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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

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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.

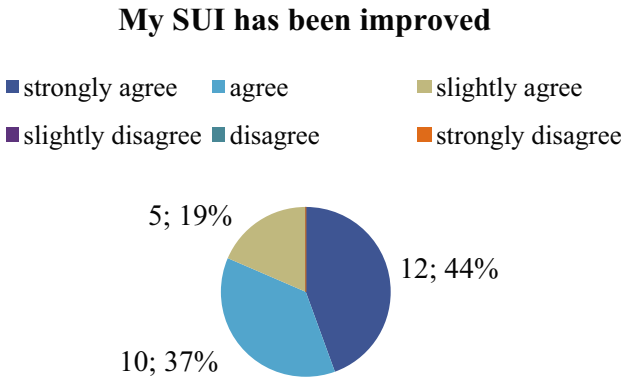

FIGURE 1 Stress urinary incontinence (SUI) improvement (Post-treatment)

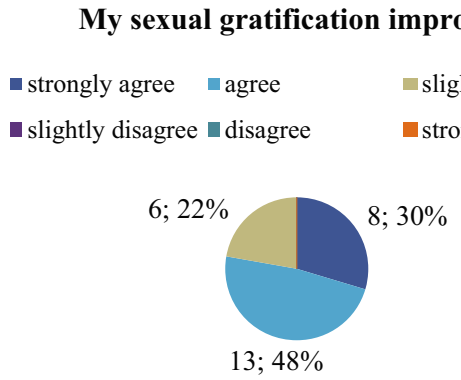

FIGURE 2 Stress urinary incontinence (SUI) improvement (1-month follow-up visit)

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.

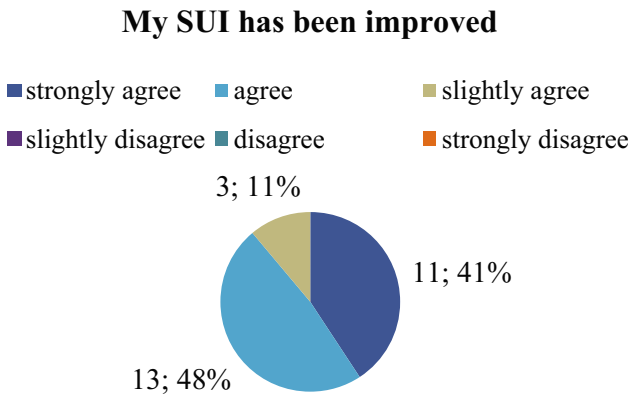

FIGURE 3 Sexual gratification improvement (Post-treatment)

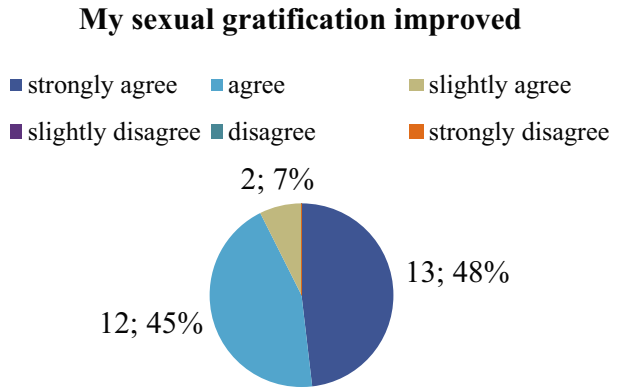

FIGURE 4 Sexual gratification improvement (1-month follow-up visit)

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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