Evaluation of the Safety and Efficacy of a Novel Radiofrequency Device for Vaginal Treatment

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ABSTRACT

Introduction: Vaginal laxity and atrophy are caused mainly by aging and vaginal childbirth, which lead to a loss of strength and flexibility within the vaginal wall. As a result, women may experience vaginal, pelvic, sexual and urinary symptoms that significantly affect their quality of life.

Objective: The aim of this study was to evaluate the safety and efficacy of a novel radiofrequency (RF) device for internal and external vaginal treatment.

Methods: Thirty women who had been diagnosed with symptoms of vaginal laxity and pelvic relaxation received a single treatment that consisted of continuous RF in the internal genitalia and continuous RF followed by fractional RF in the external vulva. Three different treatment conditions were examined. The results were evaluated by questionnaires and photos at two months post-treatment compared to baseline.

Results: For all parameters that were scored in the questionnaires, including vaginal symptoms, sexual matters, quality of life, pelvic floor impact and Stress Urinary Incontinence, significant improvements were found at a 2-month follow-up, compared to baseline ($p<0.001$). No significant or unexpected adverse events were noted.

Conclusions: The present results suggest that this novel RF-based device with continuous and fractional RF technologies is useful, safe and effective for treating vaginal relaxation and atrophy symptoms.

INTRODUCTION

The anatomy and physiology of female genitalia can change due to various causes such as childbirth, aging and menopause, genetics or trauma. If the female genital region becomes loose and lax over time, this can cause medical and aesthetic concerns that can adversely affect female sexual health and quality of life. Symptoms include atrophic vaginitis, decreased sensation during coitus, loss of sexual gratification, stress urinary incontinence (SUI), pelvic organ prolapse and general dissatisfaction with the appearance of the area. Since vaginal laxity is common and may impact important sexual and medical functions, greater knowledge regarding pathophysiology and treatment is of benefit to women patients.[1]

Vaginal rejuvenation is a general term used to describe a range of procedures intended to restore the optimal structure of the vagina and surrounding tissues. These procedures include topical and systemic treatments, surgical procedures and, recently, energy-based technologies. Noninvasive energy-based procedures are often preferred by women who are reluctant to undergo surgery due to the risk, expense, and recovery period.[2]

New energy-based vaginal rejuvenation modalities include lasers, such as fractional CO_2 [3] or erbium:yttrium-aluminum-garnet (Er:YAG),[4-6] and radiofrequency (RF)-based devices.[7-9] RF is one of the more innovative approaches to treating vulvo-vaginal laxity and SUI. It has gained significant popularity in recent years due to its non-invasiveness, absence of adverse events, and rapid results. The mechanism of action is based on elevating the temperature of the treated tissue to initiate biological changes.[10] RF energy heats the connective tissue of the vaginal wall to 40 - 43°C, triggering micro-inflammatory stimulation of fibroblasts to stimulate collagen contraction, neocollagenesis and neoelastogenesis to revitalize and restore the strength, elasticity and moisture of the vaginal mucosa.[2,7-9]

Numerous studies have demonstrated the therapeutic efficacy of RF-based devices in the rejuvenation of other areas such as the face and neck,[10,11]; their application in the vaginal canal is a relatively new concept that is currently being studied.[2]

The aim of this prospective study was to evaluate the safety and efficacy of a novel system that includes both continuous and fractional RF handpieces for vaginal rejuvenation treatment.

METHODS

Study Design

Thirty female subjects between the ages of 40 and 60 y (mean 48.6 y) with symptoms of pelvic relaxation and vaginal laxity who desired vaginal rejuvenation treatment were recruited from a private practice into this prospective study, which was performed from late 2017 to early 2018. Medical history, demographic information, and reproductive factors were obtained at a baseline screening visit. The study included women who had had at least one vaginal

Figure 1. The Votiva System (Reprinted with permission from InMode MD, Ltd.)

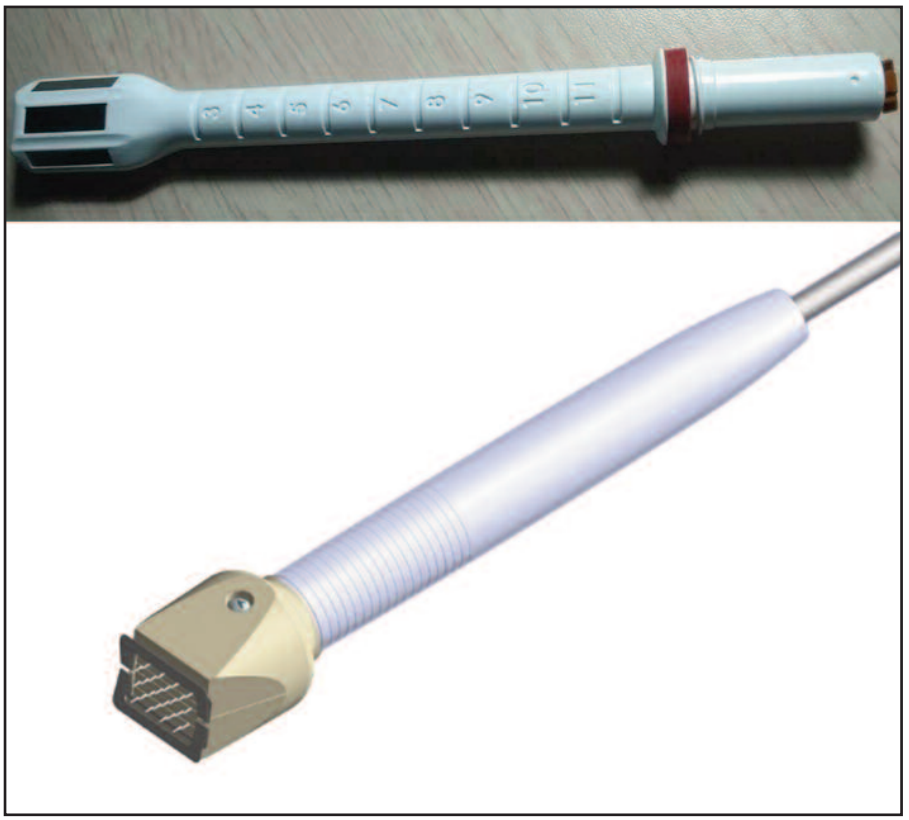

Figure 2. The FormaV (Top) and FractoraV (Bottom) handpieces (Reprinted with permission from InMode MD, Ltd.)

delivery, negative PAP smear, and a pelvic exam performed within the previous 2 years.

Exclusion criteria included pacemaker or internal defibrillator, or other implanted metallic or electronic device, permanent implant in the treated area, current or history of cancer or pre-malignant conditions, cardiac disorders, pregnancy or lactation, use of hormone replacement therapy, impaired immune response, history of or current diseases stimulated by heat, diabetes, active skin condition in the treatment area, skin disorders, bleeding disorder, treatment or surgery performed in the treatment area within a year prior to treatment, any therapies or medications that may have interfered with the use of the study device or compromised health as determined by the supervising physician.

The study was approved by an Institutional Review Board (IRB) and signed informed consent was obtained from all participants prior to enrollment in the study.

Table I
Repeated measures analysis of all outcomes

	P-value		
	Difference over time	Difference between groups	Interaction
Vaginal symptoms	<0.001	0.578	0.423
Sexual matters	=0.001	0.280	0.446
Life quality	<0.001	0.437	0.964
Pelvic floor	<0.001	0.189	0.150
Incontinence impact	<0.001	0.111	0.546
Consultation on incontinence	<0.001	0.206	0.556

Treatment

Treatment was performed using a bipolar RF-based device (Votiva, InMode MD Ltd., Lake Forest, CA) with two handpieces: FormaV, which delivers continuous RF, was used to treat the vaginal and external genital areas, and FractoraV, which delivers fractional RF in the external genital area (labia). Figures 1 and 2 show the device and the two handpieces, respectively.

Both handpieces are based on experience gathered from the use of similar handpieces that applied continuous or fractional RF (Forma and Fractora, respectively; InMode MD Ltd) which are used for various skin-tightening and rejuvenation applications. Studies have demonstrated that these handpieces are both safe and effective when used either alone[10-13] or in combination.[14]

The overall system enables the individual adjustment of RF power and monitoring of RF parameters to achieve maximum efficiency, safety and comfort for each patient.

A cut-off temperature of 43°C is constantly maintained for the FormaV handpiece. As the measured temperature approaches the cut-off temperature, a beeping tone increases in speed until the cut-off temperature is reached, at which point RF is automatically and instantly deactivated. As soon as the temperature drops below the cut-off temperature, RF restarts automatically, thus safely maintaining the desired temperature. Temperature is monitored by a temperature-sensor in the handpiece, which serves as a safety feature.

Subjects were divided into three groups of 10 subjects each, which received continuous RF (FormaV) treatment for different durations: Group I: treated 16-20 minutes internally in the vaginal canal and 8-10 minutes per labium, Group II: treated 10-12 minutes in the vaginal canal and 5-6 minutes per labium and Group III: treated for 6-8 minutes in the vaginal canal and 3 minutes per labium.

Treatment parameters were adjusted according to the patient's tolerance and condition. FormaV treatment parameters included an RF energy level of 25-30 and a cut-off temperature of 43°C. FractoraV with a coated 24-pin tip was used with an RF energy level ranging from 15 to 30.

Table II
Within-group percent change from baseline at 2 months (mean ± SD)

	Group I (N=8)	Group II (N=8)	Group III (N=9)	Total (N=25)
Vaginal Symptoms	38.72 ± 27.42	68.15 ± 31.75	45.54 ± 28.36	50.60 ± 30.67
Sexual Matters	62.12 ± 38.21	84.57 ± 36.02	69.92 ± 30.13	72.08 ± 33.99
Life Quality	70.83 ± 56.69	65.94 ± 70.18	57.94 ± 37.84	64.62 ± 53.68
Pelvic Floor Impact	81.04 ± 33.99	48.21 ± 57.06	55.04 ± 34.88	61.17 ± 43.52
Incontinence Impact	85.32 ± 19.25	54.29 ± 44.65	50.00 ± 48.15	62.68 ± 41.44
International Consultation on Incontinence	40.27 ± 45.13	41.00 ± 39.71	30.68 ± 22.09	37.05 ± 35.22

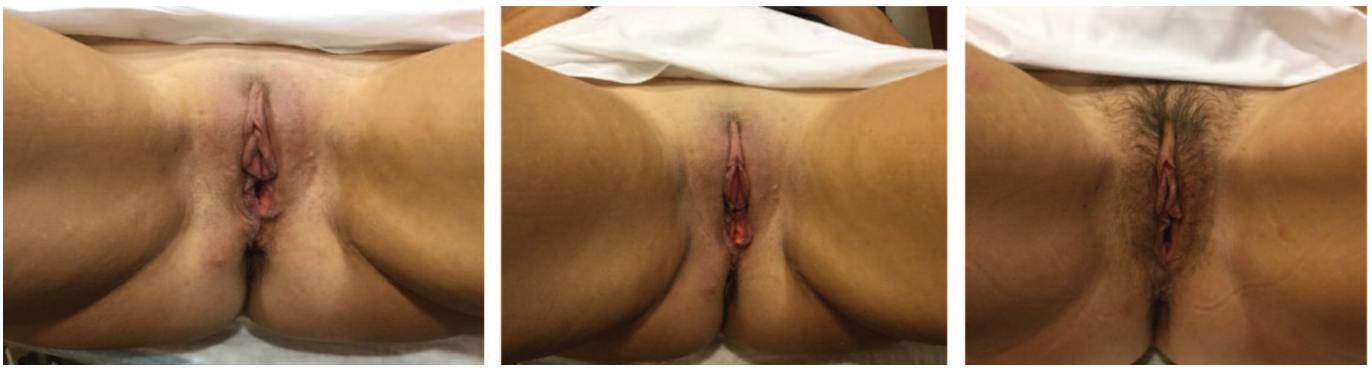

Figure 3. Example of results in a light-skinned subject treated with the FormaV for 12 minutes in the vaginal canal and 6 minutes per labium, followed by FractoraV in the labia area. Before treatment (Left), Immediately after treatment (Middle) and at a 2-month follow-up visit (Right).

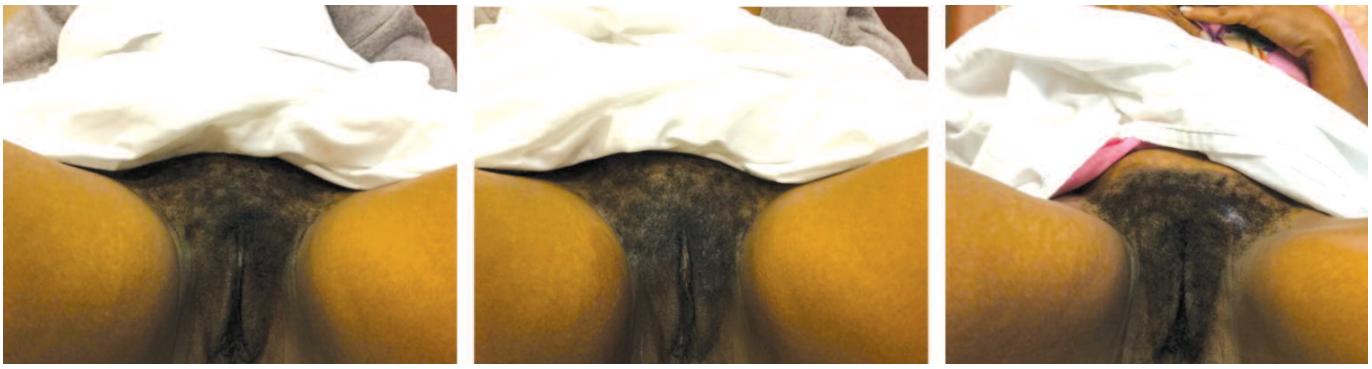

Figure 4. Example of results in a dark-skinned subject treated with the FormaV for 18 minutes in the vaginal canal and 9 minutes per labium. Before treatment (Left), Immediately after treatment (Middle) and at a 2-month follow-up visit (Right).

Evaluations

Standardized questionnaires were completed by the subjects before treatment and at a follow-up visit 2 months post-treatment. The questionnaires were intended to reflect the patients' genitourinary conditions, such as vaginal, sexual, pelvic and urinary.

Vaginal, sexual and life-quality matters were assessed by the International Consultation of Incontinence – Vaginal Symptoms questionnaire (ICIQ-VS), which is a brief and robust measure that is used to assess the impact of vaginal symptoms, such as dragging pain, soreness in the vagina, reduced sensation, vagina too loose, lump felt inside or outside the vagina, and vagina too dry, and associated sexual matters on quality of life and outcome of treatment.[15]

Pelvic floor impact was assessed through a valid questionnaire for women with pelvic floor disorders including bladder, bowel or vaginal symptoms. A short form of Pelvic Floor Impact Questionnaire PFIQ-7 was used to evaluate the pelvic floor condition.[16]

Stress urinary incontinence (SUI), a condition of involuntary urine leakage from the urethra, was assessed by using two questionnaires. The Incontinence Impact Questionnaire – Short Form IIQ-7[17] examined how accidental urine loss may affect the subject's activities, relationships, and feelings. The standardized International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF)[18] is intended to identify whether people leak urine and how much this bothers them.

Photos of the genital area were taken before treatment, immediately after treatment and at a follow-up visit 2 months post-treatment.

Treatment efficacy was evaluated by comparing baseline parameters with the 2-month follow-up questionnaires, photos and biopsies.

Safety was evaluated by observation, and by assessing and recording patient reactions immediately after treatment and at the follow-up visit.

Statistical analysis

Questionnaires were summarized and percentage changes (%) from the baseline scores were calculated. The percentage changes from baseline over time and between treatment groups were evaluated using a repeated measures model. Analyses were carried out using SPSS 25.0 (IBM, Armonk, NY). The significance level was defined as $p<0.05$.

RESULTS

Twenty-five subjects returned to the 2-month follow-up visit; two subjects from group I; two from group II; and one from group III dropped out and did not attend the follow-up visit.

All subjects tolerated the procedure well. No side effects were reported in any case.

There were no significant differences among the treatment groups with respect to demographic characteristics or any of the baseline reproductive parameters (Kruskal Wallis test, $P>0.2$)

For all of the tested parameters in the four questionnaires, a significant improvement was found at the 2-month follow-up compared to baseline ($p<0.001$) (Table I).

Improvements were noted both for each group and for the subjects overall.

The percentage improvement for all subjects was 50.6% for the vaginal symptoms score, 72.1% for the sexual matters score, 64.6 % for the life quality score, 61.2% for the pelvic floor impact score, 62.7% for the incontinence impact score and 37.1% for the International Consultation of Incontinence score (Table II).

No significant differences in change (%) from baseline between treatment groups or interaction effects were detected (Table I).

Photos were used to record the external effects of treatment with FormaV combined with FractoraV. Figures 3 and 4 exemplify the results in two patients with light and dark skin types, respectively, showing baseline, immediately after treatment and at the 2-month follow-up.

DISCUSSION

Recent technological developments include fractional laser and radiofrequency technologies for vaginal non-surgical thermal treatment in women with vaginal atrophy and laxity suffering from aesthetic and medical symptoms. Studies have shown that the controlled application of thermal energy to the vaginal wall and labia stimulates biological processes in the vaginal skin layers such as proliferation, neovascularization and new collagen formation, resulting in an improvement of symptoms.[19]

The current pilot study was intended to evaluate for the first time a novel RF-based device that combines continuous and fractional RF handpieces for internal and external vaginal treatment.

The results indicated that RF-based therapy can be used safely and successfully for the treatment of various vaginal-related symptoms, including sexual matters and urine incontinence.

The treatment was safe and well-tolerated by the patients. Patients with either light or dark skin types can be treated. There were statistically significant improvements in all of the treatment outcomes tested.

In this study, there were no differences between the groups and a short treatment duration was as effective as a longer treatment duration. However, an even longer treatment duration, more treatment sessions and an objective quantitative evaluation could result in significant differences.

Additional studies will be needed to substantiate the clinical experience with the Votiva device. Results based on a larger sample size, more treatments and longer follow-up periods, as well as the use of a control group, may expand the clinical and scientific understanding of the potential outcome with this device. STI

AUTHOR'S DISCLOSURES

Dr. Caruth reports no conflicts of interest.

InMode MD Ltd., the manufacturer, provided the device for the study.

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