LETTER TO THE EDITOR

A new concept radiofrequency device for the treatment of cellulite

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To the Editor,

As known, the so-called "cellulite" affects a great percentage of women worldwide. To treat this condition, which in itself is bound to worsen over the years, there are many current treatments, in addition to the common recommendations such as lifestyle changes, appropriate diet, exercise and weight control. The different therapeutic approaches available can be classified into topical (for example products containing methylxanthines, retinol, and botanical derivatives), massage (performed manually or by means of devices, to promote lymphatic drainage and improve the microcirculation of the subcutaneous tissue), pharmacological (oral treatment), non-invasive (acoustic waves, radiofrequency, infrared light and intense pulsed light, ultrasound, cryolipolysis) and minimally invasive (carboxytherapy, mesotherapy, subcision) (1-3). Among these, there is a technology based on the application of radiofrequency energy (RF). Moreover, this technology is also normally used to treat abdominal laxity and any fat local accumulation, having a positive action on the adipocyte metabolism and stimulating production of new collagen.

A new device, based on the application of radiofrequency energy, which seems innovative and very promising, has just been made available on the market. This device, unlike other RF-based technology delivering only a single signal, is able to simultaneously deliver 4 different RF signals, optimizing the deepness level and massively increasing the efficacy of the energy interacting in 4 different ways with different tissues. The four signals have frequencies of 0.4 MHz; 0.9 MHz; 1.3MHz; 2.4 MHz, respectively, and they are managed by the algorithm of the technology crosslinking the signals in function of the purpose. With this technology, it is therefore possible that the applied energy reaches four different depths simultaneously, which is not possible with other devices.

The purpose of this study, intended as a preliminary study, is to clinically evaluate whether this equipment allows to obtain appreciable results.

MATERIALS AND METHODS

Twenty cellulite patients aged between 30 and 60 years were enrolled in the study. Exclusion criteria were those commonly adopted as contraindications to skin treatments with RF (pacemaker wearers, skin infections, etc.). All patients were recommended, for the entire duration of the study, not to change their own usual lifestyle. Before recruitment, each patient signed informed consent.

Firstly, a clinical assessment of each patient's cellulite

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grade was performed, according to the Nürnberger-Müller grading scale. This assessment showed 3 patients in grade I, 9 in grade II and 8 in grade III. Each patient also underwent an ultrasound assessment (Hitachi Aloka Medical ProSound F75, Olympus Corporation, Tokyo, Japan) of the legs, performed on the thigh, knee and ankle area, using a 15 MHz probe. The same evaluation was repeated, for each patient and in the same way, at the end of the treatment. As is known, this allows the effectiveness of the treatment to be objectively assessed, by measuring the thickness of the subcutaneous tissue (4). Before treatment, the leg circumference was bilaterally measured. In fact, the measurement of leg circumference has long been used to evaluate any improvements in cellulite therapy (3, 5). In addition, photographs of each patient were taken in standard projections. Finally, a questionnaire was submitted to each patient, before and after the treatment, to evaluate the perception of the appearance of the area affected by cellulite, and of the presence of feelings of heaviness or tenderness in the legs. The feeling of heaviness is certainly a subjective fact, but it represents one of the symptoms that push patients to consult a healthcare professional. Therefore, the persistence, reduction or disappearance of this sensation is in any case an indicator, albeit subjective, of the degree of satisfaction of the treatment by the patients.

Each patient underwent 10 sessions of application of radiofrequency energy, by an Italian device named Thuzzle® (GMV, Rome, Italy). The energy was supplied by a handpiece identified as TetraWave handpiece, since it is able to deliver 4 electromagnetic waves simultaneously, each one different from the other in power, frequency, duration, and electrode geometry (multi-wave technology). These parameters, in fact, are the ones influencing the deepness reached by the energy during the treatment, plus the conductivity of the specific tissue the energy is passing through (dermis, fat, muscle, bones, etc). Therefore, the Tetrawave handpiece, differently from any other RF-based technology delivering only a single signal, is able to deliver 4 different RF signals, optimizing the deepness level and massively increasing the efficacy of the energy interacting in 4 different ways with different tissues. The four signals have respectively frequencies of 0.4 MHz; 0.9 MHz; 1.3MHz; 2.4 MHz, and they are managed by the algorithm of the technology crosslinking the signals in function of the purpose.

For this study, the cellulite protocol embedded in the device was used, maximizing the signal with lowest frequency, and delivered by the most distant electrodes placed on the handpiece, to generate a deeper electromagnetic field. The power and the duration of every single signal is regulated by the algorithm, while the total power (maximum 200 W) can be adjusted by the operator in function of the skin temperature shown on the handpiece and on the screen of the device (the target temperature was 42°C at the dermis level) and the sensitivity of the patient.

There are no standard protocols for RF treatment time in the literature and the number of sessions varies from 1 to 24 (5). It was therefore decided to follow the instructions provided by the manufacturer of the device. Each session lasted 40 min, 20 min per leg. A cycle was 10 sessions, one week apart. No anesthesia was administered before, during, or after the treatment. Each leg was treated from knee to hip. The haunch was divided into 4 quadrants, each of which was dealt with for about 5 min. Firstly, the upper quadrant was treated; an inert conductive gel was applied on the skin, then, by placing the handpiece flat, and making sure to always keep the entire surface of the handpiece in contact with the skin, a continuous slow rotary movement was performed, moving the handpiece backward and forward. The other quadrants were treated in the same way. At the end of the cycle, the clinical assessment of each patient was repeated according to the Nürnberger-Müller grading scale; ultrasound evaluation and leg measurement, of the same previous areas, were again performed for each patient, as well as photographing in standard projections.

RESULTS

Two patients gave up before the end; one because she had mild vascular disease and another because she started a laser hair removal treatment. The first of these had suffered from postpartum vasculopathy which she had not reported in the medical history before treatment. Vasculopathy is actually a contraindication to the use of radiofrequency. The second, however, despite advice, wanted to start another different treatment, and two simultaneous treatments do not allow us to correctly evaluate the effectiveness. In both cases, it was obviously decided

to stop the treatment of cellulite. All the remaining 18 patients showed an improvement in cellulite. A reduction was recorded in the leg diameters, a diminished thickness of the subcutaneous tissue by ultrasound imaging, and an improvement in the appearance of the skin. The clinical assessment of each patient's cellulite grade according to the Nürnberger-Müller grading scale, showed 9 patients in grade I, 9 in grade II, and none in grade III (Figs.1-4). After each session a redness was observed on the treated areas, as well as an increase in local temperature, however, both phenomena had a short duration. No other *sequelae* or complications were observed after treatment in any of the patients; in fact, radiofrequency cosmetic treatments are generally well-tolerated and do not involve particular side effects or complications (5).

DISCUSSION

In the international scientific community, there is a lack of unanimous agreement on recognizing

Fig. 1. ***A)*** *Patient A, before and after, front section.* ***B)*** *Patient A, before and after, right side section.* ***C)*** *Patient A, before and after, left side section.* ***D)*** *Patient A, before and after, rear section*

the nosological identity of cellulite and on the pathophysiological mechanisms that underlie it (3). According to some, cellulite would originate from alterations of the lymphatic system at the level of adipose deposits (6). In the initial phase of cellulite, there would thus be an accumulation of fluids and other substances in the interstitial space, which would give rise to a local reaction which, in turn, would worsen the condition (6). At the origin, there would be the action of female sex hormones on fat deposits and on vessels (6). The most widespread opinion today is that cellulite results essentially from an excessive accumulation of fat in the subcutaneous adipose tissue, which exerts considerable pressure on the surrounding skin tissue, creating an irregular dimpled appearance (7). The disorders of the extracellular matrix and of the lymphatic system, with regional lymphostasis, may in turn represent the pathophysiological mechanism leading to cellulite (7).

The application of radiofrequency energy to treat cellulite is based on internal thermogenesis induced by applied energy (8). The increase in internal temperature then determines vasodilation and increases microcirculation, new collagen formation, and contraction of existing collagen fibers (9-11). Monopolar, bipolar or multipolar radiofrequency, however, acts only at a single depth; notably, monopolar radiofrequency acts deeply, whereas bipolar acts superficially, as known. The multipolar radiofrequency, instead, acts always at the same depth, depending on the distance between the electrodes at the surface of the handpiece. The equipment we used (Thuzzle®), instead, employing the same handpiece and simultaneously 4 waves different for power, frequency, duration, and electrode geometry, reaches 4 different depths at the same time (simultaneously controlled electromagnetic multi-energy, or concentrated controlled multi-wave). Thus, it acts on 4 different tissues: adipose tissue, lymphatic vessels, blood vessels, and skin collagen. In other words, Thuzzle® acts on the causes of cellulite, in the same session and simultaneously, allowing better and faster results. The shape of the handpiece, furthermore, permits an easy and wide contact with the skin surface. The device allows, moreover, to check, in real time, as mentioned before, 3 parameters: dermis temperature, power density absorbed by the tissue, and quality contact (i.e., the correct positioning of the handpiece on skin surface). This enhances the safety and the quality of the treatment. In fact, a single cycle of treatment allowed to obtain good results, as shown by leg measurement and ultrasound imaging, photographs, and clinical assessment according to the Nürnberger-Müller grading scale.

Despite the exiguous number of patients enrolled

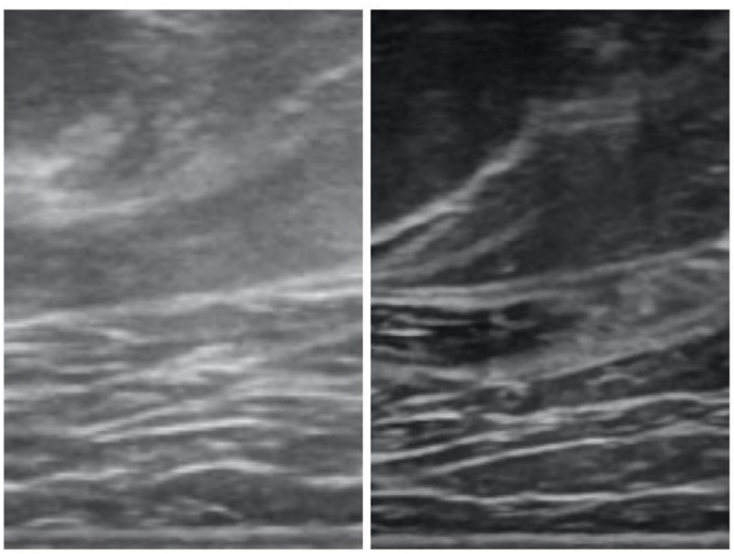

Fig. 2. *Patient A: ultrasound scan, before and after.*

Fig. 3. ***A)*** *Patient F, before and after, front section.* ***B)*** *Patient F, before and after, right side section.* ***C)*** *Patient F, before and after, left side section.* ***D)*** *Patient F, before and after, rear section.*

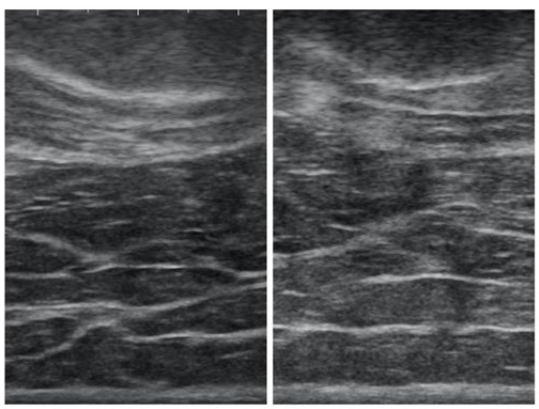

Fig. 4. *Patient F: ultrasound scan, before and after.*

in this study, the obtained results show the high effectiveness of the performed treatment. In fact, all patients who finished the cycle of treatment showed an improvement in skin appearance, a reduction in the diameters of the legs, and a reduction in the thickness of the subcutaneous tissue, as confirmed by the final clinical assessment of each patient's cellulite grade, according to the Nürnberger-Müller grading scale. Further studies are needed to confirm our initial observations.

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