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Application Notes

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Temperature Controlled Radiofrequency for Vulvovaginal Laxity: A Pilot Study

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INTRODUCTION

The condition of vulvovaginal laxity and its relevance as a concerning medical condition has recently become a discussion point between women and their physicians. The attention and discussions surrounding gynecological and urological issues that women face may have historically gone by without any discussion, but thankfully today women are openly sharing their concerns with their doctors. In turn physicians are recognizing the clinical importance of vulvovaginal laxity and are looking for solutions for their patients.

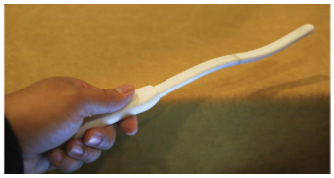
The term 'vaginal rejuvenation' has received a lot of attention and scrutiny. According to an article by Lauri Romanzi, M.D. (http://www.urogynics.org/2010/06/20/vaginal-rejuvenation-defined/) public perception of the term seems to fall into any of three categories: correction of incontinence and prolapse, improvement in the appearance of vulvar structures, and enhancement of female sexual gratification.

Vulvovaginal laxity (as with vaginal laxity) is associated with advancing age and the trauma of childbirth. Treatment of vulvovaginal laxity and related aspects in the past lay within a short spectrum heavily weighted at the ends. On one side stood non-invasive but minimally effective Kegel exercises to strengthen the pelvic floor, with risky, costly, and highly invasive surgery at the other end. Only recently have alternatives appeared to fill in the center of that range.

ThermiVa Generator

In response to this gap, modalities harnessing laser or radiofrequency (RF) energy and others for vaginal use have emerged. Vulvovaginal rejuvenation with energy based devices, as is done in aesthetic dermatology and plastic surgery on the face, neck, and décolleté, is a fairly new concept with real potential for success. Numerous studies in aesthetic medicine have demonstrated tissue contraction and determined a therapeutically ideal temperature range (40°C to 45°C) in which neocollagenesis (via the healing cascade) is stimulated without causing unnecessary damage to the skin or integral tissue structures.

Transcutaneous temperature controlled radiofrequency (TTCRF) brings with it numerous advantages to treatment. It is an established modality for tissue tightening via stimulation of neocollagenesis, denaturation of collagen, contraction, activation of the healing cascade. Unlike laser-based treatments skin type (color, or pigmentation) is not an issue with RF energy, and while it is showing consitent positive results when used for surface skin on the face and other areas of the body, RF energy is even more effective in tissue that is naturally moist and well hydrated, as seen with vaginal and labial tissue. The RF electrode used in temperature controlled procedures have a temperature sensor located at the tip; the thermocouple measures tissue temperature and and impedance, which provides feedback to the RF Generator; in turn the generator will adjust the power allowing the device to maintain a given set temperature throughout the treatment. The benefit is the physician can, for the first time, treat using precisely controlled RF energy at a preselected temperature setting.



ThermiVa Handpiece

The RF electrode has a treatment active area of the size similar to a postage stamp. This active part of the electrode rests within one side of the electrode close to the tip. The form of the electrode and location of the active treatment tip allows for easy placement on targeted tissue. The TTCRF treatment electrode is about 8 inches long with a slight 'S' curve at center, patterned after the highly successful Hegar dilator that has been in gynecologic use for decades. During TTCRF the RF electrode is passed back and forth over the desired area until the tissue is gradually heated to the therapeutically relevant level to induce collagen, shrinkage and create an inflammatory response which results in neocollagenesis, and its effect of tissue tightening. Patients report comfort during the procedure with no need for external cooling.

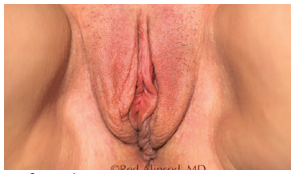
The purpose of the study is to evaluate the safety, tolerability and clinical efficacy of TTCRF as well as anecdotally document possible ancillary beneficial effects of treatment, to promote further study.

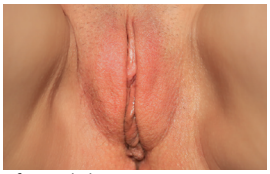
MATERIALS AND METHODS

Subjects (n=23; age range 21-65 years, mean 44; 5 menopausal, 5 perimenopausal) presented with self-described mild to moderate primary or secondary vulvovaginal laxity. Associated secondary conditions (orgasmic dysfunction, stress incontinence, atrophic vaginitis, etc.) were present in most subjects. Exclusion criteria included pelvic surgery less than 5 years from the beginning of study, presence of major psychiatric conditions or related need for medication, pregnancy or planned pregnancy within the study period, recent abnormal Papnicolaou test result, presence of vulvar lesions or disease (dermatitis, human papillomavirus, herpes simplex, vulvar dystrophy, etc.), or the presence of any condition or circumstance that, in the opinion of the investigating physician, may be unsafe or otherwise interfere with the study. Informed consent was obtained from all subjects prior to commencement of the study. Pre-treatment digital photography was performed at baseline along with physician evaluation of patients. Treatment was performed in a clinical office setting and no anesthesia was required. During treatment subjects were placed on a treatment table in the dorsal lithotomy position. A neutral return electrode pad was placed on the subject, with a coupling fluid used as a lubricant for treatment with the ThermiVa

ThermiVa Pilot Study Summary Data					
Total Number of Patients	23				
Patients with 1 Treatment	6				
Patients with 2 Treatments	8				
Patients with 3 Treatments	9				
Average Age	44				
Average Parity	1.7				
Average Procedure Time: Majora	10 Min				
Average Procedure Time: Vagina	15 Min				
Average Procedure Time Total	25 Min				
Complications	None				
		10 Days			
	Baseline	Post	1 Tx	2 Tx	3 Tx
Vaginal Laxity Questionnaire Average Change From Baseline*	0	2.1	2.9	4.2	4.6
Sexual Satisfaction Questionnaire Average Change From Baseline**	0	1.2	1.4	2.1	2.2
Global Assessment:	All patients completing 3 treatments strongly agreed they would recommend the procedure to a friend or family member and were very satisfied with the overall satisfaction with the procedure.				

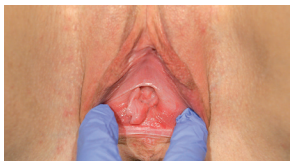
*Very Loose to Slightly Tight is a 4 point change
**No Sexual Satisfaction to Fair is a 2 point change

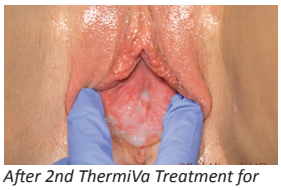

Before ThermiVa Treatment


After 2nd ThermiVa Treatment.


Before ThermiVa Treatment


After 3rd ThermiVa Treatment


Before ThermiVa Treatment for Atrophic Vaginitis


After 2nd ThermiVa Treatment for Atrophic Vaginitis

TTCRF ™ device (ThermiGyn, SouthLake, TX). Once patients were settled and comfortable they were treated using the TTCRF device for 3-5 minutes per zone: the left and right labia majora, and the ventral, dorsal, left and right surfaces of the vaginal wall. Clinical endpoint was achievement of the target temperature in the range of 40°C to 45°C. Total treatment time was less than 30 minutes. A complete course of therapy consisted up to three treatments with the TTCRF device, at an interval of approximately one month (4-6 weeks).

In addition to photography and physician evaluation, patients completed a questionnaire about their experience, treatment comfort and satisfaction with results.

Follow-up occurred for at least one year for all subjects.

RESULTS AND DISCUSSION

There were no burns, blisters or major complications during and after treatments, which were described as pleasant and very comfortable. Patients were able to resume all activity, including sexual intercourse, as normal immediately after each treatment. All patients saw significant improvement, averaging 50%; measurable changes were revealed via patient questionnaire. Notable improvement was also seen in cases including atrophic vaginitis (n=5, improved moistness and comfort), stress urinary incontinence (n=5, noticeable reductions in leakage), and orgasmic dysfunction (n=6, noticeable improvement reported). Of the perimenopausal (5) and menopausal (5) patients who had complaints of vaginal dryness prior to treatments, all were able to eliminate the need for lubricant use and vaginal estrogens. Six women who had difficulties in achieving orgasms reported that the time to orgasm was dramatically shortened. All patients were happy or very happy about the treatment and results, and would both undergo it again and recommend treatment to others. Some tightening result is visible immediately after the first treatment but the full outcome takes a few months to fully manifest. The course of follow-up from one year and beyond revealed that outcomes last 9 to 12 months before a touch-up is required, so patient can expect to need an additional maintenance session once or twice a year; additional study with larger populations examining protocol refinements may reveal more ideal treatment parameters and further delineate persistence of outcomes. It is interesting to note that 6 patients received only one treatment, 8 patients completed two treatments, and 9 received a third treatment to reach a satisfactory endpoint. The patients who dropped out early were extremely happy with their results after only one or two treatments feeling that it was not necessary because they had achieved all of their endpoints.

While the variety of possible medical and aesthetic concerns associated with the vagina and related structures are not novel to gynecologists and urologists, increasing social acceptance of the vagina and reference to it have not only shed additional light on the prevalence, but will continue to boost demand for therapies addressing those issues. This is a boon to patients otherwise left to their own devices. Given the safety, simplicity and ease of treatment associated with TTCRF as well as the remarkable results and high patient satisfaction with virtually no risk, downtime, or discomfort, this novel therapy shows much promise in both the medical and aesthetic arenas in an increasingly accepting social climate.

In conclusion, TTCRF for vulvovaginal rejuvenation is safe, tolerable and effective for vulvovaginal rejuvenation. Evidence strongly suggests applications in the treatment of atrophic vaginitis, orgasmic dysfunction, stress incontinence, and prolapse of the bladder or rectum. Further investigation via randomized, controlled trials isolating and exploring various potential indications is more than warranted.

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