Received: 9 November 2022 | Accepted: 16 February 2023

DOI: 10.1002/nau.25170

CLINICAL ARTICLE

Neurourology Urodynamics | SUFU | WILEY

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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Funding information
Inmode

Abstract

Introduction: Radiofrequency (RF) energy application stimulates collagen and elastin remodeling to restore the elasticity, and moisture of the superficial vaginal mucosa. This is the first study to report on the use of microneedling to deliver RF energy to the vaginal canal. 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, 2, or 3 mm.

Objective: A prospective study to evaluate the safety and short-term 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, 2, 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-, 3-, and 6-months post-treatment compared to baseline. Biopsies were performed at baseline and 3-months on five 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-, 3-, and 6-month follow-up sessions compared to baseline.

Conclusions: The results showed evidence that fractional RF energy delivered vaginally is safe, well tolerated, and provide short term improvement of SUI and or MUI in conjunction with GSM.

KEYWORDS
GSM, mixed incontinence, Radiofrequency, stress incontinence

1 | INTRODUCTION

Stress urinary incontinence (SUI) is the involuntary leakage of urine with exertion, sneezing, or coughing while urgency incontinence is involuntary leakage that is associated with sensation of urgency. Mixed incontinence (MUI) occurs when both conditions are present together.[1] Low 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 genitourinary syndrome of menopause (GSM).

SUI, MUI, and GSM are extremely prevalent conditions and thus commonly coexist in post-menopausal women. The demand for in-office, minimally invasive treatments for these conditions is increasing as awareness of nonsurgical options becomes more prevalent.[3]

Until now, Radiofrequency (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°C, 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] While fractional CO_2 laser had recently demonstrated similar findings, the depth of penetration is less than 1 mm,[10]

With more restrictions on the use of slings to treat SUI in some countries, such as the United Kingdom, New Zealand, and Australia,[11–13] and patients' perceptions of slings because of bad media portrayals, further efforts to develop alternate solutions for treating SUI are needed. Less invasive and office-based treatments are becoming more common, including procedures that use energy sources like laser and RF.

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

2 | METHODS

This was an IRB-approved prospective study at a single site (Study # 8447; Protocol number D0609885A). All procedures were performed by one of two board certified gynecologists. Twenty consecutive patients who met inclusion criteria were recruited from a single private practice between October 2020 and May 2021. All patients signed a written informed consent to participate in the study. The patients were not reimbursed for the study and did not pay to participate in the study.

Inclusion criteria included postmenopausal female patients between the ages of 50 and 75 with symptoms of GSM in conjunction with SUI and/or MUI with no history of systemic or local estrogen therapy. The SUI was confirmed by stress cough test, The cough stress test was performed by asking the patient to void 30 min before the test, to drink 0.5 L of water and not to empty their bladder. A preweighted pad was applied, and subject was be asked to cough three times in standing position after which the pad weight was checked. Other inclusion criteria included a score of at least 18 out of 27 on the Medical, Epidemiologic (MESA-SI), and Social Aspects of Aging Urinary Incontinence (MESA) subscale questionnaire for SUI, body mass index (BMI) < 36 and general good health. All subjects were also required to have not used any other vaginal esthetic treatment methods for the 6-months before the study or during the entire study period which included any RF or vaginal laser treatments. 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, any history of treatment with medications, Botox or Sacral Neuromodulation for urgency incontinence or any surgery in the treated area within 3-months before the treatment.

Pretreatment evaluation included medical history, menopausal status, and gynecological exam with assessment of vaginal atrophy via Vaginal Health Index (VHI) and cough stress test. Fitzpatrick scale[14] was used to assess for skin type as a part of medical history. It is a commonly used classification to describe skin type in terms of response to ultraviolet radiation exposure. It consists of six categories with type I being always burns, never tans and type VI never burns. Incontinence Quality of Life Questionnaire (I-QOL), Urogenital Distress

Inventory-6 (UDI-6), and MESA-SI, and Social Aspects of Aging Urinary Incontinence (MESA) Questionnaires were all completed by the patient before treatment.

Subjects were pretreated with Lidocaine 23%—Tetracaine 7% cream for 20 min before the procedure. Five study subjects randomly had a baseline biopsy of the vaginal mucosa taken before 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 1, 2, and 3 mm. The Morpheus8V applicator is shown in Figure 1. The treatment protocol was described by the manufacturers. Patients were instructed to avoid intercourse for 48 h after procedure.

After treatment the patients were given a voiding diary to complete for the remainder of the study. At 1, 3, 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 UDI-6 questionnaire. For the patients who had a baseline biopsy, another biopsy was taken at 3-months post-treatment.

The side effects were evaluated as pain reported by patient during or after treatment, worsening of urinary symptoms and the presence of vaginal burns after treatment.

2.1 | Outcomes measures

The outcome measures included both subjective and objective outcome. Subjective outcomes included IQOL, UDI-6, and MESA which were administrated pretreatment and at 1-, 3-, and 6-months post-treatment. The MESA questionnaire consists of 15 items total divided into stress and urge subscales, higher MESA score indicates more frequent symptoms overall (range of 0–45) and for each incontinence subscale (range of 0–27 for SUI and range of 0–18 for UUI).[15] The I-QOL questionnaire consists of 22 items, all of which use a 5-point ordinal response scale in which 1 = extremely, 2 = quite a bit, 3 = moderately, 4 = a little, and 5 = not at all. The total I-QOL is calculated by summing the unweighted item score and transforming them to a 100-point scale where 0 = most severe, and 100 = no problem.[16] UDI-6 questionnaire consists of 6 items: 1—Frequent urination, 2—Leakage related to feeling of urgency, 3—Leakage related to activity, 4—Coughing, or sneezing small amounts of leakage (drops), 5—Difficulty emptying the bladder, and 6—Pain or discomfort in the lower abdominal or genital area. Higher scores in UDI-6 indicate higher disability. Total score is from 0 to 100.[17] Objective outcome measures included VHI, bladder diary, cough-pad stress test and vaginal biopsy results. The VHI is one of the most common tools used to evaluate vulvovaginal atrophy. It consists of five parameters (vaginal elasticity, vaginal secretions, pH, epithelial mucous membrane, vaginal hydration). 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. The degree of atrophy of the vagina is defined by the final score obtained after the evaluation of each parameter. The final score can vary between 5 and 25, with a cut-off <15 meaning that there is VA vaginal atrophy.[18] The cough stress final weight scores ranged from 0 to 39, with lower values indicating less urine, and higher values indicating more urine captured in the pad. The bladder diary has also been used routinely as a primary outcome measure in incontinence research.[19] Patient is given a 7-day bladder diary and asked to return it the day of their procedure. Patients were also given a 7-day voiding diary which were completed before each subsequent follow-up visit. Vaginal biopsies were taken pretreatment and repeated at 3-month after treatment. Table 1 shows the outcome measures with range and its interpretation.

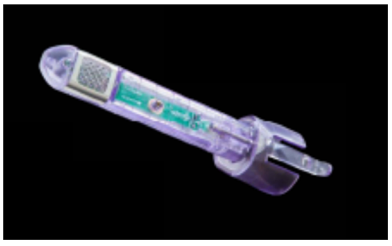

FIGURE 1 Morpheus8V applicator.

TABLE 1 Repeated measure analysis of variance pairwise comparison results (Three measurements).

Item	BL mean	3 M mean	6 M 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

Note: $p < 0.05$ are considered significant.

Abbreviations: BL, baseline; iQOL, Incontinence Quality of Life Questionnaire; MESA-SI, Medical, Epidemiologic, and Social Aspects of Aging stress subscale, MESA-UI, Medical, Epidemiologic, and Social Aspects of Aging urgency subscale; VHI, Vaginal Health Index.

2.2 | Statistical analysis

All outcome data were measured at three, or four time points. Repeated measures analysis of variance (ANOVA) tests were employed. The omnibus test was used as a statistical test to determine whether multiple outcomes means are equal or not. It is used to test whether the populations mean of multiple groups are equal or not as opposed to testing each mean individually. It provides a quick and efficient way to determine whether any significant differences exist between groups. The interpretation of the omnibus test is based on the *p*-value. A *p*-value less than the significance level (0.05) indicates that at least one population mean is significantly different from the others.

SPSS software was used for all statistical analyses (IBM SPSS statistics for windows; version 26, IBM Corp., 2019).

3 | RESULTS

20 patients were enrolled in the study. The median age was 53.5 (46−73), median BMI is 29.5 (26−40). In terms of skin type, 10 (50%) patients had skin type II, 6 (30%) patients had skin type III, and 4 (20%) patients had skin type IV. All the patients were followed for 6 months and completed the 3- and 6-month assessments. The previous five random patients who had vaginal biopsies where rebiopsied at 3-months follow-up for histological comparison.

No major side effects were reported in any patient including pain other than mild discomfort during the procedure, no worsening urinary function and vaginal burns.

4 | REPEATED MEASURES ANOVA RESULTS

4.1 | (Outcomes with three measurements)

The mean value was represented for outcomes measures like MESA, UDI-6, iQOL, and VHI as they all had a normal distribution. The MESA additive SI battery instrument ranged with scores from 1 to 27. Measurements were taken at baseline, 3-, 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.

TABLE 2 Repeated measure ANOVA means (four measurements).

Item	BL mean	1 M mean	3 M mean	6 M mean
Cough stress	13.05	4.32	3.84	2.79
UDI-6	43.85	18.20	21.05	26.76
Voiding frequency	55.07	44.33	45.00	47.87
Voided quantity	448.07	416.0	388.60	343.07

Abbreviations: BL, baseline; UDI-6, Urogenital Distress Inventory-6 cough stress final weight scores ranged from 0 to 39, UDI-6 score from 0 to 100.

The MESA additive UI battery instrument ranged with scores from 1 to 18. Measurements were taken at baseline, 3-, 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 I-QOL measurements were taken at baseline, 3-, 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 to 25. Measurements were taken at baseline, 3-, 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. Table 2 presents the three-time period means and corresponding pairwise comparison *p*-values.

5 | REPEATED MEASURES ANOVA RESULTS

5.1 | (Outcomes with four measurements)

The following clinical evaluation baseline and post-treatment results are shown in Figure 2 and 3; The cough stress final weight scores ranged from 0 to 39. Measurements were taken at baseline, 1-, 3-, 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- and 6-months, which indicates that

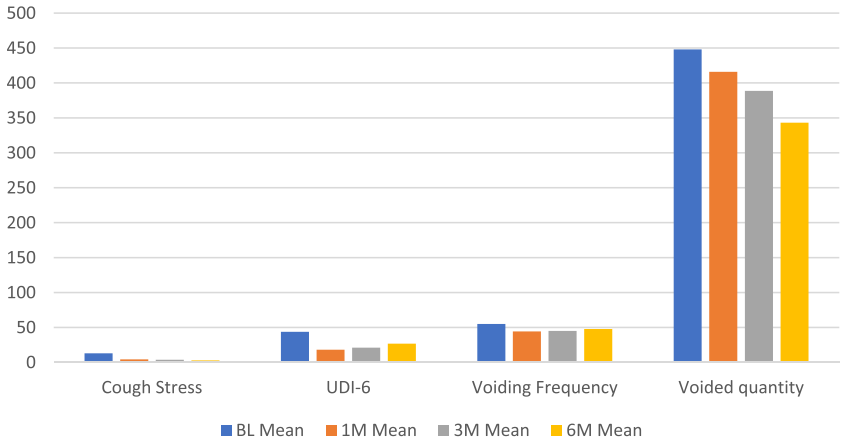

FIGURE 2 Repeated measure ANOVA means (4 measurements). ANOVA, analysis of variance.

TABLE 3 Repeated measure ANOVA pairwise comparison *p* values (four measurments).

Item	BL-1 M	BL-3 M	BL-6 M	1–3 M	1–6 M	3–6 M
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
Voided frequency	0.009	0.02	0.04	0.81	0.06	0.22
Voided quantity	0.39	0.12	0.05	0.23	0.17	0.28

Note: $p < 0.05$ are considered significant.

Abbreviations: BL, Baseline, UDI-6, Urogenital Distress Inventory-6.

symptoms maintained their improved status from 1 to 6-months.

The UDI-6 additive scale ranged with scores ranging from 0 to 39. Measurements were taken at baseline, 1-, 3-, 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.

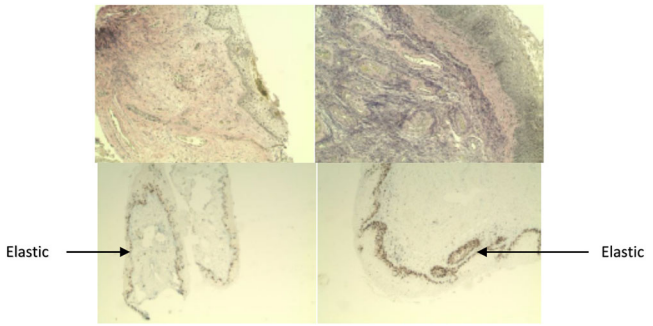

FIGURE 3 Histological section of skin biopsies before (Left) and 3-months following fractional treatment (Right) demonstrating increase in elastic fibers density. Bottom, Ki-67×4; Top, Elastic x10.

6 | HISTOLOGICAL RESULTS

Five biopsies were performed. 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 3 shows biopsies performed before treatment and at 3-months post-treatment stained with elastic and Ki-67 stains.

7 | DISCUSSION

Collagen deficiency is likely to play a role in the development of both GSM and UI. RF therapy increases collagen formation, which is thought to help with UI and vulvovaginal atrophy symptoms.

In this study, we assess safety, tolerability and short-term Efficacy, of a single treatment of fractional RF in treating Stress and or MUI in conjunction with GSM. The 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 is safe, well tolerated, and efficacious in the short term.

Multiple studies have discussed the use of laser and contact RF treatment for GSM and UI, with patients typically receiving three treatments spread out over 3 months. Those studies have demonstrated a benefit when treating GSM and UI symptoms using either technology.[20,21] We believe the pathophysiology in part of vaginal atrophy and UI is linked to collagen production, and by increasing collagen production, both problems can potentially be improved. This is the first study to report the use of fractional RF treatment of the vaginal mucosa. The primary objective was to document safety and tolerability as well as record standard outcomes regarding symptoms of SUI and GSM. For this reason, only a single treatment was performed. Fractional RF is known to penetrate tissue up to 3 mm while laser treatment only penetrates < 1 mm. Further studies in which a series of 3 treatments are currently underway and will be necessary to truly determine outcomes and durability of fractional RF therapy.

Also due to potential concerns regarding the development of scar tissue from a deeper penetration than previous laser therapy, vaginal biopsies were taken pretreatment and 3 months post treatment. Histologic assessment confirmed that the RF injury created more elastin and vascularity with no evidence of any scar formation.

In summary, Fractional RF appears to hold the potential to treat, in-office, two very common conditions that millions of women suffer from. This procedure was noted to be safe, well tolerated and improved both SUI and GSM.

8 | CONCLUSION

Preliminary data on fractional RF would seem to indicate that such an intervention can result in improvement of vaginal atrophy and UI.

Further prospective studies are underway in which three consecutive treatment sessions are performed in the hope of maximizing efficacy and increasing the durability of the treatment.

AUTHOR CONTRIBUTIONS

All authors have been personally and actively involved in substantial work leading to the paper and will take public responsibility for its content.

ACKNOWLEDGMENTS

This study is funded by In mode Study # 8447, Protocol number D0609885A.

CONFLICT OF INTEREST STATEMENT

Tracy Blusewicz: Inmode National/International speaker and trainer.

Mickey Karram: Consultant and speaker for Biote, Inmode, Pathnostics, Allegran, Astellas, Urovant, Colpoplast and Caldera. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENTS

This material is the authors own original work, which has not been previously published elsewhere. The paper is not currently being considered for publication elsewhere. The paper reflects the authors' own research and analysis in a truthful and complete manner. The paper properly credits the meaningful contributions of coauthors and coresearchers. The results are appropriately placed in the context of prior and existing research. All sources used are properly disclosed (correct citation). All patients participated were consented to enroll in the study. A permission to reproduce materials from other sources were obtained if needed.

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How to cite this article: Abdelaziz A, Blusewicz TA, Coley KP, Karram M. 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. *Neurourol Urodyn*. 2023;1-7. doi:10.1002/nau.25170