, the “healing effect” of shock waves in cases of nonunion of bone fractures was first detected by Valchanou and Michailov.⁸ Similarly, shock waves have also proved effective in the dissolution of shoulder calcifications. In fact, radiographs taken after shock wave therapy confirmed complete elimination of the calcifications.⁹

According to Wang,¹⁰ shock waves trigger a cascade of effects, which begins with the application of physical energy in the form of acoustic waves and ultimately leads to the neoformation of vessels and to improved metabolic activity through various physiologic mechanisms. These effects are accompanied by healing processes that have not been precisely specified thus far, but that lead to successful therapy in the treatment of indications such as Peyronie’s disease¹² or cardiologic disorders, such as angina pectoris.¹³ The observations and results of this study confirm the acoustic wave effects on biologic tissue, such as the stimulation of microcirculation and the improvement in cell permeability.¹⁴⁻¹⁶

In vitro tests have shown that the application of acoustic pulses leads to increased short-term cell permeability that allows distinct active substances (eg, cytostatic agents) to be transferred to the cells.¹⁷ This cell permeability may stimulate the exchange of substances of fat cells and activate fat-splitting enzymes (phospholipases) through the beta-receptors on the fat cell membranes.^{5,7,18}

The evaluation of the ultrasound images documents a visually detectable change in tissue structure. It was observed that the network of collagen/elastic fibers in the dermis and subcutis becomes denser and measurably firmer. In the parallel biochemical examinations, reduced

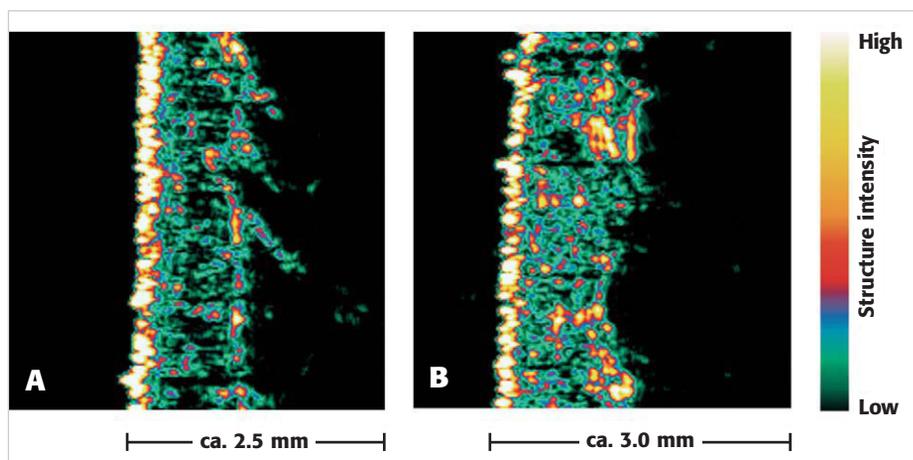


Figure 5. DermaScan images of cellulite skin in 54-year-old female patient. **A**, Before therapy, the interface between the corium and the subcutis appears as a broken, irregular line; the black structures are fat cells and lymphatic fluid. **B**, Immediately after the last of 6 EPAT treatment sessions, the skin tissue has become measurably more compact, indicating a strengthening of the connective tissue. Echo-free interspaces (black) have been reduced. Reprinted with the permission of Cortex Technology (Hadsund, Denmark).

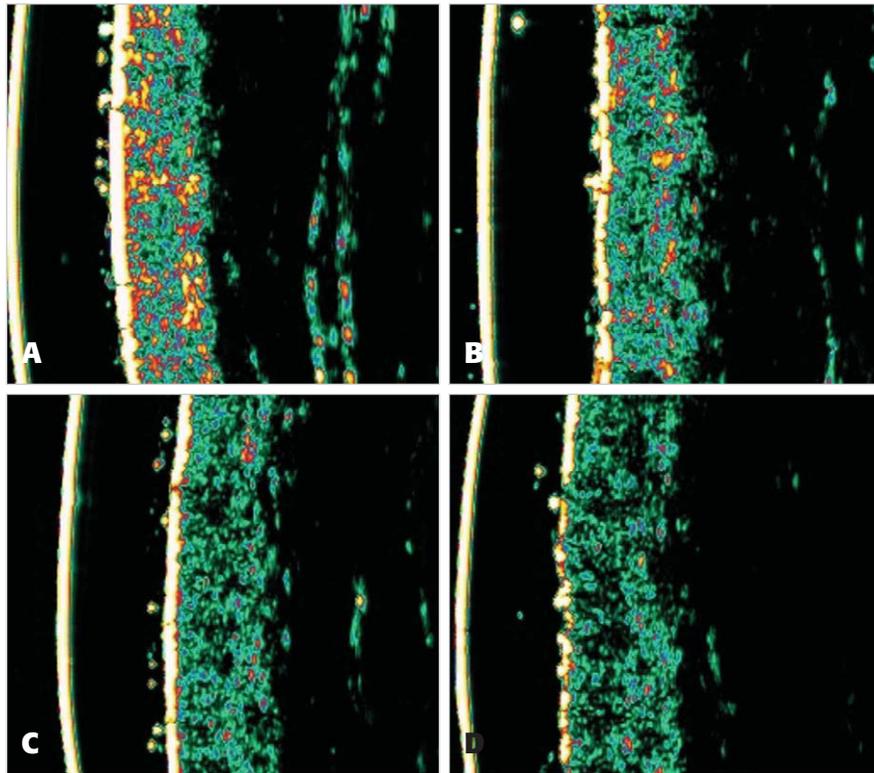


Figure 6. **A**, Typical skin of an approximately 20-year-old female without cellulite. **B**, Typical skin of an approximately 30-year-old female without cellulite. **C**, Typical skin of an approximately 40-year-old female without cellulite. **D**, Typical skin of a 50-year-old female without cellulite. Reprinted with the permission of Cortex Technology (Hadsund, Denmark).



Figure 7. **A**, Pretreatment view of the lateral thighs of a 43-year-old female. **B**, Posttreatment view immediately after the last of 6 extracorporeal pulse activation therapy treatment sessions. **C**, Posttreatment view at 3-month follow-up.

oxidative stress by EPAT was shown by our group by means of increased lipolysis and by the release of toxic aldehydic products of lipid oxidation, such as 4-hydroxy-2-nonenal (HNE) and malondialdehyde (MDA), from lipedematous and cellulite tissue.¹⁹ The protective and therapeutic effects of EPAT are, therefore, complex and include stimulation of lipolysis, release of toxic aldehydic lipid oxidation products,¹⁹ reduction of oxidative stress,¹⁹ strengthening of antioxidants, improved collagen synthesis, and measurable and visible improvement of skin condition. It was clearly demonstrated that the improvement

in skin elasticity was long-lasting (up to 6 months), and from a quantitative point of view was much stronger compared with other methods currently in use.

Whereas the beneficial effects of acoustic waves on oxidative stress and aldehydic lipid oxidation products were measured directly,¹⁹ the strengthening of antioxidants was only indirectly concluded. Nevertheless, the positive effects of reduced oxidative stress and increased antioxidants, including ascorbic acid (vitamin C), on biosynthesis of collagen²⁰ were directly demonstrated. An extensive series of earlier experimental and clinical

results and clinical studies have supported the close positive interaction between reduced oxidative stress, vitamin C, and collagen stability in the skin.²¹⁻³²

A 1997 European study²⁰ on the effectiveness of a suction roller massaging device for cellulite treatment revealed an up to 60% reduction of echo-free structures at the corium/subcutis interface, based on the same ultrasound parameters as those used in our study. However, the authors of the European study confirmed that the improvement in the tissue status only lasted 1.1 months.³³ Judged by the findings gathered to date from stage 2 studies into the effectiveness of EPAT therapy, the improvement in tissue status resulting from EPAT lasts up to 6.5 months after completion of the last session.

Finally, the patients we recruited for our study were women who not only suffered cellulite but also exhibited poor skin elasticity. The latter problem primarily affects more mature, postmenopausal women between 40 and 65 years of age. The responders to our advertisement primarily included women in this age group. The EPAT treatment of these subjects was especially effective in increasing skin firmness.

Younger patients who received EPAT therapy had usually higher initial skin elasticity values. Thus, the improvement of skin firmness in the patient group was less obvious. In general, a combination of healthier nutrition, sufficient intake of water, and increased body activity (walking, fitness training) further improves the treatment results.

CONCLUSIONS

EPAT is a noninvasive therapy method that requires relatively little time on the part of doctors and patients. Serious side effects have not as yet been encountered. Nevertheless, side effects must continue to be monitored and documented in ongoing investigations to confirm the safety of this methodological approach. With further investigation, EPAT therapy may prove to be a safe and long-lasting therapy for body shaping and skin rejuvenation providing metabolic and structural improvements. ▀

DISCLOSURES

Supported by Storz Medical AG. The study design was developed by Dr. Christ together with Storz Medical. Drs. Siems, Brenke, and Sattler contributed to the evaluation and interpretation of the study results. Dr. Christ received no compensation, but Storz paid for the treating nurse. Dr. Siems received financial compensation for time spent on the study evaluation and review of the manuscript. Drs. Brenke and Sattler received no compensation. Dr. Novak is an employee of Storz Medical, and Ms. Daser was an employee at the time this study was conducted.

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