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RADIO FREQUENCY VOLUMETRIC HEATING FOR VAGINAL LAXITY TREATMENT AND EFFECTS ON SEXUAL SATISFACTION

Evans, K.L.[1]
[1]Obstetrics, Gynecology and Wellness, Houston, TX

Introduction: Stretching of the vaginal tissue caused by natural factors as aging or childbirth is the primary cause of vaginal laxity and loss of sexual satisfaction in women. Such medical condition can lead to physical and/or psychological health problems that impact relationship happiness. This prospective study investigates the treatment of vaginal looseness and sexual dissatisfaction with a noninvasive radiofrequency device.

Materials and methods: We enrolled 51 patients (average age 44.43 ± 9.85 years) who reported vaginal looseness symptoms and sexual dissatisfaction. They received 3 treatments with the Exilis Ultra 360 device (BTL Industries, Boston MA, USA) spaced by one week. Each session consisted of separate consecutive intravaginal and extravaginal application using the disposable tips. Therapy parameters were set according to the manufacturer's recommended protocol. Patient sexual satisfaction was evaluated by the Female Sexual Distress Scale-Revised questionnaire (FSDS-R) and the degree of vaginal looseness was measured by the Vaginal Laxity Questionnaire (VLQ) at the baseline and 90 days post treatments. Patient comfort during each procedure was assessed using a Visual Analogue Scale (VAS). Signed informed consents were obtained from all patients.

Results: The average FSDS-R score improved (p<0.001) by 72.75% from 15.60 ± 9.22 to 4.24 ± 5.71 points, with 93 % of patients showing improvement in sexual satisfaction. Over 55 % of patients reported complete absence of any dysfunction 90 days post treatments. VLQ showed vaginal tightness improvement in 96 % of patients (p<0.001) with the average increase of 3.45 ± 1.26 points (1-7 scale). At the follow-up, all patients uniformly reported they don't feel any degree of vaginal laxity at all (VLQ£4). Some level of discomfort was reported in 0.03 % of treatments, with the average VAS discomfort score reaching zero.

Conclusion: The Exilis Ultra 360 proved safe and effective for treatment of vaginal looseness which resulted in a significant improvement of sexual life satisfaction.

Disclosure: Work supported by industry: no.

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IMPROVEMENTS IN PERCEIVED GENITAL SENSATIONS AND SEXUAL AROUSAL FOLLOWING APP-BASED INTERVENTION: PRELIMINARY RESULTS FORM A RANDOMIZED-CONTROLLED TRIAL

Stanton, A.[1]; Fogarty, J.[1]; Meston, C.[1]
[1]The University of Texas at Austin, USA

Objective: Low resting heart rate variability (HRV) has been associated with poor sexual arousal function in women. Recently, a single session of autogenic training, an intervention shown to increase HRV, led to increases in both physiological and subjective sexual arousal and perceived genital sensations in women experiencing decreased arousal (Stanton, Hixon, Nichols, & Meston, under review). The current study expands upon these findings by examining the efficacy of HRV biofeedback, with and without autogenic training, for sexual arousal dysfunction in an at-home setting.

Methods: Women with sexual arousal complaints were eligible to participate if they scored below the clinical cut-off for sexual function on the FSFI, endorsed generalized rather than situational deficits in arousal, and reported significant distress. Participants ($N = 37$) were randomized into one of three conditions: HRV biofeedback, HRV biofeedback + autogenic training condition, or waitlist control. Each condition included three laboratory sessions, spaced two weeks apart, during which both subjective sexual arousal and perceived genital sensations were measured. Participants in the two active conditions completed 4-6 biofeedback sessions at home between each laboratory visit using a Polar H7 strap and a mobile app. Participants in the HRVB+A condition listened to a 14-minute autogenic training recording before completing the biofeedback. Preliminary self-report data were analyzed with repeated measures ANOVAs.

Results: Across the three laboratory visits, participants in the three conditions differed in their subjective sexual arousal ($F(4,68) = 2.89$, $p = .029$) and their perceived genital sensations ($F(4,68) = 2.81$, $p = .032$). Participants randomized to the two active treatments outperformed the control group on both of these measures.

Conclusions: Women who engaged in HRV biofeedback at home, with and without additional autogenic training, experienced increases in subjective sexual arousal and perceived genital sensations compared to women in the control group. These results provide support for the use of either of these interventions in the treatment of sexual arousal concerns.

Disclosure: Work supported by industry: no.

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EXAMINING THE EFFECTS OF MINDFULNESS ON PREFERRED AND NON-PREFERRED DESIRES

Dickenson, J.A.[1]; Diamond, L.M.[1]
[1]University of Minnesota Medical School

Objectives: Mindfulness illuminates how individuals observe, attend, and relate to their visceral experiences, including sexual desire. Mindfulness facilitates women's sexual desire for the preferred sex(es), but it remains unclear whether mindfulness also augments desires toward the non-preferred sex(es). Although desires toward the non-preferred sex infrequently reach conscious awareness, heterosexual women have the capacity to experience such desires and show comparable bodily responses to preferred and non-preferred sexes. Because the subjective experience of desire depends on attention and awareness, becoming aware of bodily sensations without judgment should also enhance desires for the non-preferred sex. To examine this hypothesis, we examined the day-to-day association between present moment awareness and preferred and non-preferred desires and whether such associations were moderated by interoceptive awareness among predominantly heterosexual women.

Materials and Methods: Predominantly heterosexual women (N=28) completed the Multidimensional Assessment of Interoceptive Awareness (MAIA) and subscale scores were calculated. For 7 days during the follicular phase of their menstrual cycle, women rated their present moment awareness and the intensity of desires for men and women. We ran two multilevel models to examine how the MAIA subscales moderated the daily link between present moment awareness and (1) same-sex and (2) other-sex desires.

Results: We found that the tendency to actively listen to one's body for insight affected heterosexual women's desire for men and women differently. Women experienced more intense desires for men on days they felt more in the present moment than they was typical for them. This effect was larger among women who more actively listened to their body for insight and had greater ability to sustain attention to body sensations. In contrast, women who more actively listened to their bodies for insight experienced *less* intense desires for women on days they felt more in the present moment.

Conclusions: Results suggest that for mindfully observing one's body augments women's natural desire responses. It is plausible that heterosexual women's desires for the non-preferred sex may not merely be inhibited as a result of judgment and attention.

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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

Suneel Chilukuri MD[1] | Dominique Denjean MD[2] | Linda Fouque MD[3]

[1]Refresh Dermatology, Houston, TX, USA

[2]Cabinet de Dermatologie Esthetique, Paris, France

[3]Dermatologue Esthetique, Nice, France

Correspondence
Suneel Chilukuri, MD, Refresh Dermatology, Houston, TX, USA.
Email: dermsurg@gmail.com

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

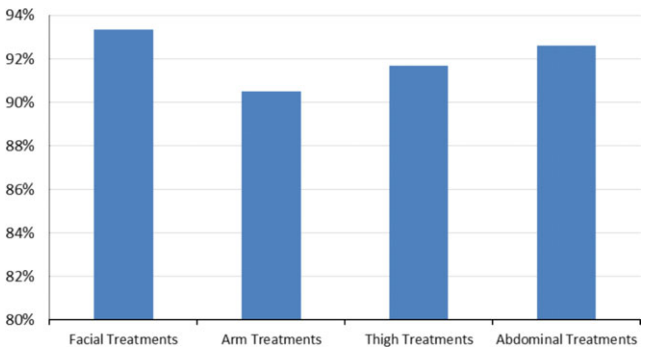

FIGURE 1 Recognition rate of aesthetic improvement in the treated area as per reviewers' evaluation

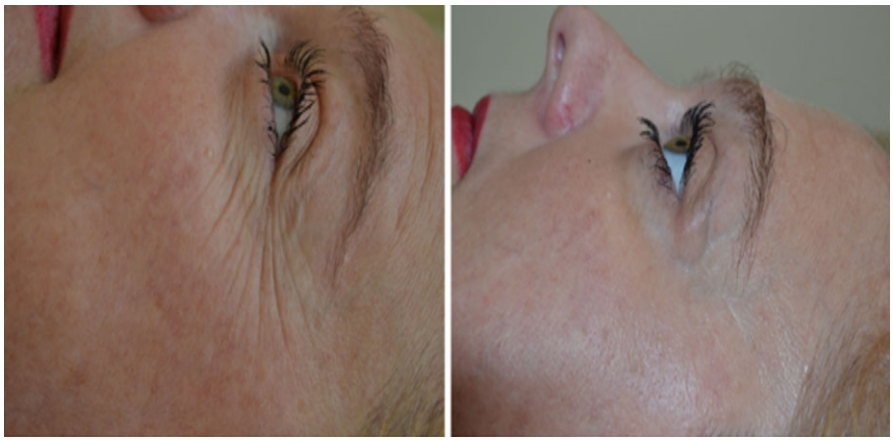

FIGURE 2 Example of patient images taken at baseline and 3 mo after the last treatment

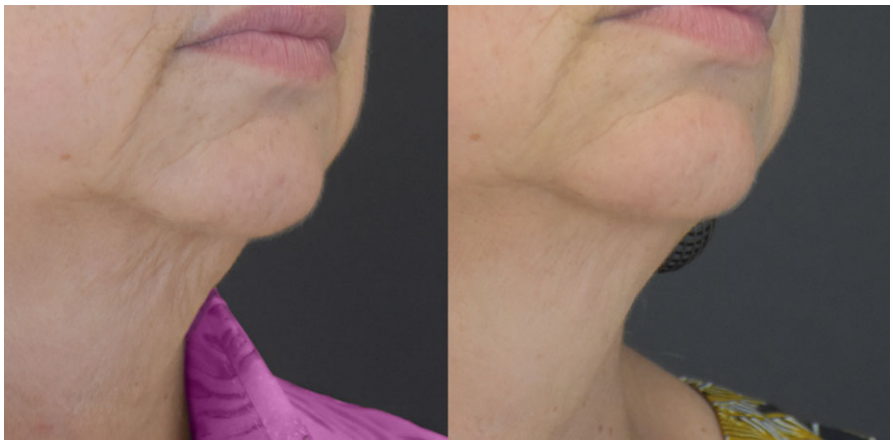

FIGURE 3 Example of patient images taken at baseline and 3 mo after the last treatment

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.

ORCID

Suneel Chilukuri http://orcid.org/0000-0002-4331-8305

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ORIGINAL CONTRIBUTION

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Evaluation of the safety and efficacy of a monopolar nonablative radiofrequency device for the improvement of vulvo-vaginal laxity and urinary incontinence

Shelena Lalji MD[1] | Paula Lozanova MD[2]

[1]Dr. Shel Wellness & Medical Spa, Houston, TX, USA

[2]Department of Dermatology and venerology, Medical University, Sofia, Bulgaria

Correspondence
Shelena Lalji, Dr Shel Wellness & Aesthetic Center, Houston, TX, USA.
Email: drshel@drshel.com

Summary

Background and objective: Vaginal childbirth, natural process of aging, congenital factors, and surgical interventions are considered the main causes of vulvo-vaginal laxity driven by changes in collagen and elastin fibers. This causes a loss of strength and flexibility within the vaginal wall. As a result, women may experience lack of sensation and stress urinary incontinence (SUI)—the condition of involuntary loss of urine associated with activities that cause an increase in intra-abdominal pressure (eg, sneezing, coughing, and lifting). Both vaginal laxity and urinary incontinence significantly affect patients' quality of life (QoL).

The aim of this study was to evaluate efficacy and safety of a noninvasive radiofrequency device when used to treat SUI and vulvo-vaginal laxity through its heating effect which stimulates collagen and elastin fibers.

Methods: Twenty-seven women (average age 44.78±10.04 years) with indications of mild/moderate SUI as well as vulvo-vaginal laxity were treated with a monopolar radiofrequency device. The treatment course consisted of three once-a-week sessions. Each session included intravaginal treatment followed by treatment of labia majora and the perineum.

Improvement in the SUI condition was evaluated by applying the International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF). Data were collected at the baseline, after the last treatment and at 1-month follow-up visit.

Vaginal laxity was assessed by subjective vulvo-vaginal laxity questionnaire (VVLQ). Data were collected before the 1st treatment and during the 1-month follow-up visit.

Patient's satisfaction was recorded using a satisfaction questionnaire. Data were collected after the last treatment and at the 1-month follow-up visit. Any adverse events related to the treatments were monitored.

Results: On a scale of 0 to 5, the average frequency of urine leak improved from "2-3 times a *week*" (2.15±1.03 points prior to treatment) to "*once a week*" (1.00±0.78 points post-treatment), and on to "*never*" (0.44±0.51 points at the 1-month follow-up visit). Sixteen subjects (59.3%) reported decrease in the amount of

leakage, with 15 women (55.6%) becoming completely leak-free at the 1-month follow-up. At the 1-month follow-up visit, 24 subjects (88.9%) expressed their condition's interference with everyday life decreased and 17 patients (62.9%) said the condition did not interfere with their everyday life at all as a result of the treatment. All results are statistically significant ($P<.05$). No adverse events were recorded.

All subjects reported improvement in vaginal laxity, from average perception of "*very loose*" (2.19±1.08 points prior to treatment) to "*moderately tight*" (5.74±0.76 points at the 1-month follow-up visit).

During the follow-up visit, 89% of the patients "*agreed*" or "*strongly agreed*" that their *SUI condition* improved, and 93% of the patients "*agreed*" or "*strongly agreed*" that their gratification during intercourse improved. None of the subjects reported dissatisfaction.

Conclusion: The study confirmed the monopolar radiofrequency method as an effective and safe treatment of SUI and vulvo-vaginal laxity. The treatments were well tolerated by all subjects with no adverse effects.

KEYWORDS

extra-vaginal, intravaginal, labia majora, noninvasive tightening, perineum, radiofrequency, sexual gratification, SUI, urinary incontinence, vaginal laxity, vulvar laxity

1 | INTRODUCTION

Stress urinary incontinence (SUI) is a condition of involuntary urine leakage from the urethra considered to be a hygiene and/or social problem.[1] Statistical data show that the most affected part of the population are women, with approximately 35% of all women worldwide affected.

Urinary incontinence (UI) is frequently linked to vulvo-vaginal laxity, which encompasses laxity of both the vaginal introitus and labia majora. This condition is most commonly linked to sexual dissatisfaction due to limited friction, feeling of looseness, and orgasmic dysfunction; all leading to lower sexual gratification during intercourse. Both of these conditions lead to a decreased quality of life (QoL) including social isolation, decreased self-confidence, and lower sexual gratification during intercourse.[2,3]

The major risk factors for the development of SUI and vulvo-vaginal laxity include childbirth, advancing age, hysterectomy, recurrent urinary tract infections, smoking, medications such as diuretics, sedative-hypnotics and alpha blockers, the presence of comorbid diseases, and excessive weight.[2,4–6] The conventional methods for treating this condition include medications, pelvic floor muscularity strengthening (exercising and/or electro stimulation), surgical procedures, and lifestyle changes (such as quitting smoking or losing weight).[7–9]

Radiofrequency (RF) is one of the more innovative approaches to treating SUI and vulvo-vaginal laxity. It has gained significant popularity in recent years due to its noninvasiveness, absence of adverse events, and fast results. The mechanism of action is based on elevating the temperature of the treated tissue to initiate biological changes. RF-generated heat stimulates the tissue matrix of collagen, elastin, and ground substances and results in immediate change in the helical structure of the collagen. Additionally, neocollagenesis and neoelastogenesis are triggered due to micro-inflammatory stimulation of fibroblasts.[10] It is also believed that the production of sex steroid precursor dehydroepiandrosterone (DHEA) is activated. DHEA supports estrogen production in the vulvo-vaginal cells which plays a big role in rejuvenating and stimulating the vaginal tissue and collagen.

The aim of this study was to investigate the efficacy and safety of a monopolar radiofrequency device for transvaginal treatment of SUI and vulvo-vaginal laxity.

2 | MATERIALS AND METHODS

2.1 | Participants

Twenty-seven women aged between 28 and 66 (mean age 44.78±10.04 years) participated in this nonrandomized, prospective, multicentric study. Only subjects who experienced mild-to-moderate stress urinary incontinence (minimum level 1 in the frequency of leakage based on ICIQ-UI SF form, ie, experiencing leakage at least once a week) and vaginal laxity (maximum level 5 of vulvo-vaginal laxity based on VVLQ questionnaire, ie, defined as no more than "slightly tight") were enrolled. Prior to the study, 19 subjects (70.4%) evaluated their vulvovaginal tightness as "moderately loose" or "very loose," 18 subjects (66.7%) reported they leak urine at least two or three times a week. Twenty-six subjects (96.3%) had a history of at least one prior delivery. The exclusion criteria included the following: abnormal cell cytology; positive urine culture; bleeding in the vulvo-vaginal area; pregnancy or breastfeeding; metal implants; unwillingness or incapability to complete the entire study protocol; any other contraindication listed by the device manufacturer. All patients were

consented. The study was approved by an independent ethics committee.

2.2 | Therapy provision

The therapy course consisted of three once-a-week (± 2 days) treatment sessions with monopolar radiofrequency device (Exilis Ultra 360, BTL Industries Inc., Boston, MA). Each treatment session consisted of an intravaginal and subsequent extra-vaginal treatment. For intravaginal treatment, the starting power was set to 30 points and 80% duty factor. The intravaginal tip was applied to the mucosal surface of the vaginal introitus behind the hymenal ring, was moved deeper inside the vaginal canal to a depth of approximately 10 cm over the course of 2.5 seconds, and then was moved back to the vaginal introitus over the course of the next 2.5 seconds. This repetitive movement continued for 5 minutes. The energy was adjusted based on patient's feedback. For extra-vaginal treatment, the initial power was set to 90 points and 100% duty factor. The extra-vaginal tip was applied to the labia majora using slow circular motions for 3 minutes on each side; the energy was adjusted based on patient's feedback. Then the extra-vaginal tip was applied to perineum using slow circular motions for 3 minutes; the energy was adjusted based on patient's feedback.

2.3 | Outcome measures and statistic evaluation

The SUI condition was assessed by applying the standardized International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF).[11] Data were collected before the first, after the third (last) treatment and during the 1-month follow-up visit. Average improvement was calculated.

Vaginal laxity was assessed by nonstandardized subjective vulvo-vaginal laxity questionnaire (VVLQ) using 7-point Likert scale (BTL Industries Inc.). Data were collected before the first treatment and during the 1-month follow-up visit. Average improvement was calculated.

All outcome data were tested for statistical significance by means of *t* test, where levels of $P<.05$ were deemed statistically meaningful.

Patients' satisfaction with the treatment results was evaluated using a 6-point Likert scale satisfaction questionnaire. The questionnaire consisted of the following statements: (1) "My UI has been improved" and (2) "My sexual gratification has been improved", with the following possible answers: strongly disagree (1); disagree (2); slightly disagree (3); slightly agree (4); agree (5), strongly agree (6). Data were collected after the third (last) treatment and during the 1-month follow-up visit.

3 | RESULTS

All 27 patients completed the study. All treatment sessions were conducted in accordance with the treatment protocol. No adverse events or side effects were observed.

3.1 | Urinary Incontinence

The outcome data and the results from ICIQ-SF and VVLQ are presented in Table 1.

The average frequency of urine leak improved from "*2-3 times a week*" (2.15±1.03 points prior to treatment) to "*once a week*" (1.00±0.78 points post-treatment), and on to "*never*" (0.44±0.51 points at the 1-month follow-up visit). Twenty-six subjects (96.3%) reported improvement of at least one level, with 15 subjects (55.6%) showing improvement of two or more levels when comparing the baseline to the follow-up visit.

Sixteen of the enrolled subjects (59.3%) also reported decrease in the amount of leakage, with 15 women (55.6%) becoming completely leak-free at 1-month follow-up.

At 1-month follow-up, 24 subjects (88.9%) expressed their condition's interference with everyday life decreased, with 12 individuals (44.4%) reporting improvement of three or more levels on a 0-10 scale. Seventeen patients (62.9%) said the condition does not interfere with their everyday life anymore.

All measured results were proven statistically significant ($P<.05$).

3.2 | Vaginal laxity

On a scale of 1-7, the average vulvo-vaginal laxity improved from "*very loose*" (2.19±1.08 points prior to treatment) to "*moderately tight*" (5.74±0.76 points at the 1-month follow-up visit). Twenty-seven subjects (100%) reported improvement of at least two levels, with 23 subjects (85.2%) showing improvement of three or more

TABLE 1 Changes in Stress urinary incontinence (SUI) and vulvo-vaginal laxity

Questionnaire	Score range	Pretreatment	Post-treatment	*P* value	1 mo post-treatment	*P* value	Improvement (Pre to Post)	Improvement (Pre to 1 mo post)	*P* value
ICIQ-UI SF									
Frequency	(0-5)	2.15±1.03	1.00±0.78	<.001	0.44±0.51	<.001	1.15±0.53	1.70±0.87	<.001
Volume	(0-5)	1.04±0.19	0.70±0.47	<.05	0.44±0.51	<.001	0.33±0.48	0.59±0.50	<.05
Interference	(0-5)	3.41±2.34	1.26±1.32	<.001	0.59±0.93	<.001	2.15±2.01	2.81±2.20	<.05
VVLQ									
Tightness	(1-7)	2.19±1.08	n/a	n/a	5.74±0.76	<.001	n/a	3.56±0.97	n/a

Data are mean±SD.

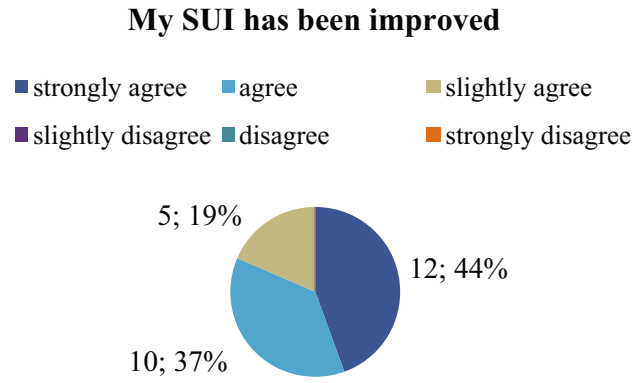

FIGURE 1 Stress urinary incontinence (SUI) improvement (Post-treatment)

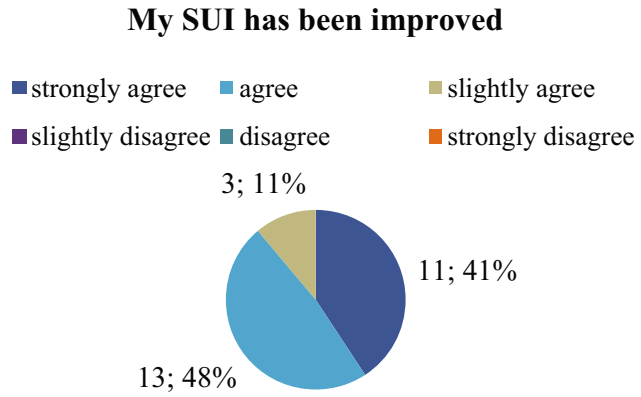

FIGURE 2 Stress urinary incontinence (SUI) improvement (1-month follow-up visit)

levels when comparing the baseline to the follow-up visit. 1 month after the last treatment, all (100%) subjects evaluated their vulvo-vaginal sensation to be slightly, moderately or very tight.

3.3 | Patient satisfaction

The data from the satisfaction questionnaire are presented in Figures 1-4.

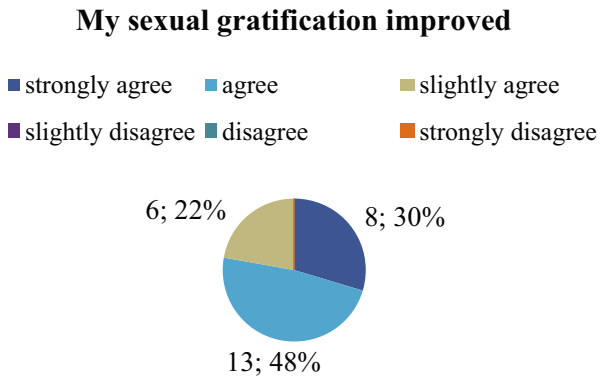

FIGURE 3 Sexual gratification improvement (Post-treatment)

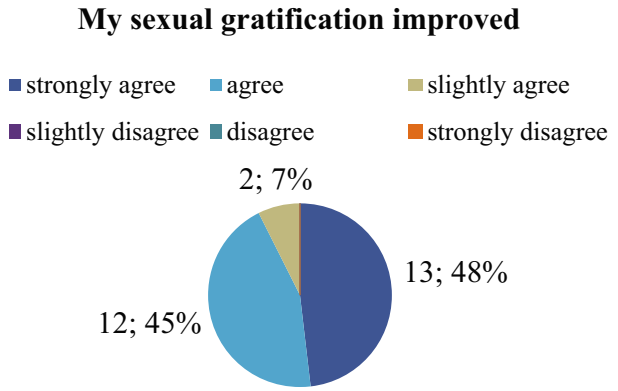

FIGURE 4 Sexual gratification improvement (1-month follow-up visit)

Eighty-one percentage of the patients "*agree*" or "*strongly agree*" that their *SUI condition* improved post-treatment compared to the baseline, and the share increased to 89% during the follow-up visit. The remaining 19% and 11%, respectively "*slightly agreed.*" None of the subjects reported dissatisfaction (score 0-3).

Seventy-eight percentage of the patients "*agree*" or "*strongly agree*" that their gratification during intercourse improved post-treatment compared to the baseline, and the share increased to 93% during the follow-up visit. The remaining 22% and 7%, respectively, "*slightly agreed.*" None of the subjects reported dissatisfaction (score 0-3).

4 | CONCLUSION

The primary goals of the study have been met as the monopolar radiofrequency treatments demonstrated good results both in terms of efficacy, and safety in all evaluated areas. The results show zero nonresponding subjects when treating vulvo-vaginal laxity and 3.7% of nonresponders when evaluating improvement in SUI in terms of frequency of leakage. Most subjects also reported decrease in the amount of leakage and improvement with the interference in their everyday life. In addition to the originally designed areas of improvement which were monitored, subjective perception of better lubrication during intercourse as a result of the treatments was reported by the majority of the patients.

Improvement in treated conditions was reported immediately after the last treatment session and was even more significant after the 1-month follow-up visit. Improvement of results with time is driven by the collagen remodeling process which takes up to 90 days to fully complete. It should be investigated by future studies with longer follow-ups to understand how the results develop over time.

Patients reported high satisfaction rate when evaluating improvement in SUI conditions and in sexual gratification. The treatments were well tolerated by all subjects; no adverse events were observed. This study demonstrates efficacy and safety of a monopolar radiofrequency for SUI and vulvo-vaginal laxity treatments. Every patient is likely to recognize the improvement at different points in time depending on their individual physiological processes. This

study captures significant improvement in the treated conditions at the 1-month follow-up visit. Although further controlled study is needed to confirm the data and evaluate the long-term effects in the endovaginal treatment.

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"Deep Heating" Noninvasive Skin Tightening Devices: Review of Effectiveness and Patient Satisfaction

Suneel Chilukuri MD FAAD FASDS[a] and Jason Lupton MD[b]
[a]Refresh Dermatology, Houston TX
[b]San Diego Dermatology & Laser Surgery, San Diego CA

ABSTRACT

Non-surgical aesthetic devices intended for treatment of lax and loose skin have gained popularity due to their ability to non-invasively improve patient's aesthetic condition and its low side effect profile. This study is intended to review available peer reviewed literature about Ultherapy, ThermaCool, and Exilis Ultra 360 non-invasive skin tightening devices to compare their treatment efficacy and patient subjective satisfaction.

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INTRODUCTION

Aesthetic improvement in the appearance of facial wrinkles, redundant facial, neck, or body laxity is a major feature of aging. Monopolar radiofrequency (RF) and ultrasound sources became a treatment of choice for non-ablative tissue tightening by volumetric tissue heating of the deep dermis.

Non-ablative radiofrequency devices have gained popularity because of their ability to offer improvement of skin laxity without the postoperative recovery or financial burden of surgical procedures. It remains in demand secondary to its lower side effect profile and remarkably short post procedural downtime.

This continuing shift away from ablative and invasive aesthetic procedures continues to be driven largely by patient and clinician preferences.[1] According to the American Society Aesthetic Plastic Surgery, 526,000 non-surgical skin tightening procedures (annual growth of 11 %) were performed in 2016 in the United States.[2]

The aim of this clinical paper is to review available literature for selected aesthetic devices utilizing deep tissue heating (Ultherapy, ThermaCool, Exilis Ultra 360). The data reported herein are based on a retrospective review of peer-reviewed clinical studies. Aforementioned devices are evaluated for safety and efficacy. In everyday practice, patient's perceived improvement typically outweighs the practitioner's scoring. Therefore, most of the clinical studies utilize subjective patient satisfaction scores.

DISCUSSION

Ultherapy (Ulthera, Merz North America, NC)

The Ultherapy procedure is indicated for use in: lifting skin on the neck, on the eyebrow and under the chin as well as improving lines and wrinkles on the décolletage.

The first aesthetic use of high intensity focused ultrasound (HIFU) was introduced in 2008 and it was FDA cleared for brow-lifting a year later. Currently, the microfocused ultrasound (MFU) is being used for non-invasive tissue remodeling.

Currently available transducers emit frequencies of 10.0 MHz, 7.0 MHz, and 4.0 MHz with focal depths of 1.5 mm, 3.0 mm, and 4.5 mm, respectively. The higher energy transducers allow energy deposition in smaller anatomical regions. The ultrasound beam is focused to a point less than 1 mm^3 in size below the skin surface (in the superficial muscular aponeurotic system) to form "thermal coagulation points".[3] Temperature inside of such points is increased to 65°C. Superficial layer of skin remains un-affected. This results in immediate collagen contraction and initiates collagen synthesis. The device incorporates automatic ultrasound imaging of the tissue for controlled energy delivery and acoustic coupling of the probe. The treatment zone is 25 mm and 14 mm in length, for the standard and the narrow transducers, respectively. Treatment is administered in a "stamping" manner.

A prospective cohort study[4] described results of facial treatment with the 4 MHz and 7 MHz transducers. At 90 days, 30 patients (86%) showed clinically significant brow-lift with a 1.7 mm mean elevation of the eyebrow. Fabi et al[5] treated 70 patients on the neck. Quantitative assessment indicated that 72.9% of subjects achieved a visible tissue lift of > 20.0 mm^2 in the sub-mental area. Three months after, the improvement was still visible for 68.6% of patients treated in sub-mental and neck area, and for 67% of patients treated on face and neck.

The long-term efficacy was studied also by Fabi et al.[6] At 180 days, physician GAIS score revealed that 77.7% patients achieved improvement in the face and upper neck area, while

patient evaluation resulted in 77.8% improvement. Blinded reviewers assessed photographs with an average score of 67%.

Park et al[7] treated 20 patients with approximately 420 shots each spread among the supraorbital, zygomatic, infra-orbital, periorbital, cheek, pre-auricular, and jawline areas. Physician's GAIS scale evaluation (improvement: 0- none, 1- mild, 2- mild/moderate, 3- moderate, 4- severe) showed 0.9 overall improvement after 90 days, and it stayed unchanged when re-evaluated at 180 days. Patient satisfaction score was 3.80 and 3.65 at 3 months and 6 months, respectively (1- not satisfied; 2- somewhat satisfied; 3- satisfied; 4- very satisfied; 5- extremely satisfied).

Another study investigated improved efficacy when multiple treatment passes had been used.[8] Neck and face were targeted using the 4 MHz transducer followed by the 7 MHz transducer on 10 patients. Clinicians reported 80% improvement at 90 days, with 20% patients showing no change. Patients reported 90% improvement by self assessment, but the overall outcome was in most cases described as mild or moderate (N=7). The mean pain score was 3.9 ± 1.66 (range, 2-7) on the VIS. No patient reported pain at the follow up.

Oni et al[9] performed a large Ulthera sponsored study, evaluating improvement in lower face/neck appearance in 93 patients treated with 4 MHz and 7 MHz transducers. At 90 days, 65.6% patients reported their satisfaction with results, the remaining 34.4% saw no improvement. According to masked evaluators, improvement of skin laxity occurred in 54 patients (58.1%). In 16 patients (17.2%) there was no change, and in 23 patients (24.7%) their condition worsened. On a 0-10 scale, the average pain scores were between 5.68 and 6.53 for submandibular region (5- moderate pain, 6- increasing discomfort, 7- significant discomfort).

MFU was also studied for décolletage lifting and rhytids.[10] At 90 days, 96 % patients showed improvement according to PGAIS score, 1 patient showed no results. According to SGAIS score, 100% of patients noticed some kind of aesthetic improvement, all of them were very satisfied (37.5%) or satisfied (62.5%) with provided treatment. At 180 days, they observed a decrease in all aspects of the outcomes. PGAIS decreased to 86 % and SGAIS decreased to 95%. The mean midclavicular-to-nipple distance decreased from 20.9 cm to 19.5 cm at the end of the follow up.

The most common post procedural findings were tenderness, edema, erythema, bruising, numbness, and welts. In a 2014 clinical study on Ultherapy's safety profile,[11] most unexpected AEs that happen in <0.4% of cases include pain, nerve irritation, numbness/paresthesia, lumps, swelling, tingling, itchiness, redness, hives/rash, headaches, swollen throat, and could be attributed to incorrect treatment techniques or they are classified as unrelated to the treatment. Gutowski[12] reported only mild side effects which resolved within 7 days, another study[13] reported side effects which lasted up to 3 months (skin pigment changes, neuropathic pain, bruising). To overcome pain-related side effects, topical or oral anesthetics were used in numerous studies, improving the somatic experience during the procedure.[5,8,10,12,14]

Thermage ThermaCool (Solta Medical, San Francisco, CA)

The ThermaCool procedure is indicated for use in: Dermatologic and general surgical procedures for electrocoagulation and hemostasis; non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; and non-invasive treatment of wrinkles and rhytids.

The system is made up of several components that allow delivery of electromagnetic energy to the skin through a single-use treatment tip, which cools down its surface while the RF energy is being delivered. Energy settings are determined based on anatomy of the treated area. Treatment tips come in various sizes, currently 0.25 cm^2, 1.0 cm^2, 1.5 cm^2, and 3.0 cm^2. Tip heats up the dermis to temperatures of 65–75°C, causing collagen denaturation while the epidermis is kept at 40°C. The cooling is provided by a continuous application of cryogen spray onto the inner surface of the tip membrane.

Initial studies showed modest results, particularly in improvement of wrinkle scores of the face, neck, and brow. These studies demonstrated that outcomes were more significant in younger patients and when treating larger surface area with increased number of treatments. Clinical results improved over time as 4-month scores were statistically higher than the 1-month scores. Areas less responsive to treatments included jowls, mandibular ridge, and neck. Because of significant pain, anesthesia and oral pain medication was needed.[15,16] A long-term study of the skin tightening effect confirmed that multiple treatments might be beneficial to patients as evidenced by Suh et al.,[17] where 8 patients were observed over 6 years after having an average of 4 sessions over that period.

Fitzpatrick et al[18] investigated periorbital tightening on 86 subjects. Review of photographs showed improvement in 83% cases, with 14% patients seeing no change, and 3% patients worsened. The same evaluation method showed lifting of eyebrows in 62% cases. Patients were satisfied or very satisfied with the treatment outcome in 50% of cases, with 49% patients claiming their appearance improved. According to subjective comfort rating, only approximately 7.5% of treatments (counted for both sides of face) were painless, the remaining 92.5% patients reported mild/moderate/severe/intolerable pain.

Fritz et al[19] treated one group with single treatment (N_1=11) and the second group with two treatments one month apart (N_2 = 9), to evaluate the outcome of multiple treatments to

nasolabial fold improvement. Patients who received two treatments showed higher rate of improvement in self-assessment rating. The overall change noted by physicians and patients was modest, reaching the maximum of 14-16% improvement. Three patients reported less than 10 % of overall improvement. All patients experienced mild or mild-to-modest erythema.

Another study[20] focused on cheek and neck laxity treatment found a 35% to 40% subjective improvement of nasolabial and melolabial folds appearance, and 30% to 35% subjective improvement of neck laxity after one treatment session. Patients described the procedure as moderately uncomfortable.

A multi-center study[21] evaluated low-fluence algorithm intended for facial laxity treatment. At 4 months, 95% of patients showed improvement. Most patients (65%) had reported good improvement (range, 26-50%) or very good improvement (range, 51-75%). Five percent of patients showed no improvement. Results were similar at 6 months when the number of patients with no improvement increased to 8 %. Subjective satisfaction was 78% at 4 months, and decreased to 70% at 6 months post treatment.

Short-lasting post procedural findings, such as erythema and edema, are reported in the majority of patients.[22] Edwards et al[23] reported that erythema lasted less than 24 hours in 50% patients; 1 patient had edema that lasted beyond one week. Weiss et al. performed a large-scale retrospective study[24] and identified some of the rarer side effects of crusting, oozing, scarring, bruising, pigment alteration, nerve damage, texture change, atrophy, burns, and prolonged swelling, pain, or erythema. There was one case of fat atrophy causing a small depression on the cheek, and one superficial linear crust. These resolved in 3.5 months and one week, respectively.

A degree of pain reported without pain management interventions in the earlier studies was severe (6 of 10 on a 1–10 pain scale)[17] and vibration was added to modify pain fiber recruitment.[25] Also the application of topical anesthetics is recommended prior to the treatment to increase tolerability.[16,18,20,21]

Exilis Ultra 360 (BTL Industries, Boston, MA)

The procedure is FDA cleared for use in: non-invasive dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids, to provide a temporary reduction in the appearance of cellulite.

The system is the latest generation of device based on the Exilis platform. As such the review also includes all evidence relating to the older generations of the device. It is a monopolar RF device with ultrasound component, and a number of built-in safety features, including integrated Peltier cooling. The system has 2 types of different hand applicators, one designed mainly for the face, and one for the body. During the treatment, the temperature in the treated tissue is raised to 40-45°C while the handpiece is in continuous motion so that areas of skin with the most laxity can be specifically targeted. When targeting deeper layers, the skin is cooled and protected, allowing the heat to reach deeper. Any spikes in RF delivery are automatically eliminated due to constant energy flow monitoring. This virtually eliminates the risk of burns. As such, it allows use of higher power, which then leads to shorter treatment times.

Efficacy of the system on collagen remodeling was first studied by stereological analysis in a veterinary study, which showed large-scale increase of collagen (P=0.018) in the treated area.[26] The subjects received 4 treatments. Based on evaluation of 54 histological samples of epidermis and dermal-epidermal junction, the collagen content in the tissue increased from 9% to 26% (288% increase) at the 3-month follow-up.

Weiss and McDaniel[27] confirmed that modified 2-treatment only protocol is well tolerated by subjects, and produces significant subjective as well as objective improvement. Three months post treatments, 92% of patients showed improvement in skin laxity based on evaluation of photographs. No adverse events were reported. Objectively, skin density increased by 19% at 3 months. Biopsies showed increase in dermal collagen and elastin fibers which correlated with subjective patient evaluation.

A recent study[28] proved a high degree of versatility of the system when evaluating efficacy on multiple body parts. Patients (N=34) were divided according to their indication, and were treated for laxity on face, arms, as well as for fat in thighs and abdomen. Four 30-minute treatments were applied. Independent evaluators recognized patient baseline photographs from the 3-month follow-up in 92 % cases, with all groups scoring above 90 % (the highest on facial photographs with 93%, the lowest on arm photographs with 90.5%). On average, 8% patients showed no response. Patients satisfaction averaged 4.15 on a given scale (5- Strong satisfaction to 1- Strong dissatisfaction), and they agreed that the treatment was comfortable with average score of 4.06 (5- Strongly agree, 1- Strongly disagree). There was no post-treatment pain or skin damage.

The efficacy for fat treatments was described by McDaniel et al.[29] The study proved that the unit can selectively heat fat, causing apoptosis of adipocytes. The skin surface remained intact, while subcutaneous fat showed apoptotic index increase from 7% to an average of 44% after the last treatment. Study also proved safety through histological analysis, blood chemistry, and hematology samples.

The efficacy has also been investigated when treating laxity of female intimate parts. A study published in Lasers and Surgery

TABLE 1.

Comparative Summary of Non-Invasive Skin Tightening Devices

	Ultherapy	ThermaCool	Exilis Ultra 360
Manufacturer	Merz (NC)	Solta Medical (San Francisco, CA)	BTL Industries Inc. (Boston, MA)
Technology	Microfocused Ultrasound	Monopolar RF	Monopolar RF
Mechanism of action	Collagen denaturation and subsequent synthesis[9]	Collagen remodelling[18]	Collagen remodelling; increase of elastin and collagen fibres (small applicator)[26], fat apoptosis (large applicator)[29]
Treatment Time (Full Face in min)	60-85[9]*	60-120[15]*	45[28]
Number of Treatments	1-2[9]	1-2[15]	2-4[27,28]
Therapeutic Temperatures (°C)	65	65-75	40-45
Anesthetics	YES	YES	NO
Clinical Efficacy	58.1-96.0 %[5-11]	47-95 %[18,19,20]	89-93 %[28,31]
Patient Satisfaction	65.6-95.0 %[5-11]	53-78 %[19,21,22]	77-95 %[28,30,32]
Pain (0-10 score)	3.9-6.53[9,10]	6[18]	No data
Non-responsive Patients	14 - 20.0 %[9-11]	5 - 14 %[19,22]	3 - 8 %[28,31]
Worsening of Patient's Condition	24.7 %[10]	2.5 %[19]	No Data
Serious Adverse Events	Rare	Rare	None

*Including anesthesia

in Medicine[30] presents an average 2.9 point (of maximum 4) improvement in vulvar appearance after 4 treatments, accompanied by increased sexual function measured by FSFI score from initial 75% to 87%. No adverse events were reported. Later on, vaginal treatments have also been studied by other investigators.[31,32]

In general, post procedural findings included only mild erythema which is also considered the therapeutic endpoint of a proper treatment. No adverse events, nor long-lasting side effects have been reported.

CONCLUSION

A summary of most important disciplines is in Table 1, comparing aspects crucial from both the physician's and patient's perspective. The data is based on available peer-reviewed trials. Quantitative comparison is stated in percentages due to non-uniform approaches to efficacy and safety evaluation in the respective studies.

All 3 devices have solid clinical evidence behind and proved efficacy in tissue laxity treatment. Exact clinical efficacy varies among the devices and also seems to be dependent upon the study design, treated body part and selected outcome measures. Some of the studies have been sponsored by the manufacturers (Oni et al., White et al., Polder et al., etc.), thus leaving room for bias.

Two of the devices leverage higher therapeutic temperatures to achieve results at a smaller number of treatments. This seems to be paid off by increased patient discomfort and the need to use anesthetics, which also prolongs the overall time needed for each session. Exilis Ultra 360 protocol consists of 4 treatments, but shows higher patient comfort. The efficacy of two-treatment protocol was also investigated and proved by Weiss et al. More evidence is likely to appear over time, but as of now there seems to be no clear correlation between the 3 different therapeutic temperatures and clinical efficacy.

None of the studies investigated in more detail how the patient profile influences clinical results. Number of non-responding patients is comparable for Exilis Ultra 360 and ThermaCool devices, ranging from 3% to 8%. Ultherapy studies show slightly higher percentage of non-responders, which was reported by Oni et al. (17.2%), Lee et al. (20%), or Fabi et al. (14%). Oni et al. also reported that after Ultherapy treatment, for 24.7% patients the post-treatment outcome was evaluated as worse against the baseline. Additional research is needed to allow for proper expectation management in patients.

This retrospective review primarily focused on patient satisfaction and treatment efficacy based on comparison of validated peer reviewed articles of three non-surgical skin tightening devices. Despite the slight differences in principles of mechanism

of action, all reviewed devices proved their therapeutic effect on tissue tightening. While the Ultherapy device is specialized mostly on the face, neck and décolletage area, the ThermaCool, and Exilis Ultra 360 are widely used to treat different body parts. The highest rate of versatility offers the Exilis Ultra 360 device, which can be used for treating additional areas such as back, hands, bra fat, forearms, thighs, and female intimate parts.

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. Lupton has no conflicts of interest to declare.

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AUTHOR CORRESPONDENCE

Suneel Chilukuri MD FAAD FASDS

E-mail:..... chilukuri@refreshdermatology.com

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Zeljka Clark, MD

Rahima Moosa Mother and Child Hospital, O&G, Johannesburg, South Africa

ABSTRACT

Introduction: With aging, the vulvar tissue loses its vitality and elasticity due to collagen fibers fatigue. Such changes and functional characteristics of the external genitalia often cause negative psychological effects resulting in impeded sexual function. The objective of this study is to evaluate the safety and efficacy of a radio frequency (RF) device when used for treating labial laxity and for improvement of female sexual fuction. **Materials and Methods:** Using a monopolar RF device, 19 women received four once-a-week treatments. Images taken at the baseline and at the 1-month follow-up were evaluated for improvement in vulvar appearance on a scale of 0–3. The female sexual function index (FSFI) scores were calculated and compared between the baseline, the 1-month follow-up visit, and the 12-month follow-up visit. **Results:** Average improvement in the vulvar appearance according to the patients and the physician was 2.00 ± 0.58 and 1.79 ± 0.54, respectively. Both values represent "moderate change" according to the applied scale. The average FSFI increased by 9.79 ± 4.35 and 7.10 ± 5.17 when comparing the baseline to the 1-month and the 12-month follow-up, respectively. No adverse events were reported. **Discussion:** Efficacy and safety of the investigated device were proven. Longevity of results was proven by the 12-month follow-up.

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Regardless of age, education, or socioeconomic status, such anatomical appearance together with physiological and functional characteristics of the external female genitalia often causes negative psychological effects. Embarrassment and anxiety over sexual function leads many women to seek help in ameliorating these conditions and concerns.

One possible treatment solution is represented by surgical remodeling of vulvar tissue (labia minora, labia majora, mons pubis, perineum, and vaginal introitus). Reduction labiaplasty is used for sculpting of elongated or unequal labia minora, mostly in response to labia minora protruding beyond the labia major (1). Perineoplasty is a way to rejuvenate relaxed perineum and can also enhance the sagging labia majora and labia minora. Augmentation labiaplasty can provide esthetic improvement and rejuvenation of labia majora.

The main concerns with surgical procedures and ablative laser resurfacing relate to possible adverse events (infection, scarring, keloid formation, asymmetrical appearance of the surgically treated tissue) and associated downtime.

Skin rejuvenation options with a low risk of severe adverse events and without (or with very little) downtime include various non-ablative systems: vascular lasers, intense pulse light, infrared lasers and broadband light sources, radio frequency (RF) devices, photodynamic therapy, and fractional lasers. All these devices may be used to achieve restoration of youthful appearance and to improve sexual function and performance.

RF methods were first studied in 1949 for the treatment of skin laxity, resulting in significant improvement in skin tissue appearance (2). However, the application of RF to external female genitalia only began to emerge in the last decade. The RF-induced elevation of tissue temperature leads to a break-up of intermolecular cross links, stabilization of collagen helicoid structures, and thickening of collagen fibers. The mild inflammatory response of the treated tissue stimulates fibroblasts. As a result, new collagen and elastin fibers are produced as part of the natural healing response (3).

Various RF devices are currently available on the market, with monopolar units penetrating 20–25 mm and bipolar RF reaching depths of approximately 2–8 mm (4). Lordello et al (5) used a bipolar device on women with sagging labial tissue. The protocol consisted of eight 20-minutes weekly sessions, reaching a temperature of 39–41°C. All patients reported satisfaction with the treatment outcome regarding

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sexual function, arousal, and lubrication. Average female sexual function index (FSFI) score (5) increased from 25.66 ± 5.7 to 27.30 ± 5.5 (p = 0.379).

In 2016, a prospective cohort study on 17 women was conducted in Croatia using a monopolar RF device for labial tissue tightening and improvement of labial laxity (5). The investigators reported an average "moderate change" regarding improvement in vulvar appearance. Mean FSFI scores increased from 75% to 87%.

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This is a prospective, randomized, and controlled study which aims to evaluate the safety and efficacy of a monopolar RF treatment when applied to external female genitalia for treating labial laxity and to improve female sexual function.

We enrolled 19 healthy women aged 35–64 (average age 46.7 years) who had reported dissatisfaction with the esthetic appearance of their external genitalia before the commencement of the study. Fourteen of the 19 women had a history of at least one prior delivery. Clinical and demographic characteristics of the subjects are presented in Table 1. The cohort included four postmenopausal subjects, aged 55–64, who had never been exposed to any form of hormone replacement therapy.

Consent to the treatments was obtained prior to commencement, and a detailed medical history of each individual was taken. This included obstetric and gynecological details, and any previous surgeries in the genital area. Each subject was evaluated for contraindications that would disqualify her from receiving RF treatments, including but not limited to pacemakers, defibrillators, facial implants, intradermal fillers, pregnancy, breastfeeding, gynecological or skin lesions in the genital region, or malignancy (6).

The entire study was conducted in compliance with the WMA Declaration of Helsinki's ethical principles for medical research involving human subjects.

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The treatment protocol consisted of four weekly sessions, each taking approximately 20 minutes. A monopolar RF device was used (BTL Exilis System, BTL Industries Inc.), with the starting energy set to 90 points and 100% duty factor. The energy was adjusted based on patient's feedback.

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All treatments were performed using the same starting setting and the same treatment technique, since monopolar RF application has been found to be safe for all skin types (7).

Table 1. Demographic and clinical profile of the study cohort

Personal history	*N*	Mean ± SD or %
Age (years)	19	47 ± 7.6
BMI (kg/m^2)	19	25.3 ± 5.2
Sexual activity in the last 6 months	16	84
Sexually inactive	3	16
Oral contraception	2	11
Menopausal	4	21
Birth history		
Caesarean section only	7	37
Vaginal delivery	5	26
Vaginal and caesarean	2	11
No pregnancies	5	26
Race/ethnicity		
Caucasian	12	63
African	5	26
Mixed	2	11

Outcome measures

Digital photographs of the treated area with patient in a litothomy position were taken before and after each treatment, 1 month after the last treatment, and 12 months after the last treatment. Lighting conditions were kept constant, and the same digital camera (12MP, HD) was used, placed exactly 30 cm from the genital area.

Both the patients and the physician evaluated the photographs, comparing the baseline images to the images taken 1 month after the final treatment. A 4-point scale system was used to record the improvements in vulvar appearance (0 – no improvement; 1 – mild improvement; 2 – moderate improvement; 3 – excellent improvement).

The FSFI questionnaire was completed by all subjects before the first session, 1 month after the last session, and 12 months after the last session.

All results were checked for statistical significance using the Student's t-test. Values of $p < 0.05$ were deemed statistically significant.

Any adverse events or side effects were recorded.

Results

All 19 women completed the full treatment protocol and the 1-month follow-up visit. Two patients did not undergo the 12-month follow-up visit due to personal circumstances not related to the study.

Sexual function

The following results are based on 15 out of 16 enrolled sexually active women who finished the study (one did not complete the 12-month follow-up visit). When comparing the baseline to the 1-month follow-up visit and the 12-month follow-up visit, the average improvement of sexual function as measured by the FSFI questionnaire was 9.79 ± 4.35 points and 7.10 ± 5.17 points, respectively. Both results show high statistical significance ($p < 0.001$). The average score increased from 22.59 ± 4.00 (baseline) to 32.38 ± 1.68 (1-month follow-up visit) and 29.69 ± 2.97 (12-month follow-up visit). This represents an improvement of FSFI from 63% to 90% and 83%, respectively. For details, see Table 2.

Statistically significant increase in FSFI scores was observed in five out of six FSFI dimensions at both follow-up visits. The improvement in these five dimensions averaged 1.94 points (32pp) and 1.44 points (24pp) 1 month and 12

Table 2. Change in the FSFI score 1 month and 12 months after the final treatment

Patient/Pregnancies/Deliveries	Sexual activity	Before	1-Month post Tx	12- Months post Tx	Change 1-Month post Tx	Change 12-Months post Tx
A. No pregnancies	YES	27.5	31.5	31.8	4.0	4.3
B. No pregnancies	YES	23.4	27.9	23.4	4.5	0
C. P2G1 – NVD and ectopic	YES	24	33.6	27	9.6	3
D. P2G2 – NVD	YES	18	31.5	30.3	13.5	12.3
E*. P2G2 0 NVD	YES			Didn't finish the study		
F. P2G2 – 2X C-Section	YES	24.5	30.9	29.2	6.4	4.7
G*. P2G2 – 2X C-Section	NO			Not sexually active		
H. P2G2 – 2X C-Section	YES	22.4	31.4	33.2	9	10.8
I. P1G1 – 1X C-Section	YES	21	34.8	29.9	13.8	8.9
J. No pregnancies	YES	24	33.1	33.9	9.1	9.9
K. No pregnancies	YES	30	33.9	31.8	3.9	1.8
L. P2G2 – 2X C-Section	YES	26	33.7	28.3	7.7	2.3
M. P3G3 – 3X C-Section	YES	13	33	33.3	20	20.3
N. P2G2 – NVD	YES	20	34.5	32.1	14.5	12.1
0. P3G3 – NVD	YES	23	32.2	28.6	9.2	5.6
P*. No pregnancies	NO			Not sexually active. Didn't finish the study		
Q. P3G3 – 2X NVD 1 X C-Section	YES	23.6	32	26.8	8.4	3.2
R. P1G1 – 1X C-Section	YES	18.4	31.7	25.7	13.3	7.3
S*. P4G4 – 3X NVD 1X C-Section	NO			Not sexually active		
Mean ± SD		22.59 ± 4.00	32.38 ± 1.68	29.69 ± 2.97	9.79 ± 4.35	7.10 ± 5.17

*Key: E – 3 deaths to immediate family in the last 12 months
G – Marriage problems
P – Subject reported a sexual problem with her husband and did not think she should continue with the survey
S – Client lost her husband before starting the study

Table 3. Changes in the sexual function

FSFI Dimension	Score range	Pre Tx	1-Month post Tx	*P* value	12-Months post Tx	*P* value	Improvement (pre to 1-month Post)	Improvement (pre to 12-months Post)
Desire	(1–5)	3.15 ± 0.90	4.68 ± 0.93	<0.001	4.44 ± 1.05	<0.001	1.53 ± 1.12	1.29 ± 0.95
Arousal	(0–5)	3.43 ± 1.23	5.33 ± 0.43	<0.001	4.86 ± 0.47	<0.005	1.90 ± 1.25	1.43 ± 1.31
Lubrication	(0–5)	3.25 ± 1.23	5.47 ± 0.68	<0.001	4.68 ± 1.64	<0.05	2.21 ± 1.42	1.43 ± 1.84
Orgasm	(0–5)	3.41 ± 0.95	5.49 ± 0.47	<0.001	5.09 ± 0.88	<0.001	2.08 ± 1.08	1.68 ± 1.38
Satisfaction	(0/1–5)	3.55 ± 0.95	5.52 ± 0.70	<0.001	4.96 ± 0.87	<0.05	1.97 ± 1.17	1.41 ± 1.35
Pain	(0–5)	5.80 ± 0.75	5.89 ± 0.23	>0.05	5.65 ± 0.65	>0.05	0.09 ± 0.58	−0.15 ± 0.40
TOTAL	(2–36)	22.59 ± 4.00	32.38 ± 1.68	<0.001	29.69 ± 2.97	<0.001	9.79 ± 4.35	7.10 ± 5.17

Data are mean ± SD

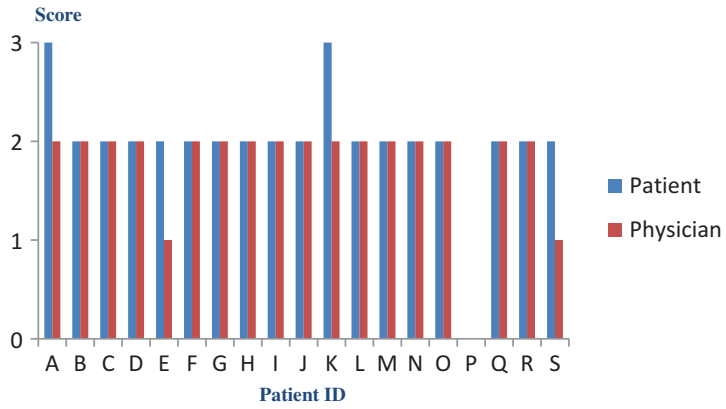
months after the final treatment, respectively. "Pain" is the only dimension in which there were no statistically significant changes.

Evaluation of digital images

The average score based on the patients' responses was 2.00 ± 0.58, with a slightly lower average score of 1.79 ± 0.54 calculated based on the physician's responses. Both results represent "moderate improvement" according to the applied scale. The data are shown in Figure 1. Photographs taken at the baseline were compared to those taken 1 month after the final treatment for all 19 study subjects. Samples of the images are available in Figure 2.

Eighteen out of 19 patients (94.7%) reported "moderate" or "excellent" improvement in vulvar appearance. One woman who later decided to quit the study had reported no change.

The physician also identified at least mild improvement on 18 (94.7%) women, with "moderate" or "excellent" improvement on 16 (84.2%) subjects.



0 - No Improvement; 1 – Mild Improvement; 2 – Moderate Improvement; 3 – Excellent Improvement

Figure 1. Improvement in vulvar appearance based on evaluation of digital images.

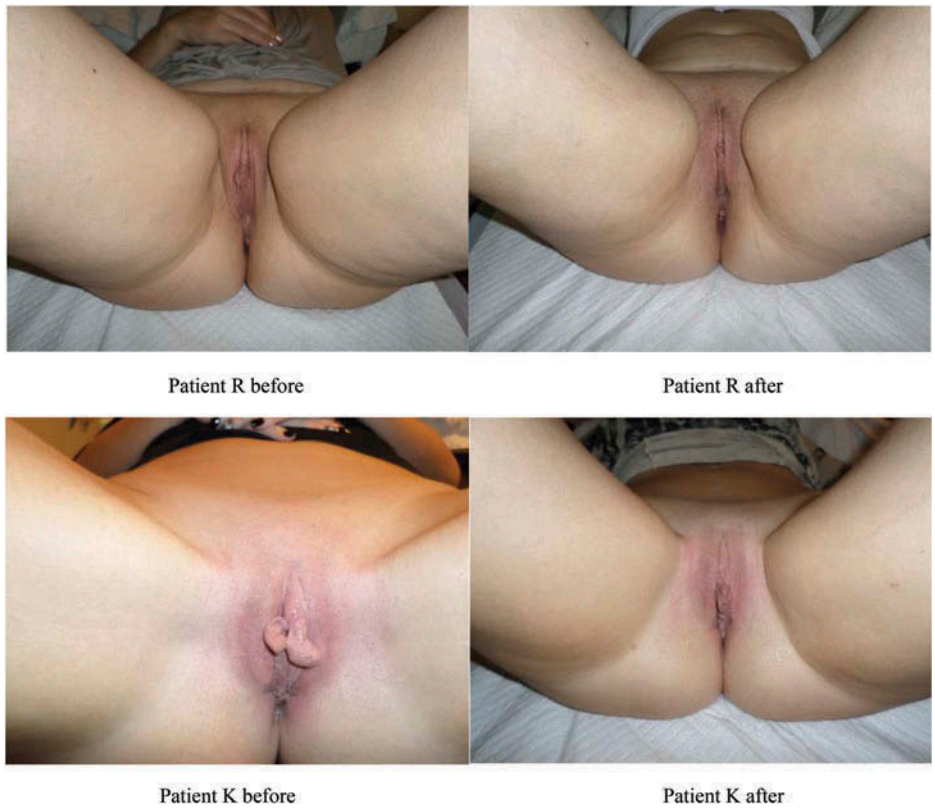


Figure 2. Examples of digital images taken at the baseline and at the 1-month follow-up visit.

Safety

No adverse events or aggravation were observed.

Discussion

The use of RF for treating facial and body skin laxity has been well described and evidenced in the last decade. However, the application of RF to treat labial skin laxity and improve sexual function is rather new. Therefore, clinical studies of this kind are essential in order to assess the real efficacy of this treatment modality.

All patients in our study reported high levels of satisfaction regarding improvement in the appearance of their genitalia. A significant change in appearance occurred as soon as after the first treatment, with maximum improvement observed after the second treatment. The third and the fourth sessions caused further improvements, but of a lesser magnitude.

With respect to sexual function, all sexually active subjects reported improvement after the treatments. All FSFS dimensions except for "Pain" showed statistical significant score increase, and the changes followed the same patterns as those observed in genital appearance. The best results were seen in better lubrication, ease of reaching orgasm during intercourse, and overall satisfaction with sexual life. No significant improvement in the "Pain" dimension was observed, nor expected. Subjects with increased tightness as a result of the treatments are likely to experience more intensive sensations during sexual intercourse. The overall increase in sexual function was also significant at the 12-months follow-up, proving the effects to be long lasting.

Our results suggest that one or two treatments may be sufficient to achieve a very reasonable level of improvement in the treated conditions; however, some patients felt that they would benefit from more than four sessions. The FSFI changes exceeded the results achieved by previous studies (5,8), suggesting the investigated device is a highly efficient modality for treating impeded female sexual function.

The results of this clinical study prove that the investigated monopolar RF device provides an effective and safe alternative to existing treatment methods for improving labial laxity and sexual function. Negative side effects of RF treatment are extremely rare.

Declaration of interests

The author is not aware of any affiliations, memberships, funding, or financial holdings that might be perceived as affecting the objectivity of this review.

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Outcome measures

Digital photographs of the treated area with patient in a litothomy position were taken before and after each treatment, 1 month after the last treatment, and 12 months after the last treatment. Lighting conditions were kept constant, and the same digital camera (12MP, HD) was used, placed exactly 30 cm from the genital area.

Both the patients and the physician evaluated the photographs, comparing the baseline images to the images taken 1 month after the final treatment. A 4-point scale system was used to record the improvements in vulvar appearance (0 – no improvement; 1 – mild improvement; 2 – moderate improvement; 3 – excellent improvement).

The FSFI questionnaire was completed by all subjects before the first session, 1 month after the last session, and 12 months after the last session.

All results were checked for statistical significance using the Student's t-test. Values of $p < 0.05$ were deemed statistically significant.

Any adverse events or side effects were recorded.

Results

All 19 women completed the full treatment protocol and the 1-month follow-up visit. Two patients did not undergo the 12-month follow-up visit due to personal circumstances not related to the study.

Sexual function

The following results are based on 15 out of 16 enrolled sexually active women who finished the study (one did not complete the 12-month follow-up visit). When comparing the baseline to the 1-month follow-up visit and the 12-month follow-up visit, the average improvement of sexual function as measured by the FSFI questionnaire was 9.79 ± 4.35 points and 7.10 ± 5.17 points, respectively. Both results show high statistical significance ($p < 0.001$). The average score increased from 22.59 ± 4.00 (baseline) to 32.38 ± 1.68 (1-month follow-up visit) and 29.69 ± 2.97 (12-month follow-up visit). This represents an improvement of FSFI from 63% to 90% and 83%, respectively. For details, see Table 2.

Statistically significant increase in FSFI scores was observed in five out of six FSFI dimensions at both follow-up visits. The improvement in these five dimensions averaged 1.94 points (32pp) and 1.44 points (24pp) 1 month and 12

Table 2. Change in the FSFI score 1 month and 12 months after the final treatment

Patient/Pregnancies/Deliveries	Sexual activity	Before	1-Month post Tx	12- Months post Tx	Change 1-Month post Tx	Change 12-Months post Tx
A. No pregnancies	YES	27.5	31.5	31.8	4.0	4.3
B. No pregnancies	YES	23.4	27.9	23.4	4.5	0
C. P2G1 – NVD and ectopic	YES	24	33.6	27	9.6	3
D. P2G2 – NVD	YES	18	31.5	30.3	13.5	12.3
E*. P2G2 0 NVD	YES			Didn't finish the study		
F. P2G2 – 2X C-Section	YES	24.5	30.9	29.2	6.4	4.7
G*. P2G2 – 2X C-Section	NO			Not sexually active		
H. P2G2 – 2X C-Section	YES	22.4	31.4	33.2	9	10.8
I. P1G1 – 1X C-Section	YES	21	34.8	29.9	13.8	8.9
J. No pregnancies	YES	24	33.1	33.9	9.1	9.9
K. No pregnancies	YES	30	33.9	31.8	3.9	1.8
L. P2G2 – 2X C-Section	YES	26	33.7	28.3	7.7	2.3
M. P3G3 – 3X C-Section	YES	13	33	33.3	20	20.3
N. P2G2 – NVD	YES	20	34.5	32.1	14.5	12.1
0. P3G3 – NVD	YES	23	32.2	28.6	9.2	5.6
P*. No pregnancies	NO			Not sexually active. Didn't finish the study		
Q. P3G3 – 2X NVD 1 X C-Section	YES	23.6	32	26.8	8.4	3.2
R. P1G1 – 1X C-Section	YES	18.4	31.7	25.7	13.3	7.3
S*. P4G4 – 3X NVD 1X C-Section	NO			Not sexually active		
Mean ± SD		22.59 ± 4.00	32.38 ± 1.68	29.69 ± 2.97	9.79 ± 4.35	7.10 ± 5.17

*Key: E – 3 deaths to immediate family in the last 12 months
G – Marriage problems
P – Subject reported a sexual problem with her husband and did not think she should continue with the survey
S – Client lost her husband before starting the study

Table 3. Changes in the sexual function

FSFI Dimension	Score range	Pre Tx	1-Month post Tx	*P* value	12-Months post Tx	*P* value	Improvement (pre to 1-month Post)	Improvement (pre to 12-months Post)
Desire	(1–5)	3.15 ± 0.90	4.68 ± 0.93	<0.001	4.44 ± 1.05	<0.001	1.53 ± 1.12	1.29 ± 0.95
Arousal	(0–5)	3.43 ± 1.23	5.33 ± 0.43	<0.001	4.86 ± 0.47	<0.005	1.90 ± 1.25	1.43 ± 1.31
Lubrication	(0–5)	3.25 ± 1.23	5.47 ± 0.68	<0.001	4.68 ± 1.64	<0.05	2.21 ± 1.42	1.43 ± 1.84
Orgasm	(0–5)	3.41 ± 0.95	5.49 ± 0.47	<0.001	5.09 ± 0.88	<0.001	2.08 ± 1.08	1.68 ± 1.38
Satisfaction	(0/1–5)	3.55 ± 0.95	5.52 ± 0.70	<0.001	4.96 ± 0.87	<0.05	1.97 ± 1.17	1.41 ± 1.35
Pain	(0–5)	5.80 ± 0.75	5.89 ± 0.23	>0.05	5.65 ± 0.65	>0.05	0.09 ± 0.58	−0.15 ± 0.40
TOTAL	(2–36)	22.59 ± 4.00	32.38 ± 1.68	<0.001	29.69 ± 2.97	<0.001	9.79 ± 4.35	7.10 ± 5.17

Data are mean ± SD

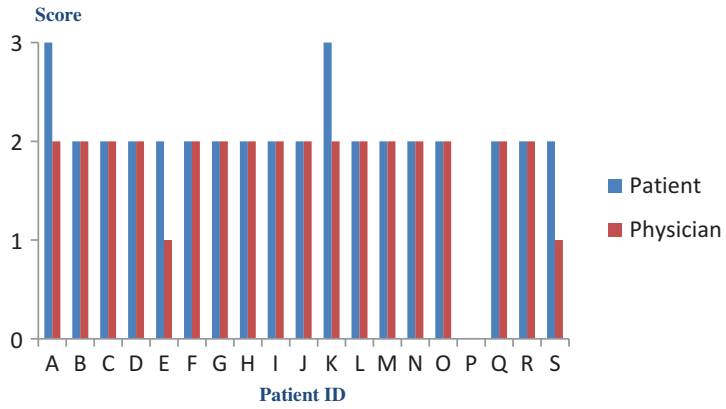
months after the final treatment, respectively. "Pain" is the only dimension in which there were no statistically significant changes.

Evaluation of digital images

The average score based on the patients' responses was 2.00 ± 0.58, with a slightly lower average score of 1.79 ± 0.54 calculated based on the physician's responses. Both results represent "moderate improvement" according to the applied scale. The data are shown in Figure 1. Photographs taken at the baseline were compared to those taken 1 month after the final treatment for all 19 study subjects. Samples of the images are available in Figure 2.

Eighteen out of 19 patients (94.7%) reported "moderate" or "excellent" improvement in vulvar appearance. One woman who later decided to quit the study had reported no change.

The physician also identified at least mild improvement on 18 (94.7%) women, with "moderate" or "excellent" improvement on 16 (84.2%) subjects.



0 - No Improvement; 1 – Mild Improvement; 2 – Moderate Improvement; 3 – Excellent Improvement

Figure 1. Improvement in vulvar appearance based on evaluation of digital images.

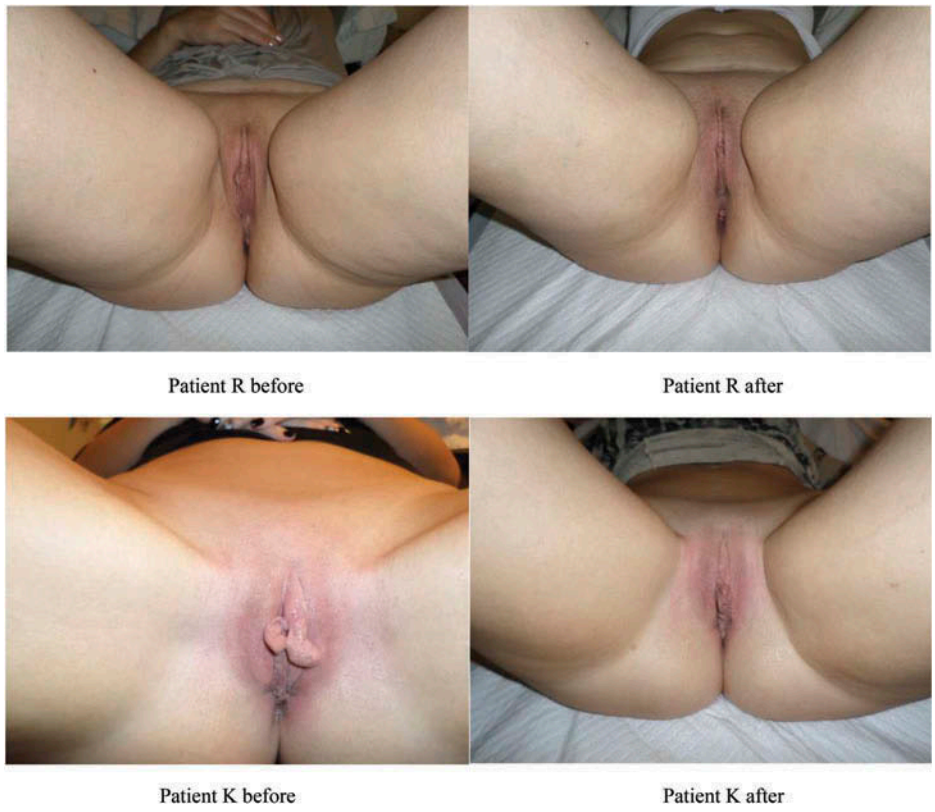


Figure 2. Examples of digital images taken at the baseline and at the 1-month follow-up visit.

Safety

No adverse events or aggravation were observed.

Discussion

The use of RF for treating facial and body skin laxity has been well described and evidenced in the last decade. However, the application of RF to treat labial skin laxity and improve sexual function is rather new. Therefore, clinical studies of this kind are essential in order to assess the real efficacy of this treatment modality.

All patients in our study reported high levels of satisfaction regarding improvement in the appearance of their genitalia. A significant change in appearance occurred as soon as after the first treatment, with maximum improvement observed after the second treatment. The third and the fourth sessions caused further improvements, but of a lesser magnitude.

With respect to sexual function, all sexually active subjects reported improvement after the treatments. All FSFS dimensions except for "Pain" showed statistical significant score increase, and the changes followed the same patterns as those observed in genital appearance. The best results were seen in better lubrication, ease of reaching orgasm during intercourse, and overall satisfaction with sexual life. No significant improvement in the "Pain" dimension was observed, nor expected. Subjects with increased tightness as a result of the treatments are likely to experience more intensive sensations during sexual intercourse. The overall increase in sexual function was also significant at the 12-months follow-up, proving the effects to be long lasting.

Our results suggest that one or two treatments may be sufficient to achieve a very reasonable level of improvement in the treated conditions; however, some patients felt that they would benefit from more than four sessions. The FSFI changes exceeded the results achieved by previous studies (5,8), suggesting the investigated device is a highly efficient modality for treating impeded female sexual function.

The results of this clinical study prove that the investigated monopolar RF device provides an effective and safe alternative to existing treatment methods for improving labial laxity and sexual function. Negative side effects of RF treatment are extremely rare.

Declaration of interests

The author is not aware of any affiliations, memberships, funding, or financial holdings that might be perceived as affecting the objectivity of this review.

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ORIGINAL CONTRIBUTION

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Evaluation of the safety and efficacy of a monopolar nonablative radiofrequency device for the improvement of vulvo-vaginal laxity and urinary incontinence

Shelena Lalji MD[1] | Paula Lozanova MD[2]

[1]Dr. Shel Wellness & Medical Spa, Houston, TX, USA

[2]Department of Dermatology and venerology, Medical University, Sofia, Bulgaria

Correspondence
Shelena Lalji, Dr Shel Wellness & Aesthetic Center, Houston, TX, USA.
Email: drshel@drshel.com

Summary

Background and objective: Vaginal childbirth, natural process of aging, congenital factors, and surgical interventions are considered the main causes of vulvo-vaginal laxity driven by changes in collagen and elastin fibers. This causes a loss of strength and flexibility within the vaginal wall. As a result, women may experience lack of sensation and stress urinary incontinence (SUI)—the condition of involuntary loss of urine associated with activities that cause an increase in intra-abdominal pressure (eg, sneezing, coughing, and lifting). Both vaginal laxity and urinary incontinence significantly affect patients' quality of life (QoL).

The aim of this study was to evaluate efficacy and safety of a noninvasive radiofrequency device when used to treat SUI and vulvo-vaginal laxity through its heating effect which stimulates collagen and elastin fibers.

Methods: Twenty-seven women (average age 44.78±10.04 years) with indications of mild/moderate SUI as well as vulvo-vaginal laxity were treated with a monopolar radiofrequency device. The treatment course consisted of three once-a-week sessions. Each session included intravaginal treatment followed by treatment of labia majora and the perineum.

Improvement in the SUI condition was evaluated by applying the International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF). Data were collected at the baseline, after the last treatment and at 1-month follow-up visit.

Vaginal laxity was assessed by subjective vulvo-vaginal laxity questionnaire (VVLQ). Data were collected before the 1st treatment and during the 1-month follow-up visit.

Patient's satisfaction was recorded using a satisfaction questionnaire. Data were collected after the last treatment and at the 1-month follow-up visit. Any adverse events related to the treatments were monitored.

Results: On a scale of 0 to 5, the average frequency of urine leak improved from "2-3 times a *week*" (2.15±1.03 points prior to treatment) to "*once a week*" (1.00±0.78 points post-treatment), and on to "*never*" (0.44±0.51 points at the 1-month follow-up visit). Sixteen subjects (59.3%) reported decrease in the amount of

leakage, with 15 women (55.6%) becoming completely leak-free at the 1-month follow-up. At the 1-month follow-up visit, 24 subjects (88.9%) expressed their condition's interference with everyday life decreased and 17 patients (62.9%) said the condition did not interfere with their everyday life at all as a result of the treatment. All results are statistically significant ($P<.05$). No adverse events were recorded.

All subjects reported improvement in vaginal laxity, from average perception of "*very loose*" (2.19±1.08 points prior to treatment) to "*moderately tight*" (5.74±0.76 points at the 1-month follow-up visit).

During the follow-up visit, 89% of the patients "*agreed*" or "*strongly agreed*" that their *SUI condition* improved, and 93% of the patients "*agreed*" or "*strongly agreed*" that their gratification during intercourse improved. None of the subjects reported dissatisfaction.

Conclusion: The study confirmed the monopolar radiofrequency method as an effective and safe treatment of SUI and vulvo-vaginal laxity. The treatments were well tolerated by all subjects with no adverse effects.

KEYWORDS

extra-vaginal, intravaginal, labia majora, noninvasive tightening, perineum, radiofrequency, sexual gratification, SUI, urinary incontinence, vaginal laxity, vulvar laxity

1 | INTRODUCTION

Stress urinary incontinence (SUI) is a condition of involuntary urine leakage from the urethra considered to be a hygiene and/or social problem.[1] Statistical data show that the most affected part of the population are women, with approximately 35% of all women worldwide affected.

Urinary incontinence (UI) is frequently linked to vulvo-vaginal laxity, which encompasses laxity of both the vaginal introitus and labia majora. This condition is most commonly linked to sexual dissatisfaction due to limited friction, feeling of looseness, and orgasmic dysfunction; all leading to lower sexual gratification during intercourse. Both of these conditions lead to a decreased quality of life (QoL) including social isolation, decreased self-confidence, and lower sexual gratification during intercourse.[2,3]

The major risk factors for the development of SUI and vulvo-vaginal laxity include childbirth, advancing age, hysterectomy, recurrent urinary tract infections, smoking, medications such as diuretics, sedative-hypnotics and alpha blockers, the presence of comorbid diseases, and excessive weight.[2,4–6] The conventional methods for treating this condition include medications, pelvic floor muscularity strengthening (exercising and/or electro stimulation), surgical procedures, and lifestyle changes (such as quitting smoking or losing weight).[7–9]

Radiofrequency (RF) is one of the more innovative approaches to treating SUI and vulvo-vaginal laxity. It has gained significant popularity in recent years due to its noninvasiveness, absence of adverse events, and fast results. The mechanism of action is based on elevating the temperature of the treated tissue to initiate biological changes. RF-generated heat stimulates the tissue matrix of collagen, elastin, and ground substances and results in immediate change in the helical structure of the collagen. Additionally, neocollagenesis and neoelastogenesis are triggered due to micro-inflammatory stimulation of fibroblasts.[10] It is also believed that the production of sex steroid precursor dehydroepiandrosterone (DHEA) is activated. DHEA supports estrogen production in the vulvo-vaginal cells which plays a big role in rejuvenating and stimulating the vaginal tissue and collagen.

The aim of this study was to investigate the efficacy and safety of a monopolar radiofrequency device for transvaginal treatment of SUI and vulvo-vaginal laxity.

2 | MATERIALS AND METHODS

2.1 | Participants

Twenty-seven women aged between 28 and 66 (mean age 44.78±10.04 years) participated in this nonrandomized, prospective, multicentric study. Only subjects who experienced mild-to-moderate stress urinary incontinence (minimum level 1 in the frequency of leakage based on ICIQ-UI SF form, ie, experiencing leakage at least once a week) and vaginal laxity (maximum level 5 of vulvo-vaginal laxity based on VVLQ questionnaire, ie, defined as no more than "slightly tight") were enrolled. Prior to the study, 19 subjects (70.4%) evaluated their vulvovaginal tightness as "moderately loose" or "very loose," 18 subjects (66.7%) reported they leak urine at least two or three times a week. Twenty-six subjects (96.3%) had a history of at least one prior delivery. The exclusion criteria included the following: abnormal cell cytology; positive urine culture; bleeding in the vulvo-vaginal area; pregnancy or breastfeeding; metal implants; unwillingness or incapability to complete the entire study protocol; any other contraindication listed by the device manufacturer. All patients were

consented. The study was approved by an independent ethics committee.

2.2 | Therapy provision

The therapy course consisted of three once-a-week (± 2 days) treatment sessions with monopolar radiofrequency device (Exilis Ultra 360, BTL Industries Inc., Boston, MA). Each treatment session consisted of an intravaginal and subsequent extra-vaginal treatment. For intravaginal treatment, the starting power was set to 30 points and 80% duty factor. The intravaginal tip was applied to the mucosal surface of the vaginal introitus behind the hymenal ring, was moved deeper inside the vaginal canal to a depth of approximately 10 cm over the course of 2.5 seconds, and then was moved back to the vaginal introitus over the course of the next 2.5 seconds. This repetitive movement continued for 5 minutes. The energy was adjusted based on patient's feedback. For extra-vaginal treatment, the initial power was set to 90 points and 100% duty factor. The extra-vaginal tip was applied to the labia majora using slow circular motions for 3 minutes on each side; the energy was adjusted based on patient's feedback. Then the extra-vaginal tip was applied to perineum using slow circular motions for 3 minutes; the energy was adjusted based on patient's feedback.

2.3 | Outcome measures and statistic evaluation

The SUI condition was assessed by applying the standardized International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF).[11] Data were collected before the first, after the third (last) treatment and during the 1-month follow-up visit. Average improvement was calculated.

Vaginal laxity was assessed by nonstandardized subjective vulvo-vaginal laxity questionnaire (VVLQ) using 7-point Likert scale (BTL Industries Inc.). Data were collected before the first treatment and during the 1-month follow-up visit. Average improvement was calculated.

All outcome data were tested for statistical significance by means of *t* test, where levels of $P<.05$ were deemed statistically meaningful.

Patients' satisfaction with the treatment results was evaluated using a 6-point Likert scale satisfaction questionnaire. The questionnaire consisted of the following statements: (1) "My UI has been improved" and (2) "My sexual gratification has been improved", with the following possible answers: strongly disagree (1); disagree (2); slightly disagree (3); slightly agree (4); agree (5), strongly agree (6). Data were collected after the third (last) treatment and during the 1-month follow-up visit.

3 | RESULTS

All 27 patients completed the study. All treatment sessions were conducted in accordance with the treatment protocol. No adverse events or side effects were observed.

3.1 | Urinary Incontinence

The outcome data and the results from ICIQ-SF and VVLQ are presented in Table 1.

The average frequency of urine leak improved from "*2-3 times a week*" (2.15±1.03 points prior to treatment) to "*once a week*" (1.00±0.78 points post-treatment), and on to "*never*" (0.44±0.51 points at the 1-month follow-up visit). Twenty-six subjects (96.3%) reported improvement of at least one level, with 15 subjects (55.6%) showing improvement of two or more levels when comparing the baseline to the follow-up visit.

Sixteen of the enrolled subjects (59.3%) also reported decrease in the amount of leakage, with 15 women (55.6%) becoming completely leak-free at 1-month follow-up.

At 1-month follow-up, 24 subjects (88.9%) expressed their condition's interference with everyday life decreased, with 12 individuals (44.4%) reporting improvement of three or more levels on a 0-10 scale. Seventeen patients (62.9%) said the condition does not interfere with their everyday life anymore.

All measured results were proven statistically significant ($P<.05$).

3.2 | Vaginal laxity

On a scale of 1-7, the average vulvo-vaginal laxity improved from "*very loose*" (2.19±1.08 points prior to treatment) to "*moderately tight*" (5.74±0.76 points at the 1-month follow-up visit). Twenty-seven subjects (100%) reported improvement of at least two levels, with 23 subjects (85.2%) showing improvement of three or more

TABLE 1 Changes in Stress urinary incontinence (SUI) and vulvo-vaginal laxity

Questionnaire	Score range	Pretreatment	Post-treatment	*P* value	1 mo post-treatment	*P* value	Improvement (Pre to Post)	Improvement (Pre to 1 mo post)	*P* value
ICIQ-UI SF									
Frequency	(0-5)	2.15±1.03	1.00±0.78	<.001	0.44±0.51	<.001	1.15±0.53	1.70±0.87	<.001
Volume	(0-5)	1.04±0.19	0.70±0.47	<.05	0.44±0.51	<.001	0.33±0.48	0.59±0.50	<.05
Interference	(0-5)	3.41±2.34	1.26±1.32	<.001	0.59±0.93	<.001	2.15±2.01	2.81±2.20	<.05
VVLQ									
Tightness	(1-7)	2.19±1.08	n/a	n/a	5.74±0.76	<.001	n/a	3.56±0.97	n/a

Data are mean±SD.

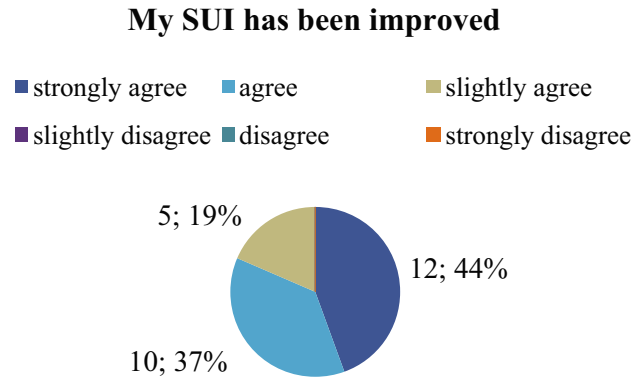

FIGURE 1 Stress urinary incontinence (SUI) improvement (Post-treatment)

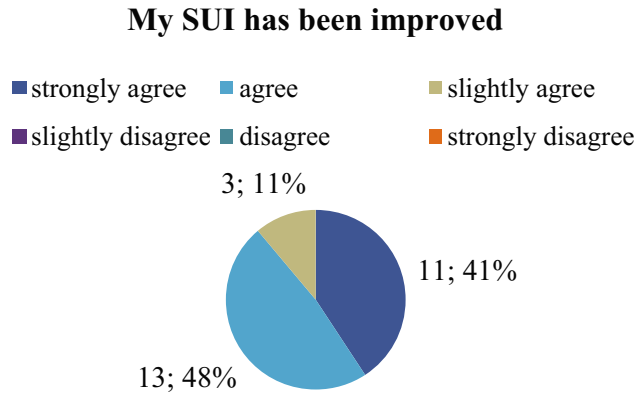

FIGURE 2 Stress urinary incontinence (SUI) improvement (1-month follow-up visit)

levels when comparing the baseline to the follow-up visit. 1 month after the last treatment, all (100%) subjects evaluated their vulvo-vaginal sensation to be slightly, moderately or very tight.

3.3 | Patient satisfaction

The data from the satisfaction questionnaire are presented in Figures 1-4.

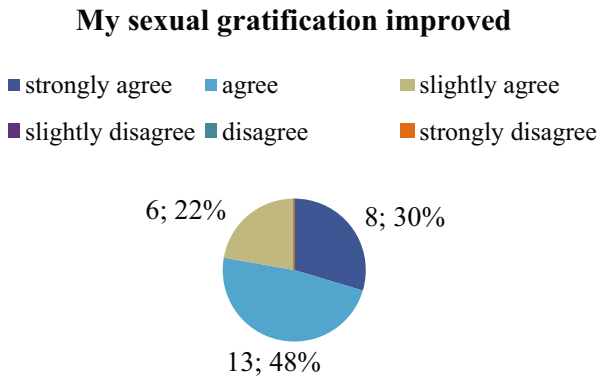

FIGURE 3 Sexual gratification improvement (Post-treatment)

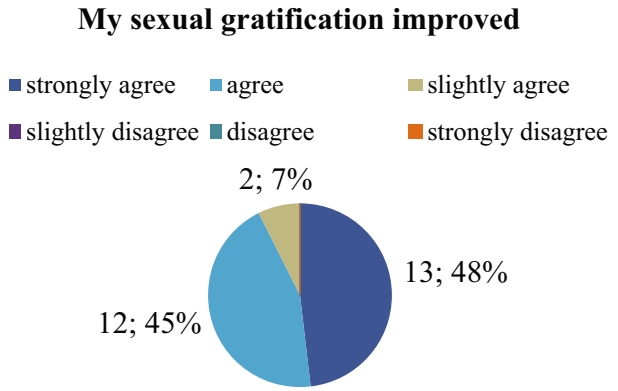

FIGURE 4 Sexual gratification improvement (1-month follow-up visit)

Eighty-one percentage of the patients "*agree*" or "*strongly agree*" that their *SUI condition* improved post-treatment compared to the baseline, and the share increased to 89% during the follow-up visit. The remaining 19% and 11%, respectively "*slightly agreed.*" None of the subjects reported dissatisfaction (score 0-3).

Seventy-eight percentage of the patients "*agree*" or "*strongly agree*" that their gratification during intercourse improved post-treatment compared to the baseline, and the share increased to 93% during the follow-up visit. The remaining 22% and 7%, respectively, "*slightly agreed.*" None of the subjects reported dissatisfaction (score 0-3).

4 | CONCLUSION

The primary goals of the study have been met as the monopolar radiofrequency treatments demonstrated good results both in terms of efficacy, and safety in all evaluated areas. The results show zero nonresponding subjects when treating vulvo-vaginal laxity and 3.7% of nonresponders when evaluating improvement in SUI in terms of frequency of leakage. Most subjects also reported decrease in the amount of leakage and improvement with the interference in their everyday life. In addition to the originally designed areas of improvement which were monitored, subjective perception of better lubrication during intercourse as a result of the treatments was reported by the majority of the patients.

Improvement in treated conditions was reported immediately after the last treatment session and was even more significant after the 1-month follow-up visit. Improvement of results with time is driven by the collagen remodeling process which takes up to 90 days to fully complete. It should be investigated by future studies with longer follow-ups to understand how the results develop over time.

Patients reported high satisfaction rate when evaluating improvement in SUI conditions and in sexual gratification. The treatments were well tolerated by all subjects; no adverse events were observed. This study demonstrates efficacy and safety of a monopolar radiofrequency for SUI and vulvo-vaginal laxity treatments. Every patient is likely to recognize the improvement at different points in time depending on their individual physiological processes. This

study captures significant improvement in the treated conditions at the 1-month follow-up visit. Although further controlled study is needed to confirm the data and evaluate the long-term effects in the endovaginal treatment.

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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

Suneel Chilukuri MD[1] | Dominique Denjean MD[2] | Linda Fouque MD[3]

[1]Refresh Dermatology, Houston, TX, USA

[2]Cabinet de Dermatologie Esthetique, Paris, France

[3]Dermatologue Esthetique, Nice, France

Correspondence
Suneel Chilukuri, MD, Refresh Dermatology, Houston, TX, USA.
Email: dermsurg@gmail.com

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

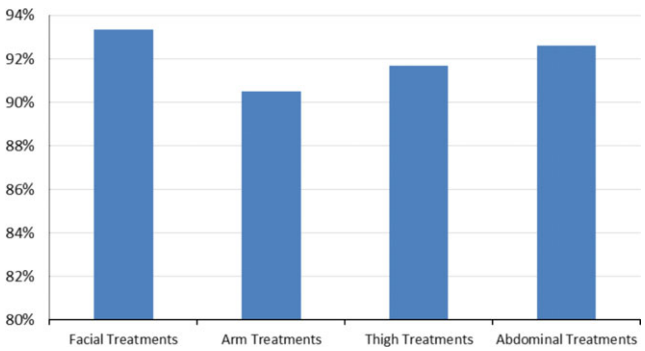

FIGURE 1 Recognition rate of aesthetic improvement in the treated area as per reviewers' evaluation

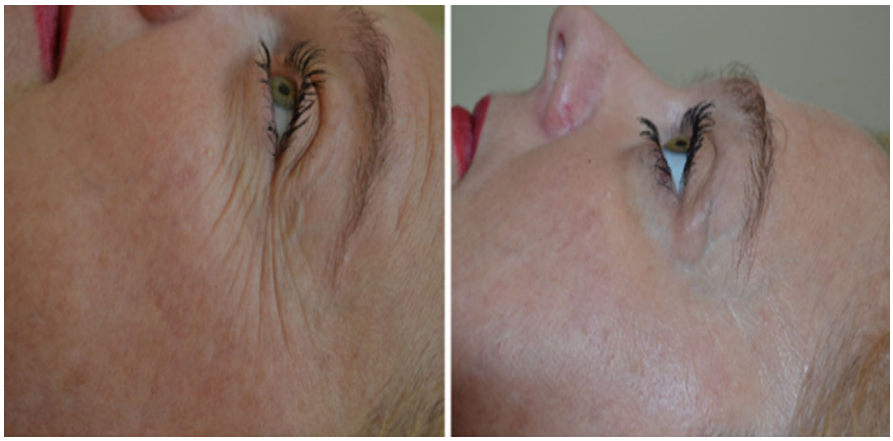

FIGURE 2 Example of patient images taken at baseline and 3 mo after the last treatment

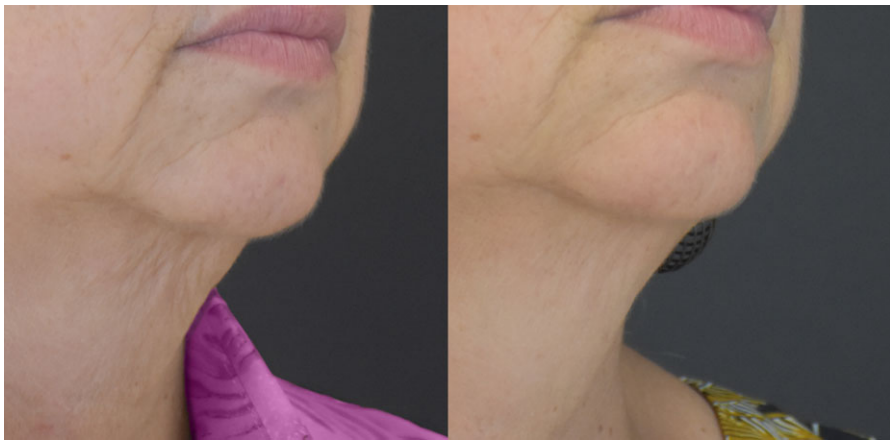

FIGURE 3 Example of patient images taken at baseline and 3 mo after the last treatment

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.

ORCID

Suneel Chilukuri http://orcid.org/0000-0002-4331-8305

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