

Temperature Controlled Radiofrequency for Vulvovaginal Laxity: A Pilot Study

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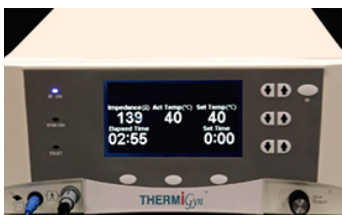
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INTRODUCTION

Vulvovaginal laxity or “looseness” as a medical or aesthetic concern is not new but is only recently becoming socially acceptable. References to the vagina—structure, function, and associated problems—both inside and outside of a humorous context (regardless of moral judgment) are less taboo. One positive result is that gynecological and urological issues that women may have been reluctant to address directly with physicians or even friends in the past are somewhat out in the open and, as such, are more comfortably discussed in a clinical setting.

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/> accessed March 16, 2015) 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, and other beneficial effects via localized

thermogenesis due to impedance as RF travels through tissue. Unlike laser-based treatments skin type (color, or pigmentation) is not an issue with RF energy, and while it is proven effective on surface skin of the face and other body regions, RF energy is even more effective in tissue that is naturally moist and well hydrated, as seen with vaginal and labial tissue. The RF electrodes used in temperature controlled procedures have thermocouples located at their tip; the thermocouple measures tissue temperature and 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

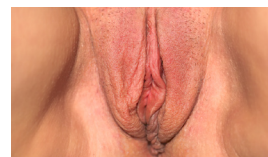
active treatment tip allows for easy placement on targeted tissue. The TTCRF treatment electrode is about 8 inches long with a slight ‘S’ curve at center, patterned after the highly successful Hegar dilator that has been in use for decades. During TTCRF the RF electrode is passed back and forth over the desired area until the tissue is gradually heated to the therapeutically relevant level to induce 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.

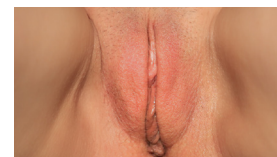
PATIENTS AND METHODS

Subjects (n=15; 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 more 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 Papanicolaou 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,

| ThermiVa Pilot Study Summary Data | | | | | |
|------------------------------------|---|--------------|------|------|------|
| Total Number of Patients | 23 | | | | |
| Patients with 1 Treatment | 23 | | | | |
| Patients with 2 Treatments | 17 | | | | |
| 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 | | | | |
| | Baseline | 10 Days Post | 1 Tx | 2 Tx | 3 Tx |
| VLQ Average Change From Baseline* | 0 | 2.1 | 2.9 | 4.2 | 4.6 |
| SSQ Average Change From Baseline** | 0 | 1.2 | 1.4 | 2.1 | 2.2 |
| Global Assessment: | All patients finishing 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. | | | | |



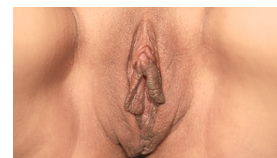
Before ThermiVa Treatment



After 2nd ThermiVa Treatment



Before ThermiVa Treatment



After 3rd ThermiVa Treatment

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

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 pad was placed on the subject, with a coupling fluid used as a lubricant for treatment with the ThermiVa TTCRF (ThermiGyn, SouthLake, TX) device. 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 of 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). 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.

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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AUTHOR CORRESPONDENCE

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