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ORIGINAL CONTRIBUTION

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Treating multiple body parts for skin laxity and fat deposits using a novel focused radiofrequency device with an ultrasound component: Safety and efficacy study

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Summary

Background and objectives: Growing demand for noninvasive skin tightening and reduction in fat results in an increasing pressure for devices with good clinical efficacy, consistency of results, and high patient comfort. The objective was to validate clinical efficacy and versatility of a novel device, which combines radiofrequency (RF) and ultrasound for treating skin laxity and fat deposits.

Methods: We treated 34 subjects with facial skin laxity and/or abundant body or arm fat deposits. Subjects were divided based on their indications. Ten subjects received treatments to the face, 7 subjects to arms, 8 subjects to thighs, and 9 subjects on abdomen. All patients received 4 treatments on a weekly basis. Photographs of patients were assessed by blinded evaluators to recognize the baseline images from the 3-month follow-up images. Patient comfort and satisfaction were evaluated using a 5-point Likert scale questionnaire. Any adverse events were recorded.

Results: Patient images were correctly recognized in >90% of cases in all study groups. Patient questionnaires showed overall satisfaction with the therapy course and results. On a scale of 1 to 5, the patients agreed (4.1) that they are satisfied with the results that the treatment is comfortable (4.1) and that they are satisfied with the treatment time (4.1). No adverse events were reported.

Conclusions: Consistent clinical efficacy was confirmed across all the treated areas, together with high patient comfort and satisfaction. We conclude the device is a highly versatile solution that can deliver results across body parts and different indications.

KEYWORDS
body contouring, non-invasive, radiofrequency, skin laxity, ultrasound

1 | INTRODUCTION

Ever growing demand for safe and effective devices for noninvasive body skin tightening and reduction in fat has dramatically risen over the last decade. Various modalities have been developed to target subcutaneous tissue as well as deeper layers of adipocytes. These primarily include ultrasound, radiofrequency (RF), and various cooling and light-based devices.[1-3]

Radiofrequency has been used in medicine for many years to ablate tissue. Oscillating electrical current is created by the RF, which induces collisions between charged ions and molecules in the tissue, resulting in generation of heat.[4,5] The biological effects of

tissue heating vary, depending on the frequency used, depth of delivery, and selectivity achieved with skin cooling.

Radiofrequency can also be used to heat and destroy fat. Heating of adipocytes with RF increases adipocyte apoptosis as well as lipase-mediated enzymatic degradation of triglycerides into free fatty acids and glycerol.[6]

Ultrasound utilizes mechanical compression or sound waves above the audible range and is characterized by its frequency and intensity. Waves propagate through the tissue causing molecules to oscillate. This mechanical effect can translate into heat in a similar way to RF.

The appearance of the face and neck is profoundly affected during the aging process. There is decreased tissue elasticity coupled with changes in facial volume, that is, compounded by the effects of gravity.[7] RF treatment of skin produces temporary shrinkage of collagen fibers and stimulates new collagen and elastin production. The amount of tissue contraction and remodeling is dependent upon the maximum temperature reached, the length of time the temperature is maintained, and the conductivity and age of the tissue. RF mediated thermal stimulation of the dermal matrix comprised of collagen, elastin, and ground substances results in an immediate change in the helical structure of the collagen.[8,9]

The investigated device (BTL Exilis system, BTL Industries) combines RF and ultrasound in each of the system's two applicators designed for a wide range of facial and body treatments. The ultrasound component is intended to alter the impedance of the tissue, increase cell permeability, and allow for better penetration of the RF energy to deeper layers. The manufacturer has also recently adjusted the facial applicator tip, which now emits the energy in a 360° manner. This allows delivering more energy to the tissue and helps treat therapeutically problematic areas such as periorbital zone very close to the eyes.

It is the purpose of this study to investigate the clinical versatility of the device stemming from its novel design, as most published studies on the efficacy of noninvasive RF procedures are based on treating subjects on a single body area only.

2 | MATERIALS AND METHODS

Our study enrolled 29 female and 7 male subjects with 34 completed. Two subjects did not finish the treatments for reasons not related to the study. Subjects were between 33 and 60 years of age (average 43) who exhibited mild-to-moderate laxity in the face and/or abundant abdominal, thigh or arm fat deposits. Based on the presence and severity of their indications at baseline, subjects were divided into 4 groups: Group A (10 subjects) was treated for facial laxity, Group B (7 subjects) was treated for fat deposits in arms, Group C (8 subjects) was treated for fat on thighs, and Group D (9 subjects) was treated for abdominal fat.

All subjects received 4 treatments administered 7 (±2) days apart using the monopolar RF and ultrasound system. Standard treatment protocols were used and were as follows: 45 minutes per treatment with the starting energy setting of 90 units for facial skin laxity treatment (full face), 30 minutes per treatment with the starting energy setting of 80 units for arm fat, 30 minutes per treatment with the starting energy setting of 100 units for fat in thighs, and 20 minutes per treatment with the starting energy setting of 120 units for abdominal fat treatment. The power settings were titrated based on the subject's verbal response for heat tolerance.

The face treatment was administered as follows: (i) from frontal area to periorbital area, (ii) from submalar region to mandible, (iii) submentum to midline. The fat deposits treatment was administered using slow circular motion across the entire treated area. Temperature of the skin was maintained at 42-43°C during every treatment, monitored using an external infrared thermometer. No topical anesthetics or oral pain medications were used.

Subjects were consented and had their medical histories taken.

The primary objective was to assess treatment efficacy using blinded expert evaluation of digital images. Photographs of appropriate areas were taken, and hard copies were generated on a 4″ × 6″ sized paper for printing at 300dpi resolution or higher. Images were randomly re-numbered, and evaluators scored each photograph as "B" for BEFORE and "A" for AFTER. The evaluation was statistically analyzed.

The secondary objective was to validate clinical efficacy across all the treated areas based on subjective patient satisfaction. A 5-point Likert Scale survey was completed at the 3-month follow-up and included the following questions: (i) I was satisfied with the treatment results; (ii) I found the treatment comfortable; (iii) I was satisfied with the overall treatment time. Patients rated their level of agreement with these claims using the following possible answers: strongly agree (5) – agree (4) – undecided (3) – disagree (2) – strongly disagree (1).

3 | RESULTS

3.1 | Evaluation of photographs

Photo assessment by blinded expert graders resulted in a total recognition rate of 92.16% (weighted arithmetic mean). This represents a very low percentage of nonresponding patients. Images

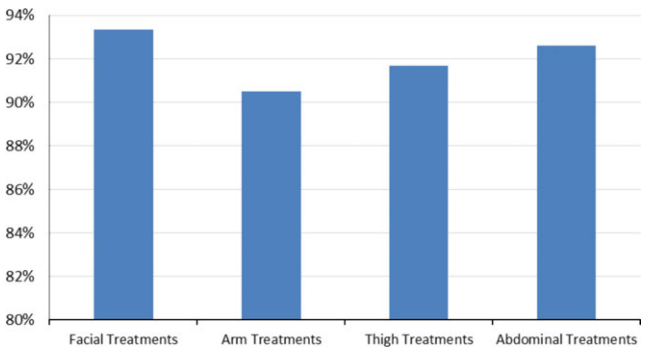

FIGURE 1 Recognition rate of aesthetic improvement in the treated area as per reviewers' evaluation

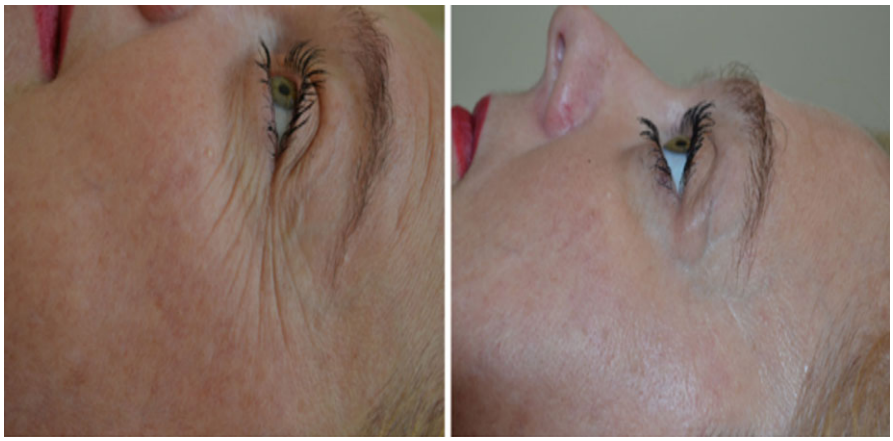

FIGURE 2 Example of patient images taken at baseline and 3 mo after the last treatment

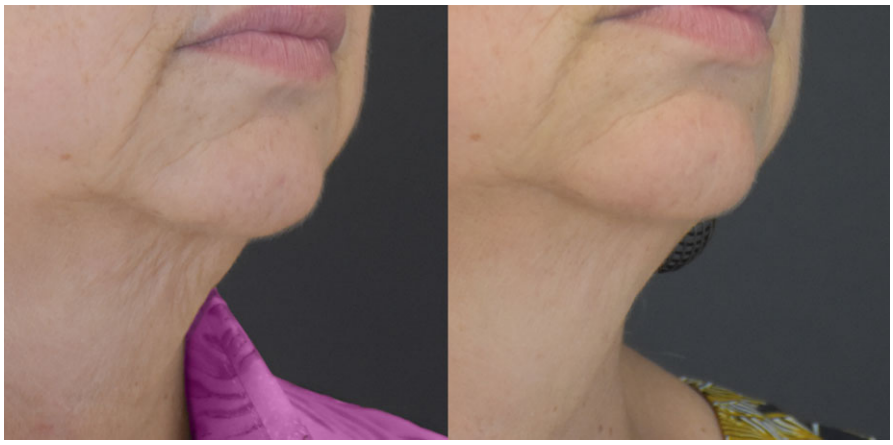

FIGURE 3 Example of patient images taken at baseline and 3 mo after the last treatment

TABLE 1 Patient satisfaction questionnaire average scores (5 – strongly agree, 4 – agree, 3 – undecided, 2 – disagree, 1 – strongly disagree)

	Q1: I was satisfied with the treatment results	Q2: I found the treatment comfortable	Q3: I was satisfied with the overall treatment time
Group A – Facial treatments (10 subjects)	4.30 (±0.78)	4.20 (±0.75)	3.80 (±0.98)
Group B – Arm treatments (7 subjects)	4.00 (±1.07)	3.71 (±0.88)	4.14 (±0.35)
Group C – Thigh treatments (8 subjects)	4.13 (±1.05)	4.00 (±0.71)	4.13 (±0.78)
Group D – Abdominal treatments (9 subjects)	4.11 (±0.74)	4.22 (±0.63)	4.33 (±0.82)
Total study average	4.15 (±0.91)	4.06 (±0.76)	4.09 (±0.82)

taken at the baseline were compared to images taken 3 months after the last treatment, and blinded evaluators successfully recognized 93.33% of facial B&A photographs, 90.48% of arms B&A photographs, 91.67% of thighs B&A photographs, and 92.59% of abdominal B&A photographs (all arithmetic mean). See Figure 1. Of the 34 patients: In 79% of cases (27 subjects), all three evaluators recognized the pictures; in 18% of cases (6 subjects), two of three evaluators succeeded; images of one patient (thigh group) was only recognized by one evaluator. See Figures 2 and 3, for examples, of patient images.

3.2 | Patient satisfaction survey

Results obtained from patient questionnaire showed overall satisfaction with the therapy course and results. In general, the patients agreed (4.1) that they are satisfied with the therapy, agreed that the treatment is comfortable (4.1) and that they are satisfied with overall treatment time (4.1). The standard deviation across all the groups averaged ±0.83 points. This shows relatively high consistency of patients' responses. See Table 1 for detailed results.

3.3 | Safety

No adverse events were observed during the study. Several subjects reported side effects including temporary skin redness and/or mild swelling, which resolved within 1-2 hours after the treatment.

4 | CONCLUSION

Most studies on noninvasive skin tightening and body shaping present results after treating one specific body part of the enrolled

subjects. The goal of our study was to validate whether the novel investigated device delivers clinical versatility in terms efficacy, safety, and patient satisfaction when treating various indications across different body areas. We treated 34 subjects for facial skin laxity and body fat deposits and followed them for 3 months.

The treatment efficacy was assessed from pre and posttreatment photographs scored by three blinded evaluators. Statistical analysis of the study results has confirmed aesthetic improvement in the treated indications with a high rate of responding patients, and consistency among all the treated body parts and indications (none of the patient groups had the average recognition rate below 90%). All patients tolerated the treatments well with no significant posttreatment pain or clinical signs of skin damage. Efficacy was also confirmed by results from the patient satisfaction questionnaire. Patients noted comfortable treatments with overall satisfaction with the treatment results and treatment time. No adverse events during the 90-day follow-up were observed. We can thus conclude that both objectives of the study were met with success.

Treatments using the investigated device produce a reduction in skin laxity and fat deposits without any significant complications. The study showed a very low percentage of nonresponding subjects. During the treatments, we used maximum energy settings, which were still within the range recommended by the manufacturer. Despite this fact, our patients reported high levels of comfort and experienced no or very little side effects. It is unclear if such efficacy coupled with high comfort is a direct effect of the additional ultrasound component and/or the redesigned applicator tips. This should be investigated further in future studies.

DISCLOSURES

Dr. Chilukuri is a speaker/consultant for the following companies: Alastin, Allergan Aesthetics, BTL Industries, Cynosure Lasers, Eclipse Micropen, Emvera Lasers, Galderma Aesthetics, PCA Skin, Skin Medica, Suneva Asthetics, and Theravent Lasers. Dr. Fouque and Dr. Denjean have no conflicts of interest to declare.

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