**ULTRA THERM:** Body Rejuvenate uses the strong vibrations caused by the ultrasonic wave, this can target the fatty cell, stimulate it, and burn them inside the skin about 5cm, thus can completely destroy the fat cells. With the use of this healthy and scientific slimming therapy and dieting adjustment, the client can release excrecent water and toxins, and dissolve the inner deep fat.

At Body Rejuvenate, we use three separate exciting technologies to kill the fat cell, tighten skin, layering our technologies for the fat loss along with lymphatic drainage, for the best possible results at the lowest price for our clients.

Each patient must drink 20 ounces of water **two hours PRIOR (do not drink water except small sips two hours before your session)** to their appointment, and 64 ounces of water a day for two weeks through and AFTER their treatments have finished.

This water drinking and eating a low fat/low carbohydrate diet will make permanent results that have been more successful than invasive plastic surgery, without cost and without the long recovery time that surgery entails. We provide educated specialists in nutrition and lifestyle to help you with changes in your lifestyle if needed.
The effects of high-power ultrasound treatment on cellulite/local fat deposits

“High-intensity focused ultrasound (HIFU) for permanent reduction of localized fat in a single treatment. The clinical development of the device took several years but it is now well-understood. For example, patients who were going to have a tummy tuck received Liposonix (high frequency ultrasound) to the tissue that was later removed, in order to document the effects. Vaser Shape and other devices use unfocused ultrasound and does not destroy fat cells.” Dr. Richard Baxter, MD; Seattle Plastic Surgeon, Baxter Plastic Surgery

It is widely accepted today that high-power, high-frequency ultrasound treatments represents one of the most effective methods of cellulite reduction and local fat reduction. It often provides immediate results - if the right equipment is used with the right protocols. The difference between Body Rejuvenate and our competitors is that we have our own equipment that is NOT PAINFUL. You will not have blood vein trauma or need medications throughout your sessions. Most clients feel that our treatments are much like getting a massage from a spa, yet with permanent fat loss results.

- Ultrasound waves preferentially and intensively vibrate the sub dermis (where cellulite and fat is located), exerting a double slimming effect on the cellulite tissues. Specifically, these ultrasound waves: Increase fat cell membrane permeability, which results in the release of fat into the bloodstream.

- Create gas bubbles (cavities) inside the fat cells, which expand and consequently implode, breaking the fat cell membrane. This results in fat release into the bloodstream, as well as the elimination of the fat cell itself (adipocytes, being very fragile cells, are damaged, whilst other cells, such as
fibroblasts, stay intact and actually benefit from the stimulus provided by ultrasound).

- **Provide mechanical stimulation, which encourages the fibroblasts to produce new collagen and elastin fibers,** thereby offering a skin tightening effect.

![Diagram of fat cells before and after ultrasound cavitation](image)

**Picture of fat cells before and after ultrasound cavitation:**

![Fat cell images](image)
Ultrasound cavitation has been used for many years in Italy (known as “cavitazione con ultrasuoni”), and Italian women swear by it’s effectiveness, provided the right intensity is used. Most clinics and salons in Europe and the states use equipment with power of 10-30 Watts (40Mkw which is low frequency ultrasound), which is simply inadequate.

High frequency ultrasound makes vibrations sound waves at a rate that are not audible to the human ear, unlike low frequency ultrasound fat removal. If you are told that there is a “ringing in your ears” you need to know that this is a LOW FREQUENCY and will NOT DESTROY YOUR FAT CELLS.

High frequency ultrasound is the only ultrasound head that Body Rejuvenate uses for permanent fat removal.

Our ultrasound head is lower frequency than our high intensity ultrasound competitors, to ensure pain free fat removal, but much higher than the low frequency ultrasound competitors which (only) temporarily melt fat. If you can hear the Ultrasound within your ears, remember, that is a low frequency ultrasound.
Our ultrasound has **no pain in the ears during treatments or bruising, and no popping of blood vessels around the treatment area.**

Competition: The higher ultrasound systems pop blood vessels around the treated area and causes a lot of pain and bruising. Studies show that higher frequency ultrasound (over 2.5MH) has a patient rate of 90% pain. This sets Body Rejuvenate’s UltraTherm apart from all other permanent non-invasive fat removal systems.

We have superior permanent fat removal, but our unique technique of removing the fat also sets us apart from every other company. We layer three different technologies for the most effective removal of fat and skin tightening and all of this in **included in one price.** Our prices are lower than our competitors. **We include three technologies that our competitors are charging separately for each kind of technology. Most of our competitors don’t even offer the three technologies that we offer at Body Rejuvenate.**
High Frequency Ultrasound Medical Research:


Shalom A, Wiser I, Brawer S, Azhari H.

February 22, 2013

Source

Department of Plastic Surgery, Assaf Harofeh Medical Center, Zerifin, affiliated with the Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel. avi_shalom@hotmail.com

Abstract

BACKGROUND:
High-intensity focused ultrasound (HIFU) lipolysis is a noninvasive alternative to existing surgical body-sculpting methods.

OBJECTIVE:
To evaluate the safety, tolerability, and histologic outcome of HIFU lipolysis using a novel device in human subjects.

METHODS AND MATERIALS:
In a single-blind pilot study, six healthy subjects scheduled to undergo abdominoplasty within 4 weeks received HIFU lipolysis on one side of the umbilicus. An identical placebo treatment was given to the contralateral side. Patient evaluation of complications, blood tests, and urine analysis were performed 1, 3, 7, 14, and 28 days after treatment. Excised tissue from the treated areas was sent for histologic review.

RESULTS:
Treatment was well tolerated. Average visual analogue pain scale scores were 3.5 ± 2.3 (range 1-7) and 0.17 ± 0.41 (range 0-1). No major adverse events were documented, and laboratory analysis after HIFU lipolysis was normal. Fat necrosis with infiltration of lymphocytes and macrophages without adjacent tissue damage was documented on histology 2 to 4 weeks after HIFU lipolysis. Damage extent correlated with size of the area treated. No pathologic findings were found on the control side.

CONCLUSIONS:
High-intensity focused ultrasound treatment was well tolerated and safe. Focal damage to target tissue was documented, with adjacent tissues remaining intact.

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A randomized, single-blind, postmarketing study of multiple energy levels of high-intensity focused ultrasound for noninvasive body sculpting.

Solish N, Lin X, Axford-Gatley RA, Strangman NM, Kane M.

Source
Dermatologic Surgery, University of Toronto, Toronto, Ontario, Canada. n.solish@utoronto.ca

Abstract
BACKGROUND:
High-intensity focused ultrasound (HIFU) is a nonsurgical, noninvasive body sculpting method.

OBJECTIVE:
To investigate preferences for treatment settings using a HIFU device.

MATERIALS AND METHODS:
HIFU was applied to the anterior abdomen in three passes of decreasing depth (1.6, 1.3, and 1.1 cm) in patients randomized to HIFU energy levels (each of 3 passes [total]) of 47 (141), 52 (156), or 59 (177) J/cm(2). The primary assessment was week 12 post-treatment change from baseline waist circumference at the level of the iliac crest for all treatment groups combined.

RESULTS:
The primary assessment achieved statistical significance (least squares mean 2.51 cm, 95% confidence interval [CI] = -3.14 to -1.88; p < .001), with no significant differences between groups. At week 12, 69% to 86% of patients and 73% to 79% of investigators rated appearance as improved or much improved. The average worst pain (100-mm visual analog scale) experienced during treatment was mild (47 J/cm(2): 17.1 mm, 95% CI = 4.33-29.81 mm; 52 J/cm(2): 24.6 mm, 95% CI = 12.24-36.95 mm; 59 J/cm(2): 30.9 mm, 95% CI = 18.71-43.17 mm). There were no serious adverse events.

CONCLUSION:
HIFU treatment at different energy levels and multiple tissue depths was well tolerated and effective in reducing waist circumference.

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PMID:

22093233

[PubMed - indexed for MEDLINE]
Evaluation of a novel high-intensity focused ultrasound device for ablating subcutaneous adipose tissue for noninvasive body contouring: safety studies in human volunteers.

Gadsden E, Aguilar MT, Smoller BR, Jewell ML.

Source
Hospital Torre Médica, México.

Abstract

BACKGROUND:
High-intensity focused ultrasound (HIFU) is an energy-based medical technology with many clinical applications. A device under clinical investigation in the United States (LipoSonix; Medicis Technologies Corporation, Bothell, Washington) uses HIFU to reduce localized deposits of abdominal adipose tissue.

OBJECTIVES:
The authors describe the results from their clinical trial investigating the safety of this HIFU device in human patients.

METHODS:
Over the course of three studies evaluating the safety of the HIFU device for ablating human subcutaneous adipose tissue (SAT), 152 healthy patients were treated with total HIFU energy doses of 47 to 331 J/cm(2)), including patients who presented for elective abdominoplasty and underwent treatment to areas identified for subsequent excision. The safety of each treatment regimen was confirmed before the energy levels were raised. Abdominoplasty was performed up to 14 weeks following the HIFU procedure, and a pathologist performed histopathological analyses of excised tissues. Safety evaluations included an assessment of clinical chemistry and hematology profiles, physical examinations, and adverse events.

RESULTS:
Posttreatment ultrasound confirmed that the HIFU effects were limited to targeted SAT layers. Histopathology revealed well-demarcated disruption of adipocytes within the targeted SAT. Phagocytosis of released lipids and cellular debris occurred after 14 to 28 days. Phagocytized lipids underwent normal hepatic metabolism. Healing progressed normally and was 95% complete after eight to 14 weeks. Adverse events consisted primarily of temporary treatment discomfort, edema, erythema, dysesthesia, and ecchymosis. There were no changes in clinical laboratory parameters, and no serious device-related adverse events occurred. Optimal clinical outcomes were achieved with lower energy levels, which provided beneficial effects with the least amount of discomfort.

CONCLUSIONS:
HIFU appears to provide a safe means for removing and remodeling unwanted deposits of abdominal SAT.
Testimonials & the Science

Medical review:

Noninvasive high-intensity ultrasound effective for body sculpting, clinical trial shows
Publish date: FEB 01, 2012

By: Cheryl Guttman Krader

Chestnut Hill, Mass. — Results of a randomized, sham-controlled clinical trial including objective and subjective efficacy endpoints have established noninvasive high-intensity focused ultrasound (HIFU; LipoSonix/Solta Medical, cleared in September 2011 by the Food and Drug Administration for noninvasive waist circumference reduction) as an effective and well-tolerated option for body contouring. Jeremy Green, M.D., originally presented the data of this preapproval study on behalf of the SCULPT Group at Laser 2011, the annual meeting of the American Society for Lasers in Medicine and Surgery. The study included 180 patients ages 18 to 65 who presented for body contouring in the anterior abdomen and flank region. Eligible participants had a body mass index less than 30 kg/m² and ultrasound-measured subcutaneous adipose tissue depth of at least 2.5 cm. They were randomized into one of three study groups to receive sham treatment (no energy) or ultrasound using a low 47 J/cm² or high 59 J/cm² energy dose. Patients were to undergo one session with three passes, and they were evaluated at one hour and one, four, eight and 12 weeks. Last follow-up was six months post-treatment. Study results

The results showed a statistically significant benefit for the active treatment groups compared with sham in the primary efficacy outcome measure of change in waist circumference from baseline to week 12. Secondary efficacy analyses that included investigator and patient subjective assessments were consistent with the objective data, and no safety concerns emerged, says Dr. Green, cosmetic surgery and laser fellow at SkinCare Physicians, Chestnut Hill, Mass.

**Focused Ultrasound for Body Sculpting**


One treatment produced subtle but statistically significant improvement in waist circumference.

Noninvasive body sculpting with various devices has been promoted with precious little hard data to support efficacy. In this industry-funded, multicenter, randomized, sham-controlled, single-blind trial, 180 subjects with body-mass index less than 30 kg/m² and with more than 2.5 cm of subcutaneous fat in the abdomen and flanks underwent one treatment with high-intensity focused ultrasound (LipoSonix). The subjects were randomized to receive three passes at 59 J/cm² (177 total), 47 J/cm² (141 total), or 0 J/cm² (sham treatment) and were followed for 12 weeks. Waist circumference was measured with a tape measure at the top of the iliac crests. No changes in diet or exercise were allowed. No significant changes in weight were observed during the study.

In all, 168 participants completed the study per protocol. The researchers found statistically significant mean waist circumference reductions of 2.5 cm in the 59 J/cm² group and 2.1 cm in the 47 J/cm² group, compared with a 1.2-cm reduction in the sham treatment group at 12 weeks after treatment. Significantly more patients in the active-treatment group than in the sham-treatment group rated themselves as improved or much improved (68% vs. 24%). However, the active-treatment and sham-treatment groups did not differ regarding the likelihood of undergoing additional treatments or in their satisfaction with the results. Most active-treatment patients experienced bruising (66%) and mild-to-moderate pain during treatment (90%) and for a few days afterward (57%). Several patients developed postprocedural edema (9%). All adverse effects resolved within 2 weeks. Lipid profiles and liver and renal function lab tests remained normal throughout the study.

**COMMENT**

High-intensity focused ultrasound was able to achieve subtle but statistically significant waist circumference reductions with one treatment. However, most patients will find a half-inch reduction clinically insignificant. Multiple treatments may improve on these results. Because the sham-treatment group showed a significant placebo effect, using robust control groups will be imperative in future clinical studies of noninvasive fat reduction and skin tightening, where objective measures are very subtle.

**CITATION(S):**


*PubMed abstract (Free)*

- See more at: http://www.jwatch.org/jd2011072900000001/2011/07/29/focused-ultrasound-body-sculpting#sthash.5JSAu8xt.dpuf
Randomized sham-controlled trial to evaluate the safety and effectiveness of a high-intensity focused ultrasound device for noninvasive body sculpting.

Jewell ML, Baxter RA, Cox SE, Donofrio LM, Dover JS, Glogau RG, Kane MA, Weiss RA, Martin P, Schlessinger J.

Source: Oregon Health Science University, Eugene, Ore 97401, USA. mjewell@teleport.com

Abstract

BACKGROUND:
High-intensity focused ultrasound presents a noninvasive approach to body sculpting for nonobese patients. The purpose of this study was to evaluate the safety and effectiveness of a high-intensity focused ultrasound device for sculpting of the abdomen and flanks.

METHODS:
Adults (aged 18 to 65 years) with subcutaneous abdominal fat greater than or equal to 2.5 cm thick who met screening criteria were randomized to receive high-intensity focused ultrasound treatment of the anterior abdomen and flanks at energy levels (a total of three passes each) of 47 J/cm (141 J/cm total), 59 J/cm (177 J/cm), or 0 J/cm (no energy applied, sham control). The primary endpoint was change from baseline waist circumference at the iliac crest level at posttreatment week 12. Subjective aesthetic assessments included the Global Aesthetic Improvement Scale and a patient satisfaction questionnaire. Safety assessments included adverse events, laboratory values, and physical examinations.

RESULTS:
For the primary endpoint, in the intent-to-treat population, statistical significance versus sham was achieved for the 59-J/cm (-2.44; p = 0.01) but not the 47-J/cm treatment group (-2.06 cm; p = 0.13). In a per-protocol population, statistical significance versus sham was achieved for both the 59-J/cm (-2.52 cm; p = 0.002) and the 47-J/cm treatment groups (-2.10 cm; p = 0.04). Investigator subjective measures of global aesthetic improvement and patient satisfaction also favored each active treatment versus sham. Adverse events included mild to moderate discomfort, bruising, and edema. Laboratory values and physical examinations were unremarkable.

CONCLUSIONS:
Treatment with this high-intensity focused ultrasound device reduced waist circumference and was generally well tolerated for noninvasive body sculpting. Reduction in waist circumference was statistically significant with both active treatments (per protocol).

CLINICAL QUESTION/LEVEL OF EVIDENCE:
Therapeutic, II. (Figure is included in full-text article.)
Multisource, Phase-controlled Radiofrequency for Treatment of Skin Laxity

Correlation Between Clinical and In-vivo Confocal Microscopy Results and Real-Time Thermal Changes
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DISCLOSURE: The authors report no relevant conflicts of interest.

Abstract

Objective: The objective of this study was to analyze the correlation between degrees of clinical improvement and microscopic changes detected using confocal microscopy at the temperature gradients reached in patients treated for skin laxity with a phase-controlled, multisource radiofrequency system. Design and setting: Patients with skin laxity in the abdominal area were treated in six sessions with radiofrequency (the first 4 sessions were held at 2-week intervals and the 2 remaining sessions at 3-week intervals). Patients attended monitoring at 6, 9, and 12 months. Participants: 33 patients (all women).
Measurements: The authors recorded the following: variations in weight, measurements of the contour of the treated area and control area, evaluation of clinical improvement by the clinician and by the patient, images taken using an infrared camera, temperature (before, immediately after, and 20 minutes after the procedure), and confocal microscopy images (before treatment and at 6, 9, and 12 months). The degree of clinical improvement was contrasted by two external observers (clinicians). The procedure was performed using a new phase-controlled, multipolar radiofrequency system. Results: The results reveal a greater degree of clinical improvement in patients with surface temperature increases greater than 11.5ºC at the end of the procedure and remaining greater than 4.5ºC 20 minutes later. These changes induced by radiofrequency were contrasted with the structural improvements observed at the dermal-epidermal junction using confocal microscopy. Changes are more intense and are statistically correlated with patients who show a greater degree of improvement and have higher temperature gradients at the end of the procedure and 20 minutes later. Conclusion: Monitoring and the use of parameters to evaluate end-point values in skin quality treatment by multisource, phased-controlled radiofrequency can help optimize aesthetic outcome.

Skin laxity is an aesthetic problem that occurs between the ages of 35 and 40 years, although it generally starts to become visible from age 40 onward. Problems with skin laxity and quality also start to appear in younger people as a consequence of pregnancy or sudden weight loss. The impact of these problems on the patient's self-esteem can become important enough to affect quality of life in psychological and in sociocultural terms.1,2 The demand for treatment of skin laxity is growing as the conventions of beauty become increasingly demanding.

Laxity is a skin disorder that occurs with natural or accelerated aging and is structurally linked to diminished collagen production. The number and vitality of fibroblasts decrease, and both the dermis and the fibrous septa undergo partial
loss of their natural ability to replace themselves. The morphological changes that appear are a consequence of diminished biosynthesis of collagen and elastin and abnormalities of the extracellular environment with a decrease in the concentration of hyaluronic acid.\(^3\) It occurs early on the inner arms and legs and on the abdominal area. Skin laxity is associated with lack of physical exercise, rigorous dieting, and other causes and it often appears in combination with cellulite. Cellulite is an inflammation of the subcutaneous adipose tissue and has several causes. It occurs mainly on the legs, buttocks, hips, breasts, arms, and neck.\(^4\) Depending on the pathogenic mechanism, it is classed as dermopanniculosis deformans, adiposis edematosa, or gynoid lipodystrophy.\(^5-9\) The fibrous structure of the interlobular septa that divide female subcutaneous cell tissue into compartments is arranged perpendicular to the skin surface. This structure enables fat lobules in each septum to move toward the skin surface, which is the only structure that contains them. Some authors consider that cellulite visible to the naked eye is caused by lengthening and weakening of connective tissue fibers accompanied by fat protrusion.\(^10-11\)

Radiofrequency is useful in treating skin laxity. Heat-induced behavior of connective tissue and the degree of contraction achieved depend on factors such as the highest temperature reached (peak temperature), duration of exposure to radiofrequency, and the mechanical stress applied to tissue during the heating process. The thermal properties of tissue can also vary depending on skin quality, age, pH, electrolyte concentration, orientation and concentration of collagen fibers, and levels of tissue hydration. Treatment involves increasing tissue temperature to between 55°C and 62°C so that local vasodilatation is triggered and new collagen is formed.\(^12-16\)

The authors have clinical experience with different radiofrequency systems (monopolar and bipolar), either alone or in combination with vacuum and infrared systems that have been analyzed in several published clinical trials.\(^15-19\) Their
results have varied, ranging from excellent on occasion to very poor or ineffective. In this study, the authors used a phase-controlled, multisource radio-frequency system (EndyMed PRO™, EndyMed Medical, Caesarea, Israel). This system allows the user to confine the emission of energy to a depth of up to 11mm and makes it possible to apply concentrated heat to the papillary dermis, reticular dermis, and fascia superficialis. The authors also searched for clinical references and performed a histological verification of the efficacy of the treatment in order to improve the results. They analyzed subjective and objective levels of improvement and their relationship with temperature modifications as well as the histological changes observed with confocal laser scanning microscopy (CLSM).

This clinical study was carried out according to the ethical principles of the declaration of Helsinki and the guidelines for Good Clinical Practice. The authors had no affiliation with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript.

Materials and Methods

Subjects. The study population comprised 33 healthy patients (all women) with skin laxity on the abdominal area and a mean (±SD) age of 44.2±13.6 years.

Inclusion criteria. All patients had skin laxity on the abdominal area. They also had to be older than 25 years, give their informed consent, and agree to undergo a complete clinical follow up.

Exclusion criteria. Patients were excluded for the following reasons: presence of a pacemaker, metallic implants in the treatment area, medication regimen that alters the cutaneous response (e.g., retinoic acid), invasive intervention in the treatment area during the previous six months, noninvasive intervention in the treatment area (e.g., depilation or other medical-aesthetic procedures) during the previous six months, weight loss (dieting), suspicious cutaneous lesions, history of keloids or hypertrophic scarring, pregnancy or breastfeeding, epilepsy or severe migraines, infection, pain or abscess in the treatment area, presence of
tattoos or body piercing in the treatment area, autoimmune disorders or diabetes, eczema or dermatitis in the treatment area, anticoagulant therapy, or clinician-based exclusion criteria.

**Treatment protocol.** All of the patients received six sessions; the first four treatments were performed every two weeks and the last two treatments every three weeks. At all sessions, the authors recorded the following data: weight, measurement of the contour of the area to be treated at a preset height measurement, and measurement of the untreated control area. The different levels at which the abdominal circumference is measured can lead to errors in data recording. Therefore, in each case, the authors recorded the height (distance from the floor) at which the abdominal circumference and control area were first measured, to ensure that they were always taken from the same point.

The authors also recorded the evaluation of the degree of skin laxity by the clinician and by an external assessor, thermographic images and temperature of the treated area (before, immediately after, and 20 minutes after treatment), total energy used for each square of skin treated, CLSM images (before the first session), and side effects. A photograph of the area also was taken. Similarly, patients were asked to subjectively evaluate the degree of improvement from the second session onward. Patients were asked to evaluate the degree of pain according to a visual analog scale. All sessions were held and data recorded in a room with a stable temperature of 24ºC.

Patients returned at 6, 9, and 12 months after the sessions to record weight, measure the contour of the area to be treated at a preset height, measure the untreated control area, and evaluate the degree of skin laxity by the clinician and an external assessor. CLSM images and photographs of the treated area were taken. Patients were asked to evaluate the degree of improvement (**Tables 1 and 2**).
**Devices.** The radiofrequency device used was an EndyMed PRO™, a phase-controlled, multisource radiofrequency system that emits at 1MHz at 1 to 65 watts. The confocal laser scanner microscope used was the VivaScope 1500 (Lucid Inc., Rochester, New York). The infrared camera used was the Flir i7 (FLIR Systems), and the infrared thermometer used was the CEM DT-880B.

**Technique.** All abdominal areas were drawn and divided into 100cm² rectangles or squares. The average number of squares/rectangles in each area was five. The squares/rectangles were drawn with a 20-percent overlap to avoid untreated areas (cold spots) and to ensure that the whole area was heated. Sufficient sweeps were made to complete the pretherapeutic (preheating) stage in which the surface temperature must reach 40 to 42ºC.14–19 Once the pretherapeutic temperature was reached, each session involved 8 X 30-second sweeps, with breaks of two seconds between each sweep. In order to prevent hot spots, the sweeps were made following the same protocol in all the squares/rectangles, at all the sessions, and for all the patients:

- First sweep—circular movement from inside to outside the square/rectangle;
- Second sweep—circular movement from outside to inside the square/rectangle;
- Third sweep—horizontal movement starting the square/rectangle at the top;
- Fourth sweep—vertical movement from left to right in each square/rectangle;
- Fifth sweep—circular movement from inside to outside the square/rectangle;
- Sixth sweep—circular movement from outside to inside square/rectangle;
- Seventh sweep—horizontal movement starting the square/rectangle at the bottom;
- Eighth sweep—vertical movement from right to left in each square/rectangle.
Contact between the skin and the handpiece was improved by applying a fine layer of tepid ultrasound gel (30°C). During the first session, preheating emission power was optimized by recording the maximum power tolerated by the patient continuously over the 100cm² area for 120 seconds (4 uninterrupted sweeps) starting from a base power of 45W. The value obtained was recorded as a reference for subsequent sessions. Once 40 to 42°C was reached, the therapeutic phase began.

Attempting to avoid interrupting sweeps was essential as sweeps intervals greater than 5 seconds decreased the surface temperature by 2 to 3°C. When necessary, power was reduced in steps of 2W and more warm contact gel (30°C) was added to prevent the grid from cooling. The operation was repeated in the neighboring grids until the area was completely treated.

During all sessions, images were recorded using an infrared camera to ensure that the whole area was evenly heated. In each square, temperature was measured before the start of the pretherapy phase (T0), immediately after the sweeps were completed (TF), and after 20 minutes (T20).

Thermographic images were captured using a Flir i7 infrared camera prepared for capture perpendicular to the skin surface. This thermal imaging camera has a meter that measures the distance between the camera and the surface to be photographed. All the images were captured at a distance of 25cm. The maximum temperature was recorded on the image captured. The images captured were stored on the follow-up form for each patient. The maximum temperature values for each image were included in the statistical analysis.

**Results.** Mean tolerated power was 40±7W. Mean variation in weight during treatment was −0.7±1.7kg after six sessions and −0.6±1.7 at the 12-month checkup. Mean reduction in the contour of the treatment area after the first six sessions was −2.9±1.6cm, which stabilized after 12 months at −1.9±2.0cm. There were no significant differences in the variation of the contour of the control
area (–0.5±0.6cm after 6 sessions and –0.5±0.5cm at the 12-month visit) (Table 1).

Both the attending physician and an external observer evaluated the degree of clinical improvement in laxity according to the following scale (0=worse; 1=no clinical change; 2=minor change; 3=visible change; 4=obvious change; 5=significant change). The patient made an objective evaluation using a similar scale—the Global Aesthetic Improvement Scale (0=dissatisfaction, worse; 1=no satisfaction, no clinical change; 2=low satisfaction, minor change; 3=somewhat satisfied, visible change; 4=satisfied, obvious change; 5=highly satisfied, significant change) (Table 1).

The clinician's evaluation of laxity after six sessions was initially 3.5±1.0 degrees (improved–much improved); at 12 months, this was 3.2±0.6. The external observer recorded values that were a few tenths below those of the attending physician (3.2±0.8 after 6 sessions and 2.9±0.8 at 12 months). The degree of efficacy and patient satisfaction was initially 3.4±0.8 degrees out of 5, and 3.1±0.9 at 12 months (Table 1, Figures 1 and 2).

The mean measurements taken using CLSM were as follows:

1. **Minimum epidermal thickness (E^{min})**. This is determined by the tip of the uppermost papillae. E^{min} would be defined as the maximum depth at which only the cellular structure of the epidermis contributes to the signal. Reduction in minimal epidermal thickness was –5.2±8.0µ at six months; –7.1±9.4 at nine months with –6.0±11.9µ at the 12-month visit (–10.72%, –14.63%, and –12.37%, respectively).

2. **Maximum epidermal thickness (E^{max})**. This is defined by the valley of the papillae. The different optical properties of the cellular structure in the epidermis and fibrous structure in the dermis cause a change in the slopes in the reflected intensity profile of images. The onset of this change in a slope at E^{max} corresponds to the depth at which a cellular structure is no longer observed in the image stack upon going from the surface to deeper
3. positions. Increase in maximum epidermal thickness was 4.6±9.5 µ at six months, 6.1±11.9 µ at nine months with an increase to 7.6±11.1 µ at the 12-month checkup (5.54%, 7.34% and 9.16%, respectively).

4. **Dermo-epidermal junction.** Determination of $E_{\text{max}} - E_{\text{min}}$ makes it possible to calculate the thickness of the dermo-epidermal junction (papillary height). Increase in papilla height of 9.5±8.8 µ at six months, 12.9±4 µ at nine months, which increased gradually to 13.3±8.7 µ at the 12-month visit (28.79%, 39.20% and 40.30%, respectively).

5. **Upper dermis.** At a certain depth, a reflecting layer of fibrous structure in the upper dermis (UD) is observed in the stacks. The location of this reflecting layer was defined as $\text{UD}^{\text{min}} + \text{UD}^{\text{max}} / 2$, where $\text{UD}^{\text{min}}$ is the location of the onset of this layer and $\text{UD}^{\text{max}}$ the location of its maximum intensity. The refringence band (UD) of the reticular dermal collagen was located deeper: +9.7±5.0 µ at six months, +8.2±8.9 µ at nine months, and this fell partially to +6.3±8.6 µ at the 12-month visit (+7.98%, +6.74%, and +5.19%, respectively) (*Table 1* and *Figure 3*).

The mean degree of pain reported by the patients was low—1.1 on a scale of 1 to 10 (*Table 2*). There were no side effects. The mean increase in temperature (°C) of each grid was as follows: first session, 11.7±2 immediately after the procedure and 3.8±1 after 20 minutes; second session, 11.5±2 and 3.5±1; third session, 11.2±1.1 and 3.6±1.5; fourth session, 11.5±1.5 and 3.7±1.9; fifth session, 11.8±1.1 and 3.8±1.5; last session, 11.6±1.5 and 3.7±1.9 (*Table 2*).

**Statistical analysis.** Qualitative variables were divided into categories and quantitative variables into intervals. Age was separated in intervals by grouping the same number of patients per group starting with patients under 25 years of age and increasing to 66 years of age. Once the variables were divided, the authors correlated clinician evaluation and external observer variation (improvement in
laxity), patient satisfaction (efficacy/patient satisfaction), CLSM values (maximum epidermal thickness, minimum epidermal thickness, papillary height, and change in the refringence area), and temperatures. Temperatures of the session were evaluated as follows: increase in temperature immediately after the session ($\Delta T_1 = T_0 - T_F$) and increase after 20 minutes ($\Delta T_2 = T_0 - T_{20}$). The most significant statistical results were as follows:

**Age.** Younger age was positively correlated with good results (Pearson P: $p=0.586$, $\alpha=0.003$).

**Increase in final temperature ($\Delta T_1$).** The clinical results clearly showed a greater degree of improvement in laxity when the final temperature was higher. Increases in final temperature ($\Delta T_1$) greater than 11.5ºC were positively correlated with a greater degree of improvement ($p=0.677$, $\alpha=0.000$).

**Increase in temperature at 20 minutes ($\Delta T_2$).** The evaluation from patient, clinician, and external observers were better at higher temperatures after 20 minutes. Increases in temperature at 20 minutes ($\Delta T_2 > 4.5ºC$ ($p=0.802$, $\alpha=0.002$) are associated with the best results. The values for the two temperature variables ($\Delta T_1$ and $\Delta T_2$) were positively correlated ($p=0.773$, $\alpha=0.003$).

**Changes with CLSM.** The association between the degree of clinical improvement and histological improvement observed with CLSM was considerable ($p=-0.860$, $\alpha=0.005$). The presence of more intense morphological changes, as measured using CLSM, was strongly correlated with increases in final temperature ($\Delta T_1$) greater than 11.5ºC ($p=0.812$, $\alpha=0.002$) and with increases in temperature at 20 minutes ($\Delta T_2 > 4.5ºC$ ($p=0.723$, $\alpha=0.009$).

**Discussion**

Radiofrequency is a widely accepted treatment for skin laxity, thanks to the increased tissue temperature and the subsequent reparative reaction it generates.\textsuperscript{19–24} Temperature gradients generated by radiofrequency vary from
patient to patient, as does the gradient necessary to induce the repair response and its intensity.

The target of this clinical study was to attempt to find a statistically significant association between tissue response and final skin temperatures. We found that increases over baseline greater than 11.5°C ($\Delta T_1$) and increases at 20 minutes ($\Delta T_2$) greater than 4.5°C were associated with better results.

In the authors’ experience, it is not always easy to reach these gradients. In fact, the sudden heat that is sometimes observed produces a burning sensation (heat peaks) that reduces the patient's tolerance and makes it necessary to stop the procedure; this results in a sharp fall in skin temperature (2–3°C in 5 seconds). The design of the handpiece and its large contact area make it much easier to prevent heat peaks and therefore improve the patient's tolerance. The three pairs of electrodes generate electrical fields with equal polarity as a result of the system's synchronized phased energy emission. As "like" poles repel, currents can run in deeper planes using bipolar radiofrequency. Very little current flows on the skin surface, which may also be a reason for the patient's better pain tolerance. Progressive, better-distributed heating facilitates a larger number of sweeps and greater tissue heating. Overlapping of heat in neighboring areas allows all the tissue treated to function as a relative heat reservoir, with the result that neighboring grids require fewer sweeps for preheating.

Clinical improvement in laxity is difficult to measure; therefore, a correlation was attempted to be established through objective histological changes using real-time CSLM. This works by detecting the photon refraction that occurs in illuminated live tissue with an 834nm diode laser. The lateral measurement resolution of the system used is 0.5 to 1µ and the optical thickness of 2 to 5µ can be compared to that of conventional histology. Contrast of confocal images is obtained by the different refraction indices of the organelles and other structures of pigmented epithelia. Current technology enables us to obtain images up to a depth of 250 to 350µ, including the epidermis, papillary dermis, and the most superficial part of the reticular dermis.
The Vivascope 1000 generates and measures images parallel to the skin surface. The software included enables the system to run in high definition, both for capture and for analysis of images. Images are captured in parallel to the surface of the skin in very adjusted axial steps (2µ in depth), that is, every image is scanned at depths that increase every 2µ, with the result that 100 images represents a depth of 200µ. The system takes 20 seconds to carry out this analysis.

The images are stored for subsequent analysis. In order to ensure that the images were captured at the same point, the area was marked and the location photographed; the same area was marked for each subsequent image capture. Ten captures were made at each point to avoid variability. The values in the table are average values.

The system is equipped with a mechanical positioner (Physik Instrumente 50) installed on the mount of the camera lens. The pressure generated by the camera-positioning arm on the skin is always the same; therefore, the thickness of the skin is not altered by the pressure.

Given the limits of depth, the authors defined four parameters to measure the potential morphological changes in the dermal-epidermal junction: $\Delta E^{\text{min}}$ (minimum epidermal thickness), $\Delta E^{\text{max}}$ (maximum epidermal thickness), $\Delta$ DEJ thickness (papillary height), and $\Delta$ UD (depth of the reticular collagen refringence band).\textsuperscript{30,31}

**Minimum epidermal thickness** $\Delta E^{\text{min}}$—measurement of epidermal thickness taken from the skin surface (stratum corneum) to the point where the first peaks of the dermal papillae become visible. The distance between the surface and the dermal crest increases with age: 50±8µ in patients over 65 years of age compared with 47±5µ in patients under 25 years of age.
Maximum epidermal thickness $\Delta E^{\text{max}}$—measurement of epidermal thickness taken from the skin surface (stratum corneum) to the depth at which a cellular is no longer observed (epidermal thickness up to the dermal valley). Maximum epidermal thickness decreases with age: 75±7$\mu$m in patients over 65 years of age compared with 89±8$\mu$m in patients under 25 years of age.

$\Delta$ DEJ thickness (papillary height). The determination of $E^{\text{max}} - E^{\text{min}}$ makes it possible to calculate the thickness of the dermo-epidermal junction (papillary height). An increase in the thickness of the dermo-epidermal junction is one of the main differences between young skin and mature skin: 25±8$\mu$m in patients over 65 years of age compared with 41±8$\mu$m in patients under 25 years of age. Mature skin undergoes flattening of the dermo-epidermal junction as a result of flattening of the papillae. Depending on image depth, the confluence of papillae can be observed in skin affected by elastosis.

Depth of the reticular collagen refringence band. At a certain depth (110–140$\mu$m), a reflecting layer of fibrous structure in the upper dermis is observed in the stacks. The location of this reflecting layer (UD) is lower in mature skin: 107±8$\mu$m in patients over 65 years of age compared with 136±10$\mu$m in those under 25 years of age.

The increase in the depth of the refringence band after treatment is also a sign of dermal structural improvement.

Furthermore, in thin skin, the morphology of dermal collagen can be observed accurately up to 200$\mu$m. Young collagen is arranged in the form of fine even mesh with structures and is made up of narrower diameter fibers than older collagen, which is arranged irregularly and in the form of clusters (elastosis). A reduction in the larger diameter of collagen fibers represents a structural improvement in dermal collagen.\textsuperscript{30–32}
We observed histological changes that reflect structural improvement in the dermis; the most significant absolute values of change, as observed by CLSM, were for the increase in papillary height (28.90% at 6 months and 40.30% at 12 months). This is a considerable improvement in the quality of the dermo-epidermal junction and is consistent with the results of other clinical studies based on conventional histology. The increased depth of the collagen refringence band (9.7±5.0 [9.7%] at 6 months and 6.3±8.6 [5.19%] at 12 months) points to the existence of long-term collagen remodeling.\textsuperscript{31–34} Despite the high degrees of temperature obtained in several patients, there were no side effects.

While it is difficult to quantify the peak temperature increase that can lead to improved skin quality in an individual patient, the relationship between the highest degrees of clinical improvement, histological changes, and $\Delta T_1 > 11.5{\degree}C$ and $\Delta T_2 > 4.5{\degree}C$ seem to indicate that some temperature gradients induce a more favorable tissue response.

**Conclusion**

Radiofrequency skin treatments, in this study, show a statistically significant association between better results at increases in end temperature $\Delta T_1 > 11.5{\degree}C$ and increases in temperature at 20 minutes $\Delta T_2 > 4.5{\degree}C$. These gradients are in turn significantly associated with higher indices of structural improvement, as seen using CLSM.
Before and after pictures (sixth session). Contour measurement change = \(-5.5\)cm; weight change = \(-2.9\)kg

**Figure 2**

Before and after pictures (sixth session). Contour measurement change = \(-2.5\)cm; weight change = \(-0.9\)kg

**Figure 3**

Changes observed with confocal laser scanning microscopy (scaled drawing)
References


Articles from The Journal of Clinical and Aesthetic Dermatology are provided here courtesy of Matrix Medical Communications
Non-invasive therapy of wrinkles and lax skin using a novel multisource phase-controlled radio frequency system.

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Abstract
Abstract The last few years have shown an increased demand for non-invasive skin tightening to improve body contour. Since light (lasers or intense pulsed light sources) has a limited ability to penetrate deep into the tissue, radio frequency (RF) modalities were introduced for the reduction of lax skin to achieve skin tightening and body circumference reduction. This study presents the use of the novel 3DEEP technology for body contouring. 3DEEP is a next generation RF technology that provides targeted heating to deeper skin layers without pain or other local or systemic side effects associated with the use of the earlier generation RF systems available today. The study included 30 treatment areas on 23 healthy volunteers at two sites. The treatment protocol included four weekly and two bi-weekly (n= 6) treatments on different body areas. Results were evaluated by standardized photography and by circumference measurements at the treatment area, and were compared to changes in body weight. Significant improvement could be observed in wrinkles and skin laxity, and in the appearance of stretch marks and cellulite. Some changes appeared as early as after a single treatment. Circumference changes of up to 4.3 cm were measured.

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