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Radiofrequency - New Solution for Treatment of Vaginal Laxity, Urinary Incontinence and Sexual Disorders

Rafal Kuzlik M.D., Ph.D[1*] and Bartosz Kuzlik[2]

[1]SaskaMed Clinic, Warsaw, Poland.

[2]Medical Student, Andrzej Frycz Modrzewski Krakow University, Poland.

*Correspondence:
Rafal Kuzlik M.D., Ph.D, SaskaMed Clinic, Warsaw, Poland, E-mail: rafal.kuzlik@gmail.com.

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ABSTRACT

Objectives: *To evaluate the safety and efficacy of transcutaneous temperature controlled radiofrequency (TTCRF) on vulvovaginal tissue for vaginal laxity, urinary incontinence and sexual disorders.*

Materials and Methods: *Study subjects included 53 sexually active women, ages 30-70, reported vaginal laxity, urinary incontinence and sexual disorders. Each patient received two sessions at interval of four weeks. Treatment was performed with radiofrequency emitter localised on the surface of the probe and lasted 30 minutes on average. No anaesthesia was required. Tissue temperature was elevated to 47°C and maintained between 45°C and 47°C. Internal (vaginal) part of the treatment was concentrated on the anterior wall and also covered right and left side of the vagina. External part covered labia majora and minora, perineal body and clitoral hood. After treatment there were no exclusions of normal activity including sex.*

Results: *All 53 patients referred improvement of quality of life (QOL). Significant effect was achieved in vaginal tightening (38,1%), reduction of urinary incontinence (33,2%) and frequency of feeling urgent (54,6%), improvement of sexual satisfaction (27,2%) and the ability to achieve orgasm (25%).*

Conclusion: *TTCRF is an effective and safe treatment of vaginal laxity, urinary incontinence and sexual disorders. This method helps women to improve self-confidence. This is non-surgical treatment and no side effects were detected.*

Keywords

Vaginal laxity, Sexual disorders, TTCRF, Urinary incontinence.

Introduction

Many women among those who have given birth vaginally complain of stretching of their vaginal tissue. The majority of them refer urinary incontinence. All of these symptoms can cause long-term physical and psychological consequences, including loss of sensation and sexual dissatisfaction, what, on the other hand, can lead to reduction in self-esteem and significantly affect their quality of life (QOL).

About 3 mln of women in Poland suffer because of urinary incontinence. 25% of female in reproductive age and over 50% of post-menopausal patients. This illness is observed also among younger group- about 65% of pregnant women and 30% of women during first year after delivery. The majority of this group it is stress urinary incontinence (SUI) [1].

Female sexual dysfunction (FSD) is a common problem, estimated to occur in about 40% of women in the United States. Only about 30% of them seek help from professionals, and only 6% declare a visit to discuss their sexual problem [2]. The main factor for women's sexual dissatisfaction includes physical changes to the vagina, referred as „vaginal laxity" in literature. They cause opening of the introitus (patients refer to see interior of the vagina), and vaginal opening to feel looser to the woman and her sexual partner during intercourse. The association of patient-reported vaginal laxity with distressing sexual function is reported in the literature by both doctors and by patients themselves. A recent study showed, that 80% of porous women concerning about vaginal laxity, failed to discuss their problem with their gynecologist [3].

Another study showed vaginal laxity negatively impacts patients' QOL. It reduces sexual satisfaction and relationship happiness. Such women identified the vaginal introitus as the main location of laxity. Symptoms arising from changes of both muscle and vaginal tissue [4].

The fact is, that presently there is no reliable objective instrument to accurately measure, diagnose or classify vaginal laxity, especially to correlate vaginal size with sexual function [5-11].

Non-invasive or minimally invasive radiofrequency (RF) energy is well -studied and popular alternative among energy-based therapies for rejuvenation of the skin in aesthetic medicine [12]. Nowadays this skin rejuvenation modality has been used for rejuvenation of the vaginal tissue in treatment of vulvovaginal laxity and urinary incontinence. Orgasmic dysfunction, like anorgasmia or increased time to achieve orgasm is one of the associated symptom [13]. RF energy has a long history of use in mucosal tissue in the vagina and skin [14-18]. By creating heat via impedance as electric current is conducted through vaginal tissue, stimulation of fibroblasts occurs, and the therapeutic outcome is achieved [19]. The target tissue temperature range lies between 40°C and 47°C. Vaginal wall tissue is similar to that of skin, and this character makes it an obvious candidate for such treatment. RF effectiveness on naturally moist was demonstrated in histological study of RF in sheep vaginal tissue [20]. RF was also shown effective for vulvovaginal rejuvenation in 2010 by Millheiser et al. [21]. The study of introital/transvaginal monopoly RF (with cryogen cooling) for vaginal laxity after natural childbirth reported significant improvement in vaginal laxity in 87% of patients. Sekiguchi et al. presented their study with low-energy RF for vaginal introital laxity in premenopausal women [22]. They reported improvements in both vainal laxity and sexual function. Effects maintained through 12-months follow-up. No adverse events were reported.

Main goal of this pilot study was to evaluate the safety and clinical efficacy of transcutaneous temperature controlled radiofrequency (TTCRF) on vulvovaginal tissue for vaginal laxity, urinary incontinence and sexual dysfunction.

Materials and Methods

Study subjects (= 53, age range 30-70 years, mean age 42,5 years) included sexually active women. All of them reported vaginal laxity, urinary incontinence and connected with these symptoms sexual dysfunction. None of them was anorgasmic. All patients reported having normal sexual relations before vaginal childbirth. Exclusion criteria included pregnancy, vaginal width more than 3 fingers, severity of SUI greater than II grade, abnormal Papanicolaou test results, vaginal bleeding, presence of vulvar lesions or disease.

Each patient received two sessions at intervals of 4 weeks. All of them filled the questionnaire 3 times- before first session (preeliminary), 1 month after the first and 1 month after the second treatment (Figure 1). Following parameters were assessed: sexual satisfaction, the ability to achieve orgasm, reduction of vaginal laxity, vaginal moisture during intercourse, controlling urinary continence during coughing, controlling urine stream (start/stop) and reduction of frequency of feeling urgent. Parameters were evaluated in range 1 to 5, where 1 meant the worse and 5- the best.

Patient's questionnaire

Please, assess laxity of your vagina

very wide 1 2 3 4 5 very tight

Please, assess your satisfaction of sexual intercourses

unsatisfied 1 2 3 4 5 very satisfied

Please, assess your ability to achieve orgasm

never 1 2 3 4 5 always

Please, assess the moisture of your vagina during sexual activity

very dry 1 2 3 4 5 very wet

How do you assess the ability to control urinary continence during coughing

no control 1 2 3 4 5 full control

How do you assess the ability to control urinary stream (start/stop)

no control 1 2 3 4 5 full control

How often do you feel urgent (you have to go to toilet immediately) ?

very often 1 2 3 4 5 very rare

Figure 1: TTCRF for vaginal use requires special probe. It is 10 cm long and thin like a finger.

Figure 2 shows the device and probe.

Figure 2: The TTCRF device (ThermiVa, ThermiAesthetics, Southlake, TX) with probe and foot switch. Photos courtesy of ThermiAesthetics.

Patients were placed in the standard, gynaecological position on the treatment chair with a neutral return pad underneath the buttocks. A gel lubricant is required. Treatment technique consists of putting the probe into vagina and making slow passing back and forth over each treatment zone of the vagina- frontal, back, left and right. The same probe is used for vulva, causing gradual heating to tighten the skin, mucosa and fascia as well as stimulate neocollagenesis. This device for vaginal use is non-invasive and painless, so it doesn't require any anaesthesia. There is also no smell and smog. Normal activities and intercourse are encouraged without a waiting period. Figures 3 and 4 show before and after pictures of the vulva and vaginal introitus respectively.

External treatments cover labia majora and minora, perineal body, clitoral hood and clitoris. RF application was concentrated on each region (in vagina and on vulva) for 5 minutes on average. In the vagina treatment was concentrated on the anterior wall, specifically

the first 5-6 cm in and on the pubocervical fascia proximal and lateral to the urethra. Treatment of the vaginal canal region took 15 minutes overall. Depending on patient feedback and physician examination, location of the „G-spot" was performed. This region of anterior vaginal wall received additional attention during treatment (3 minutes on average). This area was located using patient-guided manual digital examination.

All patients identified a region of highest sensitivity about 5 cm into the vagina at the anterior wall in some variations to the left or right side of the urethra. Treatment of the vulva took 15 minutes overall. Both labia majora and minora for 5 minutes and clitoral hood and clitoris for 5 minutes. Temperature was set on 45°C for vulva and vaginal introitus, and 47°C for vaginal part. Total treatment time was approximately 30 minutes without any anaesthesia. After procedure patients resumed normal activities, including intercourses.

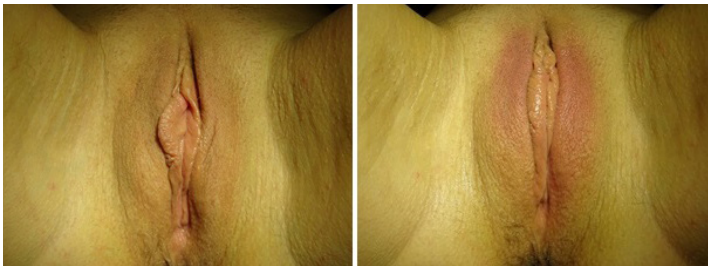


Figure 3: Vulva before (left) and after two procedures (right) with TTCRF. Photos courtesy of Rafal Kuzlik, M.D., Ph.D.

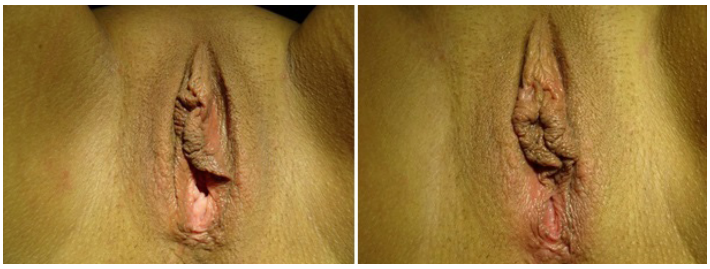


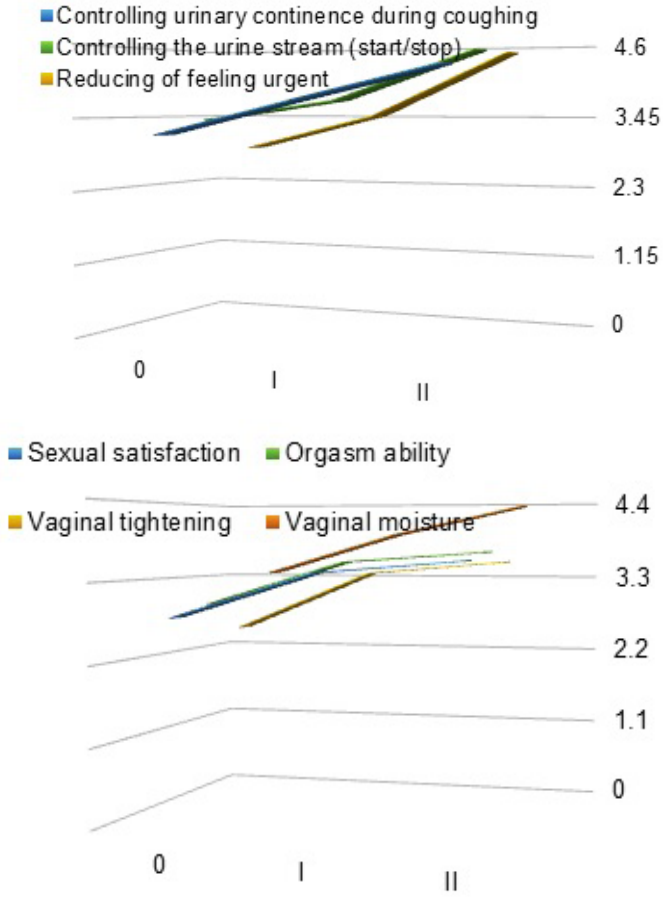
Figure 4: Vulva and vaginal introitus opening before (left) and after (right) two treatments with TTCRF.
Photos courtesy of Rafal Kuzlik, M.D., Ph.D.

Results

All treated patient completed study and no side effects were reported or observed. All 53 patient were taken under the consideration as one group. Whole group referred improvement of quality of life (QOL). Regarding the questionnaire, significant effect was achieved in vaginal tightening (38,1%) and urinary problems- controlling urinary continence during coughing and urine stream increased accordingly by 33,2% and 31,9%. It turned out however, that this therapy was the most effective in reducing frequency of feeling urgent.

This symptom was reduced by 54,6%. Thanks to all of these sexual satisfaction was improved in 27,2%. Indyvidually the ability to achieve orgasm increased by 25%. The full results are delineated in Figures 5-7.

Description	0- preliminary	After 1 treatment	After 2 treatment	Rise %
Sexual satisfaction	2,83	3,44	3,60	27,2
The ability to achieve orgasm	2,96	3,56	3,70	25
Vaginal tightening	2,57	3,38	3,55	38,1
Vaginal moisture during intercourse	3,35	3,93	4,36	30,1
Controlling urinary continence during coughing	3,19	3,73	4,25	33,2
Controlling the urine stream (start/stop)	3,41	3,73	4,50	31,9
Frequency of feeling urgent	2,91	3,47	4,50	54,6
p		< 0,001	<0,001	p,001



Discussion

The main goal of this pilot study was to assess the usefulness of TTCRF in treatment of vaginal laxity, urinary incontinence and sexual disorders. It was conducted in response to patient feedback after RF therapy for vulvovaginal rejuvenation. This particular study assessed only early effects after two treatments, but we know from Alinsod's study, that treatment outcomes persist for 9-12 months, but yearly maintenance treatment may be sufficient to preserve outcomes [13]. It should be noted, that while Alinsod reported improvement in orgasmic function in some women undergoing TTCRF, who had previously orgasmic dysfunction, in this study it was presented improvement in sexual sensation among patient without orgasmic disorders. It is worth to remember that patients were not treated to achieve orgasms, because all of them weren't anorgasmic. This effect was only complementary to whole therapy, but to assess the final result of improvement of sexual function, this aspect had to be examined.

The wide age range was chosen to allow examination of this treatment in women of all ages, who reported vaginal laxity and urinary incontinence. The majority of subjects were in their 40s and 50s, with only 3 women in 30s and 1 woman in her 70s. All of them were sexual active. It should be considered to refine range of age and demographics in future, more comprehensive study.

While the results of this pilot study suggest an alternative therapy for women with vaginal laxity and urinary incontinence, there are some limitations to consider. Primary is the lack of standardisation of treatment technique. The treatment protocol of this study was designed to treat all areas with the same way in the same time. Nevertheless, further study among a larger cohort with a control group would be beneficial.

Sexually sensitive areas of the vulva and vagina, in contrast to Alinsod's study, were not treated with concentration on this region, but during normal procedure of treatment vaginal laxity and urinary incontinence.

Conclusion

TTCRF is a non-hormonal and non-surgical method of treatment. It may be recommended for women suffering of vaginal laxity, urinary incontinence and sexual disorders. This therapy is safe, effective and free of side effects. Further study with control placebo group would be valuable to present stronger conclusions about the use of TTCRF for women with vaginal laxity, urinary incontinence and sexual disorders.

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