

Transcutaneous Temperature Controlled Radiofrequency for Orgasmic Dysfunction

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Background and Objectives: To evaluate the safety, tolerability, and clinical efficacy of transcutaneous temperature controlled radiofrequency (TTCRF) on vulvovaginal tissue for orgasmic dysfunction.

Study Design/Materials and Methods: Subjects included 25 sexually active women, ages 21–65, with self-reported difficulty in achieving orgasms during sex (anorgasmic or slow-to-orgasm). Each patient received three sessions at intervals of about 1 month. Treatment was performed using a slim S-shaped probe with a stamp-sized metal radiofrequency emitter on one surface of the tip (25 minutes total time on average). External treatments covered the labia majora and minora, lower mons pubis, perineal body, clitoral hood, and clitoris. Full length treatment of the vagina with concentration on the anterior wall was performed. Tissue temperature during therapy was elevated to and maintained between 40°C and 45°C. No anesthesia was required. After treatment, patients immediately resumed normal activities, including sex.

Results: Twenty-three of 25 patients reported an average reduction in time to orgasm of 50%. Patients also noted significant vaginal tightening effects, increased vaginal moisture, and improved vulvar and clitoral sensitivity. All anorgasmic patients reported the ability to achieve orgasms. Two patients had minimal response.

Conclusion: TTCRF is an effective non-hormonal, non-surgical option for women having difficulty achieving orgasm. Treatment also has visible tightening effects on feminine tissues and appears to increase local blood flow, resulting in increased vaginal tightness and moisture. Improved appearance and friction resulted in improved confidence and reduced performance anxiety. *Lasers Surg. Med.* 48:641–645, 2016. © 2016 The Authors. *Lasers in Surgery and Medicine* Published by Wiley Periodicals, Inc.

Key words: temperature-controlled radiofrequency; vulvovaginal rejuvenation; orgasmic dysfunction; vaginal rejuvenation; vaginal laxity

INTRODUCTION

The use energy-based therapies for rejuvenation of the skin in aesthetic medicine is common, and among them non-invasive or minimally invasive radiofrequency (RF) energy is a well-studied and popular alternative [1]. By creating heat via impedance as electric current is conducted through tissue, stimulation of fibroblasts

occurs, and the therapeutic outcome is achieved; the target tissue temperature range lies between 40°C and 45°C [2]. Recently, this skin rejuvenation modality has been harnessed for rejuvenation of vaginal tissue to treat vulvovaginal laxity resulting from age- or childbirth-related causes. Orgasmic dysfunction, manifesting as anorgasmia or increased time to orgasm, rests among the associated symptom suite [3]. As many as 35% of women may experience orgasmic dysfunction and its resultant effect on quality of life [4], and research suggests a strong need for treatment alternatives when surgical correction is not indicated [5]. Other than psychological, behavioral, and hormonal therapies, recent alternatives include injectable autologous platelet rich plasma, which is safe and without the potential side effects noted with other injectable treatments, but results were relatively modest.

Transcutaneous temperature controlled radiofrequency (TTCRF) is the combination of RF, an established technology proven safe and effective for skin laxity, with feedback controls for the monitoring and maintenance of tissue temperature via thermocouples and thermistors in the treatment probe [6]. Power is modulated in relation to tissue impedance to elevate tissue temperature near the electrode stimulating neocollagenesis plus contraction and denaturation of collagen, triggering the healing cascade to produce healthier new tissue. With the goal of raising and maintaining tissue temperature to a therapeutic target of between 40°C and 45°C, temperature feedback controls power, and thus adjusts energy delivery to maximize non-invasive delivery of RF energy while minimizing patient discomfort. There is no downtime.

The character of vaginal wall tissue, similar to that of skin, makes it an obvious candidate for such treatment. RF is particularly effective on naturally moist, well hydrated

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Conflict of Interest Disclosures: The author is a paid research consultant for Thermi, An Almirall Company, manufacturer of the TTCRF technology used during the investigation.

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tissue, and effects similar to those seen when treating skin with RF were demonstrated in histological study of RF in sheep vaginal tissue [7]. RF has been shown effective for vaginal (or vulvovaginal) rejuvenation in key human studies also. A 2010 study by Millheiser et al. [8] of introital/transvaginal monopolar RF (with cryogen cooling) for vaginal laxity after vaginal childbirth reported statistically significant improvement in vaginal laxity in 87% of subjects. Perceived improvement of sexual function (a secondary study endpoint) was noted in all patients originally reporting reduced sexual function. An investigation by Sekiguchi et al. [9] applied low-energy RF for vaginal introital laxity in premenopausal women, revealing significant improvements in vaginal laxity and sexual function maintained through 12-month follow-up with no reported adverse events.

TTCRF for vaginal use requires a specifically designed probe but works the same way, with the same feedback controls for the safe elevation and maintenance of tissue temperatures to within the therapeutically relevant range. Figure 1 shows the device and treatment probe; Figure 2 shows the treatment probe next to an index finger for scale. Patients are placed in the standard dorsal lithotomy position on the treatment table with a neutral return pad underneath the buttocks. A coupling gel lubricant is required. The probe is slowly passed back and forth over each treatment zone within the vagina (ventral, dorsal, left, and right) as well as to the vulva, causing gradual heating to tighten the skin, mucosa, and fascia as well as stimulate neocollagenesis. TTCRF for vaginal applications is non-invasive, requires no anesthesia, and has no associated downtime. Normal activities including intercourse are encouraged without a waiting period.

Recently, Alinsod [3] studied TTCRF for vulvovaginal laxity, showing statistically significant improvements based on Vaginal Laxity Questionnaire and Sexual Satisfaction Questionnaire outcomes as well as observational reporting of improvements in stress incontinence, atrophic vaginitis, and orgasmic dysfunction. In this case, improvement was most profound after the first treatment, with some additional improvement seen with second and third treatments. Figures 3 and 4

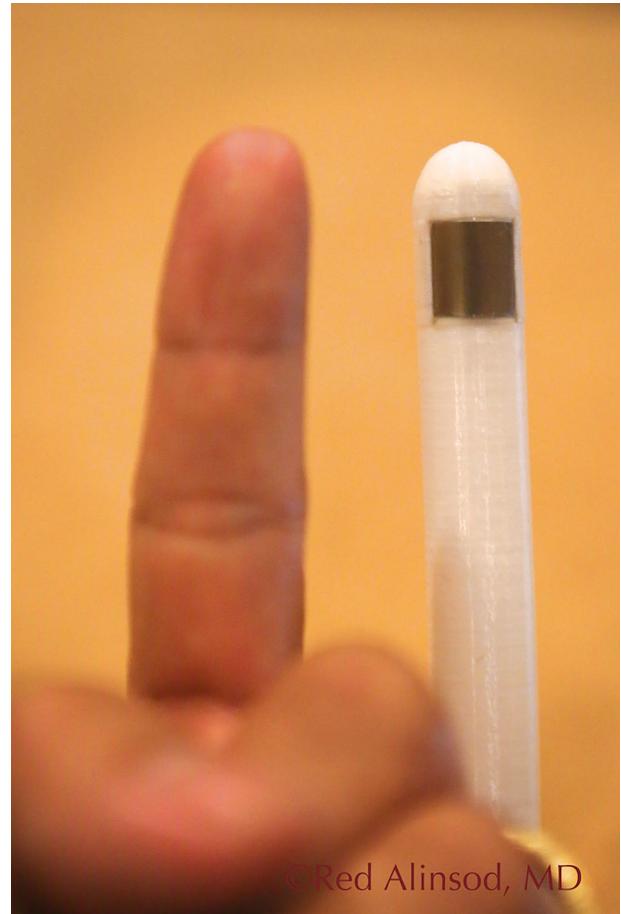


Fig. 2. The TTCRF probe tip (shown with RF emitter visible) in comparison with an index finger. Photo courtesy of Red Alinsod, M.D.

show before and after pictures of the vulva and vaginal opening, respectively. These results suggested the application of TTCRF specifically for orgasmic dysfunction.

The purpose of this pilot study was to evaluate the safety, tolerability, and clinical efficacy of TTCRF on vulvovaginal tissue for orgasmic dysfunction.

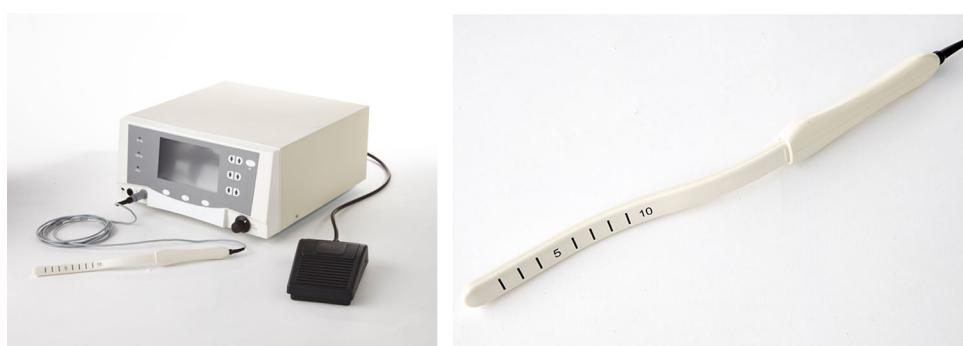


Fig. 1. The TTCRF device (ThermiVa, ThermiAesthetics, Southlake, TX) with probe and foot switch (left) as well as a close-up of the treatment probe (right). Photos courtesy of ThermiAesthetics.



Fig. 3. Vulva before (left) and after (right) three treatments with TTCRF. Photos courtesy of Red Alinsod, M.D.

MATERIALS AND METHODS

Study subjects ($n = 25$, age range 21–65 years, mean age 42 years) included sexually active women with self-reported difficulty in achieving orgasms during sex; 10 patients were anorgasmic (defined as reporting no orgasms for the previous 5–10 years) and 15 were reportedly slow to orgasm. All patients reported being normorgasmic at some stage in the past. Slow-to-orgasm patients reportedly felt it took too long to achieve orgasm resulting in a loss of interest in or desire to continue sexual activities, that sex became more work than pleasure. Exclusion criteria included pregnancy or planned pregnancy within the study period, recent abnormal Papanicolaou test result, chronic use of anti-inflammatory agents (including steroids) and immunosuppressants, presence of vulvar lesions or disease (dermatitis, human papillomavirus, herpes simplex, vulvar dystrophy, etc.), presence of any condition or use of medication known to interfere with incidence of orgasm, presence of major psychiatric conditions or related need for medication, 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. Subjects using hormone replacement therapy were also excluded. Informed consent and complete medical history was obtained from all subjects prior to commencement of the study.

Each patient received three sessions at intervals of about 1 month. Treatment was performed using a slim S-shaped probe with a stamp-sized metal RF emitter on one surface of the tip. External treatments covered the labia majora and minora, lower mons pubis, perineal body, clitoral hood,

and clitoris; RF application was concentrated on the clitoral region (3–5 minutes on average). Full length treatment of the vagina with concentration on the anterior wall was also performed; specifically, the first 5–6 cm in and on the pubocervical fascia proximal to the urethra and lateral to the urethra. Treatment of the vaginal canal took 10–15 minutes overall. Physician examination with patient feedback determined the general location of the “G-spot,” and this area received additional attention during treatment (3–5 minutes on average). This region was located using the research of Ostrzenski [10] plus careful, patient-guided manual digital examination; all subjects were able to identify a region of highest sensitivity about 5–7 cm into the vagina at the anterior wall just past the pubic bone, with some slight variation to the left or right in most cases. Figure 5 shows treatment of the vulva and G-spot area using the TTCRF probe. Total treatment time was approximately 25 minutes. Tissue temperature during therapy was elevated to and maintained between 40°C and 45°C. No anesthesia was required. After treatment patients immediately resumed normal activities, including sex.

At follow-up patients were given a questionnaire with eight questions regarding their experience with treatment and the perceived results.

RESULTS

All subjects completed the study; none were lost to follow-up and no side effects were reported in any subject. Of 25 enrolled women, 19 (76%) reported an average reduction in time to orgasm of at least 50% and 23 (92%)

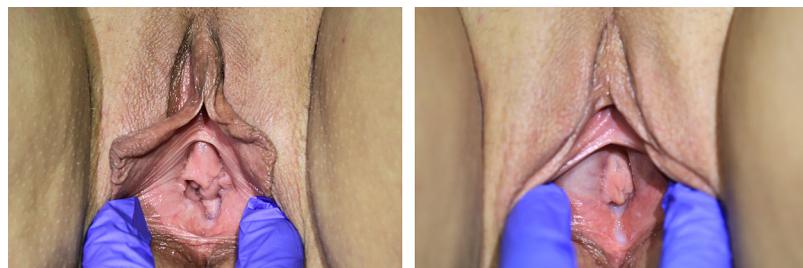


Fig. 4. Vulva and vaginal opening before (left) and after (right) three treatments with TTCRF. Improved lubrication is visible. Photos courtesy of Red Alinsod, M.D.



Fig. 5. The TTCCR probe applied to the clitoral hood at the vulva (left) and inserted during treatment of the G-spot and pubocervical fascia (right). Photos courtesy of Red Alinsod, M.D.

reported an average reduction in time to orgasm of at least 33%. Patients also noted significant vaginal tightening effects, increased vaginal moisture, and improved vulvar and clitoral sensitivity. All anorgasmic patients ($n=10$) reported renewed ability to achieve orgasms. Two patients reported minimal response.

Regarding the questionnaire, 23 of 25 subjects (92%) reported achieving orgasm after TTCCR treatment; 16 reported no change in intensity of orgasm, while nine subjects reported experiencing more intense orgasms. Reported time to orgasm was reduced by one half or greater in 19 of 25 subjects. All subjects reportedly experienced tightening of vaginal canal. Improvement in vaginal moisture was noted in 20 of 25 patients. All 25 patients reported satisfaction with treatment and would recommend it to family and friends. The full results are delineated in Table 1.

DISCUSSION

This pilot study was conducted in response to patient feedback after TTCCR therapy for overall vulvovaginal rejuvenation. Notably, patients would commonly describe improved sexual sensitivity, dramatic reductions in time to orgasm, or restoration of ability to achieve orgasm if orgasmic dysfunction had been present, although it was not a therapeutic goal at the time. This experience suggested that TTCCR may hold potential as a treatment specific to orgasmic dysfunction. While it was not specifically studied, improvements in tissue quality leading to improved blood flow may positively affect localized blood flow, and thus improve sexual response. Clinical experience also suggests that while the effects do diminish over time, treatment outcomes persist for 9–12 months, and in one case persisted to 18 months. Yearly maintenance treatment may be sufficient to preserve outcomes.

It should be noted that while the results of this pilot study suggest a profound therapy alternative for women with orgasmic dysfunction, there are key limitations to consider. Primary among them is the lack of control. Nevertheless, further study among a larger cohort with a control group would be beneficial. Use of a sham treatment would be necessary to account for potential placebo effect. Currently there is no data on improvement in orgasmic function in women undergoing TTCCR who already orgasm normally, although some patients have reported improvement in sexual sensation. Long-term follow-up

would also be useful. Sample size was predetermined as being appropriate and manageable for a pilot study, and the first 25 consecutive, consenting, eligible patients were included; the wide age range was chosen to allow examination of this treatment in women of all ages who reported difficulty achieving orgasm. In actuality, most subjects were in their 40s or 50s, with only 1 woman in her 20s. Of included subjects, 14 of 25 (54%) were perimenopausal with reported symptoms such as hot flashes, atrophic vaginitis, night sweats, and sleep disturbance; 7 of 25 (28%) were menopausal. Future refinement of age range and demographics would be ideal, especially for a larger, more comprehensive study.

Another key limitation is the lack of standardization of “time to orgasm.” Future study comparing time to orgasm before and after treatment, with comparison to current statistical information, may be revealing but were deemed beyond the scope of this pilot study. In this case, the investigation relied on the reports of the subjects.

An additional area of interest is whether variations in treatment technique have a measurable effect on treatment outcomes. The treatment protocol of this study was a slight variation on normal procedures, including the concentration of sexually sensitive areas of the vagina and vulva. Study comparison of normal TTCCR protocols compared to this (or a similar) modified protocol would more accurately determine if there was a significant difference. Regarding the term “G-spot”: The research of Ostrzenski [10] and the use of the term may be somewhat controversial but all subjects were able to identify a location of markedly increased sensitivity in that area. Any attempt to further define or elucidate the incidence of “G-spot orgasms” was not included as it would have been well outside the scope of this investigation.

Among the study population, two women did not report significant improvement in orgasms. It should be noted that these patients had prior extensive pelvic reconstructive surgeries including dissection of the anterior compartment during cystocele and/or bladder repair (without mesh). Perhaps, there is a negative effect on blood flow to the G-spot areas or some effect on the nervous structures that would account for this lack of response. In previous unpublished work by the author with a small group of five anorgasmic patients, three of five became orgasmic after TTCCR treatment after an average anorgasmic period of approximately 5 years. Of the two who did not achieve

TABLE 1. Patient Questionnaire With Responses

1. Did you achieve orgasms after ThermiVa treatments?
 - a. Yes: 23
 - b. No: 2
2. Were your orgasms more or less intense after ThermiVa treatments?
 - a. No change in intensity: 16
 - b. More intense: 9
 - c. Less intense: 0
3. If you achieved orgasms what was the reduction in time to achieve orgasms?
 - a. No reduction in time to orgasms: 2
 - b. Reduction in time to orgasms by one quarter: 0
 - c. Reduction in time to orgasms by one third: 4
 - d. Reduction in time to orgasms by one half: 15
 - e. Reduction in time to orgasms by two thirds: 3
 - f. Reduction in time to orgasms by 75% or more: 1
4. Did you feel vaginal tightening effects from ThermiVa?
 - a. Yes: 25
 - b. No: 0
5. Did you feel improvement in vaginal moisture with ThermiVa?
 - a. Yes: 20 (mostly peri and menopausal patients)
 - b. No: 5 (1 patient in their 20s and 4 in their 30s)
6. Did you have any complications or side effects from ThermiVa treatments?
 - a. Yes: 0
 - b. No: 25
7. Were you satisfied with ThermiVa treatments?
 - a. Yes: 25
 - b. No: 0
8. Would you recommend ThermiVa treatments to family and friends?
 - a. Yes: 25
 - b. No: 0

orgasm, one had prior pelvic reconstruction on the anterior compartment. The other had a lifetime history of anorgasmia; she reported improved sexual sensitivity but remained anorgasmic.

As for those experiencing orgasmic improvement, it is likely that the outcome results from a combination of factors noted in patients receiving TTCRF for vaginal application, including tightening of the vulvar and vaginal wall tissues, improvement in friction due to reduction in vaginal diameter, and improvement in local blood flow leading to increased vaginal moisture production as a transudate and improved nerve sensitivity of the clitoral complex both internally (G-Spot) and externally (clitoral).

CONCLUSIONS

TTCRF is safe and may be effective for the treatment of orgasmic dysfunction. Further study using a control group (with sham treatment) in larger populations would provide valuable insight and allow the medical community to draw stronger conclusions about the use of TTCRF for orgasmic dysfunction in women.

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