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LA Salud Íntima FEMENINA

"La incontinencia por estrés afecta a 1 de cada 3 mujeres y... ¿sabías que después del parto ese número aumenta considerablemente?"

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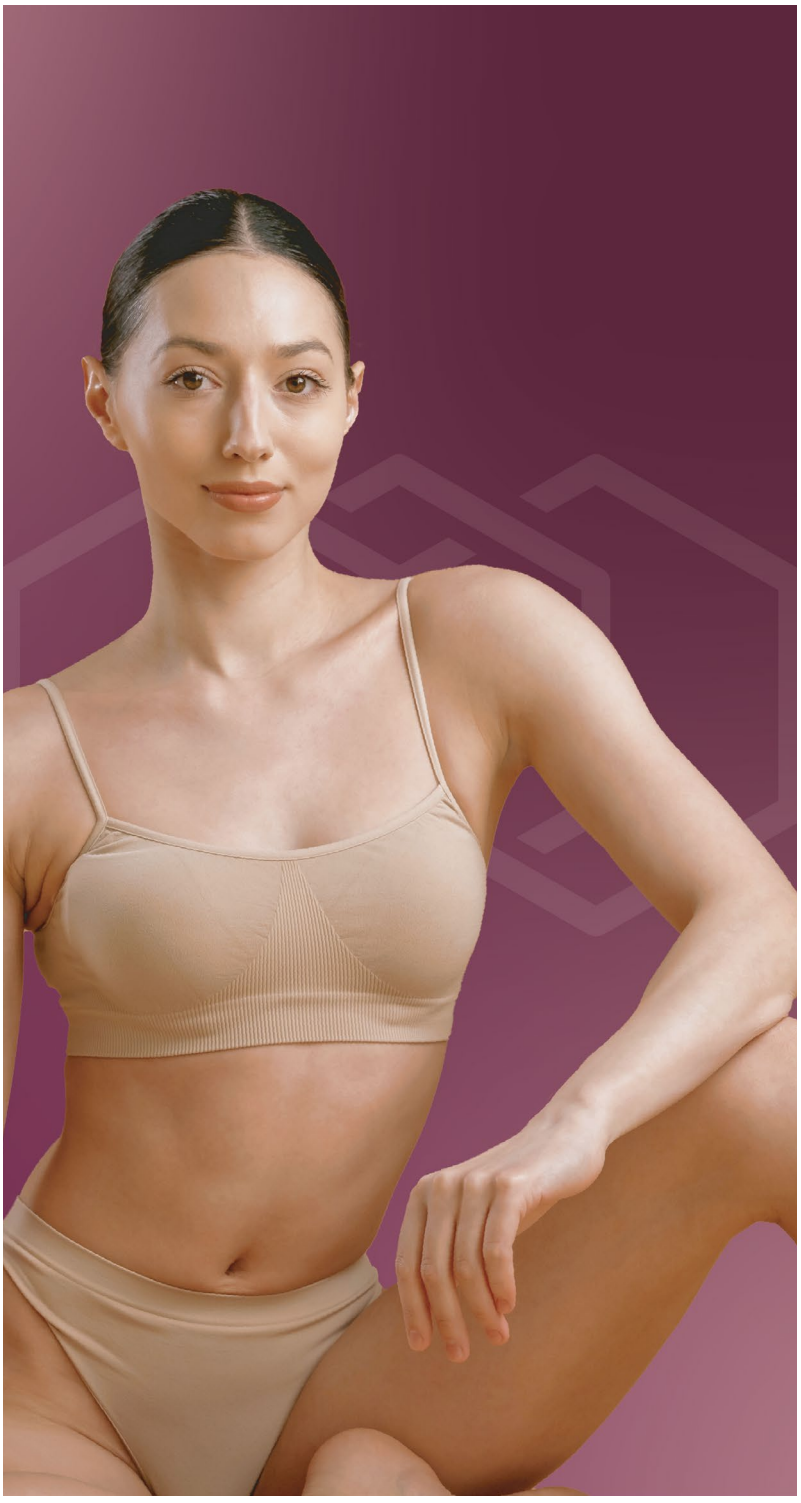

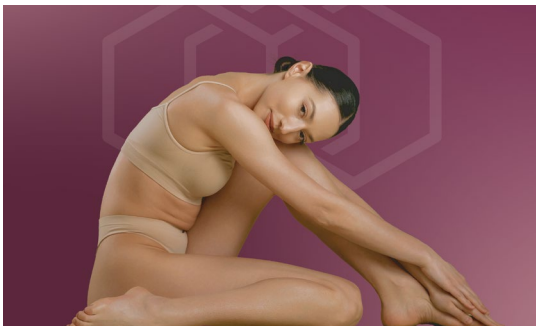

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LA Salud Íntima FEMENINA

Empoderando la Salud Íntima Femenina

En un mundo donde la salud y el bienestar de la mujer se están redibujando con elegancia y tecnología, InMode Iberia se posiciona a la vanguardia con su plataforma Empower RF. Esta tecnología avanzada está cambiando la forma en que entendemos el cuidado íntimo femenino brindando soluciones innovadoras para tratar afecciones que durante años han sido parte del tabú.

- EMPOWERRF BY INMODE -

La plataforma Empower RF incorpora siete tecnologías revolucionarias: VTone, Forma V, Tone, Morpheus8V, Morpheus8, Morpheus8 Body y Aviva. Juntas ofrecen una nueva dimensión en tratamientos no invasivos que priorizan el confort y la efectividad. De la mano de esta avanzada tecnología, las mujeres pueden abordar problemas de salud íntima como la atrofia vaginal, la sequedad vaginal, la incontinencia urinaria, el liquen escleroso, el vaginismo, la diástasis abdominal, infecciones de repetición y disfunción sexual, sin la necesidad de recurrir al quirófano.

¿Qué hace que EmpowerRF sea única? Esta plataforma de vanguardia no solo se enfoca en el tratamiento, sino también en la prevención, mejorando la calidad de vida de las mujeres al brindarles soluciones efectivas para su bienestar íntimo. De esta manera, se convierte en un aliado clave para las pacientes, ayudándolas a sentirse seguras y empoderadas en cada etapa de la vida. Con un enfoque holístico, InMode Iberia no solo resuelve problemas funcionales, sino también estéticos, devolviendo la sensación de control y confianza que merecen.

La única plataforma que combina RF bipolar, RF fraccionada y EMS intravaginal y aborda tanto cuestiones estéticas como alteraciones funcionales de la zona genital sin cirugía, sin dolor y con tiempo de recuperación mínimo.

"La incontinencia por estrés afecta a 1 de cada 3 mujeres y... ¿sabías que después del parto ese número aumenta considerablemente?"

EMPOWERRF

ESTUDIOS CLÍNICOS

USE OF RADIOFREQUENCY ABLATION OF THE VAGINAL CANAL FOR GENITOURINARY SYNDROME OF MENOPAUSE

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Abstract

Background: Genitourinary syndrome of menopause (GSM) is a prevalent condition with a constellation of symptoms including burning, dryness, dyspareunia, and irritative lower urinary tract symptoms that result from vulvovaginal atrophic changes. Though hormonal therapy is a mainstay of treatment in GSM, some patients may pursue nonhormonal therapies.

Aim: To determine the efficacy of radiofrequency ablation of the vaginal canal with the MorpheusV applicator in reducing the symptoms of GSM.

Methods: We conducted a multicenter prospective case series of women with GSM as confirmed by Vaginal Health Index Score (VHIS). Subjects received 3 treatments of radiofrequency ablation ~4 weeks apart with follow-up to 6-month posttreatment.

Outcomes: The primary endpoint was VHIS at 6-month posttreatment. Secondary endpoints were VHIS at 3 months, Visual analog scale (VAS) pain with each treatment, 3- and 6-month measurements of urogenital distress inventory-6 (UDI-6), and female sexual function index (FSFI) questionnaires.

Results: From 2021 to 2023, 71 women were enrolled in the study with 51 followed to the 6-month follow-up time point. Treatments were found to be low in VAS pain score with mean values of 2.13 ± 2.1, 2.55 ± 2.38, and 2.18 ± 2.14 at treatments 1, 2, and 3 respectively. An improvement in VHIS score was seen from baseline to 3 months after the last treatment (15.00 ± 5.37 vs. 19.62 ± 4.44) and sustained at 6 months (20.23 ± 4.12) ($P < .001$). Significant improvements in both UDI-6 and FSFI were also noted. Between baseline and 6 months after treatment (FSFI: 18.81 ± 9.57 vs. 22.81 ± 10.34, $P < 0.001$; UDI-6: 39.58 ± 15.98 vs. 22.42 ± 14.03, $P < 0.001$). No adverse events were encountered by any subject during this study.

Clinical implications: A therapy that is safe and effective in the treatment of both GSM and lower urinary tract symptoms without the use of hormonal methods is clinically impactful for the many patients who cannot receive or do not desire to receive these medications.

Strengths and limitations: Strengths of this study include the utilization of 3 treatment sessions, with follow-up of subjects to 6-month posttreatment with a comprehensive assessment of patient symptoms. Limitations include the unblinded nature of the study and the lack of a comparator group.

Conclusion: The data from this study suggests that radiofrequency ablation of the vaginal canal by the MorpheusV applicator is a safe and effective intervention for GSM. It also shows subjective improvements in stress urinary incontinence, urge urinary incontinence, and sexual function.

Keywords: vulvovaginal atrophy; genitourinary syndrome of menopause; radiofrequency; MorpheusV; stress urinary incontinence; urge urinary incontinence.

Introduction

Genitourinary syndrome of menopause (GSM) is a symptom complex consisting of burning, dryness, dyspareunia, and irritative lower urinary tract symptoms (LUTS) that result from vulvovaginal atrophic changes. These symptoms are often progressive and affect 27-84% of postmenopausal women.[1,2] Vaginal estrogen therapy is effective in the treatment of GSM.[3-5] Some women may have a contraindication to the use of estrogen, while others may simply want to avoid estrogen use.[1,4] It is in this vein that nonhormonal therapies for this very common and distressing condition are needed.

The first vaginal energy sources that had been studied and may have had an impact on GSM is the fractional CO2 laser.[6-9] The proposed mechanism of action is that light energy creates an inflammatory reaction that releases fibroblasts which stimulates the production of collagen in the stratified squamous epithelium. As this collagen is being produced, small capillaries are created to supply this collagenous tissue with blood—creating a transudate that provides some lubrication to the vaginal canal. Over time the vaginal wall thickens and the vaginal pH becomes more acidic as there is a return of lactobacilli and glycogen.[10]

Case series have irregularly demonstrated benefit in GSM patients; however, a recent randomized controlled trial noted laser to not be significantly better than a sham treatment.[8] Microneedling RF devices have been available to treat the skin of the face and body. A recently published study described the

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first microneedling device used in the vaginal canal (Morpheus V), noting safety and good short-term efficacy in the treatment of GSM.[11]

In contrast to light therapy (laser) which penetrates the vaginal epithelium to ~750 microns, RF microneedling penetrates up to 3 mm. The depth of energy delivered is of importance as prior studies performed on the face and body have shown RF energy delivered to depths of 0.5-3.5 mm promotes superior additional neocollagenesis when compared to surface applications of RF energy.[11] Further, and perhaps as a result, noninvasive RF therapy has been shown in some studies to improve bladder function.[2,8,12,13]

This potential improvement in urinary symptoms is particularly notable in the GSM population given that patients who suffer from GSM commonly have associated bladder dysfunction and female sexual dysfunction.[14-16]

The objective of this study was to determine the efficacy of radiofrequency (RF) ablation of the vaginal canal with the MorpheusV applicator in reducing the symptoms of GSM and secondarily the effects of this therapy on bladder and sexual function.

Methods

This represents a prospective case series of women recruited from 2 clinics between June 2021 to January 2023. Inclusion criteria included postmenopausal females aged 35-75 years old with absence of menstruation of at least 12 months. For inclusion, BMI was less than or equal to 36 and participants were willing to refrain from other treatments for GSM and urinary incontinence for at least 6 months.

Exclusion criteria included a history of pacemaker or internal defibrillator, any other active electrical implant anywhere in the body, and permanent implants in the treated area. Subjects with severe concurrent conditions, such as cardiac disorders, neurologic, endocrine, immune, liver, or kidney diseases were excluded. Potential subjects needed to be at least 3 months from a prior surgery in the treatment region, 6 months from any other recent treatments such as light, CO_2 laser, or RF in the treatment region, and 30 days from treatment with any vaginal estrogen medication. Subjects were also 6 months from treatment with any urge urinary incontinence (UUI) medications or procedures. Those with active urinary tract infection or genital infection were excluded.

The primary outcome was an objective evaluation of vaginal atrophy/estrogenization as measured by the globally validated Vaginal Health Index Score (VHIS) at 6 months. The VHIS is a combination of five subscales measured on a 1 (worse) and 5 (better) scale: elasticity, fluid volume, pH, epithelial integrity, and moisture. Utilizing G*Power version 3.1.9.7 (2020), and utilizing the below assumptions, a sample size of 28 patients was needed in order to detect a medium effect size (0.25) with 80% power using a repeated measures analysis of variance (ANOVA) with three measurement periods at $\alpha = 0.05$, correlation among repeated measures of 0.05, and a nonsphericity correction of 1.00.

Secondary outcomes also included a VHIS at baseline and 3 months. Other secondary outcomes included the pain/discomfort experienced during treatment was assessed with a 10-point Visual Analog Scale (VAS) pain scale immediately postprocedure. The effect of the treatment on Sexual Function was measured by a Female Sexual Function Index (FSFI) at baseline and at 3 and 6 months. A Urogenital Distress Inventory-6 (UDI-6) questionnaire was also collected at baseline, 3 and 6 months. The timing of data collection with respect to enrollment and treatment can be found in Appendix 1.

Subjects completed an informed consent form before any study procedures were performed. Subjects first presented to the study clinic for a screening visit to determine eligibility and enrollment. Surveys were performed as per Appendix 1. Demographic data including gender, age, race, and skin type (Fitzpatrick scale) was collected. The Fitzpatrick scale is a numerical classification system used to categorize skin color based on its response to ultraviolet light exposure.[17]

Subjects in this study underwent treatment with the InMode System using the MorpheusV Applicator. The InMode System with the MorpheusV Applicator is designed to deliver RF energy to the skin in a fractional manner, via an array of 24-pin electrodes. This RF energy delivery was previously described in Abdelaziz et al. This study mirrors Abdelaziz et al. in vaginal RF therapy with identical power and depth of treatment. This prior study displayed evidence of safety and short-term efficacy in the GSM population.[11]

The output of RF energy is applied to less than 5% of the total treatment area. During treatment, the RF current flows between the matrix of the pin electrodes and the return electrode, having the highest impact at the point of the pin electrodes, where it creates a small coagulation zone in the skin. The upper part of each pin is coated with an isolating material (Parylene) to minimize impact on the epidermis and deliver RF energy only from the pin's distal edge to 0.5 mm into the deeper skin layers.

All subjects received 3 treatments with the MorpheusV Applicator approximately 4 weeks apart with follow up to 6-month postprocedures (overall time-points include: baseline, treatment 1 (Tx1), treatment 2 (Tx2), and treatment 3 (Tx3), 3-month follow-up, and 6-month follow-up). Before the procedure, anesthesia was achieved through the application of Lidocaine 23%-Tetracaine 7% cream over the treatment area for 25 minutes. The treatment area included the entire vaginal canal, vestibule, posterior fourchette, and upper perineal body. RF energy output included a frequency of 1 MHz and power of 30-35 W. The MorpheusV applicator was inserted, and pulses were applied in a stamping technique rotating the applicator at the same depth at 5 points: 9, 10:30, 12, 1:30 and 3, 4:30, 6, and 7:30 until an entire circle (360°) had been completed. The applicator was then retracted 1 cm and the rotation with pulses were repeated. This process was repeated until the applicator electrodes were at the introitus. All patients were treated at a depth of 3 mm, then 2 mm; then 1 mm in each treatment session; patients received anywhere from 450 to 600 pulses. Adverse events were assessed at all treatment and follow-up visits.

All outcome data were measured at baseline, 3, 6, and 12 months. Repeated measures analysis of variance (ANOVA) tests were employed. Pairwise comparisons were used as appropriate to compare pretreatment and posttreatment variables; the Bonferroni adjustment for multiple comparisons was employed. SPSS software was used for all statistical analyses (IBM SPSS statistics for windows; version 22, IBM Corp., 2013).

Results

A total of 72 women were enrolled in the trial from June of 2021 through January of 2023 to determine the efficacy of the MorpheusV Applicator for Symptoms of GSM across

Table 1. Demographic data from included participants.

	Mean	Minimum	Maximum		
Age	55.96 ± 10.53	37	77		
	Type I	Type II	Type III	Type IV	Type V
Fitzpatrick Scale	0%	31%	53%	0%	14%
	African American	Caucasian	Hispanic	Not Identified	
Race	2%	90%	4%	4%	

two sites. Of the 72 enrolled patients, only 50 patients followed up to the 6-month time-point. The mean age was 55.96 (SD = 10.53), with the minimum age being 37 and the maximum age being 77. For skin type (Fitzpatrick Scale), 31% had skin type II, 53% had skin type III, 14% had skin type IV, and 2% had skin type VI. For race, 2% were African-American, 90% were Caucasian, and 4% were Hispanic; 2 patients' race were not identified (4%) (Table 1).

Depending on the measurement, analyses were conducted using data from 47-50 patients starting from baseline and continuing to 6-month posttreatment (Baseline, Tx1, Tx2, and Tx3, 3-month follow-up, and 6-month follow-up). During data collection, if a data element is missing for a patient data from all other time points was removed. Because of this, the number of patients for each instrument were as follows: VAS Pain Scale N = 47, overall VHIS N = 47, VHIS Elasticity N = 50, VHIS Fluid N = 50, VHIS pH N = 48, VHIS Epithelial N = 50, VHIS Moisture N = 50, FSFI N = 49, and UDI-6 N = 50.

Patients were asked to evaluate their pain after each treatment through a 10-point VAS pain score (lower being less painful).[18] Patients indicated that the pain level was significantly lower than the median value of 5 and the repeated measures ANOVA results indicated that pain did not significantly differ from each treatment; Tx1 Mean = 2.13 (SD = 2.10), Tx2 Mean = 2.55 (SD = 2.38), and Tx3 Mean = 2.18 (SD = 2.14); F(2, 92) = 0.92, p = 0.40. In other words, patients believed the procedures were qualitatively unpainful and that evaluation did not change from treatment to treatment.

VHIS was captured at baseline and at 3- and 6-month follow-up (Figure 1). The ANOVA test was statistically significant F(2, 92) = 48.32, $P < 0.001$, with the baseline mean being lowest ($m = 15.00$, SD = 5.37), increasing to 3-month follow-up ($m = 19.62$, SD = 4.44), and staying stable at 6-month follow-up (m = 20.23, SD = 4.12). Consulting the pairwise comparisons demonstrates that baseline differs from 3-month and 6-month measurements ($P < 0.001$); additionally, 3-month and 6-month VHIS data do differ statistically from one another ($P < 0.05$), indicating that the overall VHI measurement improves by 3 months and continues to improve at 6 months.

Results for the individual VHIS component subscale measurements are shown in Figure 2. For all VHIS subscale ANOVA testing, the difference between baseline, 3 months and 6 months was statistically significant ($P < 0.001$), though 3-month and 6-month mean values did not differ.

FSFI was significantly improved overall. FSFI ANOVA testing was statistically significant, F(2, 96) = 12.57, $P < 0.001$, with the baseline mean being lowest ($m = 18.81$, SD = 9.57), increasing to a 3-month follow-up high ($m = 22.61$, SD = 10.32), and maintains at 6 month follow-up ($m = 22.81$, SD = 10.34) (Figure 1). Consulting the pairwise comparisons demonstrates that baseline differs from 3-month and 6-month measurements ($P < 0.01$). Additionally, 3-month and 6-month values do not differ statistically from one another, indicating that the FSFI measurement improves by 3 months and maintains that improvement at 6 months. Moreover, at baseline, 70% of patients with 6-month follow-up data were sexually dysfunctional as per their FSFI score (a value less than or equal to 26). At 6 months, only 48% of these patients were sexually dysfunctional.

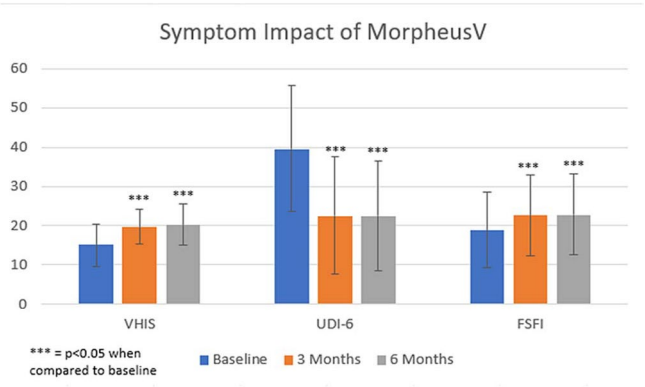

Figure 1. VHIS, UDI-6, and FSFI at baseline compared to 3- and 6-month posttreatment with MorpheusV radiofrequency microneedling.

Finally, for the UDI-6 data, the ANOVA test was statistically significant, $F(2, 98) = 43.92$, $P < 0.001$, with the baseline mean being highest ($m = 39.58$, SD = 15.98), decreasing at 3-month follow-up ($m = 22.50$, SD = 14.85), and staying stable at 6-month follow-up ($m = 22.42$, SD = 14.03) (Figure 1). Consulting the pairwise comparisons demonstrates that baseline differs from 3-month and 6-month measurements ($P < 0.001$); however, 3-month and 6-month data do not differ statistically from one another, indicating that the UDI-6 measurement improves by 3 months and stays improved at 6 months. Moreover, at baseline, 67% of patients with 6-month follow-up data had abnormal UDI-6 scores (a value greater than or equal to 33.33). At 6 months, only 26% of these patients had abnormal UDI-6 scores.

No adverse events were reported in any subject through the 6-month period.

Discussion

In this study, we assess the efficacy of RF microneedleing in the treatment of GSM as accomplished by the MorpheusV applicator. The procedure was well tolerated. Pain was found to be low with a mean value of approximately 2 on a VAS pain score with each treatment.

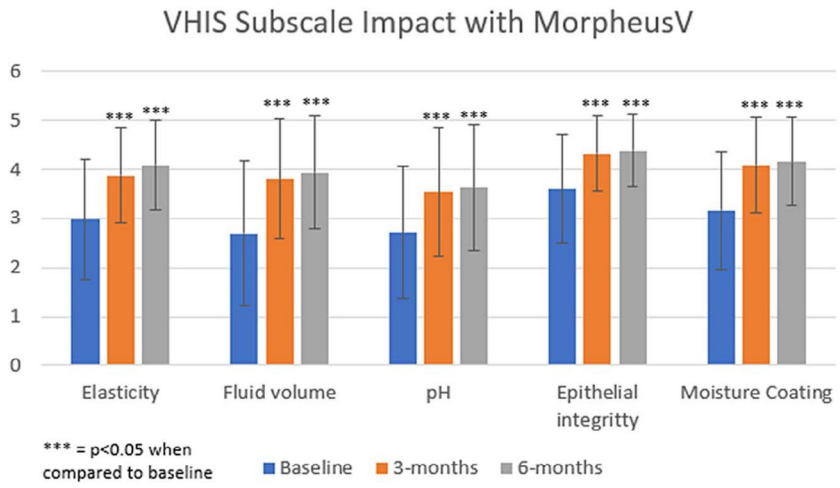

Figure 2. Elasticity, fluid volume, pH, epithelial integrity, and moisture coating at baseline as well as 3- and 6-month posttreatment with standard deviations noted.

Subjects demonstrated significant improvements in their VHIS scores and the mean VHIS scores at 3 and 6 months were greater than the VHIS threshold for GSM of 15 (3-month mean of 19.62, SD = 4.44, 6-month mean of 20.23, SD = 4.12). All values within the VHIS (elasticity, fluid volume, pH, epithelial integrity, and moisture) displayed improvement with significant ANOVA testing from baseline but no significance between 3 months and 6 months (Figure 2).

Bladder dysfunction frequently accompanies GSM and plays a major role in quality of life. The effect of vaginal RF therapy on incontinence, urinary difficulty, and urinary discomfort was assessed through the UDI-6 score. This UDI-6 score showed a significant decrease at 3 months and remained decreased at 6 months. Moreover, the baseline mean UDI-6 measurement was above the 33.33-level threshold that indicates urinary distress, while the 3-month and 6-month means were lower than that threshold. This indicates that the MorpheusV RF applicator is effective in improving these urogenital symptoms up to 6-month posttreatment.

Sexual function is also commonly affected by GSM. The effect on sexual function was assessed by the FSFI questionnaire, which showed a significant improvement from baseline to 3 months after the last treatment (18.81 ± 9.57 vs. 22.61 ± 10.32) that was sustained at 6 months (22.81 ± 10.34).

Standard treatment of GSM involves the use of vaginal estrogen. As many women have relative or absolute contraindications to the use of estrogen, a successful nonhormonal solution that adequately treats this common disorder is much needed.

The use of the fractional CO_2 laser in the treatment of GSM has been shown in multiple case series to improve the symptoms of GSM, but has not been shown to significantly impact bladder function. This may be due to the impact of energy treatments being limited to the areas where the energy is applied in laser therapy. It is likely that fractional CO2 laser probes focus on the vagina itself and are not directly applied to the urethral opening or tissue directly related to bladder function.[2,6,8,10,12,13,19-21] We believe that the vaginal epithelium will respond in a similar fashion to thermal (RF) and light (laser) energy. Further, we hypothesize our results and improvement in bladder function may be due to deeper penetration of the vaginal epithelium (3 mm vs 750 microns) as well as a more efficient treatment of the vaginal canal. This more efficient treatment in RF is due to the stamping technique with three overlapping treatment areas ultimately treating much more of the surface area of the vaginal canal when compared to manual rotation of a probe in laser treatments.

Further, this study does note a significant improvement in lower urinary tract dysfunction that is commonly associated with GSM. This could theoretically be due to a reduction in recurrent cystitis due to a change in the vaginal milieu or it could be through a change in the environment by bringing back the acidity of the vulvovaginal area.

This is the second study to report on this method of therapy.[11] This study utilized 3 treatment sessions, followed subjects for 6-month posttreatment, and assessed patient symptoms in a comprehensive manner. The authors, however, acknowledge there are significant limitations to this study. This study was not blinded and was without a comparator group. Future studies should include randomized, blinded, placebo-controlled trials with a longer duration of follow-up.

Conclusions

The significant improvement in GSM exam findings, sexual function, and bladder function is noted in this study. A lack of any adverse events and high satisfaction are also noted. It is in this setting that consideration should be given to continuing research into the use of RF therapy in GSM.

Author contributions

- M.K.: conceptualization and methodology, resource and funding acquisition, project administration, investigation, supervision, validation, and writing.
- E.K.: project administration, investigation, supervision, recruitment, validation
- J.D.: project administration, investigation, supervision, recruitment, validation

- R.D.M.: project administration, investigation, supervision, recruitment, validation
- J.R.M.: project administration, investigation, supervision, recruitment, validation
- R.R.: data curation, investigation, project administration, and writing.

CRediT taxonomy

R.R.: Data curation-Equal, Investigation-Equal, Project administration-Equal, Writing—original draft-Equal, Writing—review and editing-Equal. E.K.: Investigation-Equal, Project administration-Equal, Supervision-Equal, Validation-Equal. J.D.: Investigation-Equal, Project administration-Equal, Supervision-Equal, Validation-Equal. R.M.: Investigation-Equal, Project administration-Equal, Supervision-Equal, Validation-Equal. J.M.: Investigation-Equal, Project administration-Equal, Supervision-Equal, Validation-Equal. M.K.: Conceptualization-Equal, Funding acquisition-Equal, Methodology-Equal, Project administration-Equal, Resources-Equal, Supervision-Equal, Validation-Equal, Writing—original draft-Equal, Writing—review and editing-Equal.

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Disclosures

This manuscript has been accepted for posterior presentation at the 2024 50th Annual Society for Gynecologic Surgeons meeting. This manuscript has not been published in another form (abstract or otherwise) elsewhere.

IRB of Record: Sterling Institutional Review Board (IRB).

Conflict of interest/financial disclosure

Rodger Rothenberger, MD; Elaine Kopinga NP; Jeffrey Dell, MD have no disclosures. Robert D Moore, DO; John R Miklos, MD; and Mickey Karram, MD are speakers and consultants for Inmode.

Appendix 1: Time and events schedule

Visit type procedure	Screening baseline measures	Visit 1* Tx1	Visit 2 Tx2 (4 weeks ±5 days)	Visit 3 Tx3 (4 weeks ±5 days)	Visit 4 3 M FU (± 7 days)	Visit 5 6 M FU (± 14 days)
Medical history and demographics	√					
Inclusion/exclusion criteria	√					
Informed consent	√					
Treatment		√	√	√		
FSFI	√				√	√
"Vaginal Health Index" (VHI) score	√				√	√
UDI-6	√				√	√
Adverse events query		√	√	√	√	√
Discomfort level assessment		√	√	√		
Concomitant medication	√	√	√	√	√	√
Study end						

*Screening and treatment may occur on the same day and up to 3 weeks interval.

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A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFECT OF ABDOMINAL ELECTRICAL MUSCLE STIMULATION ON ABDOMINAL WALL RESTORATION IN POSTPARTUM WOMEN

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Abstract

Background: Diastasis of recti abdominis muscle (DRAM) is a common condition occurring postpartum and thought to be a cause for back pain and pelvic instability. Electrical muscle stimulation (EMS) had been used in abdominal muscle rehabilitation in combination with exercises in DRAM. This study looks at the effect of EMS in treating DRAM in comparison to a control group receiving no treatment.

Methods: This is a prospective randomized clinical trial. A total of 51 patients were included in the study, including group A (28 patients) that was treated with EMS, and a control group B (23 patients) that did not receive any treatment. Pre-treatment baseline, 1-, 3-, and 6-month follow-up data were collected. Results were evaluated through ultrasound measurements of inter-rectal distance (IRD), investigator assessments, patient subjective improvement and satisfaction and Pelvic Floor Distress Inventory (PFDI) questionnaire.

Results: Ultrasound IRD measurements demonstrated improvement from baseline to the 3-month and 6-month follow-up in the treatment group. Investigator assessment favored the treatment group with significant difference at all study points. Subjective assessments by patients demonstrated a significant difference between the two groups at 1-month while continued to show improvement at 3- and 6-months follow-up. PFDI questionnaire favored the treatment group over the control group in three PFDI subscales at all study points. Progress of the EMS effect over time was shown.

Conclusions: The current study supports potential efficacy of the EMS device as a stand- alone treatment modality for the improvement of DRAM in postpartum women.

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Introduction

Diastasis of recti abdominis muscles (DRAM) is defined as a separation of the two muscle bellies of rectus abdominis [1]. DRAM occurs very commonly during pregnancy with a prevalence of 27-33.1% in the second trimester [2, 3], and up to 100% in the third trimester [4]. Postpartum DRAM can persist up to 6 month ranging in 39% to 45% of women [3, 4] even lasting up to 1 year postpartum in 33% of patients [3].

The wide range of prevalence is due to lack of standardization in the definitions used to define DRAM. Some studies have used objective measures like ultrasound criteria for diagnosis (inter-rectus space > 16 mm) [4], while others have used more clinical criteria (separation ≥ 2 finger breadths) [2, 3]. DRAM occurs during pregnancy due to hormonal changes combined with uterine growth that displace the rectus abdominis muscles; the linea alba softens resulting in separation of the muscles occur in between. The inter-recti distance (IRD) varies from 2 to 3 cm wide and 2 to 5 cm long to 20 cm wide affecting the entire length of the muscle [5]. DRAM can also occur in postmenopausal women. A study in a urogynecology population showed that 66% of patient with DRAM had pelvic floor dysfunction [6]. Risk factors for developing DRAM include high age, multiparity, cesarean section, weight gain, high birth weight, multiple pregnancy and ethnicity [7-9]. The clinical implications of DRAM are not fully appreciated, but historically patient complaints of symptoms of ventral hernia such as back pain, pelvic instability and cosmetic disfigurement [10, 11].

There is increasing focus on how women may regain abdominal strength after childbirth, with much focus on exercises and physiotherapy as the most common methods for regaining the strength [12, 13].

A recent meta-analysis on published outcomes of surgical and non-surgical treatments of DRAM noted insufficient data to support physiotherapy as a stand-alone treatment modality [11].

Electrical muscle stimulation (EMS), also known as neuromuscular electrical stimulation (NMES), is the application of an electric current to elicit a muscle contraction [14]. The principle of electrostimulation mimics the process observed

during voluntary muscle contraction. The stimulator sends an electrical impulse to the nerve fibers to excite them which results in muscular contraction.

EMS application has grown significantly in recent years and has been widely used in orthopedics and physiotherapy for muscle rehabilitation, training and re-education. EMS was found to be effective for muscle strengthening in orthopedic surgery, mostly being applied to quadriceps muscle [15, 16], and in neurological rehabilitation [17, 18].

Alon et al studied the effect of EMS on abdominal muscles and found it was well tolerated and strengthened the muscles. They noted the combined use of electrical stimulation and exercise to be the most effective mode for isometric strength of the abdominal muscles [19].

Two recently published studies investigated the effect of electrical stimulation in combination with abdominal exercises on the recovery of abdominal muscle strength and reduction of DRAM in postpartum women [20, 21]; both studies noted electrical stimulation in conjugation with exercises produced better outcomes than conventional exercises alone.

These studies, however, did not have a control arm, so they could not differentiate patients who had spontaneous resolution of DRAM from those who truly benefitted from the treatment protocol.

The purpose of this study was to evaluate EMS (Evolve, InMode, Irvine, CA) as a stand-alone treatment approach for recovery of abdominal muscle strength and to compare those outcomes to a control group which was just observed for spontaneous resolution of DRAM.

Materials and Methods

Patients and study design

This was an Institutional Review Board (IRB)-approved investigational prospective randomized clinical trial. This study was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration. Postpartum women from two clinical sites were assessed routinely during their first postpartum visit 2 weeks after delivery. Patients who met the diagnostic criteria for DRAM were offered to participate in the study. DRAM was diagnosed using the criteria proposed by Boissonnault et al [2]. All clinical examinations were performed by one physician at each clinical site. IRD was measured by palpation 4.5 cm above, and 4.5 cm below the umbilicus. The women were tested in a standardized supine crock-lying position with arms crossed over the chest. They were instructed to perform an abdominal crunch till the shoulder blades were off the bench.

Recruited subjects were randomized with 1:1 ratio to either a treatment group that was treated with the EVOLVE Tone device (InMode Corporation, Lake Forest, CA) in the abdominal area, or to a control group that did not receive any treatment but were followed in an identical fashion as the treatment group.

Inclusion criteria included postpartum women aged 18 - 45 years with clinical diastasis recti and weakness of the linea alba, body mass index (BMI) of 18.5 - 32 (normal to overweight, but not obese).

Exclusion criteria included history of other energy-based therapy within 1 year, diffuse pain syndrome or chronic pain requiring daily narcotics, active electrical implant/device in any region of the body, including pacemaker or internal defibrillator, permanent implant in the treated area, pregnancy, and breast feeding, current or history of skin cancer, severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, and liver or kidney diseases, history of skin disorders, bleeding coagulopathies, impaired immune system, poorly controlled endocrine disorders, any active condition in the treatment area, any surgical procedure in the treatment area within the last months or before complete healing and any therapies or medications which may interfere with the use of the study device or compromised health as determined by the study doctor.

Study protocol included eight treatment visits once a week, and three follow-up visits at 1, 3 and 6 months post last treatment. Any adverse events were recorded.

Results were evaluated through photographs, ultrasound measurements of IRD, investigator assessments and Pelvic Floor Distress Inventory (PFDI) questionnaire.

PFDI questionnaire was included in our study since pelvic floor muscles and abdominal muscles function synergistically, we want to investigate how the effect of decreased abdominal muscles function through diastasis recti would affect the function of pelvic muscle.

Baseline and follow-up photographs were obtained, using consistent camera and subject placement settings with a digital imaging system.

The subjects underwent ultrasound and/or caliper measurements to evaluate IRD. Subjects assumed a supported and relaxed crook-lying position. Subjects were asked to relax their abdominal muscles and the transducer was placed perpendicular to the linea alba, above the umbilicus (midway between the umbilicus and the xiphoid process). Focus and depth were adjusted to visualize the medial aspects of both recti. The hyperechoic connective tissues with the hypoechoic rectus abdominis muscles were identified to measure the IRD at the end of a normal expiration with the automatic ruler to the nearest 0.1 cm.

Subjects' diastasis recti condition was classified as mild, moderate or severe based on classification proposed by Ranney [22]. An observed separation of < 3 cm between the rectus muscles was labeled mild diastasis, 3 - 5 cm separation moderate diastasis, and more than 5 cm severe diastasis.

The IRD distance was measured in each visit. In addition to the above measurements, the study investigators rated the improvement levels according to a scale with score 0 for no improvement, 1 mild improvement, 2 moderate improvement, 3 marked improvement, and 4 significantly marked improvement. This was based solely on a subjective assessment by the physician performing the exam.

Subjects also rated the improvement levels according to the same scale used by study investigators. Subjects also rated their satisfaction level according to a scale with very dissatisfied -2, dissatisfied -1, neutral 0, satisfied 1, and very satisfied 2.

The PFDI-20 (short version) was used both as a symptom inventory and a measure of the degree of bother and distress (quality-of-life) caused by pelvic floor symptoms [23, 24].

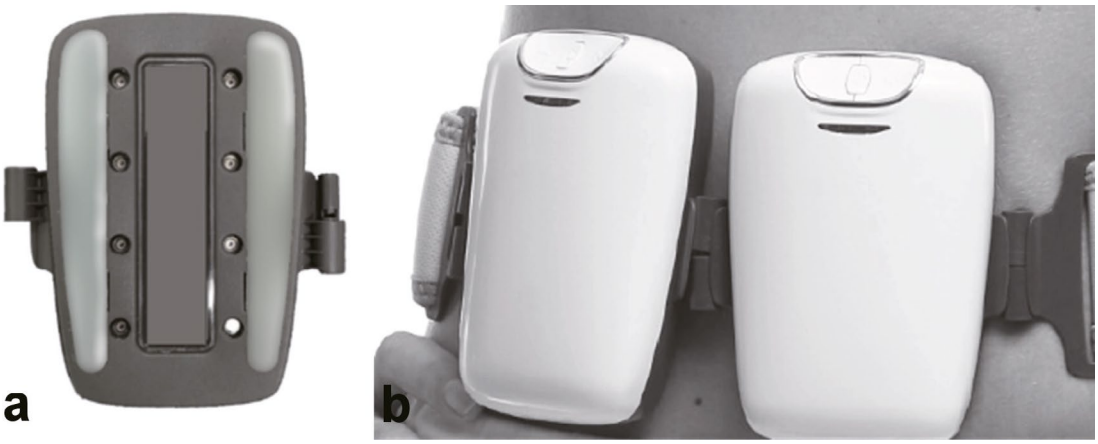

Figure 1. The Tone applicator. (a) Electrodes side of 1 unit. (b) Tone units on a belt attached to the abdomen.

This is a valid and reliable condition-specific quality-of-life questionnaire for women with disorders of the pelvic floor including urinary incontinence, pelvic organ prolapsed and fecal incontinence.

Safety of the device was evaluated by assessing the incidence, severity and persistence of adverse events, if any, occurring during the study period.

Device and treatment

The EVOLVE system Tone applicator (InMode Corporation, Lake Forest, CA) is an EMS device suitable for the treatment of skeletal muscle. EMS stimulates the muscles and assists in strengthening, training and recovering of muscles such as abdominal muscles for improved strength and endurance.

The Tone hands-free applicator (Fig. 1) is designed to deliver electrical stimulation to skeletal muscles leading to supraphysiologic contraction frequency and strength. The Tone applicators are applied to the skin surface using a belt.

The EMS system enables individual adjustment of parameters such as intensity level, pulse width and frequency to achieve maximum efficiency, safety and comfort for each patient.

The two large rectangular electrodes used for the electrical stimulation were applied on the treatment area over water-based ultrasonic gel, bilaterally to the rectus abdominis. The electrodes were fixed in their position with belt. Intensity was increased gradually until a visible muscle contraction was observed, without affecting subject's comfort. The subjects were instructed to relax their abdominal muscles during EMS application. Treatment duration was 15 - 30 min according to subject's condition, comfort and tolerance.

Results

A total of 60 patients met the inclusion criteria and agreed to participate in the study. Thirty patients were enrolled in each arm. Two patients were lost to follow-up in the treatment arm and seven patients were lost to follow-up in the control arm; data were available at 6-months follow-up on 28 patients treated with EMS and 23 patients followed for spontaneous resolution of DRAM. The average age was 29 and BMI was 27 for both groups.

Measurements were captured at every patient visit; analyses were conducted at four time points: 1) baseline; 2) 1-month follow-up; 3) 3-month follow-up; and 4) 6-month follow-up. Measurements included IRD (with head titled ultrasound), investigator assessment of improvement, subject assessment of improvement and the PFDI (split among three subscales).

The ultrasound, investigator assessment and subject improvement scores were utilized for analysis purposes. The 20 PFDI items were collapsed (averaged) into three distinct subscales. The first subscale was comprised of the first six items Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), the second subscale was comprised of the next eight items Colorectal-Anal Distress Inventory-8 (CRADI-8), and the third subscale was comprised of the last six items Urinary Distress Inventory-6 (UDI-6). While the data do allow themselves to be analyzed as a between- and within-subjects design (i.e., a repeated measures analysis of variance (ANOVA) with treatment group serving as a fixed factor), given the sample size; and for ease of interpretation, univariate, one-way ANOVA tests were conducted comparing the two groups at each time point individually. Therefore, for variables with baseline measures (the ultrasound measurements), the baseline measurements were subtracted from the 1-month, 3-month, and 6-month measurements for each patient, and univariate, one-way ANOVA test were likewise computed on the differenced scores.

There were no significant demographic differences noted between the two groups (Table 1).

Table 1. Demographics of Patients

	Group A (EMS group, n = 28)	Group B (control group, n = 23)
Age	29.65	29.22
BMI	27.62	27.76

EMS: electrical muscle stimulation; BMI: body mass index.

Table 2. IRD Ultrasound Measurements

Comparison	Control (mean ± SD)	Treatment (mean ± SD)	Difference	F	P
Base to 1-month follow-up	0.32 ± 0.45	0.47 ± 0.60	0.15	1.03	0.31
Base to 3-month follow-up	0.31 ± 0.57	0.63 ± 0.67	0.32	3.74	0.06
Base to 6-month follow-up	0.37 ± 0.55	0.63 ± 0.71	0.26	1.90	0.18

IRD: inter-rectal distance; SD: standard deviation.

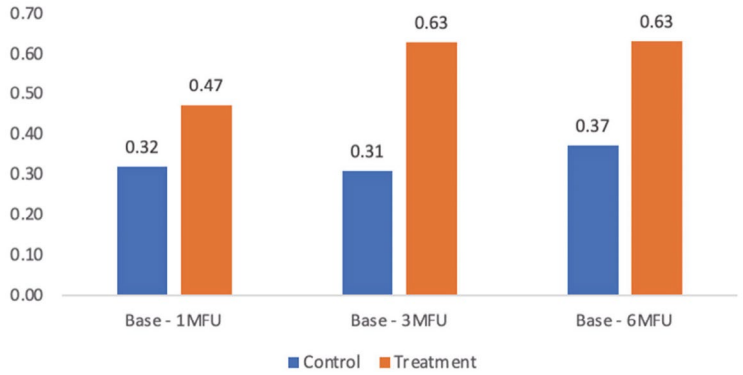

Figure 2. IRD baseline to 1-, 3-, and 6-month follow-ups (MFU). IRD: inter-rectal distance.

Ultrasound measurements of the IRD did not differ from baseline to 1 month; however there was a significant improvement in the treatment arm at 3-month follow-up (P = 0.6), and the baseline to 6-month follow-up scores, while still quite different favoring the treatment group but dropping in statistical significance (P = 0.18; Table 2, Fig. 2).

The investigator assessments of improvement scores were compared for the two groups and noted significant improvement in the treatment group at 1-month, 3-month and 6-months (Table 3, Fig. 3).

Subject assessments of improvement scores also were different between groups at 1-month follow-up; however, that difference was noted not to be significant at the 3-month follow-up or 6-month follow-up (Table 4, Fig. 4).

Table 3. Investigator Improvement Assessment (1-, 3-, and 6-Month Follow-Ups)

Comparison	Control (mean ± SD)	Treatment (mean ± SD)	Difference	F	P
Base to 1-month follow-up	0.52 ± 0.67	1.60 ± 0.97	1.08	20.90	< 0.001
Base to 3-month follow-up	1.09 ± 0.79	2.22 ± 1.05	1.14	18.01	< 0.001
Base to 6-month follow-up	0.92 ± 1.04	2.25 ± 1.04	1.33	8.54	0.007

SD: standard deviation.

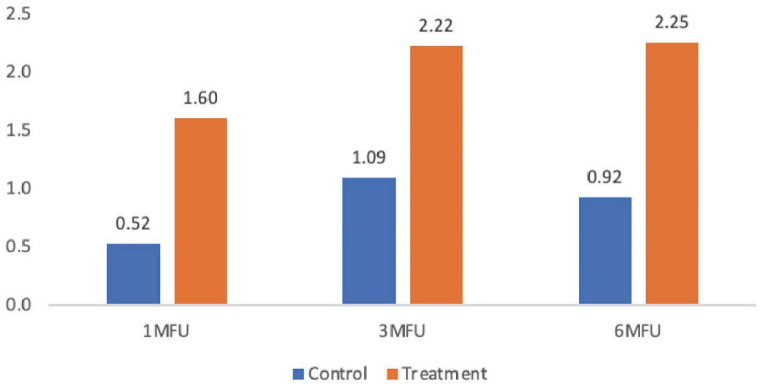

Figure 3. Investigator improvement: 1-, 3-, and 6-month follow-ups (MFU).

Table 4. Subject Improvement Assessment (1-, 3-, and 6-Month Follow-Ups)

Comparison	Control (mean ± SD)	Treatment (mean ± SD)	Difference	F	P
Base to 1-month follow-up	0.96 ± 1.22	1.64 ± 1.25	0.69	3.89	0.06
Base to 3-month follow-up	1.32 ± 1.46	1.52 ± 1.19	0.20	0.27	0.61
Base to 6-month follow-up	1.25 ± 1.55	1.79 ± 1.32	0.54	1.57	0.22

SD: standard deviation.

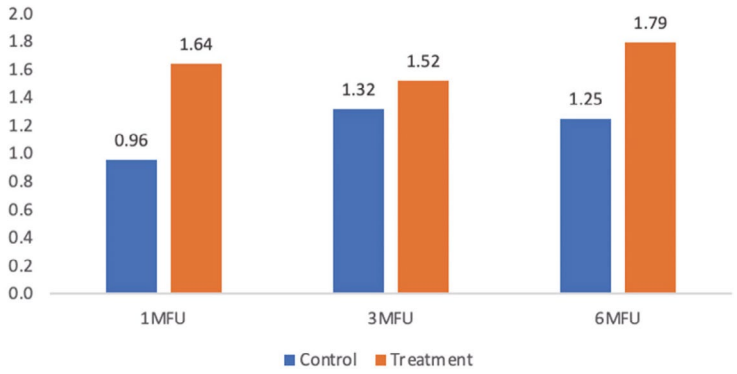

Figure 4. Subject improvement: 1-, 3-, and 6-month follow-ups (MFU).

For the PFDI subscales, at the 1-month follow-up, the treatment group had significantly lower scores (thus, improved scores) compared to the control group for the first, second, and third PFDI subscales with statistical significance value in the first and second subset. These improvements in the treatment group persisted through the 3- and 6-months follow-up visits (Table 5, Fig. 5).

Discussion

When contemplating non-surgical treatment for DRAM, it is important to determine if the treatment is truly working or if positive results are simply due to the spontaneous resolution of DRAM, which we knew occur approximately in 70% of women. This is the first study in which a control arm was included to better assess the true impact of the treatment arm.

The data collected during the study demonstrate a potential benefit of the EMS Tone procedure, as detailed by a series of comparisons made between the control group and the treatment group. The IRD ultrasound procedure demonstrated improvement from baseline to the 3- and 6-month follow-up in the treatment group compared to the control group. Moreover, the investigator assessments of improvement scores were better at the 1-, 3-, and 6-month follow-up for the treatment group compared to the control group. Subject improvement assessment scores were higher for the treatment group compared to the control group consistently over the 6-month period though it did not reach statistical significance. Subject improvement needs to be interpreted with care due to inherent bias and thus not very reliable. All three of the PFDI subscale scores were better for the treatment group compared to the control group at

Table 5. PFDI Subscales 1 - 3 (1-, 3-, and 6-Month Follow-Ups)

Comparison	Control (mean ± SD)	Treatment (mean ± SD)	Difference	F	P
Subscale 1 (1-month)	0.54 ± 0.74	0.18 ± 0.36	0.36	5.11	0.03
Subscale 2 (1-month)	0.59 ± 0.73	0.17 ± 0.26	0.42	7.90	< 0.01
Subscale 3 (1-month)	0.81 ± 0.84	0.41 ± 0.63	0.40	3.71	0.06
Subscale 1 (3-month)	0.39 ± 0.57	0.18 ± 0.35	0.21	2.60	0.12
Subscale 2 (3-month)	0.42 ± 0.71	0.16 ± 0.27	0.26	2.84	< 0.10
Subscale 3 (3-month)	0.59 ± 0.77	0.51 ± 0.62	0.07	0.14	0.73
Subscale 1 (6-month)	0.27 ± 0.47	0.16 ± 0.35	0.11	0.81	0.37
Subscale 2 (6-month)	0.37 ± 0.61	0.14 ± 0.27	0.23	2.93	< 0.10
Subscale 3 (6-month)	0.60 ± 0.67	0.38 ± 0.52	0.23	1.67	0.20

PFDI: Pelvic Floor Distress Inventory; SD: standard deviation.

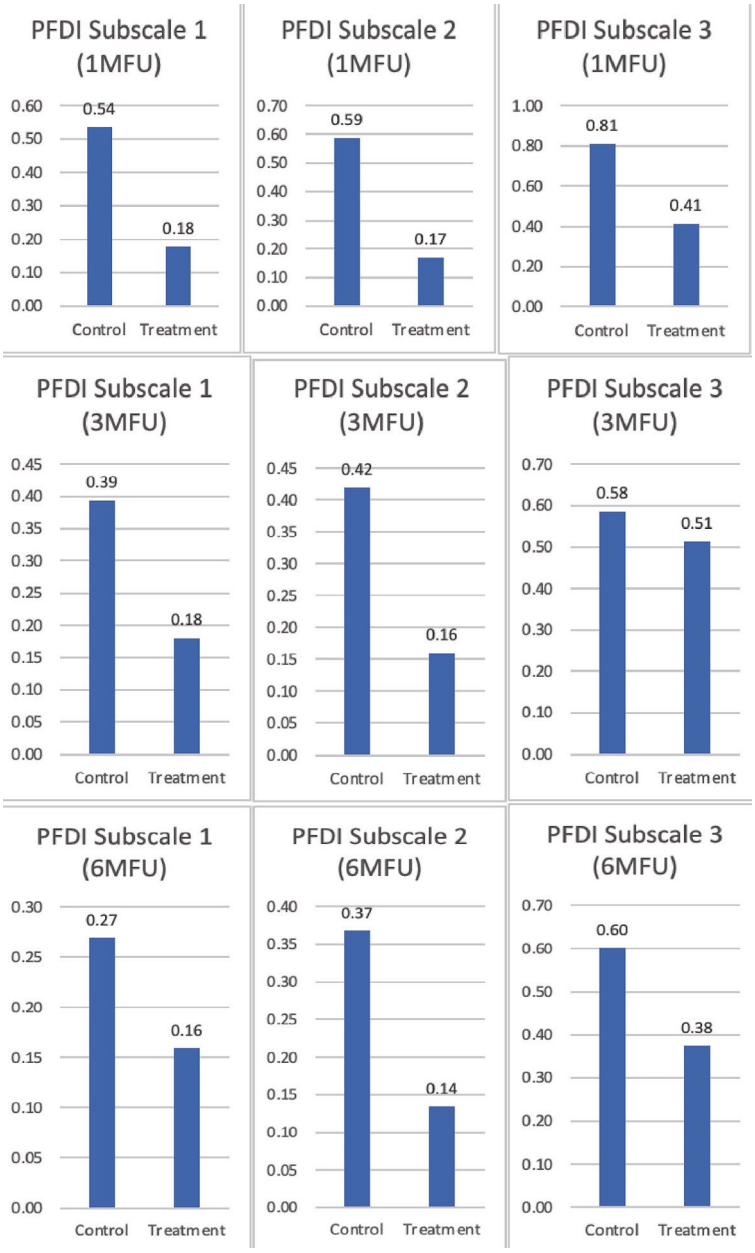

Figure 5. Pelvic Floor Distress Inventory (PFDI) subscales 1 - 3 (1-, 3-, and 6-month follow-ups (MFU)).

1-, 3- and 6-month follow-up.

The strength of this study is that it is the first study to assess EMS effect on DRAM in comparison to a control group, with relative long-term follow-up of the patients up to 6 months. We used different outcomes for assessment including subjective assessment by the patient and the investigator and objective assessment as the IRD and PFDI questionnaire for more validity of the results. Finally, this is the first prospective study to assess the relationship between DRAM and pelvic floor dysfunction. The limitations of the study are that it was not blinded, so there is always a potential for bias by the patient and the physician; also the study was not powered to statistically show a difference between the two groups, so statistical outcomes need to be evaluated with caution. More studies are needed with more patients recruited to be able to show whether there is real statistical difference that can be detected between both groups.

Conclusions

EMS can potentially be of a benefit in treating DRAM compared to natural healing. The effect is more evident in the first month postpartum, and decreases with time confirming that

overtime natural healing will significantly improve this condition. Potential clinical significance is seen with using EMS in pelvic floor dysfunction; however more specific tailored studies are needed to substantiate this finding.

Acknowledgments

None to declare.

Financial Disclosure

The study was funded by InMode.

Conflict of Interest

Ahmed Abdelaziz MD has no competing interest, personal financial interest, no funding from any organization that may gain or lose financially from publication of the article, and is not employed or has not been employed by an organization that may gain or lose financially from publication of the article. Henry Ramirez MD is a consultant and speaker for InMode. Tracy Blusewicz MD is a consultant and speaker for InMode. Mickey Karram MD is a consultant for InMode, Viveve and Cynosure.

Informed Consent

The informed consents were obtained.

Author Contributions

Ahmed Abdelaziz MD contributed to drafting the work, revising it and writing the manuscript. Tracy Blusewicz MD contributed to design of the work, analysis and interpretation of data for the work. Henry Ramirez MD contributed to design of the work, analysis and interpretation of data for the work. Mickey Karram MD contributed to revising it critically for important intellectual content and final approval of the version to be published.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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RADIOFREQUENCY TREATMENT OF LABIA MINORA AND MAJORA: A MINIMALLY INVASIVE APPROACH TO VULVA RESTORATION

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Summary: Labiaplasty has rapidly increased in popularity over the past 5 years. Traditional labiaplasty is associated with potential complications, such as dehiscence, hematoma, flap necrosis, narrowed introitus, pain, and asymmetry. Minimally invasive techniques such as radiofrequency (RF) have emerged as viable alternatives to traditional labiaplasty through a temperature-controlled bipolar mechanism to heat tissues to target temperatures of 40°C–45°C. This controlled energy delivery leads to an inflammatory cascade initiating neocollagenesis, angiogenesis, and elastogenesis over the coming 3–4 months. A single surgeon series of labia minora and majora treatment by RF (InMode, Lake Forrest, Calif.) was reviewed between April 2018–October 2018. Demographic data were collected as well grade of hypertrophy (pre/posttreatment), number of vaginal deliveries, and reason for treatment. Procedural parameters were recorded, including internal/external temperatures, total energy used, and time of treatment. All adverse events were recorded. Objective and subjective data points were obtained in the form of patient surveys and photographic evaluation by lay persons as well as plastic surgeons objective to the treatment. Ten consecutive patients were treated with bipolar RF (InMode, Lake Forrest, Calif.) between April 2018–October 2018. Mean age was 44 (29–54). Average number of pregnancies was 2 (STD 1.1). Three patients were treated for aesthetic concerns, 3 for functional complaints, and 4 desired improvement in both. Overall graded improvement in labia size/contour was +50% (STD ±15.3). Patient satisfaction scale data demonstrated 9.5/10 (±1.7). All patients (10/10) stated that they would undergo treatment again. In all cases, the surgeon observed tightening of the clitoral hood, introitus, forchett, as well as improved distribution of dark pigmentation of the labia minora. There were no significant complications and no need for additional procedures. Average recovery time was 14 days (STD 2.2). Treatment of labia hyperplasia and laxity with bipolar RF may potentially fill a treatment gap of women seeking aesthetic and functional improvements without surgical labiaplasty. A powered prospective randomized double-blinded study is needed to further elucidate the role of this technology. *(Plast Reconstr Surg Glob Open 2020;8:e2418; doi: 10.1097/GOX.0000000000002418; Published online 22 April 2020.)*

INTRODUCTION

Labiaplasty has rapidly increased in popularity for the management of functional and aesthetic problems associated with prominent labia.[1] The first description in the plastic surgery literature was by Hodgkinson and Hait (1984) who identified that labia minora protrusion past labia majora is aesthetically and functionally unsatisfactory.[1] According to the American Society of Plastic Surgeons, 12,000 labiaplasty were performed in 2016, up 40% from the prior year.[2] Demographic data show trends of younger women (<18 years) seeking labiaplasty.[3] This

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growth has been attributed to decreased stigmatization, changes in fashion trends, and increased exposure to nudity in social media.[4]

Studies show that women seek labiaplasty for a variety of reasons; including aesthetic purposes (1/3), functional impairment (ie, pain, discomfort, difficulty maintaining hygiene) (1/3), and a combination of both (1/3).[1,4] Patient satisfaction rates in the literature are consistently 90%–95%.[4] However, shortcomings have included the lack of measurable standards of care, paucity of evidence based outcomes, and inconsistent terminology.[5] Many surgical techniques have been described in the literature to treat labia hypertrophy (ie, deepithelialization, direct excision, Z-plasty, etc).[1,3–7] All operations carry their inherent advantages/disadvantages, and there is little evidence to guide which is best for a given deformity. Potential complications of surgical labiaplasty include scarring, irregular edges, over-resection, wound dehiscence, narrowed introitus, pain, paresthesia, dryness, and asymmetry.[1,5,7]

Nonsurgical options for vulvovaginal rejuvenation are among the fastest growing areas in plastic surgery.[6] A number of energy-based devices, including radiofrequency (RF) and laser (CO_2, Er:YAG) have been used to improve external genital appearance, vaginal laxity, and pelvic floor dysfunction (ie, urinary incontinence).[8] Patients and clinicians often view these minimally invasive options as more attractive to standard operative treatment. RF applied to the vulvovaginal tissue has been shown to stimulate proliferation of glycogen enriched epithelium, neovascularization, and collagen formation by creating heat via impedance, as an electric current is conducted through the target tissues.[6] Once these devices generate temperatures between 38°C and 42°C, an inflammatory cascade is initiated to induce these changes over the subsequent 3–4 months.[1,4] The purpose of this article is to describe our experience with bipolar RF for the treatment of prominent labia minora and majora, with a focus on efficacy and safety.

METHODS

A single surgeon series of labia minora and majora treatment by RF (Facetite modified to Accutite, InMode, Lake Forest, Calif.) was reviewed between April 2018 and October 2018. Demographic data were collected as well as degree of labia hypertrophy, protrusion, number of vaginal deliveries, history of trauma (ie, episiotomy), and reason for treatment. Procedural parameters were recorded, including internal/external temperatures, total energy used, time of treatment, and perioperative medications used. All adverse events were documented. Results were assessed using objective and subjective data points including a patient satisfaction survey and photographic evaluation by 2 independent plastic surgeons impartial to the treatment.

TREATMENT PROTOCOL

A detailed medical history and physical was obtained on all patients before treatment. Patients in our series were classified into one of three "treatment gap" groups: (1) women who do not want traditional invasive surgery, (2) women who had prior surgery but suffer from recurrent laxity, and (3) women with modest labia hypertrophy but not severe enough to justify traditional excision. Exclusion criteria included: unrealistic expectations, open wounds, active infection, dermatologic conditions, bleeding disorders, collagen disorders, history of keloids/hypertrophic scaring, and immunocompromised state. The distance from midline to free edge of the labia minora when extended laterally was measured to assess pre and post-treatment labia hypertrophy. While there has not been consensus on this measurement, early definition of labia minora hypertrophy included a distance of >5cm.[9] More recently, it has been proposed that this distance should be reduced to 3 or 4 cm.[10] We recorded this measurement of labia laxity as an objective data point, but candidacy for RF labiaplasty was primarily based on symptomatology. Additionally, we measured labia protrusion as described by Motakef et al based on the distance of the lateral edge of the labia minora from that of the labia majora rather than the introitus. This scale categorizes labial protrusion as class I (0–2 cm), class II (2–4 cm), and class III (>4 cm).[11]

All patients were premedicated with 10 mg of oral diazepam and 5/325mg of hydrocodone with acetaminophen. One dose of oral antibiotics was given preoperatively (cephalexin or ciprofloxacin). The patient was positioned in either a frog-leg position or in stirrups. After standard prep and draping, access points were injected at the caudal aspect of each labia (majora and minora) with 2–5 ml of local anesthesia (1% lidocaine with 1:200,000 epinephrine). Next a 14-gauge needle was used to create puncture site access. A 20-gauge spinal needle was used to infiltrate 20–40 ml of tumescent solution per treatment site (50 ml of 2% lidocaine, 12 ml sodium bicarbonate, 1.5 mg epinephrine per liter of lactate ringers). Hydrosoluble lubricating gel was placed over the labia to improve transduction and gliding between the 2 ports of the RF device. The RF settings included a controlled internal temperature cutoff at 60°C and 37°C externally. The 40 W bipolar RF cannula (Facetite modified to Accutite, InMode, Lake Forest, Calif.) was placed into the access port and moved in a radial cranio-caudal motion until the tissues reached target temperature. (**See Video 1, [online],** which displays bipolar RF treatment of labia.) (**See Video 2, [online],** which displays an animation of the bipolar RF treatment of labia.) This was done to systematically treat segments across the labia. Treatment was stopped ~1.5 cm from the access port to avoid repeat heating. Audible and visual cues from the device were used to guide treatment (faster beeping indicate that the clinician is reaching target temperatures).

Table 1. Demographic Data and Pre-postoperative Measurements on Bipolar RF Labiaplasty Patients

Age	
Labia hypertrophy	4.4 cm (±1.3)
Labia protrusion	3.9 (±2.3)
Vaginal deliveries	2 (±1.7)
History of trauma	50%
Reason for treatment	Aesthetic 30% Functional 30% Both 40%

Once target temperature was reached, treatment continued for 1 minute and then was stopped.

RESULTS

Ten consecutive patients were treated with bipolar RF (Facetite modified to Accutite, InMode, Lake Forest, Calif.) between April 2018 and October 2018. Mean age was 44 (29–54). Average number of pregnancies was 2 (STD 1.1). Three patients were treated for aesthetic concerns, 3 for functional complaints, and 4 desired improvement in both. (Table 1) Mean follow-up time was 8 months (±2.1 months). Preoperative measurements of labia hypertrophy and protrusion had mean of 4.4 cm (±1.3) and 3.9 (±2.3), respectively. Measurements were obtained for all patients 6 months post procedure with a measured average improvement of 2.7 (±2.2) and 3.1 (±2.3) representing a +38.6% (STD ±15.3) and 20.5% (STD ±17.4) change. A patient satisfaction scale [1 (unsatisfied)–10 (most satisfied)] demonstrated a score of 9.5/10 (±1.7), indicating that most patients were highly satisfied with the procedure outcome. All patients (10/10) stated that they would undergo treatment again. In all cases, the surgeon observed tightening of the clitoral hood, introitus, forchett, as well as improved distribution of dark pigmentation of the labia minora (Fig. 1). There were no significant complications and no need for additional procedures. Average recovery time was 14 days (STD 2.2).

DISCUSSION

RF treatment for skin laxity was first studied nearly 70 years ago.[6] However, application to the external female genitalia has only emerged in the last decade.[6] The use of RF in this region is of particular interest as the contractile effect is known to increase in naturally moist tissues.[1,8] Despite traditionally high satisfaction rates with surgical labiaplasty, there are associated risks and downtime. RF avoids complications of traditional labiaplasty, including

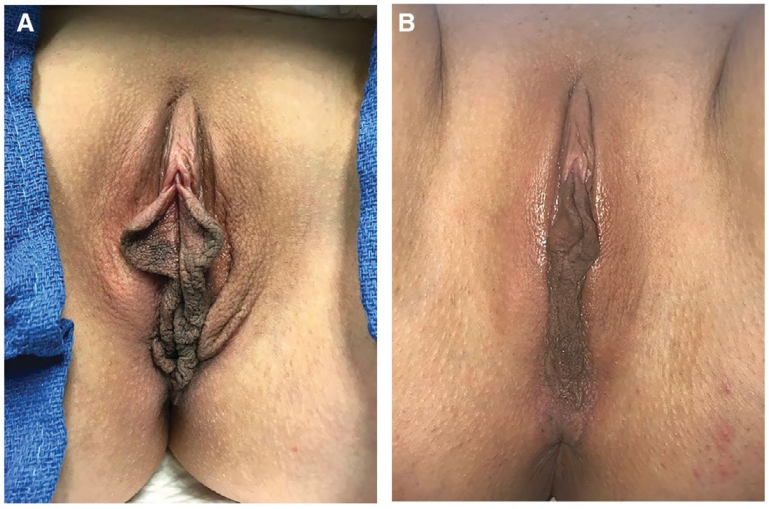

Fig. 1. Preoperative presentation (A) and 8 month postoperative (B) result after bipolar RF labiaplasty.

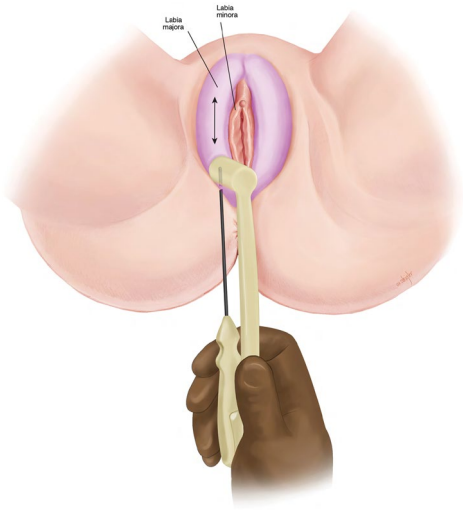

Fig. 2. Treatment of labia majora with bipolar RF.

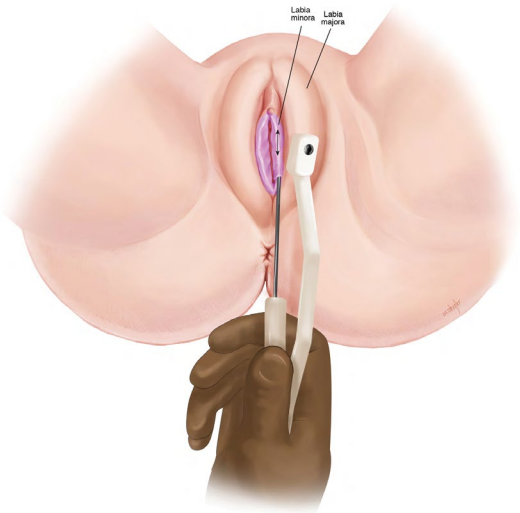

Fig. 3. Treatment of labia minora with bipolar RF.

unfavorable scarring, flap necrosis, hematoma, and over-resection.[4] However, given the generation of heat, there is a risk of burns with RF not seen with traditional labiaplasty. As seen in our study, return to normal sexual function and activities was 14 days compared with the 30–45 days typically cited after traditional labiaplasty.[5]

Using the temperature controlled device at 40°C–45°C, collagen denatures and regenerates over 3–4 months to provide an increased amount and strength of collagen/elastin, leading to long-term tightening. There is an immediate tissue tightening observed with RF treatment. This is explained by collagen contraction, causing the triple helix structure to fold, creating shorter and thicker collagen fibers.[6,8] Consistent with our study's findings, Lordella et al used bipolar RF on women with labial laxity; all patients reported satisfaction with treatment outcome in regards to sexual function, lubrication, and arousal.[6–8] Vanaman et al confirmed these changes histologically in a vulvovaginal tissue after treatment with RF.[12] Ovid models have shown the same findings.[6–8]

Uniquely, in our cohort of patients, the labia majora (Fig. 2) were treated in addition to the labia minora (Fig. 3), as there is often soft tissue laxity in this region as well. In traditional labiaplasty, there are limited surgical options for treatment of labia majora. We hypothesize that treatment of labia majora in addition to minora allows for a "Boa" contractile effect—analogous to the gradual action of a boa constrictor. This theory explains our observation of tighter clitoral hood, introitus, and forchette.

Our study showed no significant complications and an overall 50% improvement in labia hypertrophy and laxity with >95% patient satisfaction. This is in line with most clinical trials that exist using energy based technology for vulvovaginal rejuvenation.

Despite the increasing popularity of labiaplasty techniques internationally, little effort has been placed on comparing technique and establishing standardized measurements or guidelines for this procedure. This study, as well as others have been limited by lack of consensus on the definition of labia hypertrophy itself. For this reason, we evaluated labia protrusion as well as hypertrophy as separate entities. Hypertrophy was measured pre and posttreatment by placing the labia on lateral stretch from the vaginal introitus and calculating this distance from lateralmost portion of labia to introitus. Protrusion was measured by determining the distance that the labia minora protrudes beyond the majora (rather than introitus). Further, we obtained data related to patient symptoms which ultimately guided patient selection. There are a number of limitations inherent in the retrospective nature of this study, including the potential for data inaccuracies and confines in study design. The limited number patients and follow-up in this study is the result of pilot data that precede as prospective study currently in place. It may have been beneficial to have a control or sham arm to account for the potential effect of only passing the RF cannula without energy. Despite these limitations, this study represents among the earliest reports of bipolar RF for treatment of labia hypertrophy.

CONCLUSIONS

Treatment of labia hyperplasia and laxity with bipolar RF may potentially fill a treatment gap of women seeking aesthetic and functional improvements without surgical labiaplasty. A powered prospective randomized double blinded study is needed to further elucidate the role of this technology.

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UROGYNECOLOGICAL COMPLEX CHRONIC PAIN NOVEL APPROACH WITH DOUBLE BIPOLAR RADIOFREQUENCY FOR INTRAURETHRAL AND INTRAVAGINAL WOMAN DISORDERS. (NABIUR- RF PROTOCOL)

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ABSTRACT

Objective: *The purpose of this study was verifying the effectiveness of the use of double bipolar radiofrequency in the control of urethritis and trigonitis in three patients with complex chronic pain syndromes of the pelvic floor.*

Methods: *Three women were analyzed and studied for inclusion in the study and treatment. These are very complex cases with no resolution with previous treatments.*

Previous studies were carried out, incontinence test, evaluation of pain scales, quality of life test, advanced echographic analysis such as elastography, low flow Doppler and 3D / 4D volumetric study of the urethral and vaginal area to be treated. Studies of flowmetry, cystoscopy, urethrocystography and analysis before and after with functional magnetic resonance were performed. We used the Pulstrode catheter at the urethral level and the bipolar radiofrequency Votiva Inmode for the treatment and vaginal approach.

Results: *The three complex patients with severe pain above 7 on the analogue visual scale for pain decreased their pain by more than 4 points in the first 15 days after treatment. Two of them a month no longer present pain and only one pain was assessed in 2. The degree of satisfaction after the procedure was 100% for its clear improvement, absence of complications and improvement in quality of life.*

Conclusion: *100% of patients improved in pain control, general satisfaction and improvement of quality of life. His level of frustration improved and limitations in social activities.*

Keywords
Urogynecology, Radiofrequency, Chronic cystic diseases, Pelvic pain.

Introduction
Gynecologic and urologic etiologies are the sources of pelvic pain for many individuals. Among the chronic cystic diseases, the most frequent is chronic urethrotigonitis (or urethral syndrome) and interstitial cystitis, the latter being the most serious. The first description of interstitial cystitis in women was made by Hunner in 1914 who referred to this condition as ulcerative cystitis because it described a certain type of erosion of the bladder mucosa accompanying these patients. Other authors have called it parenchymal cystitis and "neurotic bladder" [1].

Trigonitis is an inflammation of the bladder epithelium in the inner zone of the urinary bladder between the beginning of the urethra and the ureteral meatus, of diverse origin. Sometimes it starts after an inflammation and / or infection, although often the cause cannot be determined [2].

The most characteristic symptom is pain during urination, with the urgency to urinate and the feeling of not emptying the bladder as often as possible, with up to 60 trips to the bathroom in one day. It is a recurrent chronic disease, difficult treatment, complex and long-lasting. Classically it has been treated with instillations of various chemical substances, usually silver salts of officinal concentration (nitrate, protein, etc.) [3], administered by the specialist in a serial way. These substances act on the bladder mucosa producing a chemical peel, forcing a superficial cellular desquamation with stimulation of epithelial regeneration. This pathological condition is greatly influenced by stress, coming to be considered psychosomatic and as such has some seasonal behavior and great tendency to relapse. The treatment must be carried out by the specialist doctor (urologist, urogynecologist, pain expert), who will try to identify the causative agent of the crisis. Supportive psychotherapy should be performed in each session [4-6].

This chronic inflammatory pathological vesical picture that is characterized clinically by irritative symptoms similar to classic but persistent acute cystitis. There is dysuria, frequency, hypogastric pain, dyspareunia, etc. It is a very variable clinical picture and occurs especially in women of the third and fourth decade of life; In the most serious cases there is a decrease in bladder capacity that leads to a disabling situation. It usually presents without urinary infection, although in some cases it can complicate the situation [7].

The fundamental examination is cystoscopy, with or without anesthesia, depending on the severity of the case, which will provide information about bladder capacity and the presence of lesions of the bladder mucosa, such as redness and / or chronic inflammation lesions. In mild cases of urethral syndrome, chronic granulomatous and sometimes desquamative inflammation of the trigone and bladder neck can be seen. Sometimes there are pseudopolyps in the bladder neck that are edematous manifestations of this inflammation. Reuter describes, from the endoscopic point of view, glandular, follicular, granulomatous and cystic lesions. There are also, but in a more exceptional way, vesical leukoplakias, which are chronic fibrous and proliferative inflammations; these can even be pretumoral [8].

Material and Method

Three women were analyzed and studied for inclusion in the study and treatment. These are very complex cases with no resolution with previous treatments.

NABIUR- RF Protocol was applicate (Non ablative Bipolar urethral radiofrequency with pulstrode Catheter) and VOTIVA, Forma V treatment with Inmode Technology (Figure 1).

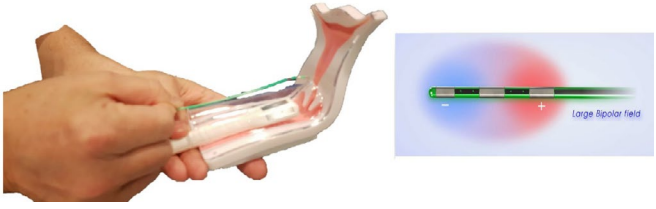

Figure 1: We show the technique used. Above you can observe the Pulstrode catheter that we introduce into the urethra, trigone and bladder and below you can observe the VOTIVA Inmode hand piece [figure 3] for intravaginal bipolar radiofrequency treatment.

Previous studies were carried out, incontinence test, evaluation of pain scales, quality of life test, advanced echographic analysis such as elastography, low flow Doppler and 3D / 4D volumetric study of the urethral and vaginal area to be treated. Studies of flowmetry, urethrocystography and analysis before and after with functional magnetic resonance were performed. We used the Pulstrode catheter at the urethral level and the bipolar radiofrequency Votiva Inmode for the treatment and vaginal approach (Figures 2 and 3).

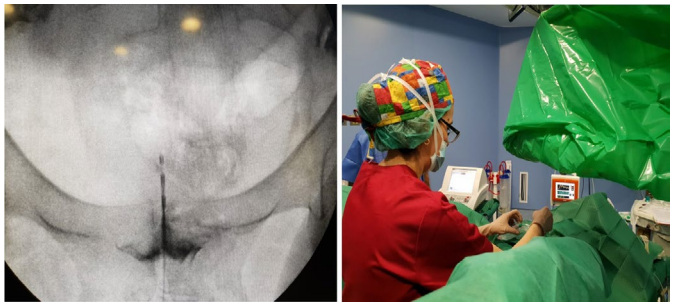

Figure 2: Real-time viewing of the Pulstrode catheter. Its correct localization is possible in the different target through advanced ultrasound and through X-rays, even with the possibility of using contrast for its work channels.

Figure 3: VOTIVA Forma V, hand piece, Bipolar radiofrecuency for intravaginal approach and Catheter Pulstrode.

Results

The three complex patients with severe pain above 7 on the analogic visual scale for pain decreased their pain by more than 4 points in the first 15 days after treatment. Two of them a month no longer present pain and only one pain was assessed in 2. The degree of satisfaction after the procedure was 100% for its clear improvement, absence of complications and improvement in quality of life.

Elastographic changes were detected in all patients. The degree of quantitative and qualitative elasticity was measured before, during and after treatment and during follow-up (Figure 4). Tissue retraction and better elasticity recovery were confirmed by improving angiogenesis. We do not observe complications or sequelae in subsequent explorations with magnetic resonances.

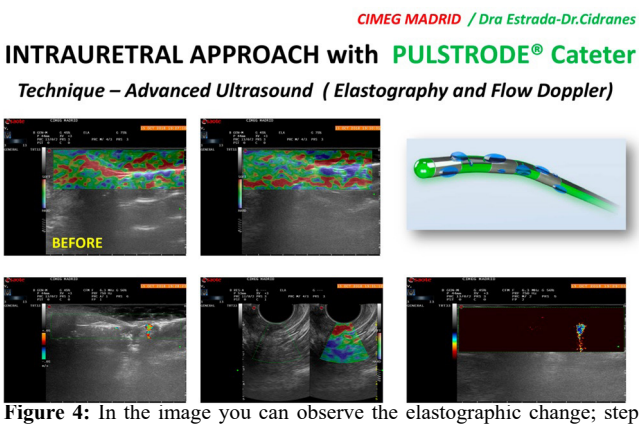

Figure 4: In the image you can observe the elastographic change; step from a state of diminution of the tissue elasticity (red color) to another state of greater retraction and hardness (blue color).

Conclusion

100% of patients improved in pain control, general satisfaction and improvement of quality of life. His level of frustration improved and limitations in social activities.

Recommendation

We recommend continuing to increase the number of cases to use this technique since it is safe, easy to perform and represents an alternative, a new tool that improves the quality of life of our patients.

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NONINVASIVE VULVAR AND INTRAVAGINAL TREATMENTS

Erez Dayan, MD

KEYWORDS

• Noninvasive labiaplasty • Vulvovaginal rejuvenation • Pelvic floor restoration • Radiofrequency

KEY POINTS

- Radiofrequency is an effective and safe method for both pelvic floor restoration and nonsurgical labiaplasty.
- Bipolar radiofrequency with temperature control is more effective than monopolar radiofrequency for volumetric heating of vulvovaginal tissue.
- Combination of electrical muscle stimulation and radiofrequency can provide combined nonsurgical restoration of the vulvovaginal tissues.

INTRODUCTION

Since its first description in the plastic surgery literature in the 1980s labiaplasty and vulvovaginal treatments have rapidly increased in popularity.[1] The American Society of Aesthetic Plastic Surgery reported 12,756 labiaplasty surgeries in 2018, more than a 53% increase over the last 5 years. The growing popularity vulvovaginal procedures have been attributed to decreased stigmatization, changes in fashion trends, and increased exposure to nudity in social media.[2] Over the last 20 years, energy-based devices including radiofrequency and laser (CO2 and Erbium:yttrium-aluminum-garnet [YAG]) have been used successfully in aesthetic and functional procedures.[3] The goal of these energy-based devices have been to contract soft tissue and stimulate neocollagenesis and neoangiogenesis. Indications for these devices included vaginal laxity, dryness, vaginal atrophy, itching, dyspareunia, and urinary incontinence.

Erbium:YAG laser devices emit a wavelength of 2940 nm with a penetration depth of 1 to 3 um of tissue per J/cm^2 allowing for surface injury with minimal thermal damage to surrounding tissue. The mechanism is to contract vulvovaginal mucosa through neocollagenesis. This contraction does not tighten the vaginal tone but rather contracts mucous membranes. Different devices have developed micropulses combined with long-pulse modes to control the heating of target mucous membranes inside the vaginal canal.[4,5] FotonaSmooth (Dallas, TX, USA), Action II (Goyang, South Korea), and MCL 31 Demablate (Jena, Germany) used in clinical trials have demonstrated decrease in Visual Analogue Scale (VAS) scores of both vaginal dryness and dyspareunia, increase in Vaginal Health Index Score, improvement in spontaneous urinary incontinence, improvement in postvoid residual urine volume, and improvement in International Consultation on Incontinence Questionnaire-Urinary Incontinence scores. Histologic findings suggested better elasticity of the vaginal wall with tightening and firming. Adverse events were mild and included transient edema and tolerable heating sensation and rare spotting.[6–9]

Numerous carbon dioxide lasers have been developed for vulvovaginal restoration (FemiLift, SmratXide [Florence, Italy], MonaLisa Touch [Florence, Italy], AcuPulse [Yokneam, Israel], Co2RE Intima [Wayland, MA, USA]). The CO2 laser ablates tissue by emitting light at a wavelength of 10,600 nm, targeting water in tissue. Carbon dioxide is 20X less specific than Erbium, which develops more heat spread to surrounding tissues, leading to neocollagenesis and alteration of vaginal mucosa. Numerous studies have shown improvement in ICIQ-UI, reduction in vaginal

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dryness, improvement in dyspareunia, improvement in VAS scores for all symptom categories, and improvement of VHI scores. Adverse events reports have been limited to mild discomfort, swelling, and mild bleeding.[10–12]

This article focuses on radiofrequency, which more recently has emerged as a promising minimally invasive treatment for both treatment of the labia as well as pelvic floor. Radiofrequency (RF) is a familiar technology in most fields of medicine (ie, orthopedics, cardiology, oncology, etc.). Its first use was in the 1920s for electrocautery.[13] RF consists of an electromagnetic current that is applied through tissue (ie, skin, muscle, collagen). RF generates heat as a result of different tissue resistance or impedance to the electromagnetic current; this follows Ohm's law: Energy (J) = Current^2 x Resistance x Time.[14] For example, collagen has a higher tissue impedance than muscle and will preferentially generate more heat for a given amount of time.[15] For example, when RF energy is directed to the subdermal adipose tissue, it has been shown to generate temperatures 7X higher than those generated by the dermis, leaving to fat necrosis with epidermal preservation.[16]

Modern minimally invasive and noninvasive radiofrequency devices have shown promise in vulvovaginal restoration. Over the past 10 years, radiofrequency devices have advanced to deliver RF in a bipolar fashion (vs monopolar) with continuous temperature control, both elements that are important to controlled volumetric heating over the duration of treatment.[17] Early monopolar radiofrequency devices delivered energy to tissue with the electrical current moving toward a remote grounding pad. Many of these devices lacked temperature control or measured tissue surface temperature as a surrogate for internal temperature, which led to treatments that were either underpowered or reached temperatures in an uncontrolled fashion, increasing the risks of complications such as burn injuries. The use of bipolar radiofrequency avoids the need for a remote grounding pad and thus allows for volumetric heating of tissue.[18] The bipolar devices use continuous internal and external temperature monitoring, which have significantly improved the safety and efficacy of vulvovaginal RF treatments.

DISCUSSION

In our practice, both minimally invasive and noninvasive bipolar radiofrequency devices are used for treatment of the vulvovaginal region. Laxity of the vulvovaginal tissue can occur for a variety of reasons, including natural aging, childbirth, genetics, and trauma. These events can lead to generalized symptoms such as stress urinary incontinence, atrophic vaginitis, dyspareunia, or aesthetic dissatisfaction. Stress urinary incontinence is a prevalent problem affecting up to 35% of all adult women.[3] Further, an estimated 76% of women have symptoms of sexual dysfunction that significantly affect their quality of life.[19,20]

Treatment of the Labia Majora and Minora

Both labia majora and minora are treated with a combination of minimally invasive bipolar radiofrequency (Aviva, InMode Lake Forest, CA, USA) as well as fractional radiofrequency (Morpheus, InMode, Lake Forest CA, USA)[21,22] (**Figs. 1** and **2**). These procedures both can be performed comfortably under local anesthesia. First, a detailed medial history and physical is obtained including patient expectations. The distance from midline to free edge of the labia minor when extended laterally is measured to assess pretreatment and posttreatment labia hypertrophy. Labia minora hypertrophy is determined at a distance of greater than 5 cm. Patients are typically premedicated with 10 mg of oral diazepam and 5/325 mg of hydrocodone with acetaminophen. One dose of oral antibiotics is given preoperatively (cephalexin or ciprofloxacin). The patient is standardly prepped and draped and placed in stirrups. Access points at the caudal aspect of the labia minora and majora on each side are injected with 3 to 5 cc of 1% lidocaine with epinephrine. Next a 14-gauge needle is used to create a puncture site for access. A 20-gauge spinal needle is then used to infiltrate 20 to 40 cc of tumescent solution (50 cc of 2% lidocaine, 12 cc sodium bicarbonate, 1.5 mg epinephrine per liter of lactate ringers) per treatment site. Water-soluble ultrasound gel is then placed over the treatment areas to allow for bipolar radiofrequency conduction. Next the bipolar radiofrequency internal cannula is placed through the access port with the external electrode on the surface of the labia. The device is activated with target temperatures of 38 C externally and 60 C internally. The device is moved in a craniocaudal motion until the targets reach these target temperatures and maintain them for approximately 30 to 45 seconds. Next the fractional RF device was used to treat the labia majora and minora at depths of 4, 3, and 2 mm and an energy of 20 to 30; this was done in double pulse fashion and 50% overlap of pulses.

In our studies evaluating this treatment, preoperative measurements of labia hypertrophy and protrusion had a mean of 4.4 cm (+/− 1.3) and 3.9 (+/− 2.3) respectively. Measurements at

Fig. 1. Bipolar radiofrequency device for soft tissue contraction of labia majora and minora (Aviva). (*Courtesy of* InMode, Lake Forest, CA.)

6 months postprocedure showed an average improvement of 2.7 (+/− 2.2) and 3.1 (+/− 2.3), representing a 38.6% (STD ± 15.3) and 20.5% (STD ± 17.4) change.

Treatment of the Vaginal Canal

In our practice, for internal pelvic floor treatment we use a combination of noninvasive bipolar radiofrequency (Votiva, InMode Lake Forest, CA, USA) and fractional radiofrequency (MorpheusV InMode, Lake Forest, CA, USA) in combination with an internal electrical muscle stimulation device (EmPower Inmode Lake Forest, CA, USA)[21,22] (**Fig 3**). RF applied to the vaginal wall has been shown to stimulate proliferation of glycogen-enriched epithelium, neovascularization, and collagen formation.[4] Once the noninvasive bipolar device reaches temperatures between 40 and 45 C, an inflammatory cascade is initiated and heat shock proteins induce fibroblasts, which leads to neocollagenesis and estogenesis.[4,23] In a previous study that our group conducted with this technology objectively measuring pelvic muscle contraction (Urostym, Portsmouth, NH), there was a direct correlation between treatments and improved pelvic muscle floor contraction. Histologic biopsies of vaginal mucosa at 3 months posttreatment demonstrate increase in elastic fiber density compared with baseline biopsy. The biopsies also find no damage to the submucosal collagen layer and no scar tissue formation in posttreatment, verifying no adverse effect of the fractional RF treatment. Although data are currently being collected to evaluate the objective contribution of electrical muscle stimulation of the pelvic floor, there is evidence of show that a synergy exists.

Fig. 2. Fractional radiofrequency device for treatment of labia majora and minors. (*A*) Morpheus8 and (*B*) Morpheus8V. (*Courtesy of* InMode, Lake Forest, CA.)

Fig. 3. Internal bipolar radiofrequency device for pelvic floor restoration (Votiva, Lake Forest, CA). (*Courtesy of* InMode, Lake Forest, CA.)

SUMMARY

- The use of bipolar radiofrequency is safe and effective for the treatment of both functional and aesthetic concerns in the vulvovaginal area.
- Temperature control has been the major advance to allow for volumetric heating without complications.
- Combination therapies (ie, addition of electrical muscle stimulation) may prove to be synergistic with radiofrequency for vulvovaginal restoration.

DISCLOSURE

Consultant/Investigator: InMode. Book Royalties: Elsevier, Thieme. Co-Founder: Core Aesthetics LLC.

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ROLE OF RADIOFREQUENCY (VOTIVA, INMODE) IN PELVIC FLOOR RESTORATION

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Background: Postpartum pelvic floor disorders are estimated to impact 24% of women in the United States. This study describes the use of a radiofrequency device (Votiva, InMode) for postpartum pelvic floor restoration using an electrostimulator to objectively measure treatment effect.
Methods: A retrospective evaluation was conducted between April 2017 and May 2018 of consecutive patients undergoing vaginal radiofrequency treatment. Inclusion criteria were patients at least 6 weeks postvaginal delivery with symptoms of pelvic floor dysfunction. Resting pelvic floor muscle tone and maximal pelvic floor contraction were measured.
Results: Fifty women were included in the study with an average age of 32 (29–40) years old, average of 2.6 pregnancies, and 1.8 vaginal deliveries. Two patients were lost to follow-up and excluded. Three complete radiofrequency treatments were performed in 31/50 patients, whereas 19 patients received 1–2 treatments. There were no adverse events from the radiofrequency treatment. No changes were found in resting pelvic muscle tone after Votiva treatment [Wilks' lambda = 0.98, F (1, 45) = 0.86, P = 0.36]. The quantity of treatments seemed to impact mean values of maximal pelvic floor contraction [F (1, 45) = 105.14, P < 0.001]. On the patient questionnaire, patients felt subjective improvement correlated to number of treatments.
Conclusions: Radiofrequency is safe for the treatment of pelvic floor dysfunction. This study showed no changes in resting pelvic muscle tone but an improvement in maximal pelvic floor contraction. A prospective randomized study is being conducted to further evaluate the efficacy of this technology. *(Plast Reconstr Surg Glob Open 2019;7:e2203; doi: 10.1097/GOX.0000000000002203; Published online 25 April 2019.)*

INTRODUCTION

The American Society of Plastic Surgeons estimated a 39% increase in plastic surgeons performing vulvovaginal restoration procedures (surgical and nonsurgical) in the United States from 2015 to 2016.[1] Nonsurgical vulvovaginal therapy has been one of the fastest growing areas in plastic surgery and urogynecology over the past 10 years.[2] The first energy-based vulvovaginal rejuvenation device became available in Europe in 2008. By 2016, there were an estimated >500,000 procedures performed annually.[3,4]

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Pelvic floor diseases (PFDs) are estimated to impact 24% of women in the United States (15% urinary incontinence, 3% pelvic organ prolapse, and 9% fecal incontinence).[5] The prevalence of these conditions increases significantly with age,[5,6] with a lifetime risk of undergoing a single operation for prolapse or incontinence of 11% and a reoperation rate of 30%.[5–8] The aging population[6] and rise of obesity[9–11] have led to increased prevalence of PFD and increased rates of surgical procedures.[12] However, studies indicate that providers are unsure of therapeutic options and are inadequately trained to manage these problems.[13] Yet, PFD is a major source of morbidity and a burden on the healthcare system, with an estimated cost of US$83 billion by 2020.[14] Current treatment options for PFD are limited and include biofeedback, laser, electrical

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muscle stimulation, and in certain cases, operative intervention.[5–7,15–19]

The increasing interest in pelvic floor restoration (PFR) is a reflection of decreased stigmatization of female health issues[2,6,7,19–21] and demonstrated safety and efficacy of energy-based devices.[2,15,18,22–26] Despite this, there are barriers preventing sound scientific evaluation of these devices including: lack of objective outcome measures, use of unvalidated surveys, paucity of case/control studies, and inadequate follow-up.

A number of energy-based devices, including radiofrequency (RF) and laser (CO_2, Er:YAG) have been used to improve external genital appearance, vaginal laxity, and stress incontinence.[2,13,18,21–24] Patients and clinicians often view these nonsurgical options as more attractive to invasive surgical treatment—with less downtime, discomfort, and cost. RF treatment may provide particular benefit in cases of disturbance to the genito-pelvic floor, where stretching of the vaginal introitus[13] can lead to decreased sexual function, lubrication, genito-pelvic sensation, stress urinary incontinence, bowel incontinence, chronic pelvic pain, and pelvic organ prolapse.[13,15,16,23,27]

RF applied to the vaginal wall has been shown to stimulate proliferation of glycogen-enriched epithelium, neovascularization, and collagen formation[21] by creating heat via impedance, as an electric current is conducted through the target tissues.[25,28] Once these devices generate temperatures between 40°C and 45°C, an inflammatory cascade is initiated and heat shock proteins induce fibroblasts, which leads to neocollagenesis and elastogenesis.[2,21,22] By controlling temperature at this level, new cells generate rather than forming scar tissue.

However, once dermal tissues reach temperatures >50°C there is a risk of thermal injury.[21]

This study describes the use of the Votiva bipolar RF device (InMode, Lake Forest, Calif.) for PFR in 50 patients experiencing PFD symptoms after vaginal childbirth. A transcutaneous electromagnetic muscle and nerve stimulator (UROstym, Mississauga, Ont.) commonly used in urogynecology was used to measure resting (UROstym min) and maximal (UROstym max) contraction of the pelvic floor pre- and post-RF treatments. The UROstym functions as a separate muscle stimulator and measuring device, uniquely providing objective data to evaluate the impact of the RF treatment. Further, this data provide insight to assess the potential effect of the RF device on muscle biofeedback, which is currently a standard treatment for PFR. Also, a patient symptom improvement index (PSI) was obtained to evaluate the patient's perceived impact of the treatment.

METHODS

A retrospective evaluation was conducted between April 2017 and May 2018 of consecutive patients undergoing vaginal RF treatment with Votiva. Inclusion criteria were patients at least 6 weeks postvaginal delivery with aforementioned symptoms of pelvic floor dysfunction. Clinical examination included either visually noting an open introitus, digital examination measuring the strength of patient's maximal contraction, or visually noting the length of the genital hiatus (from urethra to fourchette; >5 cm was considered attenuated). Patients with active infections, unhealed lacerations, smokers, and those lost to follow-up were excluded from the study. Transcutaneous muscle and nerve stimulator (UROstym) was used pre- and post-RF treatments to measure resting tone and maximal contraction strength (mV). This biofeedback system includes rectal and vaginal probes that stimulate muscles and nerves in the pelvic floor. UROstym was used as a muscle contraction measuring device in addition to biofeedback treatment device (see **video, Supplemental Digital Content 1**, which demonstrates the Votiva PFR with the use of UROstym electrostimulation unit. This video is available in the "Related Videos" section of the Full-Text article on PRSGlobalOpen.com or available at ***http://links.lww.com/PRSGO/B39***).

Video Graphic 1. See video, Supplemental Digital Content 1, which demonstrates the Votiva PFR with the use of UROstym electrostimulation unit. This video is available in the "Related Videos" section of the Full-Text article on PRSGlobalOpen.com or available at http://links.lww.com/PRSGO/B39.

Treatments began 6 weeks postpartum as all lacerations/episiotomy sites had healed and patients returned to baseline hormone levels and sexual activity. Measurements were done before the first and second RF treatments and 2 weeks thereafter. PSI data were obtained, which included verbal symptom–based questions and sexual function assessment. The score also included the clinician's ability to visualize a change in laxity. All patients received 3 UROstym measurements regardless of the number of RF treatments.

Data points collected included patient demographics (age, body mass index, race, medical history), number of pregnancies/vaginal deliveries, history of rectal tears, episiotomies, and vaginal laxity on examination by gynecologist (H.R.) (scale 0–4). The number of vaginal RF treatments and associated pre- and post-UROstym measurements were recorded in addition to detailed parameters of the RF treatment (intervals, duration, average internal/external time, and energy used). Any minor or major adverse events were recorded. Primary aims of the study were to identify safety, tolerability, and clinical efficacy of RF for PFR.

RESULTS

A total of 50 women were included in the study with an average age of 32 (29–40) years old, average of 2.6 pregnancies (STD = 1.2), and 1.8 vaginal deliveries (STD = 1.2). Two patients were excluded after the first treatment as they had been lost to follow-up. Postpartum genitorectal trauma in this cohort included 5/50 (10%) with episiotomies, 4/50 (8%) with vaginal tears, and no reported rectal tears. Three complete RF PFR treatments were performed in 31/50 patients, whereas 19 patients received 1–2 treatments. Average time between treatments was 1.6 weeks (STD = 0.8) and average time of internal treatment was 9.4 minutes (STD = 1.0). There were no reported adverse events from the RF treatment. Patients were followed for 1 year from initial treatment.

To assess the RF treatment effects on resting muscle potential (UROstym min) and maximal muscle contraction (UROstym max), analysis of variance (ANOVA) test was employed. All patients were measured 3 times using the UROstym, regardless of the number of RF treatments completed. This allowed for us to evaluate if those who did not engage in all 3 treatments would have different values across time compared with those who engaged in the complete program. For statistical evaluation, we divided the cohort in 2 groups: a first group who completed all 3 treatments (31/50) and a second group who completed 1–2 treatments (19/50).

We hypothesized that certain factors may influence the UROstym min and UROstym max recordings, such as patient age and number of pregnancies. Number of pregnancies was not normally distributed; thus, this factor was dichotomized, with 1–2 pregnancies (N = 29) and ≥3 pregnancies (N = 21). Initial UROstym min and max served as control variables in the analyses.

Impact of RF PFR on Resting Pelvic Muscle Tone (UROstym Min)

Focusing first on RF PFR on resting pelvic muscle tone (UROstym min), there seemed to be no statistically significant interaction effect of time to treatment (Wilks' lambda = 0.98, F (1, 45) = 0.86, P = 0.36) or control variables (age, number of pregnancies) (F (1, 45) = 0.63, P = 0.430). The interaction effect between time and number of treatments was also not significant (Wilks' lambda = 1.00, F (1, 45) = 0.40, P = 0.53). However, the time 1 control variable did exhibit a statistically significant main effect (F, (1, 45) = 35.75, P < 0.001), indicating that the time 1 value positively predicts subsequent values of UROstym min, which, intuitively, is not very meaningful. When analyzing the pairwise comparison between time 2 and time 3, there was no difference in mean values, indicating there was no effect of the treatment across time. The between-subjects interaction effect between time 1 and number of treatments was also not significant.

In other words, patients with lower resting pelvic muscle tone (UROstym min) at time 1 also had lower resting pelvic muscle tone (UROstym min) at time 2 and time 3. Thus, neither the passage of time nor the quantity of treatments seemed to impact the mean values of resting pelvic muscle tone (UROstym min) (Fig. 1).

Impact of RF PFR on Maximal Pelvic Muscle Contraction (UROstym Max)

Similarly, when analyzing maximal pelvic floor contraction (UROstym max), there was no significant effect of time of measurement (Wilks' lambda = 1.00, F (1, 45) = 0.12, P = 0.74), between-subjects effect (F (1, 45) = 3.12, P = 0.08) (though nearing significance), or control variables (age, pregnancies). Also, the interaction effect between time and number of treatments was not significant (Wilks' lambda = 1.00, F (1, 45) = 0.01, P = 0.95).

However, the time 1 control variable did exhibit a statistically significant main effect (F (1, 45) = 105.14, P < 0.001), indicating that the time 1 value positively predicted subsequent values of maximal pelvic muscle contraction (UROstym max). The subsequent comparison between time 2 and time 3 was also statistically significant, which is indicative of a main effect for the passage of time by itself. The between-subjects interaction effect between time 1 and number of treatments was not significant. In

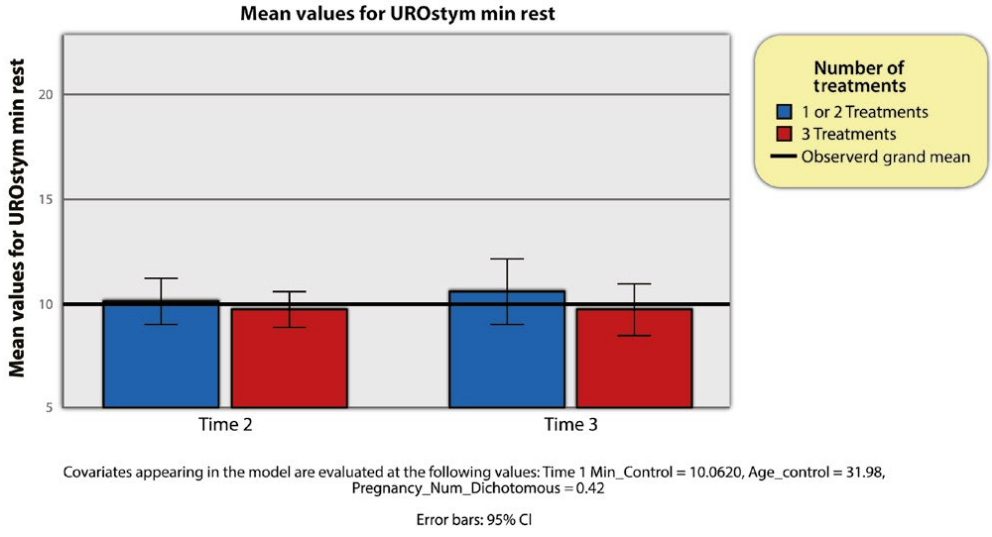

Fig. 1. UROstym min across time and by group.

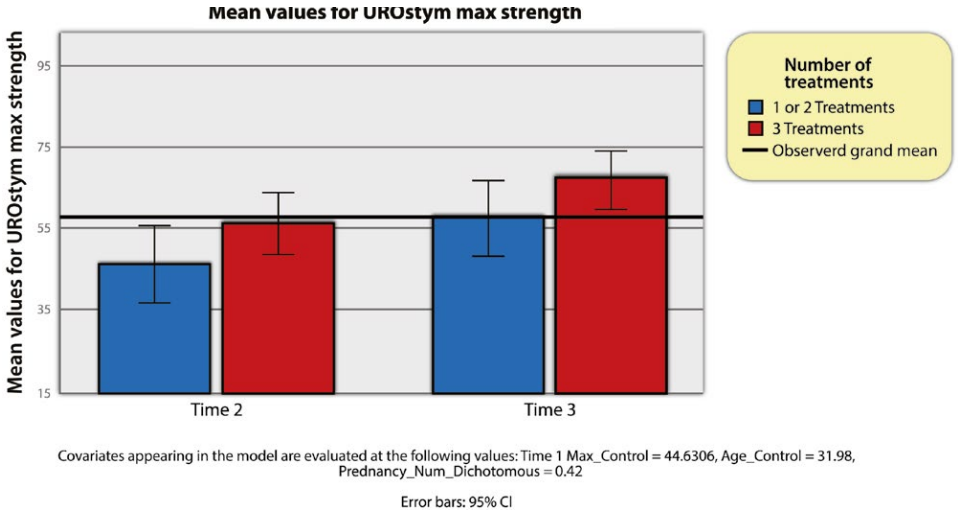

Fig. 2. UROstym max across time and by group.

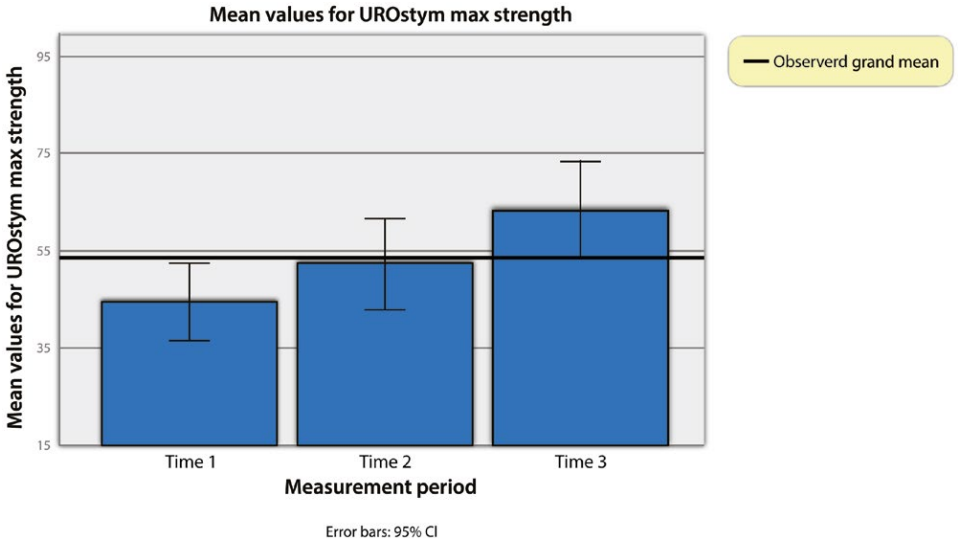

Fig. 3. Pairwise comparisons of UROstym max at different times.

other words, patients with higher UROstym max at time 1 will also have higher max at time 2 and time 3.

In sum, the quantity of treatments seemed to impact the mean values of UROstym max (Fig. 2). However, given a between-subjects main effect of time 1 on subsequent times, that the time 2 and 3 by time 1 interaction was nearing statistical significance, and that the sample size was relatively modest, more testing is warranted for this set of variables.

Based on the test results for UROstym max, it may be that too many independent /control variables are obscuring the relationship. Therefore, a simple repeated measures ANOVA with time 1, time 2, and time 3 values of UROstym max was computed. First, to ensure the assumption against sphericity was not violated, Mauchly's test of sphericity was computed (X^2 (2) = 4.01, P = 0.14). The ANOVA was found to be statistically significant (Wilks' lambda = 0.48, F (2, 49) = 24.89, P < 0.001, eta-squared = 0.34). According to the pairwise comparisons, all mean values differed from each other (μ Time 1 = 44.63, SD Time 1 = 3.92; μ Time 2 = 52.39, SD Time 2 = 4.66; μ Time 3 = 63.48, SD Time 3 = 5.03) (Fig. 3).

In summary, when excluding the between-subjects independent variable and the control variables, there is a clear and significant relationship between treatments and measurement of maximal pelvic floor contraction (UROstym max) across time. That is, after each treatment, UROstym max increased a statistically significant amount (Fig. 4).

The final element of this study was evaluation of the patient perception of improvement using a PSI with 5-level measure (0–4). The outcome of this test was more conclusive. A one-way ANOVA, with the dichotomous number of treatments variable serving as the independent factor and questionnaire score as the dependent variable, was conducted. Moreover, age and number of pregnancies served as control factors. The main effect of quantity of treatments was found to be statistically significant

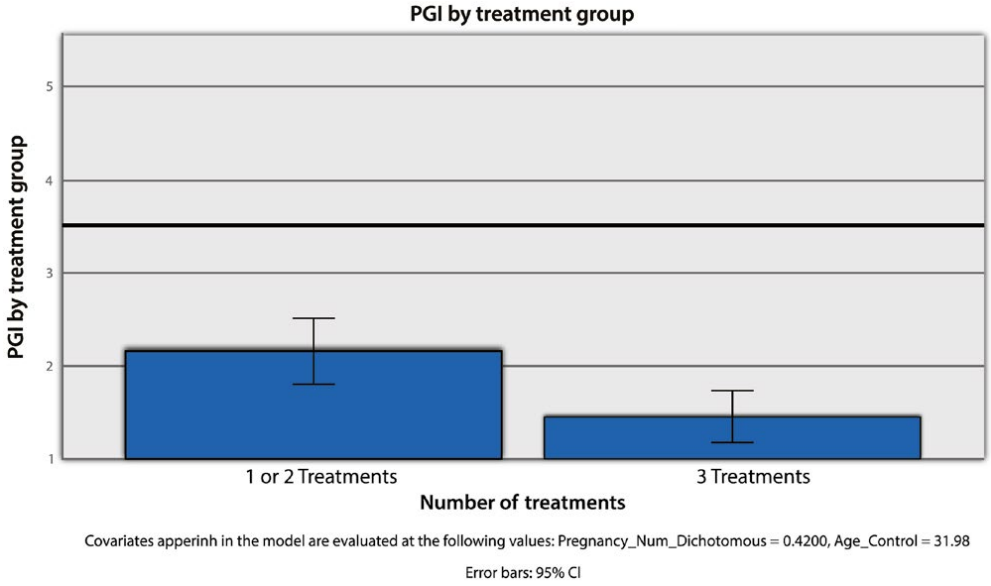

Fig. 4. UROstym max strength across time.

Pairwise comparisons of UROstym max strength at different times

Pairwise comparison	Mean difference	Std. Error with SE	Sig. with Significance	95% LLCI	95% ULCI
Time 1–Time 2	−7.76	2.93	.01	−13.65	−1.87
Time 1–Time 3	−18.85	2.80	< .001	−24.48	−13.22
Time 2–Time 3	−11.09	2.28	< .001	−15.68	−6.50

Fig. 5. PSI treatment group. LLCI indicates lower limit CI; ULCI, upper limit CI.

(F (1, 46) = 9.22, P = 0.004, eta-squared = 0.17). This indicated that those engaged in all 3 treatments exhibited values that were consistent with higher levels of progress including improved sexual function, lubrication, and decreased incontinence (μ = 1.45, SD = 0.68), whereas those who experienced fewer treatments exhibited values that were consistent with lower levels of progress (μ = 2.16, SD = 0.90). The effect size was large (Cohen's d = 0.89) (Fig. 5).

DISCUSSION

Animal models have been useful to understand histologic changes in nonsurgical PFR, yet there are limited clinical studies on RF treatments.[2,13] One major barrier to investigation is the lack of a standardized measuring device for pelvic floor muscle strength and vaginal introital laxity.[2] Several potential measuring devices have been used, including caliper measurement, balloon devices (such as barostat for measuring esophageal strictures), and comparative photographs—but all have been deemed inadequate or unreliable.[2,13] Of the clinical trials that exist, most focus on vulvovaginal rejuvenation with favorable outcomes, demonstrating improvements in vaginal laxity, lubrication, arousal, without significant adverse events (ulceration, necrosis, scarring) or pain.[2,13,18,20–24,26] Majority of patients report good tolerability of in-office procedures with a commonly reported feeling of warmth. There were no complications or adverse reactions. To our knowledge, no study has successfully used an objective measuring device to quantify pelvic floor function pre-and post-RF PFR treatment.

Our study findings significantly showed that RF improved maximal pelvic muscle contraction (UROstym max) measurements after the first treatment. Even when removing all control variables and only analyzing all 3 time points, the UROstym max increased at each time point. This indicates that UROstym max was positivity impacted by the RF treatment. Furthermore, this was the case for patients who only had 1–2 treatments. One possible explanation is that the first treatment was effective in starting a "tightening cascade" that made subsequent treatments less impactful. This may be explained by motor unit recruitment, which is a known phenomenon used to explain activation of additional motor units for increased contractile strength in a muscle.[29] Also, it is possible that the known tightening effect of RF energy restores the muscle length/tension relationship allowing for increased contractile efficacy as described in the Frank–Starling relationship. A similar phenomenon was shown subjectively

by Alinsod[25,28] who reported improvements in stress incontinence, atrophic vaginitis, and orgasmic dysfunction most profoundly after the first RF treatment, with some additional improvement noted after the second and third treatments. Millheiser et al.[23] similarly demonstrated greatest improvement within 1 month after RF treatment. This is also consistent with animal models that demonstrate stromal remodeling with fibroblast activation between 1 week and 1 month after treatment and variably increased muscularis collagen over 6-month posttreatment period. Future studies will clarify the impact of additional RF treatments beyond the initial one.

For pelvic floor resting potential (UROstym min), there seemed to be no change from time 2 to time 3 when controlling for time 1. Also, the number of RF treatments did not seem to impact resting potentials. However, this may be due to a relatively small sample size that was not sufficient to detect a change in this field. Subjectively, patients did report a decrease in resting muscle spasms which may indicate an improvement in resting muscle tone. Indeed, if the effect of UROstym min across time and groups is small, the sample size of the current study would be insufficient to detect the relationship. A post hoc power analysis was conducted, showing that a total sample size of 96 would be needed to detect a small effect—roughly double of what was used in the present study.

Finally, the PSI results indicated that patients who experienced all 3 RF treatments had significantly better assessments compared with those who only had 1 or 2 treatments. Patients stated that improvement was noticeable in areas of sexual function, lubrication, and urinary continence.

We identify a number of limitations inherent in the retrospective nature of this study, including the potential for data inaccuracies and confines in study design. It would have been beneficial to have a control or sham arm to account for the potential placebo effect and case randomization (ie, complete treatment versus 1 versus 2 treatments). This would have made a stronger case for causality, as comparing groups post hoc introduces experimental bias. Another weakness of this study was that only 31/50 patients completed all 3 RF treatments. Although this was not the intended nature of the study, it did allow for us to assess the impact of 1 or 2 treatments versus 3 treatments.

Despite the retrospective nature of this analysis, we were able to discern a number of significant findings as previously shown. Moreover, this study is the first to our knowledge that uses an objective measure to evaluate effectiveness of RF for PFR.

CONCLUSIONS

This study demonstrates the safety of using RF energy for PFR after vaginal delivery. Our data found no adverse events in 50 consecutive patients. A significant correlation was found between treatment and maximal contraction of pelvic floor muscles using the UROstym device. Furthermore, we suggest a "tightening cascade" phenomenon, where the impact of 1 treatment was all that needed to initiate patient improvement. Also, the PSI used correlated to subjective improvement with each treatment.

RF PFR may potentially fill a treatment gap of pelvic floor disorders. A powered prospective randomized double-blinded study is needed to further clarify the role of this technology.

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EMPOWER**RF**

THE NOVEL USE OF BIPOLAR RADIOFREQUENCY MICRONEEDLING IN THE TREATMENT OF LICHEN SCLEROSUS

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ABSTRACT

Introduction: Lichen sclerosus (LS) is a chronic, distressing, inflammatory process that has a huge impact on quality of life in women. Uncontrolled vulvar LS can lead to chronic symptoms of itching and pain and can lead to anatomic changes, scarring, and elevated risk of cancer. First-line therapy with corticosteroids is often not successful in controlling symptoms, especially over the long term. This is the first study to review the effects of bipolar radiofrequency (RF) with microneedling to treat the vaginal and vulvar symptoms of LS.

Materials and Methods: This retrospective study was initiated due to the recognition of improvement in vulvar skin condition and resolution of lichen sclerosus symptoms in patients who had already failed traditional treatment and underwent radio frequency with microneedling procedures of the vulva, perineum, and perianal regions. Patients were treated with three treatments of bipolar RF and bipolar RF with microneedling four to eight weeks apart. Patient questionnaires were used to assess improvement in the symptoms of LS including itching, tearing of tissue, changes in the appearance and color of tissue, and dryness of skin and mucosa.

Results: The data from the questionnaires showed a significant reduction or complete resolution in these symptoms, with 86% of the patients reporting either significant or complete resolution. In the case of itching, which is typically one of the most severe symptoms of LS, 91% of patients reported significant or complete resolution. 87% of patients reported symptom resolution lasting at least six months, with 39% of the patients having results lasting 12 months or more before recurrence. Recurrences can be retreated on an as-needed basis or with annual maintenance therapy consisting typically of just one treatment.

Conclusion: Radiofrequency with microneedling treatments for persistent LS showed significant improvement in LS symptoms. As LS is a chronic recurring condition, the treatment protocol resulted in high patient satisfaction for these women who had not experienced these results in terms of amount of symptom resolution or duration of symptom resolution with prior treatments using topical steroid cream or other modalities.

The Novel Use of Bipolar Radiofrequency Microneedling in the Treatment of Lichen Sclerosus
BLUSEWICZ/COLEY/MOORE/MIKLOS

INTRODUCTION

Lichen sclerosus (LS) is a common chronic progressive mucocutaneous, immune-mediated inflammatory disease which typically involves genital skin causing it to become thin, friable, and hypopigmented. In some cases, the skin becomes more mottled with thin, white areas interspersed with areas of erythema and edema from chronic scratching secondary to itching. The lesions are typically flat, ivory, or porcelain white spots which may coalesce into pale, crinkly, thin patches and plaques. The disease occurs at all ages and in both sexes, but is more common in females than males.[1] LS most often affects the skin and mucosa of the vulva and perianal region, and is estimated to occur in 1 in 70 women.[2] However, LS is often overlooked, underdiagnosed, or misdiagnosed, so the actual incidence is likely even higher. Regardless of its exact incidence, vulvar LS is one of the most common referrals for vulvar distress and/or structural changes.[1,3]

The entire vulva may be involved with possible extension to perineum and perianus, giving rise to the characteristic "figure of eight shape."[1] Symptoms are marked by intense itching, pain, and skin tearing. These symptoms are usually cyclical and occur in flares; however, lichen sclerosus can range from being asymptomatic to always present.[4] The exact etiology and pathogenesis of lichen sclerosus are not fully understood. There is a genetic and familial predisposition in LS, and frequent trauma, hormonal status, and certain drugs can also play a role.[5] There is a well-known historically bimodal presentation of vulvar LS with a first peak in pre-pubertal girls (average: 7.6 years) and a second one during peri- and postmenopause (average: 52.6 years), which is linked to a low estrogen status.[5,6] LS is typically diagnosed clinically by the combination of the classic appearance of the skin on the vulva and the patient's symptoms; however, biopsy can be used to confirm the diagnosis and rule out other causes such as malignancy or vulvar intraepithelial neoplasia. Four to six percent of women with LS will develop vulvar carcinoma.[2]

Traditionally, the treatment for symptomatic lichen sclerosus is the application of clobetasol propionate, a high-dose topical steroid cream or ointment, applied once or twice daily for up to three months or until symptom resolution.[4] After initial treatment, the patient will most often have to continue the use of the topical steroids on an as-needed basis whenever the condition flares again. For some women, this is a never-ending cycle that seems to be more present than not. In many patients, the symptoms of LS are not controlled or they become refractory to corticosteroid therapy. LS can have a huge effect on a woman's quality of life (QOL) as the chronic itching can be unrelenting and usually worsens at night which disturbs sleep. LS can cause skin breakdown from chronic excoriations, forming non-healing grooves in the skin. LS can also cause the clitoris and labia to become scarred and fused, the hood can become buried and flattened, unable to be differentiated from the labia. The vaginal introitus may also become narrowed from scarring. All of this affects intimacy as the thinned skin tears, causing fissures on the clitoral hood, labia, and perineum during intercourse. This leads to pain, bleeding, and scarring all resulting in sexual dysfunction.[7]

Prior studies have looked at alternative therapies to topical steroid treatment including: other topical agents such as calcineurin inhibitors and topical retinoids, platelet rich plasma (PRP), phototherapy, high-intensity focused ultrasound (HIFU), and fractional CO2 laser (FxCO2), all with various levels of improvement, but none have stood out as an ideal second-line treatment for vulvar LS that is recurrent or refractory to corticosteroids.[1,8,9]

MATERIALS AND METHODS

We conducted a retrospective study at a single site. All procedures were performed by one of two board-certified gynecologists.

Thirty-three female patients between the ages of 40 and 80 with symptoms and diagnosis of lichen sclerosus that were non-resolving with the traditional treatment of clobetasol propionate were treated with FormaV™ and Morpheus8V™ on the EmpowerRF™ platform (InMode Aesthetics, Lake Forest, California). The patients were from a single gynecology practice. The diagnosis of lichen sclerosus was made by either vulvar biopsy or clinical presentation and symptoms. The patients had made the decision to opt for further treatments due to the non-resolution of their LS symptoms. Any treatments, such as estrogen cream or clobetasol ointment were discontinued prior to treatment and for the duration of the study. The study treatment used was the combination of the EmpowerRF™ modalities: FormaV™ and Morpheus8V™ (Fig. 1a and b). FormaV™ is a bipolar radiofrequency device that provides dermal and subdermal heating. RF has been shown to produce new collagen, elastin, and blood vessel formation as skin surface temperatures reach 40–45°C [10] Morpheus8V™ is a microneedling fractional device with programmable penetration depth and energy delivery. The coated needles penetrate into the sub-dermal tissue (adjustable to 1, 2, and 3mm depths), coagulating fat and contracting connective tissue. Simultaneously, directional RF

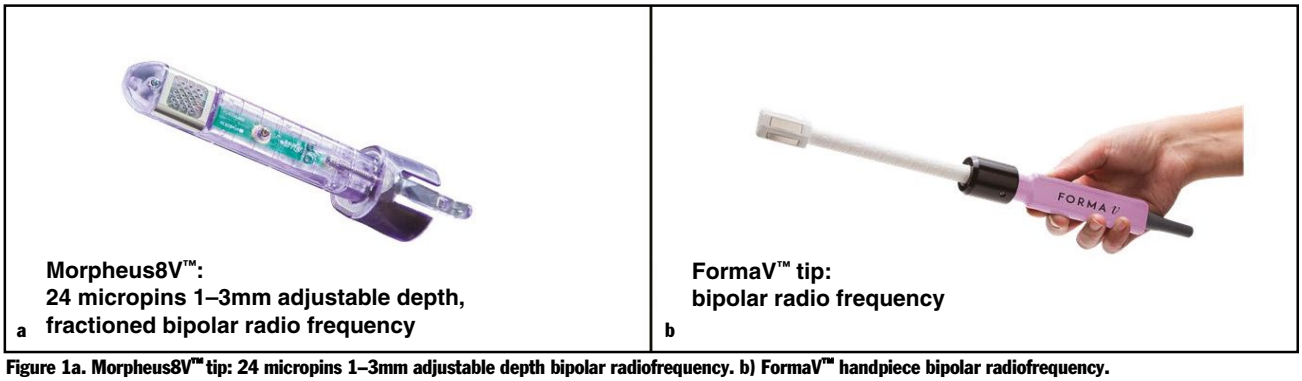


Figure 1a. Morpheus8V™ tip: 24 micropins 1–3mm adjustable depth bipolar radiofrequency. b) FormaV™ handpiece bipolar radiofrequency.

energy generates bulk sub-necrotic heat in the dermis. This directional RF energy stimulates neocollagenesis, elastogenesis, and angiogenesis.[10] Questionnaires were given to the women pre- and post treatments to evaluate the improvement in lichen sclerosus symptoms, including tearing and thinning of the vulvar and perianal skin, itching, pain, dyspareunia, vaginal infection frequency, urinary tract infection (UTI) frequency, and decreased sensation. Health intake summaries were performed and patients were excluded if they had the presence of a pacemaker, internal defibrillator, or other active electrical implant in the body. Patients were also excluded from treatment if they were pregnant or had a current vulvar or perianal cancer.

The patients underwent a series of treatments, with the initial protocol consisting of three treatments spaced four to eight weeks apart. Maintenance treatments were then performed annually or at the return of symptoms.

The patients were pretreated with Lidocaine 23% – Tetracaine 7% for 20 minutes prior to the start of the procedure. The treatment protocol was then started with a 10-minute application of the FormaV™ bipolar RF handpiece to the vaginal canal, introitus, labia majora, labia minora, clitoris, perineum, and peri-anal region. The FormaV™ handpiece was applied over all the regions of the vulva and vagina affected by lichen sclerosus, adequately heating the tissue to the optimal temperature of 42 to 43°C. The power setting was set at 35 watts. Directly after the FormaV™ treatment was completed, the Morpheus8V™ treatment was initiated. The Morpheus8V™ device was used in a stamping method to cover the entire length of the vagina internally in a 360° fashion with a 50% overlap. Two passes of single pulses were used at a depth of 3mm, 2mm, and 1mm, respectively.

Following internal vaginal treatment, the Morpheus 8V™ was then used externally in the same stamping method of 50% overlap to cover the entire vulvar and peri-anal area, again with two passes at each depth with a 50% overlap ensuring treatment of all areas affected by LS.

RESULTS

Data was collected from the patient questionnaires, pre- and post-procedure physical examinations and follow-up examinations (Figs. 2a–d). This data was

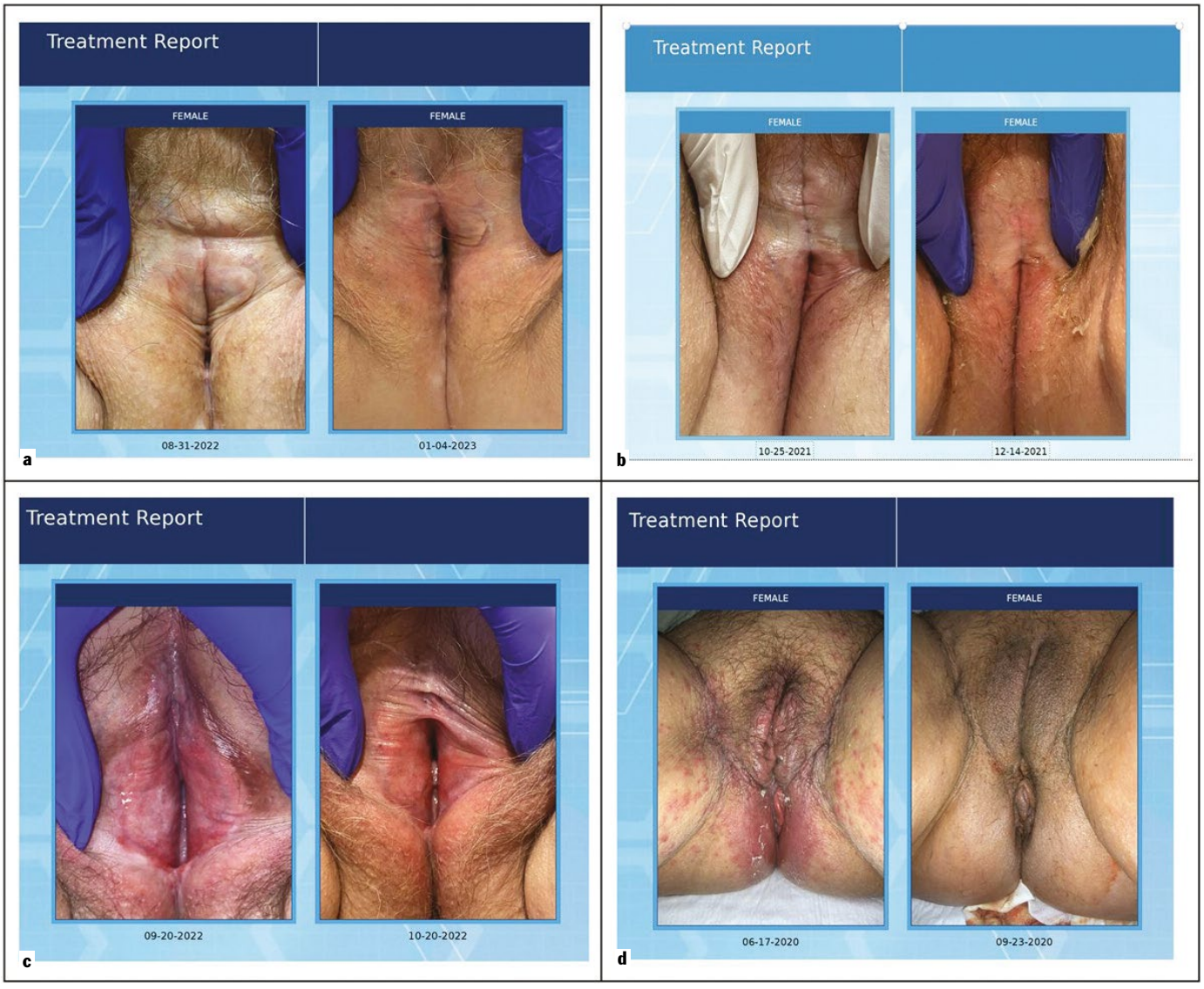
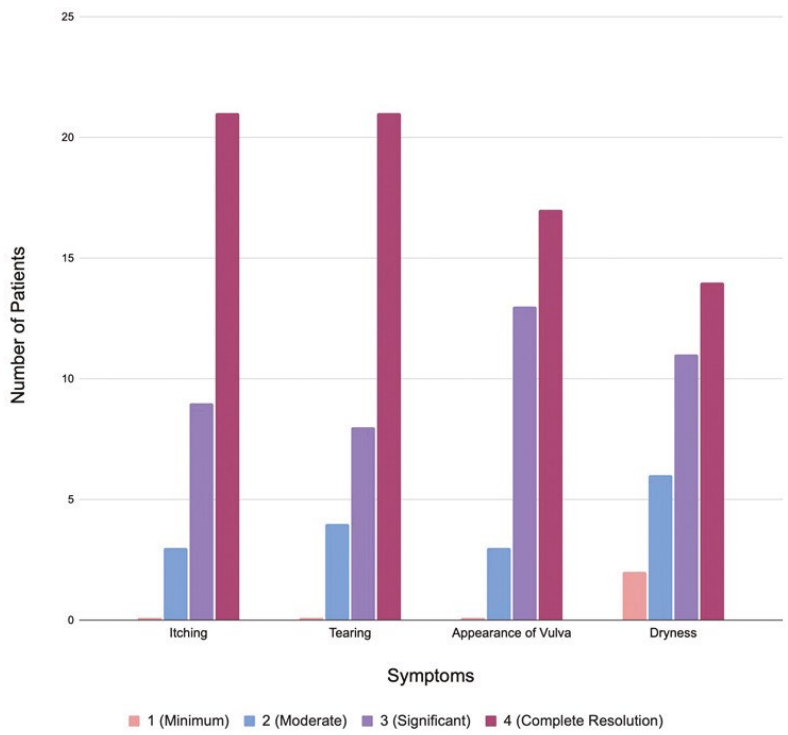


Figure 2a. Before treatment and six months post treatment. b) Before treatment and two months post treatment. c) Before treatment and one month post treatment. d) Before treatment and three months post treatment.

Table I
Lichen sclerosus symptoms



Itching Minimal Reduction (1): 0% Moderate Reduction (2): 9.09% Significant Reduction (3): 27.27% Complete Resolution (4): 63.64%	**Appearance of Vulva** Minimal Reduction (1): 0% Moderate Reduction (2): 9.09% Significant Reduction (3): 39.39% Complete Resolution (4): 51.52%	**Overall Results** Total Minimal (1): 1.5% Total Moderate (2): 12% Total Significant (3): 31% Total Complete Resolution (4): 55%
Tearing Minimal Reduction (1): 0% Moderate Reduction (2): 12.12% Significant Reduction (3): 24.24% Complete Resolution (4): 63.64%	**Dryness** Minimal Reduction(1): 6.06% Moderate Reduction(2): 18.18% Significant Reduction(3): 33.33% Complete Resolution (4): 42.43%	**86%** **of patients had either significant reduction of symptoms or complete resolution of symptoms**

used to calculate percentages (Tables I and II). Patients' responses about the reduction or resolution of LS symptoms for the vulvar, perianal region, and the vaginal canal were recorded and graphed. The most common symptoms of itching, tearing of tissue, changes in the appearance and color of tissue, and dryness of skin and tissue were recorded and compared. Scores of 1 through 4 were used to measure the response of the LS symptoms to the FormaV™ Morpheus8V™ treatment: a score of 1 representing minimal reduction of symptoms (25% improvement), a score of 2 for moderate reduction of symptoms (50% improvement), a score of 3 for significant resolution of symptoms (75% improvement), and a score of 4 for complete resolution of the symptoms.

The length of time between resolution of symptoms and the recurrence of the symptoms was also recorded and grouped in three-month increments with three to six months being the least amount of time for the duration of symptom resolution and over 12 months being the longest.

DISCUSSION

Management of vulvar LS can be very difficult and challenging. Most women get very frustrated with recurrences or lack of improvement of symptoms with traditional treatments such as estrogen or clobetasol cream. Multiple facets of the disease must be managed by the patient including symptoms, concerns of developing vulvar carcinoma, sexual dysfunction, and the associated psycho-social aspects of the disease. While standard treatment of topical corticosteroids is successful in many VLS cases, especially in those diagnosed early, there is a large subset of patients with persistent symptoms of the disease.[11,12]

Studies in the past have shown some success utilizing a CO2 laser to treat vulvar LS. Early studies showed some success; however, there were treatment complications and prolonged healing of several weeks.[11] More recent studies have shown positive outcomes in achieving remission with fractional CO2 lasers; however, maintenance was required with continued treatment of topical steroids.[10] Postoperative pain was a common report in most studies.[1] Some authors thus have concluded that CO2 lasers are not effective enough as monotherapy for vulvar LS and it should only be performed as adjuvant therapy in addition to topical steroids.[5]

Microablative fractional radiofrequency (MFR) was studied as a therapeutic option for vulvar LS. The depth of the needles are only 0.8mm and do not penetrate the skin, but they do produce microablation at 1mm intervals. The needles gently touch the tissue, without penetrating it, to transmit electromagnetic current. Twenty-six patients were studied in this pilot study with 40% of patients reporting complete remission of symptoms. After two to three treatment sessions of MFR, most participants reported an improvement of symptoms for about 11 months (range: 7–16 months) after the treatment. At histologic evaluation, type III collagen concentration significantly increased and was associated with symptom improvement. MFR has also been shown to be effective in treating genitourinary symptoms of menopause and vaginal atrophy in several studies.[13]

The current study was the first study to evaluate the use of a combination of bipolar RF (FormaV™) and RF with true microneedling at a treatment depths of 1, 2, and 3mm (Morpheus8V™) in the treatment of persistent vulvar LS. Morpheus8V™ delivers fractional radiofrequency energy through bipolar arrays of micropin electrodes providing intravaginal and vulvar submucosal remodeling.

The handpiece has 24 gold-coated micropins, each pin is 300 micrometers in diameter with an insulated 0.5mm conductive tip with adjustable treatment depth. In contrast to lasers and microablative RF, where the thermal effect is limited by the ablation crater, the RF energy flows through the whole dermis, adding volumetric heating to fractional treatment. This ultimately delivers the energy deeper into the tissues, resulting in improved treatment zones.[13] Most microneedling devices that utilize RF have delivered the energy between the needle tips alone; however, in the InMode Morpheus8™ line, the RF energy is applied between the needle and the external electrode applied to the skin surface. Each needle has a strong thermal effect, resulting in a larger and deeper treatment zone.

Results demonstrated a significant improvement of LS symptoms with the use of a combination therapy utilizing bipolar RF (FormaV™) and RF with microneedling (Morpheus8V™) therapy, with 55% of patients having complete resolution of their vulvar LS symptoms. The patients received three treatment sessions, four to eight weeks apart, that were well-tolerated. The data from the questionnaires showed a significant reduction or complete resolution in the symptoms of itching, tearing, and dryness of the tissue, with 86% of the patients reporting either significant or complete resolution of the most common LS symptoms. In the case of itching, which is typically one of the most severe symptoms of LS, 91% of patients reported significant or complete resolution. This resulted in a high patient satisfaction for the treatment.

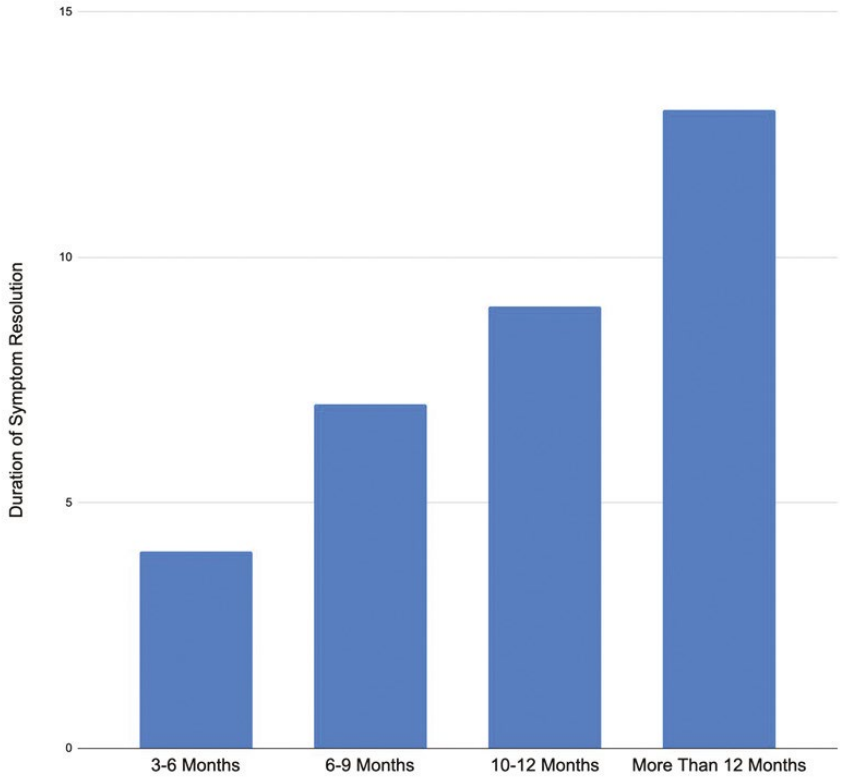
Visual inspection of the appearance of the tissue by the treating physicians also showed significant improvement with the return of color in the hypopigmented areas and the resolution of erythema and excoriations. 87% of patients reported significantly less tearing of tissue or the complete resolution of tearing, and 90% of patients reported significant or complete improvement in the overall appearance of the vulvar tissue. The resolution of clitoral adhesions and chronic inflammation can improve the patient's perception of her genitals and self-esteem. Also, improving the scarring and tears decreases dyspareunia, resulting in improved sexual function and intimacy. In a study of the histologic effects of a monopolar RF device alone on the vulvar and vaginal tissues showed 80% of the vulvar samples and 100% of the vaginal samples demonstrated thickened mucosa and neovascularization. Neocollagenesis was noted on all post-treatment vulvar and vaginal samples,[14] which ultimately leads to healthier, stronger tissue.

Dryness of the tissue also improved in the current study, with 75% of patients reporting significant reduction or complete resolution of this symptom. Though this percentage improvement is less than the improvement in the other common symptoms, it is still markedly improved from the traditional treatments for LS. Previously, non-ablative RF therapy has been shown to be effective in treating genitourinary symptoms of menopause (GSM), including dryness.[14]

The duration of resolution of the LS symptoms in the current study lasted at least six months, with the majority of the patients having results that lasted over 12 months. 87% of patients reported relief of symptoms lasting six months or more before recurrence. Historically, these patients just require one booster treatment of FormaV™ Morpheus8V™ to resolve any recurrent symptoms they may have.

One limitation of our study was that it is retrospective and limited by size.

Table II
Duration of symptom resolution



Percentage of patients with length of time for resolution of symptoms

3–6 months resolution 12%

6–9 months resolution 21%

10–12 months resolution 27%

Longer than 12 months 39%

87% **of patients with longer than 6 months of resolution of symptoms**

However, a strength was that our sample showed a wide range of women affected by lichen sclerosus with the ages ranging from 40 to 80 years old, the average age being 69.3 years.

Another limitation of our study was that the patients were not separated by the initial severity of the LS symptoms. However, all of the patients were in the moderate-to-severe range for symptoms since they had already failed traditional LS treatment. Thirty out of 33 patients were already using Estradiol cream and Clobetasol cream without significant response, leading to them seeking out further treatments.

The last limitation of our study was that post-treatment care was not standardized, with a variety of topical post-procedure creams for healing used in different patients (non-medical). In a prospective study, a standardized post-procedure treatment protocol could be utilized. Additionally, regenerative therapies, such as PRP, may have a role in adjuvant therapy with Morpheus8V™ in the future. Early studies have shown PRP to improve QOL and objective parameters in vulvar LS.[5,15]

CONCLUSION

This is the first study to report on the use of bipolar RF and RF with microneedling for the treatment of lichen sclerosus occurring on the vulva and vaginal canal. Preliminary data indicates that EmpowerRF™ treatment combination with FormaV™ and Morpheus8V™ resulted in significant improvement in the most common symptoms of lichen sclerosus in patients that were not being controlled with traditional treatment of topical steroid cream. In our clinical population, we observed improvement in LS symptoms compared to other treatments that we had been using in the past such as PRP, HIFU, and FxCO2.

In our clinical practice, we have seen overwhelmingly positive results using radiofrequency with microneedling for treatment of chronic lichen sclerosus that has been resistant to or suboptimally treated with topical steroid cream. Our retrospective collection of data shows the combination of FormaV™ and Morpheus8V™ treatments for LS had a high patient satisfaction and improvement in quality of life. Our patients experienced better symptom resolution and longer duration of symptom resolution with radiofrequency treatment over topical steroid cream that they had used in the past. The majority of our patients wanted to continue receiving treatments due to the benefits they gained and opted to receive annual maintenance treatment or treatment on first signs of recurrence. FormaV™ and Morpheus8V™ treatment for LS shows promise to become a significant option for the many women who suffer daily with lichens sclerosus. We feel that with a prospective study and a larger sample size we can show clinically significant results of treatment of lichen sclerosus with FormaV™ and Morpheus8V™. STI

AUTHORS' DISCLOSURES

Dr. Blusewicz is a stockholder, speaker, and consultant for InMode Aesthetics, California. Dr. Miklos and Dr. Moore are stockholders, consultants, speakers, and receive research grants from InMode Aesthetics, California. Dr. Coley has no conflicts of interest to disclose.

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TRANSVAGINAL RADIOFREQUENCY ENERGY FOR THE TREATMENT OF URINARY STRESS INCONTINENCE: A COMPARISON OF MONOPOLAR AND BIPOLAR TECHNOLOGIES IN BOTH PRE AND POST MENOPAUSAL PATIENTS

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Abstract

Aim: A study to compare the effect of two different radio frequency energy models (mono polar and bipolar) for the treatment of urinary stress incontinence.

Methods: Retrospective chart review, which was conducted at 2 sites, 69 patients received treatment with a bipolar radiofrequency device. Out of those 69 patients, 13 patients received bipolar in conjugation with CO_2 laser treatment, while 32 patients received monopolar frequency. The study protocol normally consists of three sessions of treatment. Each session was four weeks apart with a whole 6-month duration follow-up. Results were evaluated by urogenital distress inventory (UDI)-6 questionnaire before and after treatment.

Results: The bipolar group improved UDI-6 scores across time more so than did the monopolar group with some evidence suggesting that the bipolar radiofrequency treatment was more effective compared to the monopolar radiofrequency. Three months after treatment, the bipolar group UDI-6 values were lower than those of the monopolar group. Six months after treatment, the UDI-6 scores increased in both groups, suggesting decrease efficacy with time however, the bipolar group's UDI-6 scores were consistently lower than the monopolar group's scores.

Conclusion: This study shows benefit of both monopolar and bipolar radiofrequency device in patients with stress urinary incontinence and mixed UI, with bipolar RF more efficacious than monopolar RF. More randomized prospective studies are needed to confirm these findings.

KEYWORDS
radiofrequency, stress incontinence

1 | INTRODUCTION

It is well known that the etiology of stress urinary incontinence (SUI) is multifactorial. Weak support of the anterior vaginal wall and a weak sphincter muscle which can no longer maintain a water tight seal as well as decrease collagen in urethral walls have all be cited as contributing factors.[1–3]

The impact of SUI on women's life quality regarding everyday activities is significant. Incontinence also has a great psychological impact on women causing social isolation, obesity, and depression.[4] Women reporting UI also complain of sexual dysfunctions in a significantly higher number than women with no incontinence[5]

Over the past decades there has been an evolution in the treatment of SUI with emphasis on more conservative office-based treatment. Conservative treatment have historically included education, behavior modification and pessary[6] and physical therapy.[7] Most of these treatment are temporary and may not improve symptoms in some patients.[8] Bulking agent have been used with some success compared to more conservative therapy,[9] but commonly lack long term durability thus requiring repeated injections.[10] Synthetic mid urethral slings remain the most efficacious treatment of SUI,[11] however perceived complications rate and adverse events makes this options less appealing for many women.[12]

The recent ban of mesh in UK, New Zealand, and Australia[13–15] and the negative image that patient have on mesh promotes continued efforts to identify alternative options for treating SUI.

Less invasive and office-based treatments are becoming more popular due to safety and minimal invasiveness. These include office-based procedures with energy sources, such as laser[16,17] and radiofrequency (RF) devices.[18] Radiofrequency energy is known to improve healing of tissue by neo callogenesis through activation of fibroblasts and retraction of existing collagen.[19]

Radiofrequency energy can be delivered by either a monopolar or a bipolar platform. In monopolar the energy passes from the active electrode through a handpiece managed by the operator to the body and exits through a grounding pad (passive electrode). The advantage of monopolar RF is the ability to concentrate energy in a small area, cutting tissue with small coagulation zone and simplicity of a hand piece. In a bipolar design both electrodes are applied to the treated tissue. It limits its ability to concentrate the RF energy but allows utilization of all the RF energy for tissue heating. This method is more effective when volume heating is required. Bipolar technology has more versatility to control RF penetration and depth which is a function of the distance between the two electrodes. It also allows for more uniform energy deposition into the tissue and more accurate control of tissue heating and better control of penetration depth.[18]

Since the early 2000s, RF energy has been delivered by a variety of methods to the vagina, urethra, and periurethral tissue to address genitourinary complaints. More recently multiple RF delivery systems have been advocated to treat stress incontinence with very minimal outcome data to date.[20–23] To date there are no studies that compares the clinical outcomes of patients treated with monopolar versus bipolar radiofrequency devices. Also fractional CO_2 laser therapy of the vaginal canal has been shown to be effective for genitourinary syndrome of medicine, but is also advocated by some clinicians as a treatment for urinary incontinence. No previous study has looked at the input of combined CO_2 laser treatment in conjugation with RF treatment.

The objective of this study was to retrospectively compare outcomes of a monopolar RF platform to bipolar RF platform in women with stress and mixed urinary incontinence with or without genitourinary syndrome of medicine and to determine whether RF therapy can improve urinary function in women who have been treated with a fractional CO_2 laser for genitourinary syndrome of medicine.

2 | MATERIALS AND METHODS

This was a IRB approved retrospective chart review which was conducted at two sites. Between January 2017 to December 2019 all women who opted for conservative treatment of their stress or mixed urinary incontinence with a radiofrequency device were reviewed. All procedures were performed by the respective investigator at each site.

The inclusion criteria required females to be 18 years or older with a main complaint of SUI, which was demonstrated using a cough test. Patients with stress predominant mixed urinary incontinence were also included in the study. Exclusion criteria included pregnant women, breastfeeding women, patients with pelvic prolapse greater than stage II, patients with a history of previous surgery for SUI, patients with neurological disease affecting the bladder, and patients with previous history of having radiofrequency treatment for SUI.

Patients were categorized according to the type of radiofrequency energy received. Patients received either mono polar or bipolar radiofrequency treatment according to what device was available during that period in which patients presented with the symptoms. One hundred and one patients were eligible for enrollment in this study. Sixty-nine patients received treatment with a

TABLE 1 Showing device description of different radiofrequency devices used

Device	Votiva FormaV by Inmode	TermiVA by TermiGen	Tempsure Vitalia by Cynosure
Technology	Bi-polar RF	Monopolar RF	Monopolar RF
RF frequency	1 MHz	460 kHz	4 MHz
Maximal RF power	65 W	50 W	300 W
Temperature control	RF power is adjusted to maintain required temperature	RF power is adjusted to maintain required temperature	RF power is adjusted to maintain required temperature
Impedance monitoring	Yes	Yes	Yes

Abbreviation: RF, radiofrequency.

bipolar radiofrequency device. Out of those 69 patients, thirteen patients received bipolar in conjugation with CO_2 laser treatment at the same session to address genitourinary syndrome of menopause, while 32 patients received monopolar. Each center had different monopolar radiofrequency device, so two devices were tested in this study.

Three different radiofrequency platforms were used in the two sites, this included Votiva FormaV (InMode), ThermiVA (ThermiAesthetics), and Tempsure Vitalia (Cynosure). Table 1 shows the different devices used during the procedures.

2.1 | Procedure description

The therapy consisted of three treatment sessions approximately 4 weeks apart. A standardized technique was utilized in which the intravaginal tip was applied to the mucosal surface of the vaginal introitus and the entire anterior vaginal wall. The tip of the introducer was moved back and forth remaining in direct contact with the tissue for a period of 7–10 min at a temperature of 43°C.

The main goal of this study was to determine if there was a meaningful difference in urogenital distress inventory (UDI)-6 scores with the bipolar versus monopolar treatment from baseline to three months after treatment and baseline to 6 months after treatment. Two sets of between- and within-subjects analysis of variance (ANOVA) tests were computed, the first being for the baseline to 3-month mark, and the second being for the baseline to 6-month mark. Also referred to as a mixed model ANOVA, this procedure allows researchers the ability to determine if there is a difference between group (in this case, the bipolar and monopolar treatments) and a difference by time (also in this case, the baseline to the 3- and 6-month mark, respectively). Finally, a third ANOVA was conducted that included the three time points in one model. Given the paucity of patients who made it to the 6-month appointment compared to those who made it to the 3-month appointment, it was deemed important to run the two tests to maximize use of the sample size at the various time points as well as the third test inclusive of the patients who made it through the three time points.

2.2 | Assessment of response

One of the most widely used symptom questionaries in the study of pelvic floor disordered is the UDI. The UDI contain 19 questions about lower urinary tract symptoms separated into three scales: irritative symptoms, obstructive/discomfort symptoms and stress symptoms. Respondents are asked if they have a particular symptom and if they do, to assess the degrees it bothers them on a four-point scale from “not at all” to “greatly.” A shortened version of the UDI is the UDI-6, a six-question instrument that correlates well with the longer version. UDI-6 was used as a standardized objective method for assessment of progress regarding both the stress and urge components of leakage. The UDI-6 was administered at the screening visit and after each visit for up to 6 months. Adverse events and concomitant medications were collected at each of the follow-up visits.

Review of the chart reveals 13 patients who were previously treated with CO_2 laser for genitourinary syndrome of menopause and later got treated with bipolar radiofrequency for stress and mixed incontinence. UDI-6 questionnaire was also used with these patients as an assessment of progress to standardize the outcome across all patients. There were no patients receiving CO_2 laser treatment simultaneous with radiofrequency energy.

3 | RESULTS

There was no difference between patients in both groups in terms of age, body mass index, and type of incontinence (Table 2).

TABLE 2 Demographics of the patient

	Bipolar		**Monopolar**		**BP/CO_2**	
	Number of patients (mean)	***SD***	**Number of patients (mean)**	***SD***	**Number of patients (mean)**	***SD***
Age groups, years						
35–39	_	_	1	_	_	_
40–44	_	_	2 (43.5)	0.7	_	_
45–49	3 (47)	2.8	_	_	_	_
50–54	5 (51.6)	1.8	3 (51.6)	2	3 (51)	1.7
55–59	6 (57.3)	1.8	4 (56.5)	2	1	_
60–64	9 (62.4)	1.5	6 (62)	1.6	_	_
65–69	12 (66.9)	1.4	2 (67)	2.8	3 (67.3)	2
70–74	6 (70.5)	0.5	9 (71.8)	1.3	2 (72)	1.4
>75	15 (78.6)	3.9	5 (79)	4.5	4 (77.5)	2
	Mean	*SD*	Mean	*SD*	Mean	*SD*
BMI	28.9	5.62	29.26	6.34	28.39	4.05
BMI categories	*n*	%	*n*	%	*n*	%
BMI < 20	–	–	1	3.1	–	–
BMI < 20–24	8	14.3	5	15.6	3	23.1
BMI < 25–29	29	51.8	10	31.3	3	23.1
BMI ≥ 30	19	33.9	16	50	7	53.8
Incontinence	*n*	%	*n*	%	*n*	%
MUI	36	64.3	21	65.6	9	69.2
SUI	3	5.4	2	6.3	0	0
SUI/MUI	5	8.9	1	3.1	1	7.7
UUI	5	8.9	1	3.1	0	0
UUI/MUI	7	12.5	7	21.9	3	23.1

Abbreviations: BP, bipolar; BMI, body mass index; MUI, mixed urinary incontinence; SUI, stress urinary incontinence; UUI, urge urinary incontinence.

The first test (baseline to 3 months) included 66 bipolar patients and 32 monopolar patients. The effect of time was significant (F [1, 96] = 175.53, $p < 0.001$], while the treatment was not (F [1, 96] = 0.03, $p = 0.88$). There was no interaction effect. The second test (baseline to 6 months) included 26 bipolar patients and 30 monopolar patients. Again, the effect of time was significant (F [1, 54] = 105.55, $p < 0.001$), while the treatment was not (F [1, 54] = 0.061 $p = 0.44$). There was no interaction effect. Interestingly, the model that was inclusive of the three time points tells a more nuanced story. As in the 6-month model, there were 26 bipolar patients and 30 monopolar patients. Once again, the effect of time was significant (F [2, 108] = 116.26, $p < 0.001$), and the effect of treatment was approaching statistical significance (F [1, 54] = 2.12 $p = 0.15$); the interaction effect was also approaching marginal significant (F [2, 108] = 2.18, $p = 2.13$). This indicates that there is a subtle effect of the two treatment types at various time points. Consulting the pairwise comparisons of means display what is actually occurring. Both groups UDI scores drop significantly from baseline to three months; however, the bipolar group drops more dramatically compared to the monopolar group (F [1, 54] = 3.12, $p = 0.08$). Then, both groups slightly raise from three months to 6 months; while the interaction difference from baseline to 6 months for the two groups isn't marginally statistically significant anymore, the trend still remains

TABLE 3 UDI-6 score in MP and BP before treatment, 3- and 6-month after treatment

Method		Mean	Std. Deviation	*N*
UDI-6 before treatment	BP	42.13	11.01	26
	MP	42.35	14.10	30
	Total	42.25	12.65	56
UDI-6 after treatment 3 months	BP	15.85	7.48	26
	MP	22.75	13.09	30
	Total	19.54	11.31	56
UDI-6 after treatment 6 months	BP	20.66	9.24	26
	MP	24.57	13.17	30
	Total	22.75	11.58	56

Abbreviations: BP, bipolar; MP, monopolar; UDI, urogenital distress inventory.

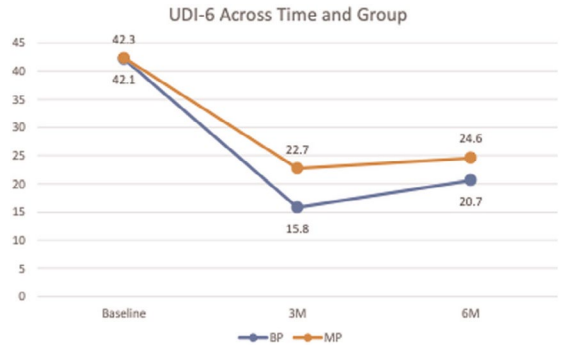

FIGURE 1 UDI-6 score in monopolar and bipolar before treatment, 3- and 6-month after treatment. UDI, urogenital distress inventory

(F [1, 54] = 0.93, $p = 0.34$]. Regardless, both groups still improved from baseline to 6-month follow-up. This lack of statistical significance from baseline to 6-month follow-up is likely a result of the insufficient sample size by which is needed to achieve sufficient power for determining interaction differences. Thus, the bipolar group improved UDI-6 scores across time more so than did the monopolar group, especially at the three-month mark, at least when considering patients who had complete baseline, 3- and 6-month records. The following table and graph display where these differences lie (Table 3) (Figure 1).

There were two secondary aims of this study. The first was to determine if incontinence type. Extrapolating from initial UDI-6 questionnaires, women were categorized into predominant SUI, urge urinary incontinence (UUI), or mixed urinary incontinence (MUI). An analysis was then performed to determine if any of the treatment regimes had an effect on UDI-6 over time. The same set of three tests were conducted. Given this was a secondary outcome of this study, the ANOVA test results will only be reported for the full model (inclusive of all three time points). In this test, there was a main effect of time (F [2, 106] = 65.33, $p < 0.001$) and a main effect for incontinence group (F [2, 53] = 5.28, $p < 0.01$). This indicates that while there are differences by incontinence group and by time, those two factors do not interact (F [4, 106] = 0.59, $p = 0.67$). In other words, all three incontinence groups decrease in UDI-6 values at the same relative magnitude across time, though the incontinence groups differ from one another. Considering the pairwise comparisons, only the MUI group differed statistically from the SUI group. That is, at the three time points, the MUI group was statistically higher than the SUI group in UDI-6 values. The following table displays the means, standard deviations, and sample sizes of the three incontinence groups across time (Table 4).

The final secondary goal of this study was to determine whether having previous exposure to fractional CO_2 of the vaginal canal had an effect on UDI-6 scores across time. The same set of three tests were conducted. Given this was also a secondary outcome of this study and that the story told by all three tests was the same, the ANOVA test results will only be reported for the full model (inclusive of the three time points). In this test, there was a main effect of time (F [2, 108] = 83.32, $p < 0.001$) but not a main effect for CO_2 group (F [1, 54] = 1.07, $p = 0.31$). There was also no interaction effect (F [2, 108] = 0.46, $p = 0.63$). In other words, CO_2 exposure did not interact the effect of passage of time. The

TABLE 4 UDI-6 score of the three incontinence groups before treatment, 3- and 6-month after treatment

Incontinence group		Mean	Std. Deviation	*N*
UDI-6 before treatment	MUI	45.93	11.45	35
	SUI	32.13	13.55	7
	UUI	38.08	11.76	14
	Total	42.25	12.65	56
UDI-6 after treatment 3 months	MUI	21.47	11.88	35
	SUI	11.89	3.54	7
	UUI	18.56	11.13	14
	Total	19.54	11.31	56
UDI-6 after treatment 6 months	MUI	24.87	11.27	35
	SUI	14.27	7.46	7
	UUI	21.71	12.57	14
	Total	22.75	11.58	56

Abbreviations: MUI, mixed urinary incontinence; UDI, urogenital distress inventory; SUI, stress urinary incontinence.

TABLE 5 UDI-6 score in previous CO_2 laser exposure vs no exposure before treatment, 3- and 6-month after treatment

Previous CO_2		Mean	Std. Deviation	N
UDI-6 before treatment	No	42.81	13.22	43
	Yes	40.37	10.81	13
	Total	42.25	12.65	56
UDI-6 after treatment 3 months	No	20.76	12.03	43
	Yes	15.53	7.54	13
	Total	19.54	11.31	56
UDI-6 after treatment 6 months	No	23.14	12.20	43
	Yes	21.46	9.59	13
	Total	22.75	11.58	56

Abbreviation: UDI, urogenital distress inventory.

following table displays the means, standard deviations, and sample sizes of the two CO_2 groups across time (Table 5).

4 | DISCUSSION

As interest in finding minimally invasive office-based approaches for addressing urinary incontinence increase, radio frequency energy has been gaining popularity in this field. The purpose of this study was to compare the effect of two modalities, monopolar and bipolar radiofrequency technologies, on treating urinary incontinence. In our study, all patients saw improvements in UDI-6 values 3 and 6 months after treatment. There is some evidence to suggest that the bipolar radiofrequency treatment was more effective compared to the monopolar radiofrequency treatment over time. Three months after treatment, the bipolar group UDI-6 values were lower than those of the monopolar group. Six months after treatment, the UDI-6 scores increased in both groups, suggesting decrease efficacy with time with more studies needed to address whether a maintenance therapy would offer a sustained benefit to patients over extended period. However, the bipolar group's UDI-6 scores were consistently lower than the monopolar group's scores, with the bipolar group's 6-month UDI-6 scores being lower than the monopolar group's three-month scores. This may suggest longer sustained effect of bipolar energy compared to monopolar.

The study also looked at the effect of radiofrequency energy on MUI and UUI as a secondary outcome. The MUI group UDI-6 mean scores were higher than the SUI and the UUI group mean at baseline. Those values were consistent across the 3-month and the 6-month period. There was consistent improvement in all three groups of incontinence with no statistical difference favoring one group over other, suggesting positive outcome of radiofrequency treatment among different urine incontinence types. Finally, it appears that previous CO_2 exposure had no effect on UDI-6 values on patients who were previously treated with CO_2 for genitourinary syndrome of menopause.

This is the first study that addresses the outcome of different types of radiofrequency energy in the treatment of stress and mixed urinary incontinence for a relatively long follow up period up (up to six months) with a relatively large number of patients (101). It is the also the first study which addresses treatment with radiofrequency in patients who were previously treated with CO_2 laser.

Limitations of the study are that it is a retrospective study with the risk of collection bias. Our outcome is the UDI-6 scores which is a subjective outcome and gives the measure of "overall" bother and lacks the granularity to see the impact of the treatment on different components of urinary incontinence, however it is widely used as quality-of-life measure in the urogynecology population. We also didn't include any objective outcome like pad test or cough stress test due to the unavailable data from all patients regarding these outcomes which needs more compliance from patients. Second, our sample size was based on number of patients who received the treatment at the two sites. A true power analysis was not performed to determine the number of patients who would be needed to truly show a difference. Our findings of previous CO_2 laser exposure with current RF energy users is only observational with a limited number of patients that were treated with CO_2 laser at different time intervals so the findings should be interpreted with care.

5 | CONCLUSION

The study shows clear benefit of both monopolar and bipolar radiofrequency device in patients with SUI and mixed UI, with bipolar RF more efficacious than monopolar RF. These data should be interpreted with caution due to the retrospective nature of the study. To truly compare the effects of these two RF platforms a prospective randomized trial would be required.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Ahmed Abdelaziz, Jeffrey Dell, and Mickey Karram contributed to the design and implementation of the

research, to the analysis of the results, and to the writing of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SAFETY, TOLERABILITY AND SHORT-TERM EFFICACY OF TRANSVAGINAL FRACTIONAL BIPOLAR RADIOFREQUENCY THERAPY FOR SYMPTOMS OF STRESS AND OR MIXED INCONTINENCE IN CONJUNCTION WITH GENITOURINARY SYNDROME OF MENOPAUSE

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Abstract

Introduction: Radiofrequency energy has been utilized to treat conditions such as vaginal laxity, atrophy, and stress urinary incontinence (SUI). Contact RF energy heats the mucosal surface of the vagina uniformly to deliver electrothermal energy to the connective tissues in the vaginal wall. This RF energy application stimulates collagen and elastin remodeling to restore the rigidity, elasticity, and moisture of the superficial vaginal mucosa. The limitation of this surface treatment is in the penetration depth of the energy to the vaginal tissue layers. This is the first study to report on the use of microneedling to deliver RF energy to the vaginal canal similar to what has been used to treat the skin surface of the face, neck, and chest. Microneedling increases the response of the collagen contraction and neocollagenesis in deeper layers of tissue, thus increasing the support to the surface. The novel intravaginal microneedling device used in this study allows penetration of the needles to 1 mm, 2 mm, or 3 mm.

Objective: A prospective pilot study to evaluate the outcome of a single fractional RF treatment of the vaginal canal in a series of women with coexistent stress or mixed incontinence (MUI) and genitourinary syndrome of menopause (GSM).

Methods: Twenty women who had symptoms of SUI and or MUI in conjunction with GSM were given a single vaginal treatment that consisted of fractional bipolar RF energy using the EmpowerRF platform with the Morpheus8V applicator (InMode). RF energy was delivered into the vaginal walls via 24 microneedles, at a depth of 1 mm, 2 mm, and 3 mm. Outcomes were evaluated by “cough” stress test, questionnaires (MESA SI, MESA UI, iQoL, UDI-6) and evaluation of vaginal tissue through the VHI scale at 1-month, 3-months, and 6-months post-treatment compared to baseline. Biopsies were performed at baseline and 3-months on 5 patients for histological reference and tissue evaluation.

Results: Eight out of eight outcomes measured from baseline to 6-months post-treatment showed improvement. The parameters scored in the questionnaires including frequency, urgency, nocturia, urge incontinence, and stress incontinence showed significant improvement in all areas at the 1-month, 3-month, and 6-month follow-up sessions compared to baseline.

Conclusions: The results showed significant evidence that fractional RF energy delivered vaginally is safe, well tolerated, and helps treat symptoms of SUI and or MUI in conjunction with GSM.

Stress urinary incontinence (SUI) is the involuntary leakage of urine with exertion, sneezing, or coughing. SUI often coexists with an overactive bladder and is termed mixed incontinence (MUI)[1]. Lowered estrogen levels after menopause and lack of the effect of estrogen stimulation to the vaginal tissue cause loss of collagen and elastin. The vaginal walls become thinner, more friable and have less vaginal secretions [2], resulting in the symptom complex of GSM. SUI and GSM very commonly coexist. The demand for in-office, minimally invasive treatments for these conditions is increasing as awareness of non-surgical options becomes more prevalent [3].

Until now, RF treatments have been available for surface and superficial treatment without an option for fractional RF vaginal treatment. RF energy heats the connective tissue of the vaginal wall, triggering a micro inflammatory activation of fibroblasts to stimulate collagen contraction, neocollagenesis and neo elastogenesis to revitalize and restore the strength, elasticity and moisture of the vaginal mucosa [4]. The role of the transvaginal application of continuous bipolar RF energy has previously been shown to be efficacious and safe in treatment of vaginal laxity and atrophy [4], as well as SUI [5] and pelvic floor restoration [6]. Continuous RF energy is applied to the vaginal mucosa to heat the underlying connective tissue to a temperature of 43^0C, causing collagen remodeling and soft tissue contraction to improve strength and elasticity of the vaginal wall and mucosal lubrication. Studies performed on the face and body have shown that microneedling with fractional RF energy devices that deliver RF energy to depths from 0.5 to 3.5 mm below the surface of the skin induce additional thermal stimulation which provides superior additional neocollagenesis than that seen with surface applications of RF energy alone [7-9].

Our goal was to evaluate the safety and efficacy of a novel transvaginal RF microneedling device which penetrates the vaginal mucosa and vulvar skin to deliver fractional RF energy to depths of 1 to 3 mm for treatment of women with coexistent SUI or MUI and GSM.

Methods

We conducted an IRB-approved prospective study at a single site. All procedures were performed by one of two board certified gynecologists.

Twenty female patients between the ages of 35 and 75 with symptoms of SUI, stress and/or mixed incontinence in conjunction with GSM, were recruited from a single private practice from October 2020 through May 2021. An examination of the treatment area was performed to complete the Vaginal Health Index (VHI) and multiple questionnaires were provided (iQOL, UDI-6, and MESA) pretreatment and at 1-, 3-, and 6-months post treatment. Medical history, demographic information, a bladder diary and questionnaires were collected at the baseline visit. Women who were included had a score of at least 18 out of 27 for the Stress Incontinence Questions and were confirmed as having predominant SUI on the Medical, Epidemiologic, and Social Aspects of Aging Urinary Incontinence (MESA). These parameters were evaluated through MESA Stress Incontinence (SI) and MESA Urinary Incontinence (UI) scales. All subjects were also required to have not used any other aesthetic treatment methods for the 6-months prior to the study or during the entire study period. Exclusion criteria included presence of a pacemaker, internal defibrillator, or any other active electrical implant anywhere in the body, pregnancy, current condition of cancer, or any active condition in the treatment area, or any

surgery in the treated area within 3-months prior to the treatment.

Subjects were pre-treated with Lidocaine 23% - Tetracaine 7% cream for 20 minutes prior to the procedure. Five study subjects had a baseline biopsy of the vaginal mucosa taken prior to the treatment. The treatment procedure was conducted by applying fractional bipolar RF energy through the EmpowerRF Morpheus8V device (InMode) using a stamping method with 50% overlap along the full length of the vagina to the introitus at 9, 10:30, 12, 1:30, 3, 4:30, 6, and 7:30. Two passes were conducted for each depth of 1mm, 2mm, and 3 mm. The Morpheus8V applicator is shown in Figure 1.

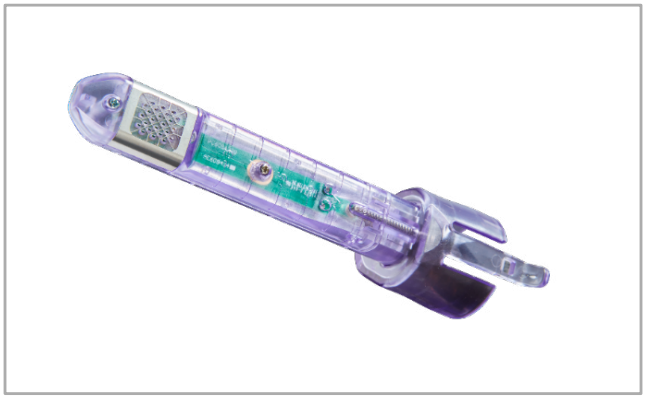

Figure 1. Morpheus8V applicator

After treatment the patients were given a voiding diary to complete for the remainder of the study. At 1-month, 3-month and 6-month follow-up visits, the voiding diary was collected, and the patient had a physical examination to assess the tissue and filled out the Urogenital Distress Inventory (UDI-6) questionnaire. For the patients who had a baseline biopsy, another biopsy was taken at 3-months post treatment.

Results

Based on a variety of outcome data measured at various time points, the treatment with Morpheus8V System for symptoms of SUI and vulvovaginal atrophy was statistically effective. In all, 20 patients were recruited into the study, with the average age being 52.7 years. All outcome data were measured at two, three, or four time points; for outcomes with only two time points, paired sample t-tests were employed to determine if the means improved. For outcomes with more than two measurements, repeated measures ANOVA tests were employed.

Repeated Measures ANOVA Results (Outcomes with Three Measurements)

The MESA additive SI battery instrument ranged with scores from 1-27, with lower values (1-9) indicating mild symptoms, and higher values (19-27) indicating severe symptoms. Measurements were taken at baseline, 3-months, and 6-months. The omnibus test was statistically significant $F(2, 36) = 30.52$, $p < 0.001$. Scores decreased from baseline to 3-months, then stayed flat at 6-months, which indicates that symptoms maintained their improved status from 3- to 6-months.

The MESA additive UI battery instrument ranged with scores from 1-18, with lower values (1-6), indicating mild symptoms, and higher values (13-18) indicating severe symptoms. Measurements were taken at baseline, 3-months, and 6-months. The omnibus test was statistically significant $F(2, 36) = 41.22$, $p < 0.001$. Scores decreased from baseline to 3-months, then stayed flat at 6-months, which indicates that symptoms maintained their improved status from 3- to 6-months.

The iQoL final instrument ranged with standardized scores from 1-100; it is a composite score of 22 questions, each of which was assessed at 1 (extremely) to 5 (not at all) scale. Thus, the higher the value of the score, the better the patient's assessment is of improvement after the treatment. Measurements were taken at baseline, 3-months, and 6-months. The omnibus test was statistically significant $F(2, 38) = 13.24$,

$p < 0.001$. Scores increased from baseline to 3-months, then stayed flat at 6-months, which indicates that symptoms maintained their improved status from 3 to 6-months.

The VHI additive instrument ranged with scores from 1-25; it is a composite score of 5 questions, each of which was assessed via a 1 (abnormal) to 5 (normal) scale. Thus, the higher the value of the score, the better the patient's assessment is of improvement after the treatment. Measurements were taken at baseline, 3-months, and 6- months. The omnibus test was statistically significant $F(2, 36) = 19.83$, $p < 0.001$. Scores increased from baseline to 3-months, then stayed flat at 6-months, which indicates that symptoms maintained their improved status from 3 to 6-months. The following table (Table 1) presents the three-time period means and corresponding pairwise comparison p-values.

Table 1: Repeated Measure ANOVA Pairwise Comparison Results (Three Measurements)

Item	BL Mean	3M Mean	6M Mean	BL-3M p	BL-6M p	3M-6M p
MESA SI	19.00	10.05	11.11	0.00	0.00	0.30
MESA UI	10.00	3.25	4.37	0.00	0.00	0.16
iQoL	44.21	75.23	67.16	0.00	0.00	0.27
VHI	16.00	21.84	22.58	0.00	0.00	0.33

Repeated Measures ANOVA Results (Outcomes with Four Measurements)

The following clinical evaluation baseline and post-treatment results are shown in Tables 2 and 3; The cough stress final weight scores ranged from 0-39, with lower values indicating less urine, and higher values indicating more urine captured in the pad. Measurements were taken at baseline, 1-month, 3-months, and 6-months. The omnibus test was statistically significant $F(3, 54) = 15.96$, $p < 0.001$. Scores decreased from baseline to 1-month, then stayed flat at 3-months and 6-months, which indicates that symptoms maintained their improved status from 1 to 6-months.

The UDI-6 additive scale ranged with scores ranging from 0-39 depending on the measurement; the additive scale was anchored by 1 = a little bit, and 3 = greatly. Thus, lower

values indicate symptom improvement, with the cutoff value of 33.3 being considered the top of the normal range Measurements were taken at baseline, 1-month, 3-months, and 6-months. The omnibus test was statistically significant $F(3, 54) = 26.81$, $p < 0.001$. Scores decreased from baseline to 1-month, then stayed flat at 3-months, then began to rise again at 6-months, which indicates that symptoms maintained their improved status from 1 to 3-months, but then began to increase again at 6-months. Regardless, the 6-month mean (26.76) was below the cutoff range of 33.3; thus, the increase from 3- to 6-months, while statistically significant, is clinically negligible.

Table 2: Repeated Measure ANOVA Means (Four Measurements)

Item	BL Mean	1M Mean	3M Mean	6M Mean
Cough Stress	13.05	4.32	3.84	2,79
UDI-6	43.85	18.20	21.05	26.76
Pee Frequency	55.07	44.33	45.00	47.87
Pee Quantity	448.07	416.0	388.60	343.07

Table 3: Repeated Measure ANOVA Pairwise Comparison p-Values (Four Measurements)

Item	BL-1M	BL-3M	BL-6M	1M-3M	1M-6M	3M-6M
Cough Stress	0.001	< 0.001	< .0.001	0.72	0.25	0.78
UDI-6	< .0.001	< 0.001	< 0.001	0.24	0.02	0.03
Pee Frequency	0.009	0.02	0.04	0.81	0.06	0.22
Pee Quantity	0.39	0.12	0.05	0.23	0.17	0.28

Histological Results

Histological biopsies of the vaginal mucosa at 3-months post-treatment demonstrate an increase in elastic fibers density compared to the baseline biopsy. Both superficial and deep elastic fibers are seen. The biopsies also find no damage to the submucosal collagen layer and no scar tissue formation in post-treatment, verifying no adverse effect of the fractional RF treatment.

Figure 2 shows biopsies performed prior to treatment and at 3-months post treatment stained with elastic and Ki-67 stains.

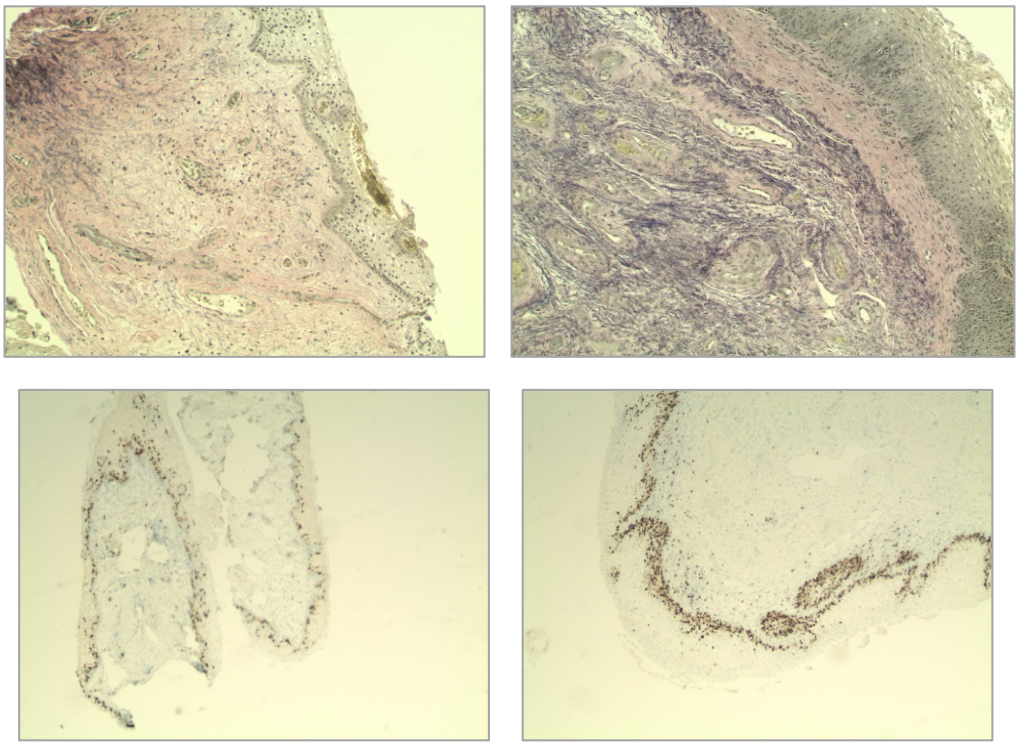

Figure 2. Histological section of skin biopsies before (Left) and 3-months following fractional treatment (Right) demonstrating increase in elastic fibers density. Up - Elastic x10, bottom – Ki-67x4.

Discussion

In summary, nine of the 13 outcomes measured from baseline to 6-months post-treatment improved statistically. That is, patient scores of MESA SI, MESA UI, iQoL, VHI, cough stress, and UDI-6, all improved from baseline to the various post-treatment periods, with most improving at the second measurement and staying improved at the third or fourth measurement compared to baseline. Also, data from voiding diaries noted a significant reduction in urinary frequency with a significant increase in functional bladder capacity. For the single-measure metrics, intravaginal pain and UDI change were better compared to a hypothesized value or cutoff value, whereas MESA UI Change and MESA SI Change were

marginally significantly better over their respective cutoff values. Subject satisfaction did not change from 3 to 6-month measurements, indicating that subjects were as satisfied with the treatment 3-months post-treatment to 6-months post-treatment, and were generally highly satisfied, as evidenced by the high mean values at both periods. In all, there is significant evidence to suggest that the Morpheus8V System for symptoms of SUI and vulvovaginal atrophy was highly efficacious. Further studies need to be performed with longer follow up to determine durability of success and whether additional treatments would be required.

Conclusion

This is the first study to report on the use of RF microneedling in the vaginal canal. Preliminary data would seem to indicate that such an intervention can result in improvement of vaginal atrophy which would be consistent with the data available on fractional CO2 laser treatments. Also, in addition through a different mechanism of improving connective tissue and support of the anterior vaginal wall stress and stress predominant mixed incontinence seem to improve. This procedure had a high patient satisfaction and improvement in quality of life. Fractional RF appears to hold potential to treat, in-office, two very common conditions that millions of women suffer from.

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MULTIMODAL RADIOFREQUENCY THERAPY FOR MIXED URINARY INCONTINENCE: A PILOT STUDY

Pablo Gonzalez Isaza[a] , Diana Lorena Velez Rizo[b, c]

Abstract

Background: Mixed urinary incontinence (MUI) significantly affects patients' quality of life (QOL) and poses a therapeutic challenge owing to its multifactorial etiology. Traditional treatments, including pharmacotherapy and surgery, often yield suboptimal outcomes or entail considerable risk. This study aimed to evaluate the efficacy and safety of a novel multimodal radiofrequency (MMRF) therapy for improving MUI symptoms, QOL and histological markers of pelvic tissue integrity.

Methods: A prospective pilot study was conducted on 20 female patients diagnosed with MUI. Participants underwent MMRF therapy, which consisted of two modalities: Morpheus V, delivering fractional radiofrequency energy, and Forma V, providing bipolar energy for superficial tissue tightening (Empower Bipolar Radiofrequency Platform InMode Aesthetics, Lake Forest, California, Serial Number R30326211). Treatment was administered over two to three sessions with follow-up at 3 and 6 months. Subjective outcomes were assessed using validated scales, including the International Consultation on Incontinence Questionnaire-Short Form (ICQ-SF), Potenziani scale, overactive bladder symptom score (OAB-SS), and QOL measures using a visual analog scale (0 - 10). Punch biopsies from the anterior vaginal wall were obtained at baseline and at 6 months to evaluate histological changes. Statistical analyses were performed to determine the significance of the pretreatment and posttreatment differences.

Results: Twenty participants were included in this study. ICQ-SF scores decreased from 14.05 ± 4.22 at baseline to 10.05 ± 3.79 at 3 months and 7.65 ± 4.44 at 6 months ($P < 0.01$). The Potenziani and OAB-SS scores exhibited similar reductions, indicating enhanced bladder control and urgency relief ($P < 0.001$). QOL improved significantly, with mean QOL scores declining from 6.00 ± 1.03 at baseline to 2.95 ± 0.94 at 6 months ($P < 0.001$). Histological analyses revealed increased collagen density, enhanced vascularization, and reduced inflammatory infiltrates, supporting tissue remodeling and functional recovery.

Conclusions: MMRF therapy is a safe, effective and minimally invasive treatment for MUI that addresses both the structural and functional contributors to incontinence. Significant improvements in symptom severity, QOL, and tissue integrity position of MMRF are promising non-surgical options for managing pelvic floor dysfunction. Further research with larger populations and extended follow-up is recommended to confirm these findings and to establish MMRF as a standard treatment for MUI.

Keywords: Mixed urinary incontinence; Quality of life; Multimodal radiofrequency; Safety

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Introduction

Mixed urinary incontinence (MUI) is a prevalent condition, especially among women, and is characterized by a combination of stress and urgency urinary incontinence. Affecting the quality of life (QOL), MUI imposes a considerable psychological and social burden on up to 15.7-20.5% of women in the United States in the 2017 - 2018 cycle. This prevalence was higher in women aged 60 years and older (12.9-19.0%) [1], with similar values in other locations [2] and a mean annual worldwide incidence of all-types urinary incontinence ranging from 1% to 9% [3]. Traditional management approaches include lifestyle modifications, pharmacological therapy, pelvic floor exercises, and surgical interventions for severe cases [4-8]. Despite these options, many patients experience limited efficacy, side effects or poor long-term adherence to treatment regimens [9-11]. In recent years, energy-based devices have emerged as minimally invasive alternatives that utilize lasers, radiofrequency (RF), and high-intensity focused ultrasound technologies. These modalities promote collagen remodeling and tissue tightening, potentially improving the structural and functional integrity of the pelvic floor and urethral support. Among these, multimodal radiofrequency (MMRF) technologies, including Morpheus V and Forma V, have shown promise in enhancing vaginal and urethral tissue health [7, 12, 13]. However, robust evidence of their efficacy in managing MUI remains sparse, necessitating further research [14, 15].

While emerging technologies have gained traction, criti-

cal gaps persist in understanding their long-term efficacy and mechanisms of action in MUI. Previous studies have primarily focused on subjective symptom improvement, often relying on patient-reported outcomes without correlating them with objective biomarkers or histological data [16, 17]. Furthermore, research often emphasizes single modalities or fails to account for the multifaceted nature of MUI, which encompasses both structural and functional deficiencies [18-20]. The clinical applicability of MMRF therapy, which combines tissue remodeling and neuromodulation effects, has yet to be thoroughly evaluated. This evaluation requires comprehensive studies integrating patient-reported outcome measures (PROMs) and objective outcome measures [9] to delineate the true potential of these technologies for MUI management.

We hypothesized that MMRF therapy using Morpheus V and Forma V could significantly improve MUI symptoms by enhancing the structural support and neuromuscular function of the pelvic floor. This hypothesis is grounded in the dual action of RF technology, which promotes tissue tightening and modulates the overactive bladder pathways. The central research question is whether this therapy leads to measurable improvements in validated outcome scores, including the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), Potenziani scale, and overactive bladder symptom score (OAB-SS) while correlating these outcomes with the histological changes observed through punch biopsies. This study aimed to provide a comprehensive evaluation of MMRF technology as a novel, minimally invasive treatment for MUI, bridging the gap between subjective symptom relief and objective tissue-level outcome changes.

To address these gaps, we employed a systematic approach involving a 6-month follow-up of patients undergoing Morpheus V and Forma V therapies. This study integrated PROMs and objective evaluation methods, including validated questionnaires and punch biopsies, to provide a holistic assessment of therapy outcomes. By combining two complementary RF modalities, our approach sought to leverage the synergistic effects of deep tissue remodeling and surface-level tightening, targeting both structural and functional contributors to MUI. This dual-action mechanism represents a novel paradigm for non-surgical MUI treatment. Importantly, this study fills critical gaps in the current literature by linking patient-reported outcomes to histological changes, thereby providing new insights into the mechanisms underlying symptom improvement. Our findings aim to guide clinical decision-making and establish MMRF therapy as a viable evidence-based option for managing MUI.

Materials and Methods

Study design and setting

A prospective, descriptive, experimental pilot study was conducted between August 2023 and February 2024 at the Urogynecology Unit of the Obstetrics and Gynecology Department at the Hospital Universitario San Jorge in Pereira, Colombia.

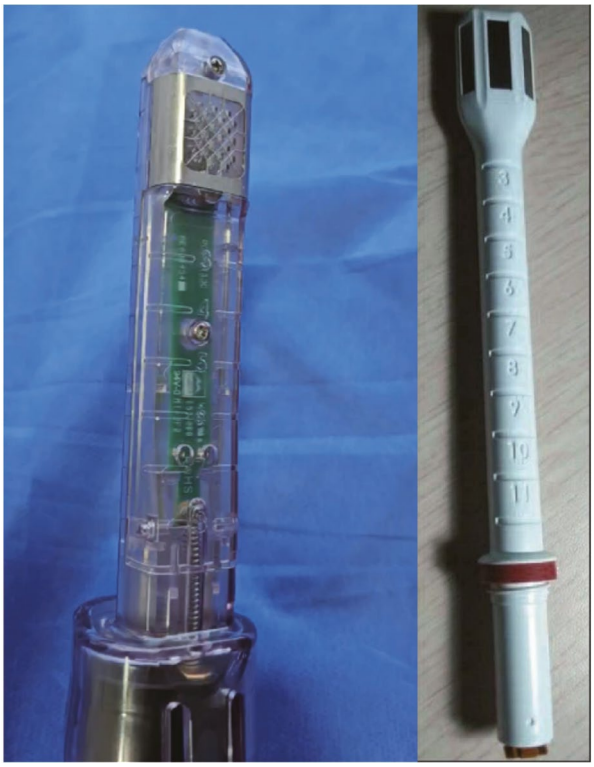

Figure 1. Morpheus V (left) and Forma V (right) probes.

Participants

Adult female patients presenting with clinically diagnosed MUI, a condition defined by concurrent symptoms of stress and urgency urinary incontinence, were invited to participate. To ensure homogeneity and reliability, strict inclusion and exclusion criteria were used. Women with no prior pelvic organ prolapse (POP) surgeries and willingness to adhere to a 6-month follow-up protocol were eligible. Conversely, patients with advanced POP (pelvic organ prolapse quantification (POP-Q) stage > 1), undiagnosed uterine bleeding, or a history of rectovaginal or vesicovaginal fistulas were not considered. Additional exclusion criteria were current smokers, individuals undergoing concurrent energy-based therapies or pelvic floor rehabilitation, and those with significant medical comorbidities that could confound the study results. These criteria were carefully chosen to focus on a population that would benefit the most from MMRF therapy and to eliminate factors that might influence the outcomes.

MMRF therapy

MMRF therapy was delivered using a two-step protocol combining Morpheus V and Forma V technologies (Fig. 1). The first step involved the Morpheus V probe, which features a transparent casing with visible internal circuitry and utilizes fractional RF energy delivered at 1 MHz and peak power of 65 W. A specialized probe equipped with 24 microneedles was used to target specific areas within the vaginal cavity, particu-

larly those contributing to continence mechanisms. The microneedles allowed for adjustable penetration depths of 1 - 3 mm, delivering approximately 200 mJ per pulse to remodel the tissue through thermal energy while minimizing damage to the surface layers. The temperature used during the two steps of RF therapy depends on the device used. Morpheus8 V delivered fractional bipolar RF at temperatures of 58 °C and 61 °C, and Forma V delivered bipolar RF at 40 °C and 43 °C. The second step employed the Forma V probe equipped with flat and spherical electrodes that delivered 1 MHz with a peak power of 40 W through a bipolar RF modality. This phase aims to provide surface-level tissue tightening and neuromodulation through rectangular pulse configurations using a specially designed ergonomic probe. Both modalities have integrated cooling systems and built-in impedance sensors and were administered in multiple sessions at predetermined intervals as part of a structured rehabilitation program. The duration of the sessions depended on the patient and was not standard. Morpheus8 V session time depended on the number of passes (usually three passes with different levels of energy and depth of penetration were performed), and the Forma V bipolar RF lasted 20 min. The interval between sessions depended on the device used. Morpheus8 V consisted of three sessions at 4-week intervals, and Forma V consisted of six sessions at 2-week intervals. All procedures were performed under standardized conditions by trained and experienced nurses from the study center.

Outcome measures

Both PROMs and objective outcome measures were incorporated to evaluate the efficacy of MMRF therapy comprehensively. PROMs included validated scales such as the ICIQ-SF [21, 22], Potenziani scale (Potenziani-14-CI-IO-QOL-2000) [23], and OAB-SS [24], all of which were administered at baseline and 6 months post treatment. These instruments provided quantitative assessments of symptom severity, patient QOL, and functional impact of MUI [25]. For objective evaluation, punch biopsies were collected from the anterior vaginal wall at the urethrovaginal junction before therapy initiation and after 6 months. Histological analysis (hematoxylin/eosin) of these samples aimed to identify morphological and structural changes indicative of therapeutic effects, including collagen remodeling and vascular alterations. Integrating PROMs and objective measures was intended to provide a comprehensive understanding of the treatment efficacy.

Ethical considerations

The study adhered to the ethical principles outlined in the international guidelines, including the Declaration of Helsinki, Belmont Report, and Council for International Organizations of Medical Sciences (CIOMS) standards. All participants provided written informed consent after receiving detailed explanations of the study's purpose, procedures, risks, and benefits. This research was classified as minimal-to-beyond-minimal risk, as supported by preclinical and clinical evidence demonstrating the safety of RF-based interventions in humans. Ethical approval was obtained from the hospital's ethics committee to ensure compliance with national regulations. Measures to protect the participants included anonymized data collection, secure storage of medical records, and the option to withdraw at any time without consequences.

Statistical analysis

Continuous variables were reported as means with standard deviations (SD), whereas categorical variables were analyzed using the Chi-square test. Pretreatment and posttreatment scores on validated scales were compared using Mann-Whitney, Kruskal-Wallis, and Dunn pairwise tests to determine the significance of the observed changes. Histological findings from punch biopsies were evaluated qualitatively and quantitatively to assess tissue-level changes according to clinical outcomes. Statistical significance was set at $P < 0.05$.

Results

Participant characteristics

Twenty participants were included in the study, with a mean age of 56.15 years (SD 9.78), ranging from 44 to 84 years. The median parity among the participants was three, with the majority (40%) having three live births. Approximately 60% of the participants presented with POP-Q stage 0, and the remaining 40% presented with stage 1. Most participants (65%) completed three treatment sessions, whereas the remainder underwent two sessions. Baseline urodynamic evaluations revealed a mix of normal findings and variable abdominal leak point pressures (ALPPs) distributed across the different thresholds (Table 1). None of the 20 patients presented adverse events, unwanted treatment-related symptoms, or complications.

PROMs

The mean baseline score for the ICQ-SF was 14.05 (SD 4.22), reflecting moderate symptom severity. At 3 months, the mean score reduced to 10.05 (SD 3.79), with a further decrease to 7.65 (SD 4.44) by 6 months. Significant improvements in ICQ-SF scores at both 3 and 6 months compared with baseline were observed ($P < 0.01$). Similarly, the Potenziani scores demonstrated marked improvement over time. The baseline scores averaged 12.55 (SD 2.44), decreasing to 10.05 (SD 2.06) at 3 months and 6.20 (SD 1.91) at 6 months. The changes were statistically significant, with a robust correlation observed between the baseline and follow-up scores (Pearson's correlation, $r = 0.89$, $P < 0.001$).

The mean OAB-SS at 3 months was 11.68 (SD 2.45), decreasing to 8.68 (SD 1.45) at 6 months, representing an improvement of 25.7%. A statistically significant reduction in OAB-SS scores was observed between these time points ($P < 0.01$), with a moderate correlation ($r = 0.64$). QOL measures demonstrated substantial improvement, aligning with the re-

Table 1. Baseline Clinical Characteristics

Category	Frequency (n)	Percentage (%)
Parity		
1	3	15
2	5	25
3	8	40
4	3	15
5	1	5
Sessions		
2	7	35
3	13	65
Q-tip test		
< 30 degrees	11	55
> 30 degrees	9	45
Urodynamics		
Normal	10	50
ALPP 54	2	10
ALPP 65	2	10
ALPP 80	2	10
ALPP 56	1	5
ALPP 70	1	5
ALPP 76	1	5
ALPP 90	1	5
POP-Q		
Stage 0	12	60
Stage 1	8	40

ALPP: abdominal leak point pressure; POP-Q: pelvic organ prolapse quantification.

ductions in symptom severity. Scores averaged 6.00 (SD 1.03) at 3 months and declined to 2.95 (SD 0.94) at 6 months ($P < 0.001$). These improvements reflected enhanced posttreatment patient satisfaction and perceived well-being (Table 2).

Histological findings

Punch biopsies taken from the anterior vaginal wall revealed notable posttreatment tissue remodeling. Collagen density increased at 6 months compared with baseline, with evidence of enhanced vascularization, epithelial maturation, and reduced inflammatory infiltrates. These histological changes corroborated the observed clinical improvements, suggesting that MMRF therapy effectively promotes tissue regeneration and functional restoration (Figs. 2, 3).

Correlation analysis

Significant correlations were found between the baseline and follow-up scores for all scales, indicating the consistency of improvements. Potenziani scores showed the strongest correlation ($r = 0.89$, $P < 0.001$), followed by ICQ-SF ($r = 0.54$, $P < 0.01$) and OAB-SS ($r = 0.64$, $P < 0.01$).

Discussion

We found that MMRF was both effective and safe. Over 6 months, it produced significant improvements in validated scales, such as the ICQ-SF, Potenziani scale and OAB-SS. Furthermore, the improvement in QOL underscores the meaningful impact of therapy on daily living. Histological analyses provided complementary evidence, revealing increased collagen density and enhanced vascularization in treated tissues. These results on a novel treatment approach support the hypothesis that MMRF acts through mechanisms distinct from conventional pharmacotherapy, offering a promising alternative for patients who are either non-responders or intolerant to traditional treatments.

Our findings align with those of recent studies on energy-based modalities, including RF [12, 15, 17-20, 26], which corroborate this mechanism, emphasizing the role of thermal energy in collagen contraction and neocollagenesis. In 2013, Chinthakanan et al conducted a randomized controlled trial comparing low-energy RF vaginal therapy to sham treatment in postmenopausal women with mild to moderate stress urinary incontinence (SUI). Among the 49 participants, the RF group (n = 23) achieved a 69.6% success rate at 1 year, defined by improvements in the 1 h pad weight test, compared to 38.5% in the sham group. However, secondary outcomes, such as the incontinence quality of life (I-QOL) and urogenital distress inventory-6 (UDI-6) were not statistically different [20]. On the other hand, in 2024, Rabiai et al investigated the addition

Table 2. PROMs Mean (SD) Score and Percentage of Improvement

PROMs	Baseline	3 months	6 months	% of improvement
ICQ-SF	14.05 (4.22)	10.05 (3.79)	7.65 (4.44)	45.5%
Potenziani	12.55 (2.44)	10.05 (2.06)	6.20 (1.91)	50.5%
OAB-SS		11.68 (2.45)	8.68 (1.45)	25.7%[a]
QOL		6.0 (1.03)	2.95 (0.94)	50.8%

[a]Only the 3-month and 6-month time points were assessed, with 19 patients providing complete data. PROMs: patient-reported outcome measures; SD: standard deviation; ICQ-SF: International Consultation on Incontinence Questionnaire-Short Form; OAB-SS: overactive bladder syndrome score; QOL: quality of life.

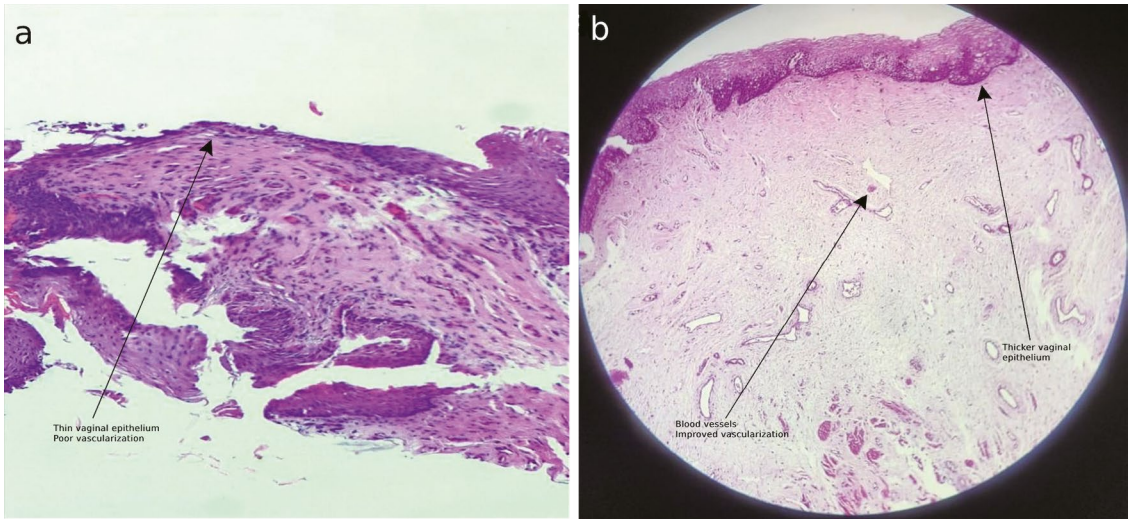

Figure 2. Histological findings. (a) Before protocol: atrophic epithelium. (b) Poor epithelial maturation.

of monopolar non-ablative RF to pelvic floor muscle training (PFMT) in a randomized controlled trial of 38 women with moderate SUI. The RF group (n = 18) achieved a 9.4-point reduction in ICIQ-SF scores (95% confidence interval (CI): -12.6 to -6.3), surpassing the minimal clinically important difference, compared to a 3.9-point reduction (95% CI: -6.9 to 1.0) in the PFMT-only group. Additionally, the experimental group exhibited significant improvements in the 1 h pad test ($P < 0.05$) and fewer weekly SUI episodes, with a time-group interaction effect observed over 6 months ($P < 0.001$) [18].

In 2024, Long et al evaluated the Viveve® System, applying 90 J/cm^2 of fractional RF energy in a single session to 34 women with SUI. At 6 months, significant reductions in SUI symptoms were reported, with improved scores in the UDI-6 (-3.1 points), Incontinence Impact Questionnaire-7 (-2.8 points) and ICIQ-SF (-4.5 points), along with reduced bladder neck mobility and proximal urethral rotation angle. Sexual function also improved, as evidenced by increased Female Sexual Function Index scores in all domains except for pain [15]. In 2023, Abdelaziz et al explored the safety and short-term efficacy of fractional bipolar RF delivered through microneedling in 20 women with MUI and genitourinary syndrome of menopause (GSM). Using the EmpowerRF platform, significant symptom improvements were observed at 1, 3, and 6 months post treatment. For example, UDI-6 scores decreased from 37.2 to 25.4, and I-QOL scores improved by 45%. Histological findings revealed enhanced collagen remodeling and neocollagenesis, providing a mechanistic basis for the observed benefits [19]. Furthermore, the neuromodulatory effects of RF energy, which may influence bladder hyperactivity and urgency symptoms, offer an additional explanation for improvements in urgency-related scales [26, 27]. This dual-action mechanism, which combines structural reinforcement with functional modulation, underscores the unique therapeutic potential of MMRF for MUI.

Although promising, this study has limitations. The small sample (n = 20) limits generalizability, and the single-center design without a control group introduces potential biases. The 6-month follow-up, while sufficient for initial efficacy, does not assess long-term outcomes. The absence of baseline data

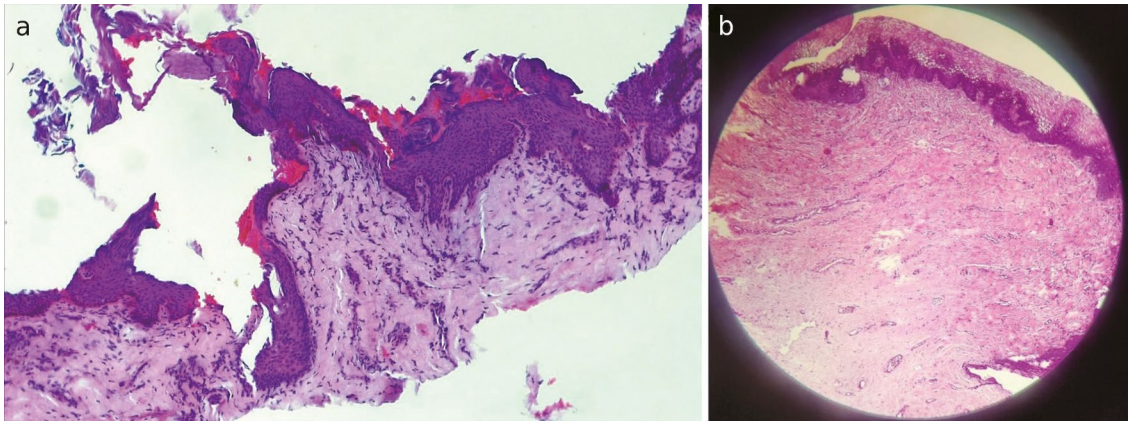

Figure 3. Histological findings. (a) 6 months after the treatment protocol: increased epithelium maturation and vascularity. (b) Increased epithelial maturation, dense stroma papillae formation, and increased vascularization.

further limits evaluation. The lower OAB-SS improvement between 3 and 6 months may reflect a ceiling effect or reduced sensitivity to change, as indicated by score clustering at 3 months. In contrast, broader measures like QOL and Potenziani scales continued detecting improvements. Despite these limitations, rigorous methodologies and validated measures enhance result reliability [21, 22, 24] and ensure that the observed improvements are both clinically meaningful and statistically robust. Moreover, the consistent alignment between subjective reports and objective histological findings strengthens our conclusions. The absence of adverse events further supports the feasibility and safety of MMRF therapy, making it a viable alternative for patients seeking noninvasive options. Anticipated criticisms regarding the sample size or lack of controls are mitigated by the pilot nature of this investigation, which serves as a necessary foundation for future large-scale studies.

The findings from this pilot study pave the way for future research to build upon these insights. Larger, multicenter, randomized controlled trials are essential to validate the efficacy and safety of MMRF therapy. These studies should aim to compare MMRF with established treatments such as pharmacotherapy, pelvic floor physical therapy and surgical interventions to determine their relative effectiveness and cost efficiency. Extended follow-up periods are also necessary to evaluate the durability of symptom relief and the progression of histological changes over time. Additionally, mechanistic studies exploring the neuromodulatory effects of RF energy could provide deeper insights into the pathways involved, potentially identifying biomarkers for predicting treatment responses and optimizing patient selection.

The MUI is a multifaceted condition that profoundly impacts patients' physical and psychological well-being. Current treatment options often fail to address both the structural and functional contributors to incontinence, leaving a significant proportion of patients dissatisfied or untreated. This study positions MMRF therapy as a transformative approach that bridges the gap between conservative and surgical treatment. By simultaneously targeting tissue integrity and bladder function, the MMRF offers a comprehensive solution that is minimally invasive, safe and effective. Its ability to improve the QOL while avoiding the risks and recovery times associated with surgery makes it a particularly attractive option in the continuum of care for pelvic floor dysfunction.

Conclusion

Our study demonstrates that MMRF is a promising noninvasive treatment for MUI. MMRF addresses critical gaps in the current therapeutic landscape by significantly reducing symptom severity, improving QOL, and promoting histological tissue remodeling. Although further research is needed to confirm these findings in larger and more diverse populations, the results of this pilot study highlight the MMRF as an innovative and effective option for managing MUI. This approach offers hope for patients seeking relief from a condition that has long been challenging to treat, marking an important step forward in pelvic floor health.

Acknowledgments

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Conflict of Interest

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

Informed Consent

All participants provided written informed consent.

Author Contributions

PGI was responsible for the conception, design and first draft of the manuscript, as well as data collection and analysis. DLVR contributed to the interpretation of data, critically revised the manuscript for important intellectual content and provided the final approval of the version to be published.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

ALPP: abdominal leak-point pressures; I-QOL: incontinence quality of life; ICQ-SF: International Consultation on Incontinence Questionnaire-Short Form; MUI: mixed urinary incontinence; MMRF: multimodal radiofrequency; OAB-SS: overactive bladder symptom score; PROMs: patient-reported outcome measures; PFMT: pelvic floor muscle training; POP: pelvic organ prolapse; QOL: quality of life; UDI-6: urogenital distress inventory

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EMPOWERRF

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DOLCE VITA
BY MARIE CLAIRE
Junio 2024

salud

El nuevo bienestar femenino

HOY EN DÍA LA GINECOLOGÍA OFRECE TRATAMIENTOS SIN CIRUGÍA PARA LAS DISFUNCIONES Y LA ESTÉTICA VAGINAL, COMO LA PLATAFORMA 'EMPOWER RF', DE INMODE.

por **Úrsula Fernández**

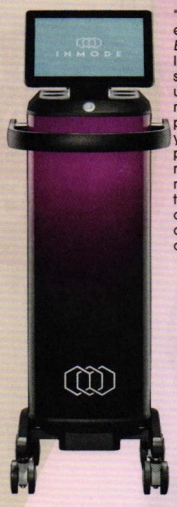
Los *accesorios* que más utilizan las mujeres a partir de los 50 años son compresas y pañales", señala el doctor Moore, experto en reconstrucción vaginal con cuatro clínicas en Estados Unidos y una en Dubái. Gracias a su visión global sobre la salud íntima femenina, logra tratar a todas las mujeres que quieren y necesitan mejorar su bienestar íntimo, no solo por la estética, sino también por su salud y por mejorar su calidad de vida. "Ahora las mujeres hablan con más naturalidad de sus problemas postparto y durante y después de la menopausia. Comentan que sufren pérdidas de orina, que les duele mantener relaciones sexuales, que se ven los labios caídos… Pero antes esto era impensable. De hecho, en Estados Unidos, cuando las mujeres tenían estos problemas –que siempre los ha habido– se prohibió realizar labioplastias y rejuvenecimientos vaginales cuando yo empecé a estudiar este campo. Se oían frases como 'las mujeres no necesitan estos tratamientos, no hay evidencias científicas'", apunta el experto y añade: "El bienestar femenino es igual de importante que el nuestro y ya iba siendo hora de que fuésemos conscientes y de que pusiésemos medidas para poder mejorarlo".

LA GINECOESTÉTICA EN ESPAÑA

Hablar de estética vaginal en España hace más diez años era un auténtico tabú. Pero gracias a diferentes testimonios de pacientes de nuestro país, la ginecología empezó a ver que existía una necesidad por mejorar el bienestar genital femenino. La doctora Zuramis Estrada Blanco (directora médica de CIMEG Madrid y experta en suelo pélvico) fue una de las ginecólogas pioneras en realizar diferentes terapias en la vulva y la vagina hace más de una década para mejorar aquellas alteraciones que suelen aparecer con los cambios hormonales tras la pubertad/adolescencia, postparto y la perimenopausia o postmenopausia. "Mi intención era no solo mejorar la estética, sino también la función de los genitales femeninos y del suelo pélvico", apunta la experta y señala que las mujeres de más de 50 años suelen solicitar terapias por dispareunia (dolor a la penetración del pene) por la atrofia urogenital que se produce debido a la pérdida de hormonas estrogénicas y de colágeno entorno a un 1 % cada año (desde los 30) y se incrementa por supuesto con el paso de los años. También solicitan terapias por incontinencia urinaria o por sensación de picor vulvar o escozor que no mejora con ciertos tratamientos en cremas o pomadas locales, que es cuando presentan otra patología ginecodermatológica denominada Liquen escleroso-atrófico.

SIN CIRUGÍA

Todas estas disfunciones siempre se habían tratado con cirugía. Y aunque hay procedimientos que son ambulatorios, tienen una recuperación y un riesgo de infección… Por suerte, *EmpowerRF,* de InMode es capaz de acabar con todos los problemas de la salud íntima femenina en tan solo tres sesiones y sin tener que pasar por el quirófano. Esta plataforma ofrece tratamientos para acabar con la incontinencia urinaria, los dolores y… hace que la mujer tenga mejores orgasmos. *EmpowerRF,* de InMode, aúna seis tecnologías que son capaces de solucionar las diferentes afecciones vaginales de la mujer: *V Tone* (proporciona una estimulación electromuscular, intravaginal y una reeducación neuromuscular que rehabilita los músculos de un suelo pélvico débil y trata la incontinencia urinaria originada por estrés, urgencia o mixta), *Morpheus 8V* (logra una remodelación integral completa que ayuda a tratar la atrofia de 'la zona V', la distensión del canal, la sequedad vaginal y la dispareunia), *Forma V* (radiofrecuencia que proporciona un calor profundo para modelar el tejido; está indicado para el síndrome de relajación vaginal y en genitales externos, incontinencia urinaria por estrés y disfunción sexual), *Morpheus 8* (aporta mayor tensión a los labios menores y mayores), *Aviva* (permite realizar una labioplastia no quirúrgica que logra una reducción de la hipertrofia de los labios vulvares o del capuchón del clítoris) y *Tone* (causa contracciones musculares involuntarias para restaurar la fortaleza de la zona y así acabar con la incontinencia urinaria y reforzar el suelo pélvico). ¿El resultado? Los tejidos se vuelven más sanos, recuperan su pH natural, hay más riego sanguíneo, más sensibilidad… "Con las microagujas logramos que la radiofrecuencia penetre a mayor profundidad y lo que en un principio fue para mejorar la salud sexual, comprobamos que también reducía las pérdidas de orina", señala el Dr. Moore. ¿Es seguro? "Asusta hablar de microagujas dentro de la vagina, pero no hay riesgo, dolor ni tampoco tiempo de recuperación. Quizás lo más oportuno es no tener relaciones sexuales en unos dos días. Pero las mujeres pueden estar tranquilas porque, antes de empezar a trabajar, realizamos un pretratamiento para relajar la zona y si realizamos *Morpheus,* aplicamos anestesia para adormecer la vagina", comenta el experto. ■



"El tratamiento estándar con *EmpowerRF*, de InMode, son tre sesiones. Con una sesión mejora la pérdida de orin y la salud sexu pero se recomienda realizar el tratamiento completo" comenta el doctor Moore.

FOTO: GETTY/CORTESÍA DE INMODE.

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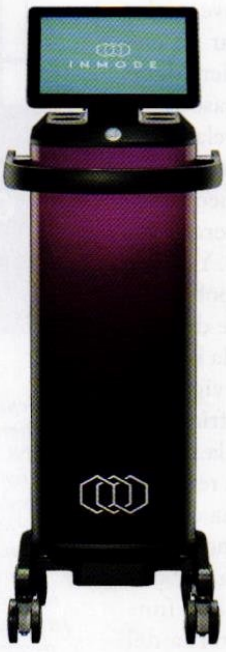
La incontinencia por estrés afecta a 1 de cada 3 mujeres y... ¿sabías que después del parto ese número aumenta considerablemente? Otro dato impactante es que el 50% de nosotras se queja de dolor durante el sexo. La salud íntima femenina sigue siendo un tabú y es necesario ponerle remedio a todos los impactos que interfieren en nuestra calidad de vida. Para solucionarlo, la ginecoestética aterriza en España con EMPOWER RF de INMODE, una plataforma que cuida y promueve el bienestar de la zona V.

La doctora Zuramis Estrada Blanco (directora médica de CIMEG Madrid y experta en suelo pélvico) fue una de las ginecólogas pioneras en realizar diferentes terapias en la vulva y la vagina hace más de una década. "Mi intención no era solo mejorar la estética, sino también la función de los genitales femeninos y del suelo pélvico", apuntaba la experta en la materia. La ginecoestética surge tras averiguar que existe una preocupación y necesidad por tratar los problemas más comunes de la vida de la mujer. Estas preocupaciones varían a lo largo de la vida, estando en la primera etapa (de los 20 a los 35 años) más enfocados en las razones estéticas, *a posteriori* se alinean más con los cambios producidos por los embarazos y los partos (de los 35 a los 50 años) y, finalmente, entra en juego la menopausia y la posmenopausia (a partir de los 50 años). EMPOWER RF de INMODE ha llegado para quedarse y para cambiar la salud, el sexo y, por consiguiente, nuestra calidad de vida, la de las mujeres. Sus tratamientos sin cirugía y sin dolor inauguran una nueva era de empoderamiento femenino con una recuperación de la zona pélvica genital (tejidos y músculos) y, por lo tanto, una mejora de la salud sexual ✣



LA GINECOESTÉTICA LLEGA A ESPAÑA

"Todas estas disfunciones siempre se habían tratado con cirugía y muchas mujeres no se atreven por el riesgo que conlleva. Con EMPOWER RF de INMODE no es necesario pasar por el quirófano. Con las microagujas logramos que la radiofrecuencia penetre a mayor profundidad y realizamos un pretratamiento para relajar la zona. No hay riesgo, ni dolor, tampoco hay tiempo de recuperación", señala el Dr. Moore, experto en reconstrucción vaginal. La plataforma incorpora 6 tecnologías (V Tone, Morpheus 8 V, Forma V, Morpheus8, Aviva y Tone) que ofrecen tratamientos sin dolor y capaces de solucionar las diferentes afecciones vaginales. Ha llegado el momento de *revivir la salud* íntima femenina gracias a EMPOWER RF de INMODE.

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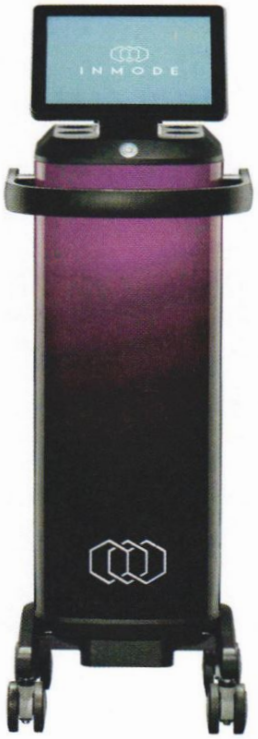

HABLAMOS CON LA DOCTORA ZURAMIS ESTRADA SOBRE LA IMPORTANCIA DE REALIZAR PROTOCOLOS PARA RECUPERAR Y CUIDAR LA SALUD ÍNTIMA FEMENINA.

por **Úrsula Fernández**

La doctora Zuramis Estrada, especialista en ginecología-obstetricia y directora médica de CIMEG Madrid, es una de las pioneras en realizar diferentes terapias en la vulva y la vagina hace más de una década para mejorar las alteraciones que suelen aparecer con los cambios hormonales tras la pubertad/adolescencia, postparto y la perimenopausia postmeanopausia. "Mi intención no es solo mejorar la estética, sino también la función de los genitales femeninos y del suelo pélvico", explica la experta.

PROBLEMAS DE LA ZONA GENITAL

Una de cada tres mujeres tiene incontinencia por estrés. Después del parto ese número sube y tienen una vagina más laxa. También existe atrofia vaginal, sequedad, y se estima que el 50 % de las mujeres pueden padecer atrofia urogenital (sequedad vaginal) durante su vida y, en consecuencia, sufren dolor durante las relaciones sexuales. "Podríamos decir que lo más común es la incontinencia urinaria tras embarazos/partos y la atrofia urogenital con la menopausia/postmenopausia o incluso tras terapias en pacientes que han padecido cáncer (sea de mama, ovario, cérvix, etc.) que hayan necesitado quimioterapia o radioterapia, que están ya libres de enfermedad (cáncer) pero ahora presentan otras alteraciones como estas que trastocan su calidad de vida, y en tercer lugar, la armonización vulvo-vaginal (labios vulvares, capuchón del clítoris, perineo) no quirúrgica o quirúrgica", explica la doctora Zuramis. Anteriormente estas afecciones eran tratadas mediante cirugía o directamente no se trataban y se usaban tratamientos paliativos tales como hidratantes o compresas. Ahora existe una plataforma, *EmpowerRF* de InMode que, sin tener que pasar por el quirófano, es capaz de solucionar todos los problemas de salud genital y el suelo pélvico. Se trata de una plataforma con seis tecnologías que ofrece tratamientos sin dolor: *VTone, FormaV, Tone, Morpheus8V, Morpheus8* y *Aviva.* ¿El resultado? Los tejidos se vuelven más sanos, recuperan su pH natural, hay más riego sanguíneo, más sensibilidad y un aumento en la calidad de vida de las mujeres. Ahora bien, ¿es un tratamiento seguro? Asusta hablar de microagujas dentro de la vagina, pero la respuesta es que sí. No hay riesgo, dolor, ni tiempo de recuperación. *EmpowerRF* es una plataforma pensada para ginecólogos y el tratamiento estándar son tres sesiones. Con una sola sesión ya mejora la pérdida de orina, la salud sexual, pero el tratamiento completo consiste en tres (una al mes). ■

GLAMOUR.ES

Revolución V-Care o por qué los cuidados de tu vagina y vulva serán tan importantes como los de tu rostro

22 DE ENERO DE 2024

Skinification es el término acuñado por la **industria de la belleza** que, en primera instancia se empleó para definir una **rutina de cuidado más multifuncional** que incluía productos de **maquillaje con activos cosméticos** que cuidan la piel. Más tarde, se extendió al **cuero cabelludo,** comenzando a aparecer cosméticos con funciones y activos que beneficiaban su equilibrio dérmico.

Ya lo dice el informe ***Pinterest Predicts*** que nos adelantaba las tendencias que arrasarán en 2024: "El enfoque en el cuidado facial está cambiando por el **cuidado de todo el cuerpo**. Las búsquedas de 'rutina de cuidado corporal' han aumentado un sorprendente **1.025%**".

Parece ser que el siguiente nivel de la corriente *skinification:* el **cuidado de la vagina y vulva**. Celebridades como **Gwyneth Paltrow** han allanado el terreno para romper los tabúes que rodean esta zona femenina. De hecho, Paltrow lanzó en su momento una vela llamada ***This Smells Like My Vagina*** (esto huele como mi vagina) para, entre otras cosas, concienciar sobre el cuidado vaginal. Otros artículos como las **copas y bragas menstruales**, así como los distintos cosméticos (geles y cremas) para el cuidado de la vagina y vulva han crecido en popularidad.

De la misma forma, aumentan los **tratamientos médicos estéticos** enfocados a esta zona del cuerpo, como la **Radiofrecuencia y terapia tecnológica vaginal de Inmode**. "La radiofrecuencia se utiliza en el mundo de la estética desde hace muchísimos años. Y cuando empezamos a estudiar si podíamos ofrecer soluciones no quirúrgicas nos preguntamos si podría tener el mismo efecto en el interior del cuerpo. Si el calor que genera logra activar el cuerpo para que empiece a regenerarse, ¿por qué no podemos conseguirlo también trabajando desde dentro y en la vagina?", señala el **Dr. Moore.**

WELIFE.ES

Cómo evitar la incontenencia urinaria cuando sales a correr

Los expertos no se cansan de repetir que las pérdidas de orina no son normales. No tienen que suceder al toser. Ni al reírse. Ni, por supuesto, al practicar ejercicio. En todos estos casos estamos ante una incontinencia urinaria -puede variar el grado- originada por algún tipo de problema en el suelo pélvico. Una afección que afecta a una de cada cuatro mujeres, según Observatorio Nacional dedicado a ella, y que cada vez es más frecuente entre quienes realizan deportes de impacto. La doctora Zuramis Estrada, directora médica de Cimeg Madrid y ginecóloga experta en suelo pélvico, señala que aproximadamente el 20% de las mujeres físicamente activas o deportistas amateur padecen algún tipo de incontinencia urinaria.

Cómo tratarlo: la eficacia de las nuevas tecnologías

Si, pese a todo, las pérdidas de orina aparecen se deben tratar. «Lo primero es someterse a una valoración profesional para a qué se deben, qué musculatura está afectada, si hay un buen tono muscular, si hay buena contracción de los músculos...», detalla Cristina Amores. Después llegará el diagnóstico. Y, en función del grado y tipo de incontinencia, la hoja de ruta a seguir. Lo habitual es combinar en consulta terapias físicas con las de energía, como la radiofrecuencia, las terapias eléctricas, la magnética focalizada o el láser. La doctora Zuramis Estrada confía de forma especial para estos casos en Empower RF, de Inmode.

«Una plataforma de radiofrecuencia con disimiles manípulos, que, en mi opinión, ha llegado para brindar un plus en la salud de la mujer y, específicamente, en la recuperación de estas disfunciones del suelo pélvico«. Para la incontinencia urinaria en mujeres que practican deporte, Estrada suele emplear el dispositivo Morpheus 8V, un manípulo de radiofrecuencia fraccionada con microagujas. «Se aplica en el canal vaginal y la zona suburetral y a través de esas microagujas se emite la onda electromagnética, logrando una mejor retracción del tejido tratado , mayor producción de colágeno y elastina», explica. No es doloroso y únicamente se aplica una crema anestésica en la zona media hora antes. Además, suele combinarlo con la terapia eléctrica vaginal (VTone, también de Empower RF), que actúa sobre los músculos del suelo pélvico mejorando su tono. Por tanto, la buena noticia es que existen múltiples opciones para acabar con esa incontinencia. Eso sí, sin olvidarse de que, como cualquier otro músculo del cuerpo, para que esté en forma hay que mantener siempre el entrenamiento.

MUJER.ES (20MINUTOS.ES)

Medicina estética genital, abajo los tabúes: ¿qué nos preocupa a las mujeres?

La hipertrofia o caída de los labios de la vulva

En mujeres jóvenes, el problema más recurrente en cuanto a estética genital suele ser la hipertrofia o caída de los labios de la vulva. Existen estudios que explican que en estos casos, a veces, las mujeres buscan ayuda porque esta situación les genera **incomodidad e irritación en su día a día, o molestias** durante las relaciones sexuales.

La solución está en **reducir el tamaño de los labios** (mayores y menores) para que las mujeres ya no tengan esos problemas vinculados con la hipertrofia o caída de los labios de la vulva y, además, se sientan más cómodas y a gusto con sus genitales, sin avergonzarse de su apariencia.

Problemas de incontinencia e hiperlaxitud

La incontinencia urinaria es uno de los principales tabúes en cuanto a estética genital que suele aparecer en mujeres de entre 35-50 años, generalmente, después de un embarazo. La Sociedad Española de Ginecología y Obstretricia (SEGO) la denomina también **"incontinencia por esfuerzo"** y su prevalencia está en torno al 12,5%, según indica.

Sin embargo, el embarazo también puede traer consigo la sensación de que la vagina se ha agrandado, lo que denominamos hiperlaxitud. El problema de esto es que, durante las **relaciones sexuales**, la fricción es menor (tal y como explica la SEGO), lo que se traduce en un menor disfrute y mayor preocupación que dificultará llegar al orgasmo.

Aunque el embarazo y el parto pueden provocar incontinencia e hiperlaxitud, la falta de tono en el suelo pélvico también es una de las causas por las que esto ocurre. La solución es trabajarlo o someterse a una **sencilla intervención** que corrija tanto la incontinencia como la hiperlaxitud de la vagina. Situaciones que generan mucha incomodidad y reparo, y de las que cuesta mucho hablar, algo que retrasa el tratamiento.

El síndrome genitorurinario de la menopausia

A partir de los 50 años, debido a la caída de los estrógenos que dan paso a la menopausia, la mitad de las mujeres sufrirán el síndrome genitourinario, según explica la SEGO, aunque este porcentaje se incrementa con la edad. En España la **dispareunia** (dolor durante las relaciones sexuales) y la **sequedad vaginal** son algunas de sus consecuencias más frecuentes. Sin olvidarnos de la **incontinencia**, que está de nuevo presente, o los **picores en el área genital**.

Las soluciones para tratar todas estas problemáticas son numerosas. Aunque la opción de pasar por **quirófano** siempre está presente (y en algunos casos puede ser la más recomendada), actualmente hay otras alternativas. Terapias con **láser, radiofrecuencia** o tratar con un fisioterapeuta especializado en suelo pélvico la falta de tono en este son algunas maneras de que las mujeres recuperen su bienestar.

OKDIARIO.ES

El lado oculto del CrossFit: puede provocar pérdidas de orina en las mujeres

Se estima que **el CrossFit** lo practican más de **1 millón de personas** en todo el mundo y las aperturas de centros de entrenamiento para realizar sus ejercicios funcionales de alta intensidad no para de crecer. Dos de los motivos principales por los que el **CrossFit** tiene tantos adeptos y sigue in crescendo son la transformación física y también mental que provoca en todos y cada uno de sus fans. Pero su práctica también puede traer consigo una serie de consecuencias no tan favorables.

La Dra. **Zuramis Estrada**, ginecóloga directora médica de CIMEG Madrid, afirma que el Crossfit puede provocar pérdidas de orina a partir de los 30 años (o incluso antes). Te contamos los porqués y cómo puede prevenirse o tratarse si ya sucede…

«Es cierto que el CrossFit puede ayudar a mejorar habilidades físicas: fuerza, r**esistencia, coordinación, equilibrio, movilidad**… También promueve la salud cardiovascular, un peso sano, que los músculos estén más fuertes y la salud mental. Pero hay que tener en cuenta que la práctica de sus ejercicios de alta intensidad también podría ser peligrosa si no se toman las precauciones adecuadas», señala la Dra. Zuramis Estrada.

¿Por qué sucede?

«A nuestra clínica acuden mujeres jóvenes (30-40 años o incluso de menos edad) que hacen CrossFit y nos cuentan que desde que practican este deporte tienen pérdidas de orina. Esto ocurre porque **los músculos que abrazan la uretra se han debilitado y el cierre del esfínter** -durante el aumento de las presiones abdominales con el esfuerzo- no es el adecuado», comenta la Dra. Zuramis Estrada.

«Hay que señalar que no sólo el CrossFit produce que se escape la orina. Otros deportes como los **levantamientos de peso, hacer running** y todos los deportes que generan gran impacto sobre los músculos del suelo pélvico pueden provocar pérdidas si no tenemos la zona entrenada correctamente», afirma.

Prevención y tratramiento

«Las mujeres tienen que ser conscientes de que tienen un complejo de músculos, ligamentos y **tendones en su zona pélvica**. Entrenar el suelo pélvico con ejercicios personalizados como Kegel o con terapias de energías específicas como es **la radiofrecuencia fraccionada con microagujas** Empower RF de InMode: sus manípulos Morpheus8V y V tone ayudan a trabajar el suelo pélvico debilitado o no entrenado, mejorar su tono y neuromodular eléctricamente todo el complejo pélvico», señala la Dra. **Zuramis Estrada.**

«En ocasiones, se necesita combinar con otras terapias en clínica como la terapia magnética focalizada, entrenamientos en casa como abdominales **hipopresivos** y consejos como, por ejemplo, evitar estreñimiento, mejorar la postura, realizar respiraciones adecuadas con entrenamiento del diafragma y dieta», comenta la experta.

Si haces CrossFit o algún otro deporte de impacto y aún no tienes pérdidas de orina, pero tienes miedo a que ocurra, ¡puedes prevenirlas!

«Las pérdidas de orina se pueden prevenir. De hecho, mi apuesta es -siempre- la medicina preventiva y las mujeres que practican CrossFit deben entrenar todas las cadenas musculares sin olvidarse de la pelvis y todo el *core* abdominal. Además, recomiendo acudir a evaluación y control especializado de su suelo pélvico y realizar terapias preventivas en clínica **cada 6 – 12 meses** y también recomiendo las terapias físicas tipo fisioterapia de suelo pélvico con tablas específicas».

VOGUE.ES

Así se adaptan (con mucho éxito) los retoques de medicina estética a la zona íntima

"Hace diez o doce años, cuando comencé a aplicar estas terapias de medicina estética en el área genital con 'fines estéticos' –y pongo comillas porque siempre hay una alteración funcional detrás– se comentaba que era pura tendencia o moda, tanto a nivel médico como social", recuerda la doctora Zuramis Estrada, ginecóloga experta en desórdenes del suelo pélvico, ginecología estética y terapias regenerativas. El caso es que, además de esta injusta fama de frívola, la ginecoestética tiene cada vez más cosas en común con la **medicina estética facial**, como sus tratamientos estrella.

¿Lo más novedoso? La dra. Estrada indica que es Empower RF, de Inmode: "Con sus manúpulos Morpheus8v (radiofrecuencia fraccionada por agujas intravaginales) y Vtone (electroestimulación intravaginal), es una plataforma de radiofrecuencia que también aplicamos para alteraciones funcionales de suelo pélvico, incontinencia urinaria, síndrome de hiperlaxitud vaginal, etc.".

Los tratamientos más demandados

1. "El tratamiento más demandado a nivel estético es la **armonización vulvar**", aseguran desde InMode. Su tecnología trata labios (mayores y menores), capuchón del clítoris y perineo con radiofrecuencia –no con cirugía–.
2. El más solicitado a nivel funcional en InMode es el tratamiento no quirúrgico para la **incontinencia urinaria o escapes de orina**. "Aquí también usamos terapias de energías tipo radiofrecuencia fraccionada intravaginal y electroestimulación para trabajar el suelo pélvico.
3. Clínicas Dorsia destaca el **estrechamiento vaginal y/o corrección de prolapsos genitales**, cuando la vagina queda demasiado amplia tras el parto. "Los defectos leves se pueden corregir con láser; si son más importantes, con cirugía convencional", indican.
4. El r**ejuvenecimiento vaginal** con láser o radiofrecuencia es uno de los más completos: "Mejora el tono, reduce ligeramente la amplitud, potencia la lubricación, corrige la incontinencia urinaria de esfuerzo leve y aumenta la satisfacción en la relaciones sexuales", comentan desde Clínicas Dorsia.
5. "El plasma rico en plaquetas (PRP) y el ácido hialurónico, ampliamente utilizado en otras especialidades médicas, aportan soluciones en la **ginecología regenerativa**", señalan desde Allergan. Su aplicación conjunta sirve para acabar con los inconvenientes que suelen derivarse del parto vaginal.

INMODE

IBERIA

EMPODERA LA SALUD ÍNTIMA FEMENINA

EMPOWER**RF**

COSMOEXPOBEAUTY.ES

"MENOS PAUSAS" Y MÁS ORGASMOS: Cómo abordar la menopausia de forma positiva con EmpowerRF de InMode.

Durante la menopausia aparece la atrofia genital, cuya principal manifestación es la sequedad que incomoda y dificulta el coito y las infecciones y pérdidas de orina también pueden volverse repetitivas. La Dra Zuramis Estrada* explica cuáles son los temas qué más cuesta abordar a las mujeres en la peri y menopausia y cómo Empower RF de InMode puede solucionar las problemáticas de la salud íntima.

La Dra. Zuramis Estrada Blanco (directora Médica de CIMEG Madrid y experta en suelo pélvico fue una de las ginecólogas pioneras en realizar diferentes terapias en la vulva y la vagina hace más de una década para mejorar aquellas alteraciones que suelen aparecer con los cambios hormonales tras la pubertad / adolescencia, postparto y la perimenopausia o postmeanopausia).

LO QUE PASA DURANTE LA PERIMENOPAUSIA Y MENOPAUSIA

Durante estas etapas, la Dra Zuramis afirma que a las mujeres les preocupa y les cuesta abordar diferentes temas que se pueden englobar en dos grupos:

– Estético: La flacidez que aparece en toda la zona vulvar por la pérdida de colágeno y elastina y la hipertrofia de los labios. En ocasiones las mujeres se sienten inhibidas por si por la edad no pudiesen sentirse con la necesidad de mejorar su zona íntima, que en muchas ocasiones no solo es por estética sino porque sienten molestias o no están cómodas con la ropa interior, durante el coito e incluso con ropa de deporte.

– Funcional: El dolor durante las relaciones sexuales causado casi siempre por la atrofia (sequedad) que sufre la zona genital (vulva- vagina) por la disminución o pérdidas de hormonas (estrógenos, andrógenos, gestágenos). Diríamos que entre el 42 a 46 % de las mujeres en esa etapa lo pueden sufrir según estudios estadísticos y, aun así, llegan a nuestras consultas en etapas avanzadas o agravadas de esta disfunción, porque incluso dentro de sus grupos de amigas o familias no lo comentan.

ASUMÁMOSLO, LAS PÉRDIDAS DE ORINA NO SON NORMALES

Durante años se han ido normalizando ciertas problemáticas relacionadas con la menopausia como, por ejemplo, las pérdidas de orina. Y, según la Dra. Zuramis, esto es un auténtico error. "Las pérdidas de orina no son normales: ni muchas ni pocas. En ocasiones las pacientes creen que por haber tenido 1 o 2 partos o por estar en la etapa menopáusica es normal y es «lo que toca». Incluso comentan que algún médico se lo comentado y… mo es así y deberíamos seguir educando al respecto".

“**La incontinencia urinaria es una «epidemia silenciosa»** -señala la experta- teniendo en cuenta que **1 de cada 4 mujeres en España la sufre** y en etapa postmenopáusica alcanza cifras estadísticas de hasta un 50%. ¿Lo bueno? Tiene tratamiento, pero lo más importante, se puede prevenir”.

“Las pérdidas de orina se pueden tratar con terapias de energías vaginal y suburetral como es la radiofrecuencia fraccionada Empower RF de InMode”.

EMPOWER RF DE INMODE ES UNA PLATAFORMA QUE INCLUYE VARIAS TECNOLOGÍAS PARA TRATAR, ADEMÁS DE LA INCONTINENCIA URINARIA, LA CIRCULACIÓN SANGUÍNEA, ALIVIO DEL DOLOR, SUELO PÉLVICO DEBILITADO Y ATROFIA GENITAL, ¡SIN CIRUGÍA!

“A todas las mujeres que acuden a nuestras consultas ginecológicas, les diría que nuestros genitales y suelo pélvico son una parte importante de nuestro organismo y de nuestra vida y que no deben sentir pudor o vergüenza por preguntar cómo sentirse mejor, cómo mejorarlos e incluso al abordar una patología como la incontinencia urinaria”, señala la Dra. Zuramis.

“Tenemos que tener en cuenta que, con el paso de los años, estas zonas requieren cuidados o «mimos» al igual que hacemos con la cara o incluso el cuello. También tienen un proceso de envejecimiento y sufre cambios por la edad, cambios de peso, embarazos partos y por las modificaciones hormonales de la perimenopausia- menopausia, e, incluso, genéticas”, añade.

“La salud íntima femenina es el estado de bienestar de los genitales (vagina- vulva) los cuales se mantienen en condiciones fisiológicas que le permiten a la mujer disfrutar una vida sexual plena y libre de síntomas como picor, sequedad, dolor, flacidez, incontinencia, infecciones, etc. La edad, hormonas, microbiota cambian a lo largo de la vida de la mujer por lo que hay que tenerlo en cuenta” finaliza.

ENPOZUELO.ES

CrossFit: Beneficios y Riesgos para la Salud del Suelo Pélvico en Mujeres

Así lo asegura la dra. Zuramis Estrada, ginecóloga.

Se estima que **el CrossFit lo practican más de 1 millón de personas en todo el mundo** y las aperturas de centros de entrenamiento para realizar sus ejercicios funcionales de alta intensidad no para de crecer. Dos de los motivos principales por los que el CrossFit tiene tantos adeptos y sigue in crescendo son la **transformación física y también mental** que provoca en todos y cada uno de sus fans. Pero su práctica también puede traer consigo una serie de consecuencias no tan favorables. La Dra. Zuramis Estrada, ginecóloga directora médica de CIMEG Madrid, afirma que **el Crossfit puede provocar pérdidas de orina a partir de los 30 años (o incluso antes)**. Te contamos los porqués y cómo puede prevenirse o tratarse si ya sucede…

La cara A y la cara B del crossfit

"Es cierto que **el CrossFit puede ayudar a mejorar habilidades físicas: fuerza, resistencia, coordinación, equilibrio, movilidad**… También promueve la salud cardiovascular, un peso sano, que los músculos estén más fuertes y la salud mental. Pero hay que tener en cuenta que **la práctica de sus ejercicios de alta intensidad también podría ser peligrosa** si no se toman las precauciones adecuadas", señala la Dra. Zuramis Estrada.

"Su naturaleza de alta intensidad, los movimientos complejos propios del levantamiento de pesas olímpico, la gimnasia, la calistenia, etc. pueden conducir a lesiones, cansancio extremo, estrés cardíaco y otras alteraciones como el **desbalance muscular**. Es cierto que no siempre ocurre, pero es probable cuando los entrenamientos se enfocan solo en ciertos tipos de ejercicios o patrones de movimientos en los que ciertos músculos se trabajan más que otros. Si se mantiene así con el tiempo, puede desembocar en **debilidades musculares** que afectan la funcionalidad en general", añade.

Por qué el crossfit puede provocar pérdidas de orina

"A nuestra clínica acuden mujeres jóvenes (30-40 años o incluso de menos edad) que hacen CrossFit y nos cuentan que desde que practican este deporte tienen pérdidas de orina. Esto ocurre porque los músculos que abrazan la uretra se han debilitado y el cierre del esfínter -durante el aumento de las presiones abdominales con el esfuerzo- no es el adecuado", comenta la Dra. Zuramis Estrada.

"Hay que señalar que **no solo el CrossFit produce que se escape la orina**. **Otros deportes como los levantamientos de peso, hacer running y todos los deportes que generan gran impacto sobre los músculos del suelo pélvico** pueden provocar pérdidas si no tenemos la zona entrenada correctamente", afirma.

Cómo podemos prevenir y tratar las pérdidas de orina provocadas por el crossfit y por otros deportres que impactan en el suelo pélvico

"Las mujeres tienen que ser conscientes de que tienen un complejo de músculos, ligamentos y tendones en su zona pélvica. Entrenar el suelo pélvico **con ejercicios personalizados como Kegel o con terapias de energías específicas como es la radiofrecuencia fraccionada con microagujas Empower RF de InMode:** sus manípulos Morpheus8V y V tone ayudan a trabajar el suelo pélvico debilitado o no entrenado, mejorar su tono y neuromodular eléctricamente todo el complejo pélvico", señala la Dra. Zuramis Estrada.

"En ocasiones, se necesita combinar con otras terapias en clínica como la terapia magnética focalizada, **entrenamientos en casa como abdominales hipopresivos** y consejos como, por ejemplo, **evitar estreñimiento, mejorar la postura, realizar respiraciones adecuadas con entrenamiento del diafragma y dieta**", comenta la experta.

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