Original Article

Transcutaneous Temperature-controlled Radiofrequency for Vaginal Rejuvenation

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ABSTRACT

Background: Vaginal laxity and sexual dysfunction are commonly experienced by women, but are typically stigmatized and considered inappropriate to discuss openly. This study was designed to assess the effectiveness and safety of transcutaneous temperature-controlled radiofrequency (TTCRF), in addressing these concerns. The study used a single-blinded randomized sham-control design. **Aims and Objectives:** The aim was to study the role of TTCRF for vaginal rejuvenation using subjective and objective measurements. **Materials and Methods:** Two hundred parous women were randomly assigned to either a treatment group (n = 110) or a sham group (n = 90). Participants who were between 35 and 55 years of age and reported complaints of vaginal laxity, as well as those who presented symptoms such as vaginal flatus or sexual issues, were included. The treatment group was administered TTCRF therapy, whereas the sham group had a placebo procedure to ensure blinding was maintained. The outcome measures included subjective assessments, such as the Female Sexual Function Index (FSFI), the Vaginal Laxity Questionnaire (VLQ), the Vaginal Flatus Score (VFS), and the Vaginal Laxity and Bother Score (VLBS), as well as objective measurements, such as the Modified Oxford Score (MOS) and the Genital Hiatus (GH) questionnaire. **Results:** Baseline characteristics were comparable between the groups. Significant improvements in FSFI, VLQ, and VLBS were noted in the treatment group compared to sham at 1 month, 3 months, and 6 months. The MOS improvements did not reach statistical significance, suggesting potential limitations in its use as an objective measure. VFS showed improvement in both the groups, indicating a potential placebo effect. No significant changes were observed in GH. Adverse events were mild and transient, with no serious incidents reported. **Conclusion:** Despite societal taboos, TTCRF demonstrated notable improvements in subjective measures of vaginal laxity and sexual dysfunction over a 6-month period. The safety and outpatient feasibility of TTCRF were established. The findings contribute to understanding the role of TTCRF in managing these sensitive concerns among women.

Keywords: *Female Sexual Function Index, Medical Outcomes Study, Vaginal Flatus Score, vaginal rejuvenation, Visual Libido and Body Satisfaction Scale*

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Introduction

Vulvovaginal laxity, a common issue affecting 24%–50% of women after childbirth, refers to both physical and functional alterations that can harm a woman's sexual satisfaction and overall quality of life.[1] Childbirth, aging, and hormonal variations cause

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changes in the strength and flexibility of the vaginal tissues, resulting in a syndrome characterized by reduced sexual satisfaction and increased distress associated with vaginal looseness.[2]

The laxity can be further exacerbated by the physiological changes linked to menopause, precisely due to a lack of estrogen.[3,4] The cessation of estrogen in the tissue is evident by the weakening of the epithelium, impaired function of smooth muscle, deterioration of connective tissue, and reduced levels of collagen and elastin in the dermal layer of the vagina. These alterations constitute the pathological foundation for sexual dysfunction, which can have a substantial influence on a woman's quality of life.[3,4]

Addressing these concerns has become crucial to women's health, leading to investigating advanced noninvasive techniques such as transcutaneous temperature-controlled radiofrequency (TTCRF). In recent times, there has been an increase in the utilization of radiofrequency and laser equipment for the treatment of vulvovaginal diseases, specifically addressing vaginal laxity.

TTCRF, a monopolar radiofrequency device, is an up-and-coming technology for treating vulvovaginal laxity and related sexual dysfunction.[1,5] The radiofrequency modalities work by raising the temperature of the dermal layer of the vaginal mucosa, which then triggers a cellular regeneration response.[5]

The main aim of this study was to evaluate the effects of TTCRF treatment on both subjective and objective measures of vulvovaginal laxity and sexual function in women who have given birth and are 18 years of age or older. To accomplish this, a thorough collection of verified assessments, such as the Female Sexual Function Index (FSFI), Vaginal Laxity Questionnaire (VLQ), Vaginal Flatus Score (VFS), and the Vaginal Laxity Bother Score (VLBS), were utilized to measure the subjective experiences of the participants. The objective assessments involved the utilization of the Modified Oxford Score (MOS) and the measurement of genital hiatus (GH) length. These assessments give a precise and quantitative evaluation of any possible anatomical changes.

The choice to utilize a single-blinded randomized sham-control approach was based on the need to thoroughly assess the genuine effectiveness of TTCRF, guaranteeing that any noticed enhancements are not simply due to a placebo response. Through the random assignment of individuals to either the treatment or sham group, our goal is to reduce bias and create a solid basis for making significant conclusions about the therapeutic effectiveness of TTCRF in the realm of vaginal rejuvenation.

As we begin this investigation, we aimed for the results of this study to not only enhance the scientific knowledge of TTCRF's effectiveness in treating vulvovaginal laxity but also provide valuable insights into the broader range of noninvasive interventions for women's health and well-being.

Materials and Methods

This prospective single-blinded randomized sham-control trial was conducted on 200 parous women. The study was designed and implemented by ethical principles outlined in the Declaration of Helsinki.

The study included parous women aged 35–55 years and who reported complaints of vaginal laxity or looseness after delivery or presenting with symptoms of vaginal laxity such as vaginal flatus or sexual concerns relating to vaginal laxity. Exclusion criteria comprised women with active genital infections, a history of pelvic surgery within the past 6 months, current pregnancy, and contraindications to radiofrequency therapy. Informed consent was obtained from all participants before enrollment.

Randomization

Using computer-generated random numbers, participants were randomly assigned to either the treatment group (n = 110) or the sham group (n = 90). Allocation concealment was maintained throughout the trial to ensure unbiased group assignments.

Intervention

The treatment group underwent TTCRF therapy using the TTCRF device. The active probe was applied to the treatment group, delivering therapeutic temperatures (42°C–47°C) to the target tissues. In contrast, the sham group received treatment with probes designed to reach subtherapeutic temperatures (25°C−27°C), ensuring blinding of participants to the nature of the intervention. The sham probes were explicitly engineered to induce a perception of warmth and emitted operational sounds to ensure that participants remained unaware of their true purpose. The vagina was partitioned into four quadrants, and each quadrant was subjected to a 3-min treatment. Clinicians were instructed to allocate an identical amount of treatment time to patients in the sham group.

Outcome measures

Subjective measures

- FSFI: A validated questionnaire assessing sexual function (it assesses the domain, including sexual arousal, orgasms, satisfaction, and pain). A score

of <26.55 indicates an increased risk of developing sexual dysfunction.

- Vaginal Laxity Questionnaire: A questionnaire capturing subjective perceptions of vaginal laxity. The present study used the vaginal laxity questionnaire, which is an unvalidated subjective measure of success. Female participants were requested to assess their subjective perception of vaginal laxity using a Likert scale ranging from 1 (indicating a high degree of looseness) to 7 (indicating a high degree of tightness). Given the limited number of samples, the results were examined and categorized into three groups based on the level of tightness: loose, neither loose nor tight, and tight. The analysis demonstrated a statistically significant shift from the "loose" category to the "tight" category in the treatment group compared to the sham group.
- Vaginal Flatus Score: Self-reported frequency of vaginal flatus. The VFS was used as an additional subjective measure of success. This sensation is frequently experienced by women who have vaginal laxity, and so it was seen as another appropriate indicator of the subjective effectiveness of the treatment. During treatment review appointments, patients were requested to rate the frequency of their vaginal flatus using a Likert scale. The Likert responses were categorized into three groups: patients who reported having vaginal laxity "most of the time," "sometimes," and never or only a few occasions. The initial survey requested women to assess the occurrence of vaginal flatus on a scale of 1–5, with options ranging from extremely rare (score =1) to consistently present (score =5).
- Vaginal Laxity Bother Score: A measure of the bother associated with vaginal laxity. The VLBS is a subjective evaluation that has not been validated and used to assess the perceived impact of vaginal laxity on a patient's quality of life. Women assessed their level of discomfort caused by vaginal laxity during the therapy period using a 10-point Likert scale. A score of 1 signified a complete lack of concern, while a score of 10 represented the highest level of distress.

Objective measures

- Modified Oxford Score: Objective assessment of pelvic muscle tone. The MOS was utilized as an objective metric to assess the level of achievement in the present trial. The conventional MOS scoring system uses a 5-point scale to determine the severity of a condition. The scale ranges from 0, indicating no symptoms, to 5, indicating intense symptoms with noticeable improvement. To streamline statistical analysis, the grading system was consolidated into two grades. Given the limited sample size, the MOS scoring system was modified to consist of two categories: "nothing-weak" and "moderate-strong."
- Genital hiatus length: Measurement of anatomical changes in the genital hiatus.

Baseline assessments were conducted before the first treatment session, and subsequent evaluations were performed at 1 month, 3 months, and 6 months posttreatment follow-up to complete the questionnaires on subjective measurements. Adverse events were documented and reported according to established protocols.

Blinding

The study employed a single-blinded design, with participants unaware of their group assignment. The researchers, outcome assessors, and data analysts were also blinded to group allocation to minimize bias.

Ethical considerations

The study received approval from the institutional review board, and informed consent was obtained from all participants before enrollment. Data confidentiality and privacy were strictly maintained throughout the study.

Statistical analysis

All the data analyses were performed using IBM SPSS Version 25 software (IBM Corporation, Armonk, New York, USA). Quantitative data were expressed as mean and standard deviation (SD), whereas categorical data were expressed as proportions. Descriptive statistics were used to summarize participant demographics. Between-group differences were assessed using appropriate statistical tests (e.g. *t*-tests for continuous variables and Chi-square tests for categorical variables). Changes in outcome measures from baseline to posttreatment were analyzed using paired *t*-tests. Statistical significance was set at $P < 0.05$.

Results

Baseline characteristics

A total of 200 parous women participated in the study, with 110 allocated to the treatment group and 90 to the sham group. Baseline characteristics were comparable between the two groups, ensuring a balanced distribution of relevant variables. The mean age of participants was 34.5 years (SD =2.6), and most participants were 30–40 years' old. The distribution of parity, body mass index (BMI), and medical history were similar in both groups, minimizing confounding factors [Table 1].

Female sexual function index

The mean initial baseline FSFI scores for the treatment group (52.3) and the sham group (51.4) were comparable ($P = 0.782$). Table 2 presents the alterations

in FSFI based on the specific domains evaluated by the questionnaire. The average alteration in FSFI is shown in Table 3. Between the baseline and 3-month period, an average discrepancy of 9.1 points between the treatment and sham groups (P = 0.001). During 3–6 months, the treatment group consistently exhibited higher average FSFI scores than the sham group. The 6-month data analysis revealed notable enhancements in FSFI, with a mean difference of 8.1 points between the treatment and sham groups (P = 0.001).

Vaginal laxity questionnaire

Initially, 83.3% of patients in the sham group and 90% of patients in the therapy group identified themselves as "loose" on the VLQ. At 1 and 3 months, 83.3% and 81.1% of patients in the sham group continued to identify as "loose" compared to 50.9% and 37.3% of patients in the treatment group (P = 0.018). After 6 months, 78.9% of patients in the sham group still reported feeling "loose," while only 20% of patients in the active group said the same [P = 0.008; Table 4].

Table 1: Baseline characteristics of the study population

Characteristics	Treatment group (n=110), n (%)	Sham group (n=90), n (%)	P
Mean age (years)	34.2 (2.5)	34.8 (2.8)	0.282
Mean BMI (kg/m²)	25.1 (3.0)	25.3 (2.9)	0.672
Diabetes	12 (10.9)	9 (10.0)	0.819
Hypertension	15 (13.6)	12 (13.3)	0.982
Hormonal therapy	28 (25.5)	24 (26.7)	0.745
Previous pelvic surgery	7 (6.4)	6 (6.7)	0.92

Data presented as mean±SD or n (%). BMI: Body mass index, SD: Standard deviation

Vaginal flatus score

The analysis of the results revealed that women in both the treatment and sham groups had an improvement in the symptom of vaginal flatus, suggesting the presence of a placebo effect. The enhancement in VFS did not achieve statistical significance when comparing the sham and therapy groups at 1, 3, and 6 months (P = 0.898, 0.986, and 0.882, respectively). The information is shown in Table 5.

Vaginal Laxity bother score

The data analysis revealed a notable enhancement in women's impression of vaginal laxity after 3 months (P = 0.012), which continues to be evident at 6 months (P = 0.008) when treated with TTCRF, as compared to the sham treatment [Table 6].

Modified oxford score

Patient outcomes in the therapy group showed improvement at 1, 3, and 6 months, although the comparison was not statistically significant [Table 7].

Genital hiatus

The measurement of the genital hiatus was used as second objective criterion for determining success. There was no notable disparity observed in GH levels between the treatment and sham groups from the baseline to the end of the 6-month period [Table 8].

Adverse events

No serious adverse events were reported during the study. Mild and transient side effects, such as erythema and edema, were observed in both groups, with no significant differences in their incidence between the treatment and sham groups.

Table 2: Female sexual function index

Domain	Time point	Pretreatment	1 month	3 months	6 months
Desire	Treatment group	5.21±2.1	5.321±2.3	5.472±2.1	6.024±2.5
	Sham group	5.28±2.0	5.326±2.4	5.372±1.5	5.552±2.3
	P	0.886	0.778	0.556	0.127
Arousal	Treatment group	9.872±3.5	10.886±4.0	11.456±3.4	12.632±3.5
	Sham group	10.023±3.6	10.701±3.7	11.003±4.2	11.782±4.2
	P	0.667	0.882	0.784	0.405
Lubrication	Treatment group	10.842±4.5	11.678±4.3	12.125±3.4	12.783±4.6
	Sham group	11.278±4.3	11.852±4.7	12.262±3.6	12.889±4.5
	P	0.227	0.778	0.884	0.825
Orgasm	Treatment group	4.872±1.5	5.452±2.3	5.889±2.6	6.562±2.7
	Sham group	5.421±1.8	5.568±2.5	5.724±2.5	6.423±2.4
	P	0.572	0.885	0.689	0.799
Satisfaction	Treatment group	10.886	11.521	12.968	13.562
	Sham group	9.682	10.883	11.024	12.887
	P	0.621	0.421	0.012	0.241
Pain	Treatment group	8.422	10.883	11.782	12.521
	Sham group	7.346	10.268	11.572	12.221
	P	0.682	0.886	0.796	0.892

Table 3: Change in mean total Female Sexual Function Index

FSFI	Treatment group	Sham group	*P*
Pretreatment	52.3	51.4	0.782
1 month	57.4	51.8	0.132
3 months	61.5	52.4	0.001
6 months	65.6	57.5	0.001

FSFI: Female Sexual Function Index

Table 4: Change in VLQ - sham versus treatment

Domain	Time point	Loose, *n* (%)	Neither loose or tight, *n* (%)	Tight	*P*
Pretreatment	Treatment group	99 (90)	9 (8.2)	2 (1.8)	0.521
	Sham group	75 (83.3)	12 (13.3)	3 (3.3)	
1 month	Treatment group	56 (50.9)	22 (20)	32 (29.1)	0.021
	Sham group	75 (83.3)	13 (14.4)	2 (2.2)	
3 months	Treatment group	41 (37.3)	29 (26.4)	40 (36.4)	0.018
	Sham group	73 (81.1)	17 (18.9)	0	
6 months	Treatment group	22 (20)	45 (40.1)	43 (39.1)	0.008
	Sham group	71 (78.9)	18 (20)	1 (1.1)	

VLQ: Vaginal laxity questionnaire

Table 5: Change in VFS - sham versus treatment at baseline, 1 month, 3 months, and 6 months

Domain	Time point	Most time/ always, *n* (%)	Sometimes, *n* (%)	Never/a few times, *n* (%)	*P*
Pretreatment	Treatment group	5 (4.5)	20 (18.2)	85 (72.3)	0.778
	Sham group	2 (2.2)	18 (20)	70 (77.8)	
1 month	Treatment group	2 (1.8)	18 (16.4)	90 (81.8)	0.898
	Sham group	1 (1.1)	16 (17.8)	73 (81.1)	
3 months	Treatment group	2 (1.8)	17 (15.5)	91 (82.7)	0.986
	Sham group	0	15 (16.7)	75 (83.3)	
6 months	Treatment group	1 (0.9)	14 (12.7)	95 (86.4)	0.882
	Sham group	0	12 (13.3)	78 (86.7)	

VFS: Vaginal flatus score

Discussion

The current study aimed to assess the effectiveness of TTCRF in treating vulvovaginal laxity and sexual dysfunction in women who had given birth. The trial sought to determine the efficacy of radiofrequency therapy by evaluating both objective and subjective indicators of success at the beginning, 1, 3, and 6 months, when also monitoring for any potentially harmful side effects.

Table 6: Mean change in VLBS - Sham versus treatment at baseline, 1 month, 3 months, and 6 months

Domain	Time point	Mean (minimum–maximum)	*P*
Pretreatment	Treatment group	5.9 (5.2–7.2)	0.689
	Sham group	5.4 (4.6–6.7)	
1 month	Treatment group	4.8 (4.1–5.3)	0.126
	Sham group	5.3 (4.6–6.2)	
3 months	Treatment group	4.1 (3.4–5.5)	0.012
	Sham group	5.1 (4.5–5.9)	
6 months	Treatment group	3.8 (3.1–4.5)	0.008
	Sham group	5.0 (4.5–6.1)	

VLBS: Vaginal laxity and bother score

Table 7: Change in modified Oxford score - sham versus treatment

Time points	Treatment group, *n* (%)	Sham group, *n* (%)	*P*
Baseline			
Nothing-weak	38 (34.5)	42 (46.7)	0.664
Moderate- strong	72 (65.5)	48 (53.3)	
1 months			
Nothing-weak	32 (29.1)	38 (42.2)	0.152
Moderate- strong	78 (70.9)	52 (57.8)	
3 months			
Nothing-weak	25 (22.7)	33 (36.7)	0.226
Moderate- strong	85 (77.3)	57 (63.3)	
6 months			
Nothing-weak	24 (21.8)	30 (33.3)	0.421
Moderate- strong	86 (78.2)	70 (77.7)	

Table 8: Change in genital hiatus - sham versus treatment

Time points	Mean length (cm)	*P*
Baseline		
Treatment group	3.421	0.678
Sham group	3.332	
1 months		
Treatment group	3.244	0.236
Sham group	3.562	
3 months		
Treatment group	3.267	0.178
Sham group	3.578	
6 months		
Treatment group	3.342	0.352
Sham group	3.510	

The balanced distribution of baseline characteristics between the treatment and sham groups establishes a robust foundation for interpreting subsequent results. Similarities in age, parity, BMI, and medical history mitigate potential confounding factors, enhancing the study's internal validity.

The FSFI questionnaire is an empirically verified subjective assessment tool that evaluates various aspects

of sexual function. Women with an FSFI score below 26.5 have a higher likelihood of experiencing sexual dysfunction. Most women participating in the present study did not meet the criteria for being "at risk" of experiencing sexual dysfunction, as determined by the FSFI parameters. However, the scoring system used in the present study was implemented to evaluate gains in sexual satisfaction, regardless of the beginning score. The selection of a questionnaire is crucial for assessing sexual dysfunction after medical intervention, as research has shown that the perceived effectiveness can differ significantly based on the specific assessment tool employed.[6,7] Vanaman *et al*. in a similar series also reported improvement in vulvovaginal laxity (n = 10) post-TTCRF on day 10 (P = 0.001), which was maintained till day 120 (P = 0.001).[8]

The presence of women with normal FSFI scores creates a relevant concern regarding the selection of patients for vaginal rejuvenation therapy. The gadget was initially intended for individuals who are prone to experiencing sexual dysfunction and signs of vaginal laxity. However, it also can be utilized by women who have normal physiological genitalia. These women seek medical intervention not to alleviate symptoms but rather to rectify their perceived vulvovaginal abnormalities. Females who lack anatomical understanding and face societal taboos regarding genital appearance are a vulnerable group that seeks vaginal rejuvenation therapy even without any pathological indication. While it is important to respect patient choice, doctors should utilize the initial appointment to engage in a discussion of female anatomy and the significant variations in vulvovaginal appearance. This consultation offers clinicians a favorable opportunity to challenge societal norms regarding the physical look of genitals and foster a candid conversation about the patient's reasons and desired outcomes for treatment.

This study revealed a rise in the average FSFI score in both the sham and treatment groups, indicating a general enhancement in subjective sexual satisfaction. The enhanced FSFI observed in the sham group provides evidence of the placebo effect, a phenomenon not previously observed in research examining TTCRF. However, it is worth noting that the FSFI mean improvement in the therapy group was significantly higher at 3 months and reached statistical significance at 6 months. No significant statistical differences were observed in the specific areas of the FSFI such as desire, arousal, lubrication, orgasm, satisfaction, and pain. The Viveve Trial has already confirmed the enhancement of FSFI following radiofrequency therapy.[9] This study was a randomized control trial that assessed the effectiveness of their radiofrequency device exclusively by tracking enhancements in FSFI domains. The Viveve Trial demonstrated substantial improvements in arousal, lubrication, and orgasm. In addition, some smaller studies have documented improvements in FSFI due to radiofrequency treatment.[10]

The present study differs from the Viveve Trial using a set of Likert questionnaires, which were used as a supplementary method to assess subjective success. The questionnaires evaluated the subjective perception of vaginal looseness (vaginal laxity questionnaire), the occurrence of vaginal flatus (vaginal flatus score), and the impact of looseness on a woman's quality of life (vaginal laxity bother score). Leibaschoff *et al*. did subjective and objective symptoms assessment of patients with stress urinary incontinence In subjects suffering stress urinary incontinence using TTCRF treatment. The study reported significant (P < 0.01) improvement of Incontinence Questionnaire-Urinary Incontinence Short Form and Urogenital Distress Inventory-6 scores posttreatment.[11]

The Vaginal Laxity Questionnaire is a 5-point Likert questionnaire. The analysis of the present study results indicates that women in the treatment group had a higher likelihood of transitioning out of the "loose" category, which suggests a subjective perception of vaginal tightening due to the treatment. The findings also indicated a notable disparity at 3 months, which can last for up to 6 months, although without statistical significance.

The present study results suggest that the therapy of vaginal laxity has been subjectively successful and may have lasting effects for up to 6 months. These findings have been duplicated in comparable, small sample size investigations. Millheiser *et al*.[10] and Alinsod[1] conducted small trials with 25 and 24 participants, respectively. These trials used VLQ questionnaires as the leading indicator of the effectiveness of radiofrequency in treating vaginal laxity. Both investigations observed an enhancement in the subjective evaluation of vaginal laxity. Millheiser *et al*.[10] found that women reported a substantial and ongoing sensation of tightness 6 months after treatment, compared to their ratings before treatment (P < 0.001). Alinsod[1] found that subjective improvement in sexual dysfunction was supported by a 50% reduction in the meantime to orgasm after treatment in 19 out of 25 individuals.

Vaginal flatus is a natural bodily reaction that occurs when the vagina becomes more relaxed. The present study results showed that both the sham and treatment groups included women who reported a reduction in the frequency of vaginal flatus during the treatment

period. There was no significant difference in the perception of vaginal flatus between the treatment and sham groups. This suggests that the VFS may not be a dependable subjective measure of the effectiveness of vaginal rejuvenation therapy, or it could imply that the study needs to have a larger sample size to uncover its importance.

Both the CLOSER and REVIVE studies have conclusively shown that sexual dysfunction has a profound impact on a woman's overall well-being and places considerable strain on personal relationships.[12] The findings of the present study emphasized the significance of sexual intimacy in maintaining long-term relationships. There should be a topic that women should openly discuss with their primary care physician or gynecologist. Laxity is a recognized factor that significantly contributes to sexual dysfunction. The VLBS is a questionnaire that has not been verified. Its purpose is to assess the degree to which vaginal laxity affects a woman's quality of life. The analysis of the results revealed a notable reduction in vulvovaginal laxity among women who underwent TTCRF treatment. The beneficial effect was observed during the evaluation at the 3-month and was evident until the 6-month evaluation.

There is currently no universally accepted measurement technique to evaluate or quantify the degree of vaginal laxity objectively. This study's findings revealed no statistically significant alteration in the genital hiatus between the treatment and the sham group. The MOS was devised as an impartial metric to assess the robustness of the pelvic floor.[13] The hypothesis proposed that an increase in collagen production, blood circulation, and flexibility of vaginal tissues would be associated with enhanced pelvic floor muscle function, leading to an improvement in the measure of sexual satisfaction (MOS). Women who underwent active treatment demonstrated enhancements in their MOS (measures of symptom) for 6 months in contrast to those who got a sham treatment. This modification did not achieve statistical significance within the 6-month duration. Alternatively, clinicians should take into account that radiofrequency devices only focus on the dermal and epithelial layers of the vagina and do not address the underlying fascial and muscular structures. As a result, these devices do not measure any actual objective change in vaginal laxity, nor do they restore these structures to their original anatomical positions.

The objective measurements of success in the present study did not replicate the positive subjective assessments of success. The physiological alteration resulting from TTCRF treatment does not lead to a reduction in the vaginal introitus, as would be expected with lowering GH values. The findings further suggest that therapy with TTCRF is not correlated with an enhancement in pelvic floor function, as seen by the lack of improvement in MOS score. The trial's positive subjective success suggests the need for a more appropriate objective tool to assess the physiological changes linked to radiofrequency treatment. Vaginal tactile imaging has demonstrated its utility in characterizing pelvic organ prolapse. It may play a role in future investigations aimed at establishing an objective metric for evaluating the effectiveness of vaginal rejuvenation therapy.[14]

Various previous investigations have established the physiological alterations that could account for the favorable subjective outcomes linked to TTCRF.[15,16] Most of this research was performed on ovine/swine models due to their structural resemblance to the human vagina. Wilson *et al*. did a study with a limited sample size of 10 women with moderate vulvovaginal laxity.[8] Five participants had biopsies of the labia majora and vaginal canal before and after treatment to examine the tissue under a microscope. The symptoms of vaginal laxity showed a significant improvement on day 10 and continued to be present until day 120 (P = 0.001 and 0.001, respectively).[8]

The present study findings demonstrate statistically significant enhancements in subjective vaginal laxity. The proposed indicators of objective success did not show any meaningful change during the 6-month therapy period. The amelioration of symptoms is analogous to other surgical rejuvenation therapies that are more invasive. In addition, several other studies have reported a rise in FSFI scores 6 months after surgical therapy. However, it is worth noting that these treatments have been linked to higher rates of dyspareunia.[17,18] In a prospective trial, Goodman *et al*. investigated the effects of genital plastic/cosmetic surgery (female genital plastic surgery) on sexual dysfunction. They utilized the validated Index of Sexual Satisfaction (ISS) to measure these effects. The study found that the subjective success of surgical intervention, measured by the ISS, remained significant for up to 24 months ($P < 0.0001$).[2]

Although these studies showed subjective success, they could not construct a standardized objective measure of success to complement the verified subjective changes. An important observation made during the present research was the absence of any negative responses to the medication over 6 months.

The present study faced notable limitations, primarily due to challenges in recruiting adequate participants, impacting the study's statistical power. Societal

hesitancy surrounding the taboo nature of vaginal laxity hindered recruitment, relying mainly on word-of-mouth due to resistance to advertising in medical clinics. Many potential participants needed to be more interested, expressing uncertainty about treatment success. As societal awareness improves, future recruitment may become less problematic.

Conclusion

Despite the prevalence of vaginal laxity and sexual dysfunction symptoms among women, these topics remain largely taboo. TTCRF, a minimally invasive radiofrequency treatment, addresses vulvovaginal laxity symptoms. The present study demonstrated significant improvements in subjective measures, including the VLQ, VLBS, and FSFI, when comparing TTCRF treatment to sham. While the MOS showed improvement, it did not reach statistical significance, suggesting GH and MOS may not be ideal objective measures for vaginal laxity treatment success. Notably, the present study established the safety and ease of TTCRF as an outpatient treatment for vaginal laxity over 6 months.

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Conflicts of interest

There are no conflicts of interest.

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