Effects of cellulite treatment with RF, IR light, mechanical massage and suction treating one buttock with the contralateral as a control

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Abstract

Background and objectives: A system that combines bipolar radio frequency (RF) and intense infrared light (IR) together with mechanical massage and suction has recently been reported as being efficient for cellulite treatment. The present split study was designed to evaluate the efficacy of such a system through various treatments of cellulite located on the buttocks. Methods: Ten patients were enrolled for 12 sessions of 30 minutes each performed over one buttock, the other buttock serving as an untreated control. Sessions were conducted twice a week for a period of 12 weeks. Clinical photography and profilometry were carried out to assess textural changes before (baseline) and 2 months after the final treatment. Histopathology was performed at baseline, 2 hours after the first session, and just before the 12th session and 2 months thereafter. Results: All patients noted improvement in the treated buttock before the final session, which was maintained at the 2-month assessment. Improved skin appearance was noticed after the first session and was maintained throughout the study. All patients were satisfied with the results and requested further treatment in order to balance the results in both buttocks. Random histological analyses suggested dermal firmness, fibre compaction and tightening of skin layers, including the subcutis, as possible reasons for the effects achieved. The authors recognize that the small number of participants limits the statistical power of the study. Conclusions: Treatment sessions with the combined RF, IR light and mechanical massage and suction system were complication free, produced improvements in the overall cellulite appearance and skin condition, suggesting that further treatment sessions for maintenance could sustain patient satisfaction index (SI) and lead to lasting results. Based on the good results in the limited trial population, further studies with larger patient populations are warranted.

Key words: Cellulite, IR light, radio frequency, skin condition

Introduction

Cellulite is characteristically represented by irregularities in skin contour, in the form of small bumps or orange peel-like dimples, mostly located over the buttocks, thighs and around the inner part of the knees. The excess of adipose tissue in females at the post-pubertal age (1,2) is retained by fibrotic tissue division. The characteristic of cellulitic subcutaneous tissue, whereby fibrous septae keep cells together, causes protrusions up into the dermis, thus giving the skin its distinctive irregular appearance (3). The fibrous septae retaining the adipose tissue are anchored vertically upwards to the surface and deeply in the skin, extending even to the muscle fascia.

Cellulite aetiology is unknown; however, it is described as being related to hormone receptors in specific body regions (4). The increase in the volume of adipocyte cells is related to the effect of lipolysis inhibition, which increases the glucose concentration entering the cells (5,6).

Radio frequency (RF) electrical current causes a thermal effect in biological tissue. RF tissue heating properties, operated in monopolar or bipolar mode, have been extensively used for electro-surgery and homeostasis. In a bipolar RF device, energy is delivered through paired electrodes in a single handpiece applied to the skin. Electrical current propagation is limited to the area of skin between the electrodes and the depth of penetration is approximately half the distance between them. Temperature elevation is induced in a well-defined volume of tissue (7). If, in addition to RF energy, intense infrared light (IR) is used, an increased thermal effect in the target biological tissue can be obtained,

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provided a chromophore-specific wavelength is selected (8).

If mechanical massaging and suction were added to these two energy sources in the same system, the combination of the different mechanisms could work synergistically and, when applied to the skin for the treatment of cellulite, might well generate an active tissue reaction which could be more effective than when either RF or diode laser energy is used alone.

Electrically conducted RF energy is chromophore independent, not sensitive to skin type or target pigment, and the bipolar electrodes deliver RF current inside the tissue along the lowest route of impedance. Deep heating has previously been achieved in the tissue with the combination of RF and IR energy (9) and the addition of mechanical stimuli, namely massage and suction, to that combination has been previously reported to improve the external bumpy appearance of cellulitic skin (10,11).

The present study was designed to ascertain the efficacy of a system which combines four functions (RF, IR light, mechanical massage and suction) for the treatment of cellulite located in the buttocks, treating only one buttock, with the other serving as an untreated control.

Participants and methods

Ten patients, all females, were recruited for the study, with ages and skin phototypes presented in Table I. The mean age was 48 years (range 28–52 years) and phototypes ranged from types II to IV. Full blood analyses were carried out on all patients, concentrating on any hormonal irregularities. The inclusion criterion was the presence of even distributions of cellulite in both buttocks. Patients agreed to stay on their usual diet and any exercise programme, and were informed of the goal of the treatment sessions, namely to maintain weight fluctuations within ±1 kg. Exclusion criteria were any other type of cellulite treatment immediately before or during the study; pregnancy or lactation; the presence of diabetes or any hormonal irregularity; the presence of any skin disease; and any circulatory abnormality in the extremities. After having been informed of the purpose and possible outcomes of the study, patients signed forms of consent for clinical photography and for the study, which was approved by the Ethics Committee of the Antoni De Gimbernat Foundation.

Before starting, measurements were taken with a measuring tape, with the anatomical reference points being the most prominent parts of the bilateral hips, namely the greater trochanters. This assessment was recorded, together with the weight, on a graduated scale (KRUPS fit control memo, Germany).

All patients were treated with the Vela Smooth™ system (Syneron Medical Ltd, Israel). The device incorporates various actions such as mechanical massage and suction, IR light and RF electrical current. The latter delivers 20 W and IR light over a waveband from 700 to 2000 nm – both of which are applied simultaneously to the tissue. At the same time, mechanical massage is given and suction is applied corresponding to 750 mmHg of negative pressure. All these actions are delivered through the handpiece, held in both hands, which is manually applied to the skin by the physiotherapist giving the treatment. The specific geometry of the electrodes, which double as massage rollers, provide the possibility of deep RF penetration when the handpiece is slid over the skin.

The handpiece permits treatment at an intensity ranging from 0 to 3. Treatment in the present study was given with intensity 3, which produces continuous irradiation with IR light and RF – giving rise to the heat sensation, during which a rolling massage is performed together with a suction action. In the event of pain or an unpleasant heat sensation, the operator moved the handpiece away. Sets of parameters for treatment were constant during all 12 sessions: two sessions per week, administered for 30 minutes with six to eight passes on only one buttock, chosen at random, while the opposite buttock served as a control. Treatments were twice a week and were always given by the same physiotherapist, who was trained in interviewing techniques and also administered a questionnaire to the patients for subjective assessment of their skin condition after every treatment.

<table>
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<tr>
<th>Patient no.</th>
<th>Age (years)</th>
<th>Phototype</th>
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<th>Stable weight</th>
<th>Stable size</th>
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General skin condition was checked subjectively by patients at every session using a five-point analogue scale: 1 = worse; 2 = little or no change; 3 = fair results; 4 = good results; 5 = very good results. The general skin condition of the treated area was also checked objectively using profilometric data at baseline (beginning of all treatments), before the final session (session 12), and 2 months after the final session, with a CLINIPRO Antiaging SD device (Barcelona, Spain) based on a 3D optical skin surface camera. The area of cellulite chosen for testing was constant and mapped out in order to repeat measurements.

Mapping of the area of treatment was done following natural references in order to be very accurate about checking for any possible tissue changes through comparison of the before and after samples. The area selected for testing comprised different areas from the total treated area of the buttock, which were all compared at baseline and after treatment. The results of these comparisons gave an average reference as to which area was the most representative, using this for the comparative study of before and after skin surface 3D analysis by the computer.

The optical skin analysis technique was used to examine for anisotropy of the skin surface as well as micro-relieves, in order to identify any changes in the skin condition via the measurement of tissue depression depth and roughness. The surface of the area of cellulite was examined with built-in 3D profilometry computer software. In vivo skin 3D profilometry was performed with patients standing erect, with the camera device placed vertically on the selected area. A microtopography in vivo scanner using optical triangulation, with a video light projection technique and digital image processor, recorded an image which was digitalized and transferred to the computer for quantitative evaluation. Mathematical algorithms embedded in the analytical software reconstructed the data into a highly precise 3D profile of the skin surface. Evaluations of the system software enabled image measurements of 5 × 5 mm (25 mm²) and the deduction of the skin texture of the cellulite area to compare with data obtained from an image taken from the area of normal skin outside the cellulite area. Accurate reproducibility of the 3D test can be obtained by mapping the treated area guided by natural anatomic references, so that images were obtained from exactly the same place for comparative control of before and after treatment images. Three-dimensional image profiles were arranged in parallel for comparative checking. The roughness index (R) was determined by the computer program, and represented the difference between the maximum mean and minimum mean values (e.g. peaks and valleys of the skin surface of the area of cellulite examined). Five and 40 were the respective minimum and maximum reference values, the former being a baby’s skin texture and the latter the skin texture of an elderly individual with severely photodamaged skin.

Patients also graded their satisfaction index (SI) regarding their cellulite condition at two assessment points, namely before the last treatment (session 12) and 2 months after this last treatment. The following scores were selected: very satisfied (61–80% improvement, VS) because the total resolution of cellulite was not anticipated; satisfied (41–60% improvement, S); somewhat satisfied (21–40% improvement, SS); not satisfied (0–20% improvement, NS); and worse if the situation of cellulite was worse than before starting. The data were subjected to statistical analysis using a standard two-sample t-test for small populations. Statistical significance was achieved at p < 0.05.

Clinical digital photography with a SONY Mavica MPEGMOVIE 2X digital camera was taken before the first session, and before and 2 months after the 12th and last session. These photographs served as the objective evaluation together with the examination of skin characteristics done with the 3D optical profilometry. An independent and blinded expert clinical aesthetician scored the results on a five-point analogue scale based on these data to objectively define the findings using the same scale that patients used to define the subjective assessment of their skin condition.

Six patients from the group of 10 volunteered to undergo 2-mm skin biopsies, which were taken before and 2 hours after the first treatment and 2 months after the last treatment session. Samples were routinely processed and stained with haematoxylin-eosin (HE). Tissue samples were taken from the non-treated control buttock and then treatment was given on the opposite buttock, samples being taken 2 hours after treatment. This ideal elapsed period post-treatment was ascertained during a pilot study prior to the present study, in which specimens taken immediately after treatment showed little or no change and the presence of an inflammatory reaction in samples taken much more than 2 hours after treatment or on the following day masked the treatment effects being analyzed.

**Results**

Pain during treatment was reported as being bearable by all patients (no patients scored more than 5 points on an 11-point visual analogue scale) and the erythema that developed lasted no longer than a few hours. Neither of these symptoms was considered a setback to the treatment. No blistering was seen and treatment was complication free. Figures 1 and 2 show representative examples of the clinical photography findings before treatment, and at 2 months after the last session.
All patients completed the series of treatments and underwent the baseline, and pre- and 2-month post-final session assessments and subjectively rated improvement in the general aspect of their skin condition (Table II, column 6). No patient scored ‘worse’. From the macroscopic aspect, almost all patients felt that the skin appeared to be smoother with better tactile texture and was plumper, giving the impression of an improvement in cellulite appearance. These positive changes in the general aspect of the skin were maintained throughout the entire treatment period with more notable improvement seen at session six or seven.

To obtain the patient SI, the ‘VS’ and ‘S’ scores, as discussed above, were summed to calculate the SI. Figure 3 shows the patient SI scores. In general, a high SI was seen at the assessment prior to session 12, but a reduction in scores was recorded 2 months after the last treatment session. The SI scores obtained from the sum of the VS and S scores at the two assessment points (before treatment session 12 and 2 months thereafter), were 90% and 70% respectively. Despite this drop-off in the SI at the final assessment, the patients still wanted treatment of the untreated buttock, which they had first expressed at the assessment point prior to the final and 12th treatment.

Skin condition and texture, as assessed by the 3D profilometry data and analysis by the computer program, showed improvement of skin characteristics at all assessment points with a slight overall increase between the pre- and 2-month post-treatment assessment points for skin condition, and a very slight overall decrease for the roughness values, although an increase was seen in some patients (Figure 4, Table II) at 2 months after the last treatment. The circumference at the greater trochanters had decreased by about 3–5 cm (average 3.9 cm) in seven of the 10 patients at the assessment before the 12th and final session (unchanged in two and slightly increased in one), but had returned to baseline values in nine of 10 patients by the final 2-month assessment, remaining slightly decreased in the other one patient (Table II). The most noticeable changes appeared at the fifth or sixth treatment session. Weight control throughout the study was
more or less maintained, with slight variations of ± 1 kg at all assessments (Table II).

Histological findings of the effects after the first treatment session when compared with before treatment revealed an undulating epidermis, due to some shrinking caused by contraction of the papillary dermis, where interfibrillary spaces appeared smaller. Such effects were more noticeable at 2 hours than at 1 hour post treatment session (Figures 5–6). Bundles of fibres were seen to be less compact and fragmented although dermal fibres were still seen aligned with, and running parallel to, the dermo-epidermal junction. At the subcutaneous layer, adipocytes appeared slightly closer together when compared with the baseline samples (Figure 7). The described changes were constant in all samples examined and, in those from the final assessment point, tightening of the dermal collagen was noted and a better cellularly organized epidermis was seen, compared with the baseline findings.

Finally, Table III compares the patient’s subjective assessment of skin condition at the pre- and 2-month post-final treatment assessments with the clinician’s assessments based on the clinical photography for the same assessment points. In common with many other studies, the clinician’s assessments were in general higher than the patient assessments but, interestingly, the patient assessment was actually slightly higher overall at the final assessment point although without statistical significance (p=0.1), whereas the clinician assessment showed an overall decrease at the same assessment point, again without statistical significance (p=0.07).

**Discussion**

Various treatments and techniques have been proposed for cellulite reduction but none has proved to be effective for long periods and in most cases it is difficult to evaluate their true effects. Most cellulite treatments on the market are for local application. The contents of these products are based on empirical observations with insufficient scientific support. Cellulite reduction and changes in skin characteristics on offer are often based on a pure marketing interest with questionably ‘good’ before and after pictures.

First, the transportation of substances inside the skin is by no means a simple process and many substances, because of their molecular size or composition, cannot pass through the epidermis, or lose their action before reaching their area of interest, which is in the dermis or subcutis. In this direction, Alster and Tanzi (11) have published a thorough review of products and techniques used for cellulite treatment. Herbal ingredients are capable of stimulating blood flow, but this effect is due to the rubifacient effect of these substances when applied and rubbed on the skin. They do not affect cellulite directly but only activate blood circulation in the area of the skin where they are being applied (12). Iontophoresis is believed to help convey substances or

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**Table II. Assessments of skin condition and roughness, hip circumference, weight control and subjective patient evaluation at baseline (Base), before (value 1) and 2 months after the final treatment, session 12 (value 2).**

<table>
<thead>
<tr>
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<th>Weight control</th>
<th>Patient evaluation</th>
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<td>5</td>
<td>0</td>
<td>2</td>
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*Baseline values normalized at zero; *b*Measured across the greater trochanters; *c*Scoring as follows: 1= worse; 2= same; 3= fair; 4= better; 5= much better. BV= base value; NC= no change (±1 cm, ± 1 kg from BV); < = smaller; > = larger.

Figure 3. Patient satisfaction index (SI) compared between the pre-final treatment and 2-month post-final treatment assessments. The SI is calculated from the sum of the VS and S scores, and expressed as a percentage. (VS, very satisfied; S, satisfied; SS, somewhat satisfied; NS, not satisfied.)
medication transdermally into the skin, and when combined with manual massage, this approach has obtained results in cellulite reduction which are, however, discreet and temporary (13).

In the treatment of cellulite, mechanical massage and vacuum action at low pressure are said to increase lymphatic drainage but results are inconsistent and not maintained for long (14). Results obtained are also discouraging with the use of aminophylline but other types of treatment such as needle surgical subcision produce some improvement (15) and, in the case of mesotherapy, studies are lacking in control groups and prolonged follow-up (16–18).

A combination of various energy sources applied to the skin to stimulate micro-collagenesis and to improve the characteristics of tissue aging has been reported (19). RF combined with IR energy, simultaneously applied with mechanical massage

Figure 4. Representative profilometry findings showing general skin condition (left column), 3D profilometry (middle column) and computer-generated line graphs from the image data. The top, middle and bottom lines represent baseline, the pre- and 2-month post-final session images. From the line graphs, the gradual smoothing of the skin is clearly demonstrated, with the improvement maintained at the final assessment.

Figure 5. Representative haematoxylin and eosin stained specimens from a patient before (left panel) and 1 hour after (right panel) the first treatment session. Please see the text for details. (Skin, HE, original magnification x 60.)
and suction is an innovative, promising treatment modality with potential applications in aesthetic medicine and can be used safely on the skin regardless of its phototype (20). The RF component is non-specific for skin type or target colour, and the IR parameters as delivered by the device used in this study are virtually painless, but interesting from the point of view of heating tissue progressively and accumulatively. Increased IR-mediated heat has a series of positive effects such as an increase in blood flow and lymphatic drainage, and, at the same time, will facilitate the action of RF electrical energy by changing tissue impedance and its absorption coefficient (21).

The combination of IR laser and RF current has already been proposed as an efficacious treatment for leg vein coagulation (22) and has been reported to achieve rejuvenation-related effects (23). It was therefore interesting to examine the combination of RF, IR light and mechanical massage and suction as proposed in previous studies, but comparatively examining the tissue through an intra-patient split treatment, assigning subjective and objective scores and also checking the histological effects on tissue.

This can offer an extra dimension of treatment effects on the overall condition of cellulite, both macroscopically and internally in the skin.

In fact, the regimen used in this study did indeed produce interesting results on cellulite, including an improvement of its characteristic appearance and the general skin condition was improved, both subjectively, as noticed by the patient, and objectively as

<table>
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*Scoring as follows: 1 = worse; 2 = same; 3 = fair; 4 = better; 5 = much better.
examined by the independent blinded clinician and by 3D skin surface analysis. Pain and erythema were not a reason for individuals to refuse to continue with treatment and, during sessions, all communicated good tolerance and practically no discomfort, except for one patient, for whom it was necessary to conduct the treatment leaving some time between passes of the handpiece over the skin. All patients reported varying sensations of heat but most of them bore the treatment very well. The fact that all patients requested treatment of the other buttock reflects the satisfactory results achieved in the treated buttock.

In the histologies performed on six individuals of the 10 in this study, an overall improvement in epidermal and dermal morphology was noted from specimens taken at the final assessment. In the specimens taken 2 hours after the first treatment session, discreet inflammatory effects were observed but the common observation was of alignment of fibres and dermal compaction.

The observed histological changes of fibre realignment could be one of the reasons for the external appearance of the ‘plumpness’ of the skin noticed by patients right after the first treatment, but this should only be a transient change because it is difficult to see how one single treatment session could cause changes in the skin texture and a feeling of smoothness to the touch. The observed changes could be more likely due to erythema produced by the treatment which changes the index of skin reflectivity to external light (24). In fact, the expected reflectance of the epidermal thickness is in agreement with the various skin phototypes treated in this study (25). The increased fraction of dermal blood as a consequence of the cellulite treatment could possibly change visual appreciation of the skin characteristics compared with baseline, and patients would then appreciate the different appearance of the skin because of the erythema-related changes in the reflection coefficients. When this change in the index of refraction was combined with the post-treatment erythema, it possibly made the treated surface area appear macroscopically better.

The deeper dermal fibres in the specimens 2 hours after the first treatment session appeared less compact giving the impression of fragmentation, which could possibly be as a consequence of the mechanical massage and suction carried out. Also, at this stage, alignment of fibres was already seen closer to the dermo-epidermal junction (DEJ), a situation which produces superficial contraction of the skin. This could be the reason why the patients felt their skin was smoother to the touch.

Thermal-related changes in tissue combined with mechanical massage and suction may produce breakage in the fibrous septae contributing to changes in the dermis and epidermis as pointed out by Alster and Tanzi (11). The histological findings in specimens taken at the final assessment showed the formation of new collagen with fibre alignment running in a wider band, parallel with and attached to the DEJ. All these changes might not be specific but as a result of microinflammatory stimuli produced in the tissue and the standard process of tissue repair as a reaction. Nevertheless, studies with a larger number of patients and a greater number of specimens are required to validate the findings of the present study.

The slight decrease in the SI at the 2-month assessment was interesting and is a possible marker regarding the timing of a maintenance treatment programme for extra cellulite improvement, even though the overall subjective assessment of skin condition showed a very slight improvement. Maintenance treatments on a monthly basis sound promising and might contribute to consolidation of the positive results achieved. Alster’s follow-up (11) was 1 month after her series of treatments, suggesting that maintenance sessions should be implemented in order to further enhance results, and the findings at our 2-month follow-up after the last treatment session agree with her observation whereby the patient SI had decreased, as had the objective clinician assessment values, so it would appear reasonable to hold once-monthly maintenance treatment sessions. There was good patient compliance with the various treatment sessions and there was practically no loss of the good effects achieved on the skin surface as detected by the 3D optical detection programme when compared with results of previous assessments.

Taking all findings into consideration, the possibility exists that the results might persist even longer than our final assessment period, but a maintenance programme helped by good patient compliance, as noticed in this study, with regularly repeated sessions, would ensure that a high patient SI would be sustained. Further investigation with the RF system in combination with IR light, mechanical massage and suction is warranted.

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Disclosure

The authors state that they have no financial interest in any of the equipment described in this article, and that no other conflicts of interest exist with regard to publication of the article.
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