

New Rotative Radiofrequency Technology: A Multicenter Retrospective Study on Efficacy and Safety

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Abstract

Background: Non-ablative radiofrequency (RF) technology is widely used for the treatment of signs of aging, skin laxity, localized fat and cellulite. However, many RF devices suffer from technical limitations that make the results highly dependent on the user's experience or clinical limitations that compromise safety, efficacy and comfort. **Objective:** To evaluate the efficacy and safety of a novel semi-automatic non-ablative RF device for skin tightening, body shaping and cellulite reduction. **Materials and methods:** A retrospective multicenter study was performed using a novel rotative RF device with temperature and impedance control (Sculpt&Shape[®], Sinclair, Spain). 58 subjects underwent a minimum of 4 treatments every 1 - 2 weeks. A total of 120 treatments (56.7% body and 43.3% facial) and 1034 sessions were performed. Efficacy was evaluated by 3 researchers using the Global Aesthetic Improvement Scale (GAIS) and anthropometric measurements were collected. Subject and practitioner satisfaction were recorded. Safety was evaluated by analyzing the perception of pain during the treatment and the side and adverse effects immediately after treatment and over the next 48 hours. **Results:** Between 25% and 50% improvement was achieved according to the GAIS. Statistically significant ($p < 0.01$) abdominal fold reduction of 5.1 mm and circumference reduction of 32.0 mm, 16.4 mm and 13.9 mm were recorded for the abdomen, legs and arms, respectively. 77.5% of subjects and 94.9% of practitioners were either satisfied or very satisfied. Minor adverse effects were found in 0.97% of the sessions. **Conclusion:** This novel semi-automatic rota-

tive RF device has been found to provide treatments that are effective, safe and comfortable for both practitioners and subjects.

Keywords

Rotative, Radiofrequency, RF, Cellulite, Skin Tightening, Body Shaping

1. Introduction

The appearance of the skin is a constant and growing concern among the population which is accentuated by aging. Decreased production of collagen and elastin causes signs of aging such as the appearance of wrinkles, fine lines, and sagging [1]. In addition to facial appearance, body issues such as cellulite or localized fat are also among the most common concerns of individuals. All these problems are caused by internal agents such as age or genetic factors, and also by external agents such as unhealthy habits, exposure to solar radiation, and poor diet [2].

Traditionally, the most common way to solve these issues has been the use of invasive surgical techniques. However, surgical risks, recovery time, and financial costs make subjects reluctant to choose these methods [3]. New scientific and technological advances make it possible to address subjects' concerns through non-surgical or minimally invasive energy-based techniques such as lasers [3]. However, laser procedures involve other complications associated with the body's chromophores, which absorb laser energy and thereby limit the accessibility or efficacy of the treatments [4].

Other energy-based technologies have emerged, such as radiofrequency (RF), which has become one of the most widely used technologies for the treatment of sagging skin and cellulite, as well as for body contouring [5]. The mechanism of action of RF relies on the use of electromagnetic waves to induce oscillations in the molecules of the treated tissues and produce heat.

Temperatures of between 40°C and 45°C in the tissue of the dermis induce a contraction of the collagen fibers and stimulate the fibroblasts to produce new collagen and elastin in the tissue [6] [7], which have been shown to improve skin tightening. In addition, temperatures of between 43°C and 50°C in the subcutaneous tissue increase the metabolic pathways of adipocytes, resulting in a decrease of their volume that can be used for body shaping [8] [9]. Moreover, the combination of both dermal and hypodermal thermal effects could also lead to an improvement in cellulite appearance [10].

There is a wide variety of RF devices available, and they differ from each other in the way the energy is delivered through their electrodes [11]. However, many of these devices have technical limitations, mainly related to how the device is used, which make the treatments highly dependent on the operator's experience and limit the repeatability and effectiveness of the results. Indeed, manual control of the RF power, measuring the temperature with external thermometers, or

making the appropriate movements to reach the target temperature, make it difficult to stay in the therapeutic temperature range of between 40°C and 45°C for the necessary period of time. This results in treatments with low levels of consistency and efficacy as well as compromising subject comfort and safety due to the uncontrolled RF delivery and heating.

There is therefore a demand for new RF devices to be designed to enable reproducible and safe results. Here we present a new non-ablative, rotative, monopolar and bipolar RF system that achieves a uniform increase and maintenance of temperature. The device also benefits from real-time measurement of the impedance and temperature of the skin to automatically achieve a constant temperature within the skin and prevent hot spots and concentrations of electrical current.

The objective of this study is to evaluate the efficacy and safety of this new system for skin tightening, body shaping, and cellulite reduction.

2. Materials and Methods

Study Design and Subject Selection

To achieve this objective, a multicenter retrospective study on the efficacy and safety of a new non-ablative rotative radiofrequency (RF) device was conducted in collaboration with Intek Medical Technology (Barcelona, Spain), Perla Medic Clinic (Dr. Joanet Perera, Alicante, Spain), Dr. Agustí Blanch Clinic (Dr. Agustí Blanch, Barcelona, Spain), and Studio Vignoli (Dr. Fabrizio Vignoli, Bologna, Italy). Clinical data were gathered and analyzed by Sinclair's scientific and clinical department (Barcelona, Spain) between October 2022 and April 2023.

The inclusion criteria included males and females between 18 and 75 years old with concerns about skin laxity, wrinkles, cellulite, or localized fat. Specific exclusion criteria for the study included active dermatological disease or infectious processes on the treatment area; pregnancy; breastfeeding; implanted electronic devices; blood disorders or the use of blood-thinning or antiplatelet medications; a history of active or recent neoplastic malignancy; heat-stimulated conditions and orthopedic surgery such as replacement of the hip, femur, etc.

8 different practitioners and 58 subjects participated in the study. Subjects were between 22 and 72 years old with a mean age of 48.1 ± 11.351 (87.9%) of them were female and 7 (12.1%) were male, and they had skin types of between II and V on the Fitzpatrick scale.

Subjects were not required to follow a special diet or exercise plan. Prior to treatment, all subjects received a detailed and clear explanation of the planned procedure and signed an informed consent form. The complete confidentiality of the subjects' data was guaranteed throughout the study.

Device

The device used in the study was Sculpt&Shape[®] (Sinclair, Spain). This device is a non-ablative rotative RF device with monopolar and bipolar tips for treatments related to skin laxity, wrinkles, body shaping and cellulite. The device in-

incorporates the Rotate RF technology. This technology is based on 360° rotation of the tips which provides homogeneous and gradual heating and enhances lymphatic drainage in the area. The device boasts 6 different interchangeable tips for full-body and facial treatments. The characteristics and working parameters of the tips are shown in **Table 1**.







All the device's tips have a real-time infrared temperature measurement system that is combined with the continuous measurement of tissue impedance to deliver the appropriate RF power and achieve a constant temperature in the skin. A high impedance measurement indicates a lack of contact with the skin. Should this occur, the device will stop the RF energy delivery and only restore it once the impedance returns to a suitable value. Therefore, the RF power is delivered automatically and without sparks due to lack of contact.

Treatment Protocol

The treatment areas were defined as the face (forehead and/or cheeks), neck, décolletage, arms, abdomen, flanks, legs, and buttocks. Glycerin gel¹ was applied to the treatment areas and no anesthesia was required. The applicator was continuously moved according to the direction of the lymphatic system to achieve homogeneous and gradual heating of the area while always maintaining contact with the skin (**Figure 1**). The target temperature for the treatments was determined to be between 43°C and 45°C depending on the subject's tolerance. The device automatically regulates the power supplied to maintain this constant temperature throughout the treatment. **Table 2** shows a description of the treatments performed and the parameters of each one.

Subjects underwent a minimum of 4 sessions of RF treatments every 1 or 2 weeks. Facial sessions lasted between 12 and 40 minutes, while body sessions,

Table 1. Summary of the characteristics and working methods of Sculpt&Shape[®] tips.

Name	Tip	Description	Type or RF [Working frequency]
Shine		Spherical, low-capacitance tip for localized facial areas	Monopolar [1.0 MHz]
Firm		Rectangular, flat, low-capacitance tip for facial and small body areas	Monopolar [1.0 MHz]
Shape		Oval, flat, capacitive tip for medium-sized body areas	Monopolar [1.0 MHz]
Boost		Circular, flat, capacitive tip with eccentric rotation for large body areas	Monopolar [1.0 MHz]
Sculpt6		6-pin tip with a concave surface for medium-sized body areas	Bipolar [0.5 - 1.0 MHz]
Sculpt8		8-pin tip with a concave surface for large body areas	Bipolar [0.5 - 1.0 MHz]

¹Sinclair internal reference: 100017252.

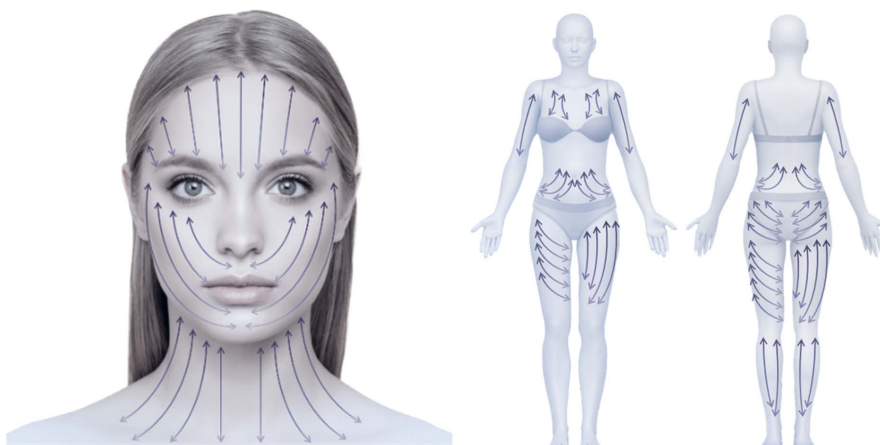


Figure 1. Movement protocol for the treatments.

Table 2. Summary of the types of treatments, tips, areas and predefined parameters on Sculpt&Shape®.

Treatment	Tip(s) used	Areas	Temperature (°C) Frequency (MHz)
Wrinkles	Shine	Forehead, crow's feet, eyebags, eyelids, marionette lines, lips	43 - 45 1.0
Face skin tightening	Firm	Forehead, cheeks, neck	43 - 45 1.0
Body skin tightening	Firm Shape Boost	Décolletage, arms, abdomen, legs, buttocks, flanks	43 - 45 1.0
Cellulite	Sculpt6 Sculpt8	Arms, abdomen, legs, and buttocks	43 - 45 1.0
Body shaping	Sculpt6 Sculpt8	Arms, abdomen, legs, and buttocks	43 - 45 0.5

depending on the areas treated, lasted between 20 and 60 minutes. Before each session, photographs of the treatment areas were taken, and anthropometric measurements were collected for body treatments. All treatments were performed in accordance with the treatment tables recommended by the manufacturer.

Efficacy Evaluation

Efficacy was evaluated by 3 experienced clinical and medical researchers who assessed paired pre-treatment and post-treatment photographs and determined the level of improvement using the Global Aesthetic Improvement Scale (GAIS) (Table 3). Various aesthetic factors were evaluated: reduction of fine lines and wrinkles, skin firmness or lifting, skin quality and texture, contouring in submental and body areas, and fat reduction and improvement in cellulite appearance.

For the body treatments, anthropometric measurements were collected before and after the sessions (arms, abdomen, and legs). Weight was measured using a digital scale, the abdominal fold using a plicometer, and the circumference using a measuring tape.

Table 3. Scores for the evaluation of GAIS, satisfaction, heating pain and endpoint response.

GAIS evaluation		Subject and operator satisfaction		Heating pain		Endpoint response	
Score	Description	Score	Description	Score	Description	Score	Description
0	Not improved	0	Unsatisfied	0	No pain	0	No response
1	Mildly improved	1	Not very satisfied	1 - 4	Mild pain	1	Mild response
2	Improved	2	Satisfied	5 - 7	Moderate pain	2	Moderate response
3	Much improved	3	Very satisfied	8 - 10	Severe pain	3	Severe response
4	Very much improved						

Subject satisfaction was evaluated at the end of the last session, as well as one and three months following said session. The subjects rated their satisfaction on a scale of 0 to 3, and they were asked about their opinion on the aesthetic improvement as well as their treatment experience. After every session, the practitioners also gave a rating of 0 to 3 for their satisfaction with regard to usability, immediate results, the safety of the treatments and the overall experience with the new device (**Table 3**).

Safety Evaluation

Subjects rated the level of pain caused by heating during the treatment on a scale of 0 to 10. The resulting endpoints of the skin (erythema and edema) were evaluated by practitioners on a scale of 0 to 3 (**Table 3**). All the other side effects that occurred were also reported immediately after the treatment and over the next 48 hours.

Statistical Analysis

Mean values and standard deviations were calculated for quantitative variables. Results are shown as mean value \pm standard deviation (SD). The statistical significance of the before and after results was determined with a student's two-tailed paired t-test. Microsoft Excel 365 was used for the statistical analysis.

3. Results

8 different practitioners and 58 subjects began and completed at least 4 sessions of RF treatments. Subjects were between 22 and 72 years old with a mean age of 48.1 ± 11.3 . 51 (87.9%) of them were female and 7 (12.1%) were male, and they had skin types of between II and V on the Fitzpatrick scale. A total of 1034 sessions and 120 treatments were completed, with an average of 8.6 ± 2.5 sessions per treatment being performed. **Table 4** presents a distribution of all the treatments

completed and the tips used for each area.

Table 4. Summary of treatment and tip distribution.

Area	% of use of each tip						Total
	Sculpt6	Sculpt8	Firm	Shine	Boost	Shape	
Body	13.3	25.8	2.5	-	9.2	5.8	56.7
Abdomen	6.7	8.3	-	-	3.3	-	18.3
Legs	3.3	10.0	-	-	2.5	-	15.8
Buttocks	1.7	7.5	-	-	1.7	-	10.8
Arms	0.8	-	-	-	1.7	3.3	5.8
Décolletage	-	-	2.5	-	-	0.8	3.3
Flanks	0.8	-	-	-	-	1.7	2.5
Facial	-	-	33.4	10.0	-	-	43.3
Face	-	-	16.7	10.0	-	-	26.7
Neck	-	-	16.7	-	-	-	16.7
Total	13.3	25.8	34.9	10.0	9.2	5.8	100.0

Table 5. Anthropometric measurement results.

Anthropometric measurement	Mean reduction \pm SD	Mean sessions performed \pm SD
Weight (kg)	-0.2 \pm 1.5	-
Abdominal fold (mm)	-5.1 \pm 3.6**	8.8 \pm 2.4
Abdomen circumference (mm)	-32.0 \pm 33.9**	8.8 \pm 2.4
Leg circumference (mm)	-16.4 \pm 24.9**	9.3 \pm 2.5
Arm circumference (mm)	-13.9 \pm 13.3*	7.9 \pm 2.8

(*p < 0.01; **p < 0.001).

The level of pain caused by heating during the treatment was given a score of 6.6 ± 1.1 out of 10 by the subjects. In 73.1% of sessions, the sensation of heat was evaluated as moderate, and in 24.6% it was evaluated as severe.

The immediate appearance of erythema and edema after the treatment was evaluated as mild or moderate in 98.0% of the sessions. Minor adverse effects were found in 10 cases from the 1034 sessions (0.97%), which included 9 cases of superficial first-degree burns caused by sparks due to the tip losing contact with the skin during the treatment session, and 1 case of severe itching after the session. No major adverse effects were reported.

The changes in the anthropometric measurements of the subjects who were treated in body areas are shown in **Table 5**.

Examples of before and after photographs are shown in **Figures 2-9**.

The GAIS evaluation, performed on the paired pre-treatment and post-treatment photographs by 3 researchers, is shown in **Figure 10**.

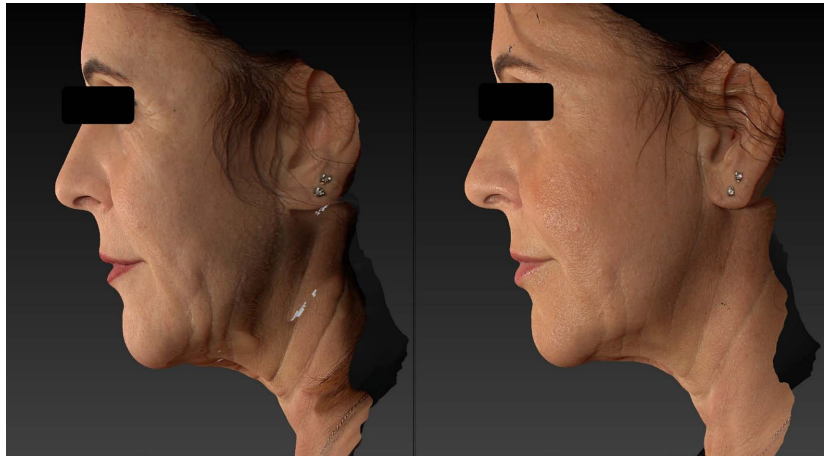


Figure 2. Female, 57; 8 sessions of skin tightening treatment (1 MHz) on the neck and submental regions with the Firm tip for 24 min at 44°C in each session. Pictures taken with a Vectra® camera.



Figure 3. Female, 49; 9 sessions of skin tightening treatment (1 MHz) on the neck and submental area with the Firm tip for 24 min at 44°C in each session. Pictures taken with a Vectra® camera.



Figure 4. Female, 44; 8 sessions of skin tightening and wrinkle treatment (1 MHz) on the full face and neck (submental area) with the Firm and Shine tips for 45 min at 44°C. Pictures taken with a digital camera.



Figure 5. Female, 62; 6 sessions of skin tightening treatment (1 MHz) on the face and neck with the Firm tip for 36 min at 44°C in each session. Pictures taken with a Vectra® camera.



Figure 6. Female, 51; 7 sessions of body shaping and skin tightening treatment (0.5 - 1 MHz) on the abdomen with the Sculpt6 tip for 20 min at 44°C in each session. Abdominal circumference: -5 cm; abdominal fold: -5 mm. Pictures taken with a digital camera.



Figure 7. Male, 50; 6 sessions of body shaping treatment (0.5 MHz) on the abdomen with the Sculpt6 tip for 20 min at 44°C. Abdominal circumference: -3 cm; abdominal fold: -7 mm. Pictures taken with a digital camera.



Figure 8. Female, 22; 8 sessions of body shaping treatment (0.5 MHz) on the legs and buttocks with the Sculpt6 tip for 60 min at 44°C. Leg circumference: -1 cm Pictures taken with a digital camera.



Figure 9. Female, 28; 11 sessions of cellulite treatment (1 MHz) on the legs and buttocks with the Sculpt8 tip for 40 min at 44°C. Leg circumference: -1.5 cm Pictures taken with a digital camera.

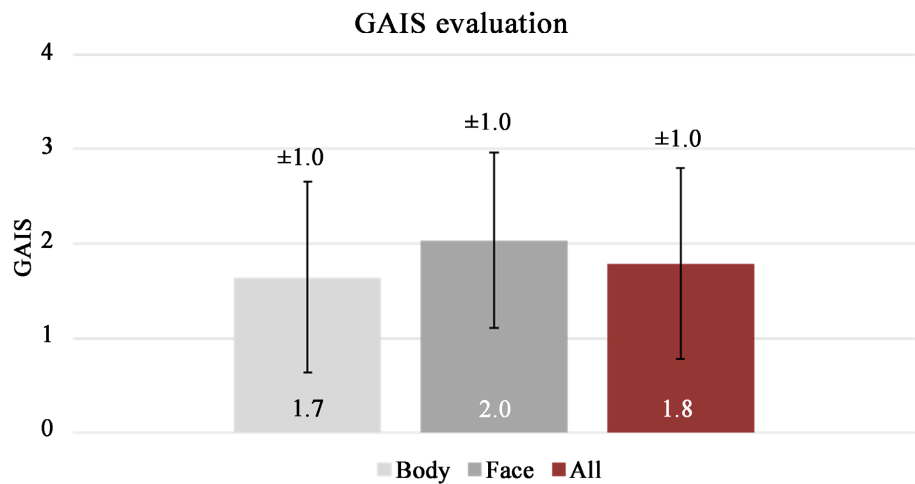


Figure 10. GAIS evaluation of before and after photographs. Mean values are shown and error bars represent the standard deviation.

Subject satisfaction at the end of last session and 1 and 3 months later is shown in **Figure 11**.

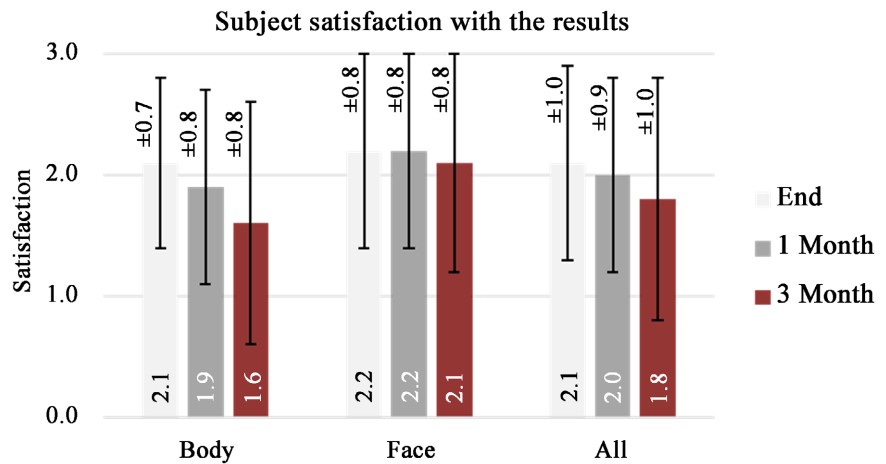


Figure 11. Subject satisfaction after completing the final session of the treatment, and 1 month and 3 months later. Mean values are shown and error bars represent standard deviation.

In 94.9% of all the sessions performed, they were either satisfied or very satisfied with the usability, immediate results and experience when using the device.

4. Discussion

The need to reduce the signs of the passage of time and those caused by external agents such as pollution, bad habits and solar radiation, for example, have led to an increasing demand for aesthetic treatments to reduce wrinkles, skin flaccidity, cellulite, and localized fat. The first choice for subjects is usually an invasive or minimally invasive treatment, which are well known throughout society and offer fast results. However, people are increasingly reluctant due to the cost, surgery risks, and recovery time associated with these treatments. Therefore, non-invasive technologies such as radiofrequency (RF) are increasingly in demand among subjects and aesthetic medicine clinics.

Non-invasive RF has been shown to help improve the appearance of the skin, body shape and cellulite [1] [5]. This study aimed to demonstrate the safety, efficacy and comfort of Sculpt&Shape[®], a new bipolar and monopolar RF device with a 360° tip rotation system combined with real-time measurement of temperature and impedance to provide fast, homogeneous, and safe heating.

A total of 58 subjects (87.9% were female and 12.1% were male) participated in this study, undergoing an average of 8.6 ± 2.5 sessions, of which 43.3% were face and neck treatments, and 56.7% were body treatments focused on the abdomen, arms, legs, and buttocks.

The key to RF lies in reaching a temperature of between 40°C and 45°C and maintaining it for a certain period of time. The higher the maintained temperature, the shorter the time taken to achieve the same biological stimulation and vice versa [12] [13]. In this study, target temperatures of between 43°C and 45°C were reached without the use of any anesthetic systems. In 73.1% of the sessions, the sensation of heat was evaluated by the subjects as moderate, and in 98.0% the

erythema after the treatment was evaluated as mild or moderate by practitioners, which is the desirable endpoint. It is worth noting that the 9 cases of mild and superficial burns from the 1034 procedures were transient, did not require medical attention, and recovery was almost immediate or occurred between 48 and 72 hours after treatment. This low number of minor adverse effects compared to other RF devices [14] [15] is explained by the uniformity of the temperature, which is achieved thanks to the 360° rotation of the device's tips and the automatic temperature and power regulation systems that provide a gradual temperature increase and keep it constant throughout the treatment. In addition, the real-time impedance measurement reduces potential electrical arcs caused by a lack of contact between the tip and the skin during the treatment, reducing the possibility of burns or unpleasant sparks for the subjects.

Regarding anthropometric measurements, a general reduction in all measurements was observed. Average reductions of 5.1 ± 3.6 mm in the abdominal fat fold, 32.0 ± 33.9 mm in abdominal circumference, 16.4 ± 24.9 mm in leg circumference and 13.9 ± 1.8 mm in arm circumference were achieved, with highly statistically significant results ($p < 0.01$) in all cases. A weight reduction of 0.2 ± 1.6 kg was measured in the subjects, but it was not statistically significant ($p > 0.05$), thus demonstrating that the results for the measurement reductions were due to the RF treatment and not influenced by weight loss. These results fall within the ranges of reduction measurements found in other similar studies with RF devices [8] [16]. The high reproducibility of the results is explained by the automatic temperature control offered by this RF device and the automatic rotation of the electrodes that induce the uniform heating in the treated area and is therefore not dependent on the operator.

A global aesthetic improvement score of 1.8 ± 1.0 out of 4 on the GAIS scale was determined, which means that on average the improvement was between 25% and 49%.

With respect to facial results, a GAIS score of 2.0 ± 1.0 out of 4 was determined, which implies an average improvement of more than 50%. A significant improvement in the laxity of face and neck skin was observed along with an improvement in the quality and texture of the skin. Practitioners highlighted the great improvement in the wrinkles and tightening of the periocular area. In addition, the results obtained in the neck and submental area, where the GAIS evaluation was highest with a score of 2.4 ± 0.9 out of 4, are especially remarkable. The treatment of this area with invasive or minimally invasive techniques is more difficult and subjects are typically more reluctant. The good overall facial results can be explained by the combination of the rotation and the temperature control, which allow the temperature to reach and maintain a uniform 44°C across the skin. This well-tolerated treatment with a high temperature being maintained therefore enhances the biological effects of RF.

As for the body treatments, a GAIS score of 1.7 ± 1.0 out of 4 was determined by the researchers. An improvement in body contouring, skin texture, and qual-

ity were observed and reported by subjects over the course of the sessions. These results are consistent with the results for the reduction in anthropometric measurements described above. Moreover, the complementary combination of the thermal effect of RF and the massage produced by the rotation has resulted in a notable reduction of edema, especially in the abdomen and legs. Likewise, lymphatic massage, to a greater extent, and thermotherapy, to a lesser extent, have been shown to improve lymphatic drainage [17] [18]. The combination of both in Sculpt&Shape[®] offers promising results for improving lymphatic drainage.

It is also worth mentioning the combined effect of body contouring and skin tightening in the subjects during the treatment sessions. This demonstrates that the energy penetration achieved with Sculpt&Shape[®] affects not only individual dermal or hypodermal tissues depending on the frequency, but that it is also possible to perform treatments that work on all levels of the skin simultaneously, enhancing the results of RF.

Subjects were asked to report their satisfaction with the results obtained at the end of the last treatment session, as well as 1 and 3 months following said session. After the last session, the mean satisfaction rating was 2.1 ± 0.8 out of 3 and 77.5% of the treatments were reported as satisfactory or very satisfactory. After 1 and 3 months, a slight decrease in these values was seen with 2.0 ± 0.8 and 1.8 ± 1.0 out of 3, respectively. As expected, subject satisfaction with the results decreases after the last treatment session. However, this satisfaction only decreases by 6.1% after the first month and by 15.3% after the third month. In addition, it is worth noting the stability in the satisfaction of subjects who underwent facial treatments, whose average satisfaction rating only decreased by 3.7% 3 months after the last treatment session. These results suggest that following the end of the full treatment cycle, the biological effects of RF are still active between 1 and 3 months later.

Practitioners also evaluated satisfaction during and after the treatments. In general, they evaluated the usability, safety, and results obtained with the new rotative RF device. 94.9% of the treatments performed were rated as satisfactory or very satisfactory. The practitioners highlighted the speed at which the target temperature is reached and the homogeneity and maintenance of the temperature in the treatment area thanks to the 360° rotation of the device's tips, as well as the good results for the improvement of the quality, texture and flaccidity of the skin and the reduction in edema and anthropometric measurements.

The main limitation of this study lies in the use by some centers of conventional anthropometric measurement techniques, compared to other centers which used 3D measurement and analysis systems, such as ultrasound, with more accurate and repeatable results. In addition, the use of more modern measurement systems increases the degree of objectivity when assessing the visual results of the treatments. Furthermore, although the overall sample size of this study is not small, the male population is. By increasing the size of this sample, we could expand and better understand the results in men, who are increasingly

opting for aesthetic treatments.

To address these limitations and understand the potential that this RF device could have, new studies with a larger sample size, especially with regard to males, and a standardization and modernization of the measurement systems are advised. Moreover, the combination of this rotative RF system with other non-invasive or minimally invasive techniques such as cryolipolysis, light-based technologies, and other invasive techniques such as fillers or other collagen stimulators such as PLLA (Poly-L-lactic acid) could reveal the wide range of applications for this device within the field of non-invasive RF devices.

5. Conclusions

Sculpt&Shape[®] is a semi-automatic, non-invasive, monopolar and bipolar, rotative radiofrequency (RF) device. Results obtained from a retrospective multi-center study and independently assessed by different researchers, practitioners, and subjects have shown that this device offers well-tolerated and safe treatments, and can produce consistent improvement in skin tightness, cellulite, and body contouring, with a high satisfaction rate among subjects and practitioners. The results were maintained for (at least) 3 months after the treatment.

Further studies with more subjects and more precise and standardized clinical evaluation techniques are recommended.

Funding Statement

No funding was received for conducting this study. Sinclair has provided the device for the study.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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