

A MULTINATIONAL STUDY ON CELLULITE TREATMENT WITH THERMALIPO™
A NOVEL RADIO FREQUENCY (RF) SYSTEM
Preliminary report based on trials done in Holland and Spain

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Running Head: Radio frequency for cellulite treatment

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ABSTRACT

Background and Aims: Radiofrequency (RF) systems have been reported as producing rejuvenation-related cutaneous effects. Clinical reports and arguments provided by physics present RF as producing therapeutic action on dermis and subcutaneous layer, based on energy absorption in tissue via the passage of electricity between electrodes whose depth is determined by half the distance in the case of bipolar electrodes. The present study was designed to evaluate a novel technological concept of a bipolar RF device to treat localized cellulite.

Subjects and Methods: Twenty patients treated for cellulite are presented as a sample of two of the Centres participating in a multinational study to determine the efficacy of an RF system which incorporates AMFLI technology. This consists of a variable RF emission operating accordingly to impedance presented by the treated area. Changes in tissue temperature make the device change to high or lower frequencies, the latter having deeper effects in skin layers. Treatment was guided by pain, redness and increase in external temperature up to 42° centigrade. In 12 sessions, 7 days apart, 3 passes were given on buttock and belly areas at 6J/cm³. Changes in cellulite and tissue condition and evaluation of the general skin appearance were examined before and immediately after the first treatment session and clinical assessments were before last session and 2 months after. Objective comparisons of skin condition were also made with a 3D optical device, histology and clinical photography and control of patients' weight and measurements of areas treated were also carried out as well as questionnaires to determine patients' satisfaction index.

Results: All patients but 4 of the 20 noted improvement in cellulite condition and in body silhouette progressively obtained through the various treatment sessions but results slightly decreased at the 2 month assessment. Improved skin appearance was objectively detected by 3D images and via photography. Histologies following RF AMFLI technology sessions showed rejuvenation in skin characteristics with effects on the subcutaneous fat layer that might be a consequence of heat conduction from the dermis which under tightening activation improves cellulite aspect.

Conclusions: AMFLI technology improved skin and general aspect of cellulite condition and the dermis collagen. Patient compliance was good and treatment was done without pain. Maintenance sessions should be given to upkeep results and might help to achieve a more prolonged, solid outcome.

KEY WORDS: Cellulite, RF technology, therapeutic radiofrequency

INTRODUCTION

Cellulite represents an aesthetic handicap in women, and various treatment modalities have been proposed for its elimination. A novel radio frequency (RF) system offering therapeutic effects based on the so-called AMFLI technology has been tested for treatment of localized cellulites of the buttock and belly areas. Several reports present RF as being effective for skin rejuvenation and cellulite treatment (1, 2 & 3), however there are still some uncertainties such as the maintenance of achieved results and proven efficacy related to treatment. A multicentre study was designed to ascertain results obtained with an RF device incorporating an electronic technology which permits the progressive build up of heat deep in the tissue, based on the energy flow controlled by the distance between the bipolar electrodes on the hand piece. AMFLI constantly amplifies different frequencies of RF emission monitored by changes in tissue impedance. Part of the multicentre study and results are presented eg: methodology and results of 20 patients treated in two of the participating centres of the study which although corresponding to preliminary data based on observations and some conclusions of two centres, represents the general opinion of all partner centres.

SUBJECTS AND METHODS

Patients and Assessment:

Twenty female patients aged 24 to 58 years (average 36 years), skin phototypes II to IV, participated in the study (Tables 1 & 2). All patients presented cellulite located in various body areas, the buttock and belly areas were selected for treatment. None of the patients had undergone any previous treatments for cellulite. Cellulite degree was established according to skin aspect, fatty tissue volume and relief present in the skin (4-5). It is known that with time cellulite develops inter-septal laxness and fat accumulation is seen in the formation of cells. Adipocytes cells occupying the dermis in groups produce the characteristic "orange peel" aspect.

The THERMALIPO™ RF (Thermamedic, Alicante, Spain) is a novel system that incorporates Automatic Multi-Frequency and Low Impedance (AMFLI) technology. When in action, simultaneously different emissions of RF reach different tissue depths, resulting in a progressive increase of heat inducing thermal effects in the subcutaneous layer. AMFLI technology has the ability to rapidly deposit a high energy load, which progressively and constantly raises the temperature of the hypodermis and dermis, without causing pain and without the need for epidermal cooling. The contact of the electrodes with the skin at the selected area of cellulite treatment enhances the RF transmission by the use of a non-cooled transparent gel. The bipolar hand-piece of the RF was applied with the following sets of parameters: 12 weekly treatment sessions, fluence 6J/cm³, 3 passes every session. A pass was considered finished once temperature reached 42°C or patient expressed a burning sensation.

Treatment sessions were 30 to 45 minutes long, depending on the treated area, and Aloe Vera gel was gently applied at the end of each session.

All patients, after having been informed of the purpose and possible outcomes of treatments, signed consent for clinical photography and biopsies, and agreed to respond to questionnaires. The study was approved by the Ethics Committee of the Antoni de Gimbernat Foundation. For the histologies, 13 patients of the 20 accepted to have biopsies for tissue examination of treatment effects. Clinical

digital photography was taken before the first session, before session 7, after session 12 (last session), and at 2 months after treatment. Photography records were also obtained at other assessment points. Based on photographs, a Doctor not involved in the study, but an expert in aesthetic treatments, was asked to give his opinion of results obtained and score outcome according to a scale of Bad; if cellulites condition visually were worse in aspect than before treatment or if there were no changes. Fair; if there were few positive changes. Good; if results were positively and visually noticeable, or Very good; if results were very noticeable.

Patients were instructed to report on pain during treatment because this manifestation, together with strong erythema and increase in temperature detected up to 42°C, was taken as the end point of treatment. Temperature was checked by an infrared thermometer which was held in hand by the RF operator. If no pain or burning sensation appeared but increase in temperature reached 42°C, the bipolar RF hand-piece was moved to another area of the buttock or belly coming back to previous treated area, and so on, up to 3 times. Pressure was put on the hand-piece at the time of treatment, tracing an 8 and also following Langerhans lines direction but also with such movement as to bring the treated area to the bony locations like a manoeuvre of holding and hooking tissue.

Patients were asked to grade their satisfaction index (SI) regarding treatment results through questionnaires administrated before session 7 and 12 and 2 months after last treatment. At the three assessment points results were scored as: Very Good (65% - 80% improvement); Good (40% - 60% improvement); Fair (0% - 39% improvement); Bad (0 improvement). Examination of skin surface roughness for judgement of texture was carried out on all patients. For this, a CLINIPRO Antiaging SD device, (Barcelona, Spain) was used examining the surface with a 3D optical skin surface camera. The area of cellulites chosen for testing was constant and mapped out in order to repeat measurements. Tests for skin texture were only done before treatment and 2 months after the last treatment session. This test was carried out in all patients from the selected area of the buttock or belly which was representative of the treated area.

The optical skin surface analysis technique is used for examining anisotropy of skin surface as well as micro relieves in order to identify skin condition via the measurement of tissue depression depth and roughness. The area of cellulite surface was examined by attached 3D profilometry computer software. In-vivo skin 3D profilometry was performed with patients in the erect position and the camera device was 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 images which it digitalised and transferred to the computer for assisted quantitative evaluation measurement. 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 5x 5 mm (25mm²) and the deduction of the cellulite texture to compare to data obtained from an image taken from the area of normal skin out of cellulite area. Images of 3D profiles were arranged in a parallel array for comparative checking. The roughness index was determined by the computer programme and this is represented by the letter R. R is the difference between the maximum mean and minimum mean values eg: peaks and valleys of the skin surface of the cellulite area examined. 5 and 40 were the minimum and maximum respectively, the lowest being a baby skin texture and 40 the deteriorated skin texture of an aged person.

RESULTS

All twenty patients completed the study. Upon visual examination, most of them scored as Very Good and Good regarding the aspect of the buttock or belly area treated at the 2 months assessment (after 12th treatment session). All patients noticed an improvement in skin condition with a decrease in surface depressions and a smoother feeling to the touch. During treatment, no complications were noted. Patient SI, identified also at this assessment was: 5, Very Good; 4, Good; and 1, Fair for the Centre in Holland and 3, Very Good, 4, Good, 2, Fair and 1, Bad, for the Centre in Spain. Patients experienced pain when the thermometer showed around 42-43°. (Tables 3, 4 & 5).

All patients showed erythema which usually disappeared 24 hours after treatment. Figs. 1, 2 & 3 are representative examples of clinical photography findings before and 2 months after the last treatment session of both centres. Fig. 4 shows assessment before starting the whole series of treatments, before session 7 and before session 12. Comparing the photography of before and 2 months after last treatment session, assessment of cellulite appearance by the Doctor was: Very good, Good, Fair, and Bad. Histology findings of immediately after first treatment session showed the separation of fibres in the dermis. This was assumed to be due to oedema. Epidermis appeared without alterations and dermis showed some inflammatory infiltrate. Subcutaneous tissue was preserved, showing in some histologies thickening of the adipocyte cytoplasmic membrane without the break-up of vacuole formation. In samples of 2 months after last treatment session, the epidermis appeared multicellular and with less keratin. The dermis presented fibre compactation and a new band of collagen was aligned in parallel and attached to the basal layer of the epidermis.

Skin texture measurement by 3D optical skin imaging of before the first treatment session, when comparing to images of the same area 2 months after session 12, (the last treatment session), showed an improvement, presenting less depth in the depressed conformation of skin surface. On the 3D scale of relief, micro relief of skin surface was between 17 and 20 points better than before, which corresponded to about 45 to 50% improvement in texture (Fig. 5). Logarithmic tables given by computer calculation were of significant improvement of skin texture adopting characteristics of younger skin.

DISCUSSION

Results obtained were detectable upon visual examination in before and after photographs. The Doctor was able to detect overall improvement in areas treated with less evident cellulite aspect. Patients were also satisfied with the treatment and there was high compliance with the programme of sessions. The fact that Thermalipo RF was not delivered in pulses, which are usually formed by a bulk block of energy, but instead with continuous emissions, meant that progressive increase in heat deposit was converted into thermal effect by tissue absorption. Good control of signs shown by the skin and information given by the patient at all times during treatment meant treatment was well tolerated. Skin improvement was clearly detected by 3D skin surface analysis, but moreover, all patients detected better condition on visual examination and manual tact of treated area. Histologies showed that absorption of RF energy transformed into inflammatory reaction on the dermis. Effects on the subcutaneous fat layer seem to be a consequence of heat migration following thermal conduction.

It was noticed during treatment that pain only existed at the time that temperature was increased to 42°-44°C. This sign of treatment end point of hand-piece passage on the skin was consequent to detection of heat by the *nociceptive* receptors located superficially in the skin. They received the wave of heat propagating towards the interior of dermis. RF emission is low at start of treatment, monitored by AMFLI, acting deeper in the skin increasing temperature. Then more emphasis on a higher frequency is operated due to changes in impedance detected by the technology incorporated in the Thermalipo. Low frequencies of RF emission penetrate deeper than high frequencies. Thermalipo with AMFLI technology delivers RF energy via bipolar electrodes. The relative distance between electrodes allows electrical energy passage at half the distance of this separation so once the skin's deeper layers increase in temperature due to thermal effects the change in impedance is detected by electronics of the device which changes the RF frequency of emission. The instrumentation of Thermalipo, based on the AMFLI technical design, is set to automatically produce variations in energy frequency guided by the tissue temperature which consequently changes impedance by the electrical energy passage.

When using high monopolar or bipolar RF energies delivered in pulsed mode, the effect in the skin is only limited to a certain volume, directly in relation to the time length of pulse and the energy programmed. Electrical energy passing through tissue is absorbed depending on the conductivity of tissue and its contents. Usually, when energy is delivered in pulses, deposits of energy occur rapidly, producing significant pain. If RF is delivered in a continuous form with lower energy packs and with variable frequencies, there is a built-in protection through the skin's *nociceptors* and therefore no sensation of pain. Because the passage of RF occurs between differently charged electrodes, we assume that this penetrates 20 to 25 mm deep, being this approximately half the distance between the Thermalipo bipolar electrodes, effects are developed such as resistive heating by continuous movement of hand-piece over skin surface which result in the accumulation and propagation of thermal effects. In the interior of the skin this phenomenon starts deep and progressively reaches the upper skin stratum as well as skin surface. Low temperature (32°C) detected by the IR thermometer, measured at skin surface, increases throughout the treatment to 42°C which in the interior is estimated to be in the range of 52 to 62°C in a maximum depth of 25 to 35 mm, which corresponds to half the distance between electrodes.

Increase in tissue temperature, due to resistance to electricity passage converted into heat obviously depends on the hydric state of tissue and its electrolyte concentration (6) Hypothetically, applying the Thermalipo hand-piece with a random hand movement would help collagen to tighten disorderly but, when tissue temperature reaches the hand-piece, movement applied with much more pressure, following traction lines and not only Langerhans lines, sensitive heat intermolecular collagen bonds will go into a gel state enabling collagen fibres to be stretched and reshaped in a *lifting* direction. This physical effect has been reported to occur under a certain pressure as proven in endothelial vessel cell cultures which make fibroblasts excrete more collagen on rhythmic unidirectional traction (7, 8).

The non-heat sensitive bonds and collagen monofilaments (peptides) shrink. When the tissue temperature returns close to its base temperature, the gel state bonds will return to a firm state but binding in another position. This will eventually lead to tightening of the skin next to the induced neocollagenesis by the inflammatory process or micro-wounds developed by RF electrical absorption.

This hypothesis will support recommendations of applying the hand-piece in a certain pattern of movement and pressure to be applied. Also of importance is to put emphasis on bony areas which act as “coat hooks” or landmarks for pulling the tissue in the desired direction. These areas may be subject to pain upon treatment, because of bone proximity to skin surface, but a firming reaction of the skin will be more clearly obtained in the treated area, as we have clinically observed. The Thermalipo provides a low programme setting for these cases in which the time delay between emissions is longer resulting in a longer skin thermal relaxation time.

The large population treated in various centres of various countries, and the results obtained point in this direction. It seems that benefits of treatment are based on carrying out the whole package of various RF sessions that produce constant tissue stimulation improving skin condition as observed in histologies done at 2 months after the 12th session assessment. The fact that progressive tissue heating with bearable pain and/or burning sensation leads to excellent treatment compliance would also be a reason for patients to accept maintenance sessions, in view of observations that after 2 months without treatment there is a slight decrease of objective and subjective good scores assessed at the last control. Further investigations are warranted to determine the effects of treatment sessions conducted for longer periods with prolonged follow-up.

ACKNOWLEDGEMENT

The authors acknowledge receipt of a grant for this study from Thermamedic. The Thermalipo device was on loan during the period of trials for this study.

On behalf of his co-authors and himself, (MAT) declares no financial or other interest in the company and equipment mentioned in this study.

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Table 1

Patients Demographics SPAIN

Pat. No	Before		
	Area	Age	Phototype
1	B	44	III
2	B	59	III
3	B	52	II
4	B	39	III
5	B	45	II
6	B	51	II
7	B	39	III
8	B	46	IV
9	B	38	IV
10	B	42	III

Table 2

Patients Demographics HOLLAND

Pat. No	Before		
	Area	Age	Phototype
1	B	53	III
2	B	45	III
3	B	43	III
4	B	34	III
5	B	53	III
6	B	50	III
7	B	57	III
8	B	59	II
9	B	43	III
10	B	58	II

Table 3

SUBJECTIVE and OBJECTIVE ASSESSMENT / SPAIN

Patient No	Patient			Doctor		
	Assessments			Assessments		
	Bef.7 session	Bef.12 session	2 months after 12	Bef.7 session	Bef.12 session	2 months after 12
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Very Good; Good; Fair; No results

Table 4

SUBJECTIVE and OBJECTIVE ASSESSMENT / HOLLAND

Patient No	Patient			Doctor		
	Assessments			Assessments		
	Bef.7 session	Bef.12 session	2 months after 12	Bef.7 session	Bef.12 session	2 months after 12
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Very Good; Good; Fair; No results

Table 5
TOTAL Index of Satisfaction (SI)

Patient No	Patient / SPAIN			Patients /HOLLAND		
	Assessments			Assessments		
	Bef.7 session	Bef.12 session	2 months after 12	Bef.7 session	Bef.12 session	2 months after 12
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

8 patients, Very Good; 8 patients, Good

SI index is obtained from the total Good and V.Good Results.

Of the 20 patients (Holland & Spain) assessed at 2 months after 12th session, the total of totals SI was high.

Fig. 1

BEFORE

AFTER

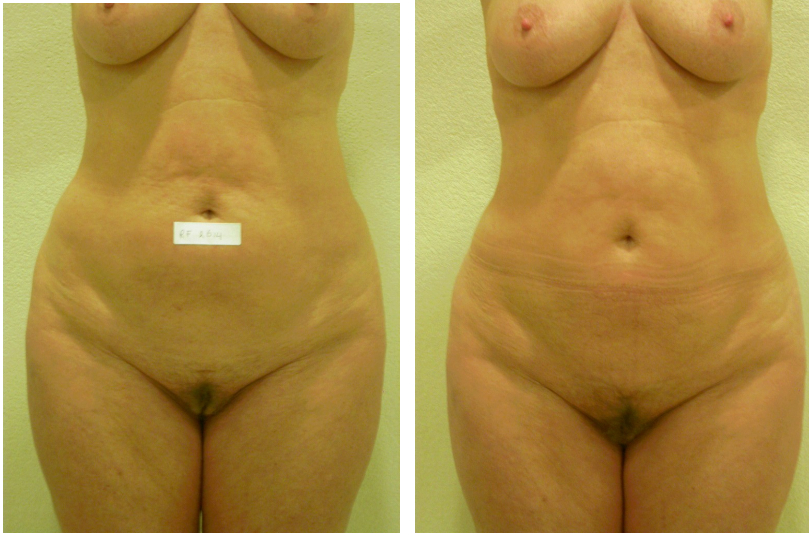
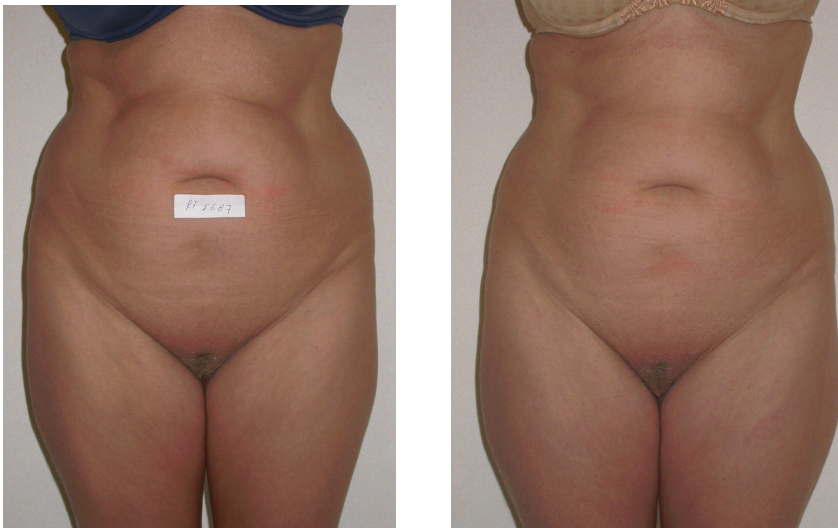


Fig. 2

BEFORE

AFTER



BEFORE

Fig. 3

AFTER



Fig. 4

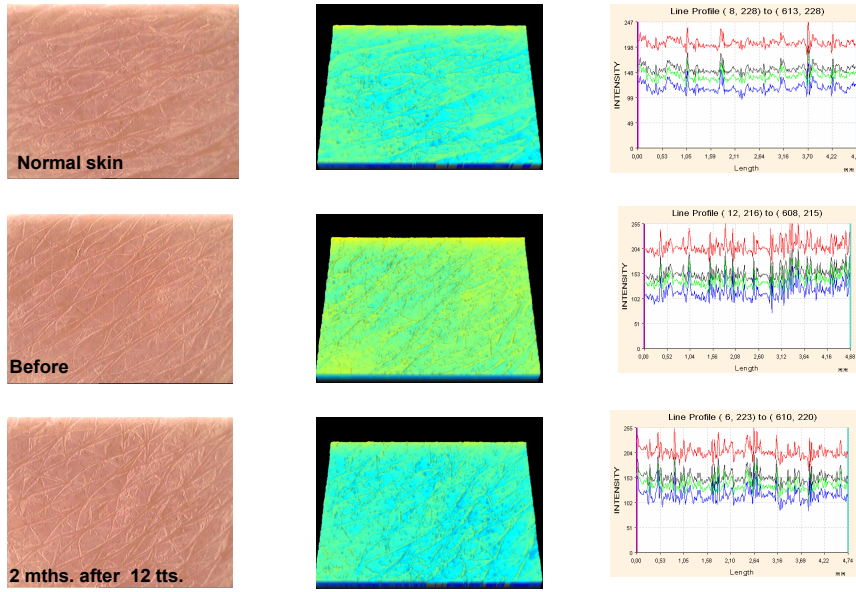


Before

Before tt. 7

2 mths. After tt. 12

Fig. 5



Notice rearrangement of skin condition 2 months after last treatment session
. Images show more similarity to normal skin.