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Therapeutic effect of the temperature-controlled radio frequency technology in female sexual dysfunction

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ABSTRACT

Objectives: To explore the therapeutic effect of the temperature-controlled radiofrequency technology in female sexual dysfunction (FSD).

Material and methods: From July 2020 to June 2021, patients with FSD who visited the Gynecology Clinic of Peking University Shenzhen Hospital were treated with the temperature-controlled radiofrequency technology once every two weeks, for a total of five times. The therapeutic effect was objectively evaluated with pelvic floor dysfunction (PFD) indicators (FSFI score, pelvic floor muscles surface electromyography, sexual function test). The pre- and post-treatment (2 weeks)/follow-up (3 months) results were compared to evaluate the feasibility of this technology for treating FSD, as well as using PFD-related indicators in objective evaluation of FSD patients.

Results: Fifty patients completed treatment; 31 patients completed follow-up. The mean FSFI score for post-treatment/follow-up was significantly higher than pre-treatment ($p < 0.05$). There were no significant changes in the mean pelvic floor resting surface myoelectric potential and its variability and mean myoelectric potential of sexual function test between pre- and post-treatment/follow-up. The mean surface myoelectric potential of the patients' type I and II muscle fibers of the pelvic floor for post-treatment/follow-up was significantly higher than pre-treatment ($p < 0.05$). The mean peak myoelectric potential for post-treatment was significantly higher than pre-treatment ($p < 0.05$).

Conclusions: Temperature-controlled radiofrequency technology has a certain therapeutic effect on FSD. Pelvic floor surface electromyography and sexual function test can be used as an objective indicator for PFD in FSD patients. Subsequent studies may involve a larger size sample and evaluate the effect over a consecutive time-point, to develop a better therapeutic approach.

Keywords: female sexual dysfunction; radio frequency; female sexual function index questionnaire; pelvic floor dysfunction

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INTRODUCTION

With the improvement in the living standards, women's requirements for their own life experience and quality continue to rise, and issues related to female sexual dysfunction (FSD) have received more and more attention. FSD refers to the occurrence of obstacles in the female normal sexual response cycle, such as sexual desire disorder, sexual arousal disorder, orgasm disorder or sexual intercourse pain. The main pathogenic factors and risk factors are relatively complex, and are closely related to the underlying diseases, age factors, physical conditions, as well as psychological and spiritual factors [1].

About 43% of women have experienced sexual dysfunction, of which 12% of them have anxiety and depression [2], which seriously affect their quality of life and emotional state. Therefore, research on the diagnosis and treatment of FSD has gradually increased. It is worth noting that damage and degeneration of the pelvic floor tissue in women can lead to the decrease in pelvic floor support function, resulting in pelvic floor dysfunction (PFD) diseases, such as stress urinary incontinence (SUI), chronic pelvic pain (CPP), overactive bladder (OAB), pelvic organ prolapse (POP), and difficulty defecation, and are often complicated by FSD. Female sexual dysfunction is present in 50% to 83% of women with PFD symptoms [3].

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Based on the traditional and new effective methods for treating PFD, it is desirable to explore effective treatment methods for FSD and make up for the current deficiencies.

Previous study found that radiofrequency is safe for treating PFD [4]. Radiofrequency is a promising treatment option for SUI [5]. Numerous studies showed tissue contraction and determined a therapeutically optimal temperature ranged 40–45°C. This temperature can promote fibroblasts to produce collagen de novo, resulting in clinical tightening. Temperature-controlled radiofrequency have been found to improve SUI in postmenopausal women [6].

In this study, we evaluate the efficacy of the newly developed temperature-controlled radiofrequency technology in the treatment of PFD for patients in our hospital. The Chinese version of the widely used female sexual function index (FSFI) questionnaire was used. The therapeutic effect was objectively evaluated through the changes in the pelvic floor tissue of patients detected by pelvic floor surface electromyography (EMG), and sexual function test.

MATERIAL AND METHODS

Research object

From July 2020 to June 2021, patients who visited the Gynecology Clinic of Peking University Shenzhen Hospital and were diagnosed as FSD by senior physicians after evaluating the medical history, chief complaints and symptoms, and at the same time completed the treatment course of the temperature-controlled radiofrequency technology and related follow-up were recruited. A total of 50 patients completed the two weeks treatment, and 31 patients completed three months follow-up. All patients signed the informed consent, and this study was approved by the Hospital Ethics Committee.

Study criteria

Inclusion criteria: 1. Women with sexual dysfunction; 2. other treatment effects were unsatisfactory or ineffective; 3. if there was treatment for other diseases, the minimum window between previous treatment and this treatment must be more than 12 months.

Exclusion criteria: 1. Congenital malformations of the reproductive tract; 2. history of previous vaginal surgery; 3. acute reproductive tract infections (such as genital herpes, Candida, trichomonas, bacterial infections, etc.); 4. patients with acute or recurrent urinary tract infection; 5. patients with pelvic organ prolapse ≥ stage II; 6. patients with previous pelvic floor reconstruction surgery with mesh; 7. patients with metal birth control rings or metal implants (such as cardiac pacemakers, etc.); 8. suffering from other malignant tumors, serious heart, brain, kidney or other systemic and mental diseases, and other chronic diseases that affect research compliance; 9. having mental and psychological disorders or diseases that affect assessment; 10. oral drugs that affect sexual function, etc.

Treatment process and therapeutic effect evaluation

Pre-treatment preparation

Basic examination: full physical examination, gynecological examination, routine vaginal secretion examination, cervical liquid-based cytology examination, blood examination (hepatitis B, hepatitis C, HIV, syphilis, etc.), three sex hormones (estradiol, follicle stimulating hormone, luteinizing hormone).

Observation index: Using the online questionnaire "Wenjuanxing" (Sojump Professional site survey, Shandong, P.R. China) platform, the general information (age, marital status, occupation, education level, birth history, etc.) and the FSFI questionnaire in Chinese version [7] was made into webpage questionnaires, and the patients were asked to filled in. The questionnaires were filled in before treatment. The Chinese version of FSFI has been developed through translation, back translation, revision by research team and pilot study. It is reliable and valid[8]. This technology has already been used abroad, and this system may be available outside China in the second half of the year.

The MEDLANDER (Nanjing, P.R. China) pelvic floor surface EMG analysis, the Glazer scheme of biofeedback training system, and PHENIX USB 8 (France) neuromuscular stimulation therapy devices were used to perform pelvic floor surface electromyography and sexual function testing, respectively. The measurements were performed by a qualified rehabilitation therapist in the Pelvic Floor Diagnosis and Treatment Center of Peking University Shenzhen Hospital.

Treatment method

FemeTite (Shenzhen Peninsula Medical Co., Ltd., Guangdong, PR. China) vaginal rejuvenation system was used for treatment.

The treatment scheme module for the inner vagina

Specific operation: unipolar treatment for 15 min: the three indication points A, B, and C of the applicator was aligned at 12 o'clock direction in turn, and each area was treated for about 5 min. When changing the area for treatment, the applicator was turned clockwise. Bipolar treatment for 10 min: It was divided into two areas for treatment. First, point A was aligned at 12 o'clock direction for treatment, then rotate 90° for treatment, and each area was treated for 5 min. When changing areas for treatment, the applicator was turned clockwise.

Parameters: power 35–40 W, temperature 40–45°C, 25 min each time.

Treatment plan module for vulva

Specific operation: The applicator was installed, the vulva module was selected, and the medical sterile gel was applied evenly on one side of the labia, clitoris, and perineum. The applicator was placed flat on the vulva, the pedal was stepped on, and the treatment started. The labia majora was operated in an inward circle for 5 min; the labia minora and clitoris were operated by sliding upwards and downwards for 2 min, and the perineal body was operated by sliding horizontally for 3 min. During the operation, the applicator should be kept close to the skin, and the power and temperature at the labia minora and clitoris should be appropriately reduced.

Parameters: Power 10–15 w, temperature 38 °C–45 °C, each side for 10 min each time.

Treatment time

The treatment time was once every two weeks, for a total of five times.

Post-treatment precautions

After each treatment, the patient was explained regarding the post-treatment precautions as follows: 1. keep the vulva clean; 2. prohibit bathing for 24 h after treatment; 3. avoid hot water baths, 4. avoid strenuous exercise and heavy physical activities for 3–4 d after treatment; 5. avoid wearing tight underwear; 6. strict contraception during treatment.

Post-treatment and follow-up

Between 1–2 weeks after completing the five treatments, a gynecological examination was performed, and the post-treatment FSFI questionnaire, pelvic floor surface EMG test and sexual function test were completed. The patients were reassessed after three months of follow-up.

Measures to ensure safety of the implementation

Before treatment: the treatment parameters were set based on the safety of the treatment, after certain basic experimental validation and pre-experimental exploration.

During treatment: the rehabilitation therapists took up their positions after training and interacted with patients in real-time to ensure their safety during the treatment process.

After treatment: ensured there was regular phone calls and outpatient followed up one week after treatment to understand whether there were any adverse reactions after treatment.

Statistical analysis

The Wenjuanxing questionnaire data were exported, and the observation index results were collected. Microsoft Office Excel 2019 was used for data entry. The Statistical Program for Social Science (SPSS) 25.0 statistical software (IBM Corp., Armonk, NY, USA) was used for data analysis. The data were expressed using mean ± standard deviation. Comparison between two groups was analyzed by t-test. $P < 0.05$ indicated that the difference was statistically significant.

Results

General information

The age of the 50 patients ranged from 25 to 55 years, with a mean of (35.60 ± 6.31) years; their height ranged from 148 to 174 cm, with a mean of (159.46 ± 5.59) cm; their weight ranged from 35 to 73 kg, with a mean of (54.02 ± 8.06) kg; and their BMI ranged from 15 to 30.39, with a mean of (21.24 ± 3.08). None of the patients received systematic treatment for FSD before enrollment. Some patients have received physical therapy for PFD more than 12 months prior to enrollment.

FSFI scores for pre- and post-treatment/follow-up

The mean FSFI scores of patients for post-treatment/follow-up were significantly higher than pre-treatment (26.20 ± 3.69 vs 22.67 ± 4.55 and 27.19 ± 1.83 vs 22.99 ± 5.0, respectively; $p < 0.05$) (Tab. 1).

Surface EMG of pelvic floor muscles pre- and post-treatment/follow-up

There were no significant changes in the mean pelvic floor resting surface myoelectric potential and its variability for pre- and post-treatment [(4.78 ± 3.04) μv vs (5.10 ± 4.02) μv and (0.21 ± 0.01) vs (0.35 ± 0.08), respectively; $p > 0.05$]. The mean surface myoelectric potential of the patients' type I and II muscle fibers of the pelvic floor for post-treatment was significantly higher than pre-treatment [(28.99 ± 1.58) μv vs (20.29 ± 1.33) μv and (40.86 ± 1.76) μv vs (29.74 ± 1.77) μv, respectively; $p < 0.05$] (Tab. 2).

There were no significant changes in the mean pelvic floor resting surface myoelectric potential and its variability

Table 1. Female sexual function index (FSFI) score pre- and post-treatment after 2 weeks (completed treatment) and 3 months (follow-up)

Group	Mean FSFI	
	2 weeks (n = 50)	3 months (n = 31)
Pre-treatment	22.67 ± 4.55	22.99 ± 5.0
Post-treatment/follow-up	26.20 ± 3.69	27.19 ± 1.83
p value	0.000	0.000
t value	–6.372	–4.360

n — number of patients

Table 2. Surface electromyography (EMG) of pelvic floor muscles pre- and post-treatment after 2 weeks (completed treatment) and 3 months (follow-up)

Group	Mean resting surface myoelectric potential [μv]		Mean resting surface myoelectric potential variability		Mean myoelectric potential of type I muscle fibers of the pelvic floor [μv]		Mean myoelectric potential of type II muscle fibers of the pelvic floor [μv]	
	2 weeks	3 months	2 weeks	3 months	2 weeks	3 months	2 weeks	3 months
Pre-treatment	4.78 ± 3.04	5.08 ± 3.35	0.21 ± 0.01	0.20 ± 0.11	20.29 ± 1.33	20.56 ± 8.66	29.74 ± 1.77	30.47 ± 12.06
Post-treatment/ /follow-up	5.10 ± 4.02	5.54 ± 3.46	0.35 ± 0.08	0.23 ± 0.35	28.99 ± 1.58	28.16 ± 10.37	40.86 ± 1.76	39.52 ± 10.37
p value	0.608	0.545	0.116	0.647	0.000	0.000	0.000	0.000
t value	–0.517	–0.612	–1.599	–0.463	–5.932	–4.292	–6.275	–4.297

Number of patients (n) = 50 for 2 weeks, n = 31 for 3 months

Table 3A. Sexual function test for pre- and post-treatment; A. After 2 weeks (completed treatment)

Group	Mean myoelectric potential [μv]	Mean peak myoelectric potential [μv]
Pre-treatment	18.42 ± 0.92	39.46 ± 1.89
Post-treatment	19.78 ± 1.02	44.34 ± 2.03
p value	0.229	0.001
t value	–1.217	–3.704

Table 3B. Sexual function test for pre- and post-treatment; B. After 3 months (follow-up)

Group	Mean myoelectric potential [μv]	Mean peak myoelectric potential of type I muscle fibers of the pelvic floor [μv]	Mean peak myoelectric potential of type II muscle fibers of the pelvic floor [μv]
Pre-treatment	19.00 ± 7.21	38.81 ± 13.67	37.03 ± 13.39
Post-follow-up	18.48 ± 6.37	36.71 ± 8.25	39.59 ± 8.13
p value	0.694	0.380	0.268
t value	0.397	0.890	–1.128

Number of patients (n) = 50 for 2 weeks, n = 31 for 3 months

for pre-treatment and post-follow-up [(5.08 ± 3.35) μv vs (5.54 ± 3.46) μv and (0.20 ± 0.11) vs (0.23 ± 0.35), respectively; $p > 0.05$]. The mean surface myoelectric potential of the patients' type I and II muscle fibers of the pelvic floor for post-follow-up was significantly higher than pre-treatment [28.16 ± 10.37) μv vs (20.56 ± 8.66) μv and (39.52 ± 10.37) μv vs (30.47 ± 12.06) μv, respectively; $p < 0.05$] (Tab. 2).

Sexual function test for pre- and post-treatment/ /follow-up

There were no significant changes in the mean myoelectric potential of patients for pre- and post-treatment [(18.42 ± 0.92) μv vs (19.78 ± 1.02) μv; $p > 0.05$]. However, the mean peak of myoelectric potential of patients for post-treatment was significantly higher than pre-treatment [(44.34 ± 2.03) μv vs (39.46 ± 1.89) μv; $p < 0.05$] (Tab. 3A).

There were no significant changes in the mean myoelectric potential, and the peak myoelectric potential of the patients' type I and II muscle fibers of the pelvic floor for pre-treatment and post-follow-up [(19.00 ± 7.21) μv vs (18.48 ± 6.37) μv, (38.81 ± 13.67) μv vs (36.71 ± 8.25) μv and (37.03 ± 13.39) μv (39.59 ± 8.13) μv, respectively; $p > 0.05$] (Tab. 3B).

DISCUSSION

The results of this study showed that the mean FSFI scores of patients after completed two weeks treatment and three months follow-up were significantly higher than pre-treatment. The mean pelvic floor resting surface myoelectric potential and its variability for pre- and post-treatment/follow-up did not show significant changes. The mean surface myoelectric potential of the patients' type I and II muscle fibers of the pelvic floor for post-treatment/follow-up was significantly higher than pre-treatment. There were no significant changes in the mean myoelectric potential for sexual function test of patients for pre- and

post-treatment/follow-up. The mean peak of myoelectric potential of patients for post-treatment was significantly higher than pre-treatment. Our study is consistent with the research by Dayan et al which found no significant changes in resting pelvic muscle tone but an improvement in the maximal pelvic floor contraction [4]. However, the mean peak of myoelectric potential of patients after three months follow-up was not significantly different from pre-treatment. This may probably be due to some patients were unable to turn up for follow-up, and thus the therapeutic outcome could not be assessed. Subsequent studies may involve a larger size sample and evaluate the effect over a consecutive time-point to view the pattern of the therapeutic outcome, to develop a better therapeutic approach.

Current situation of female sexual dysfunction

With the development of society and rise of women's consciousness, women's sexual health has gradually received more attention, and clinical research on the diagnosis, classification and treatment of FSD has also gradually increased. The incidence of FSD in Asian women ranges from 30% to 52%, and more than 50% of women in China are reported to suffer from sexual dysfunction [9]. According to the American College of Obstetricians and Gynecologists on guidelines for the management of female sexual dysfunction, the current American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition, DSM-5) classified FSD into 5 categories: sexual interest or arousal disorders, orgasmic disorder, genito-pelvic pain or penetration disorder, substance or drug-induced sexual dysfunction, and other unspecified sexual dysfunction [1]. There are many pathogenic factors of FSD, including psychological aspects, social factors, physiological changes, pathological damage and other factors [10]. Therefore, there are various treatment methods for FSD, including psychological and behavioral therapy, drug therapy, physical rehabilitation, and surgical treatment. However, due to the influence of tradition and education level, some Chinese women have weak perception about sexual health and lack of relevant physiological knowledge, so they are unable to realize the occurrence of FSD and its harm to the quality of life, as well as physical and mental health. Only 22.7% of the patients sought medical attention, 28.5% of the patients searched for information on their own, and 30% of the patients had never gone to the hospital for medical treatment [11]. Therefore, it is necessary to spread the relevant knowledge of FSD, and explore more objective diagnostic methods and new treatment methods.

Relationship between FSD and PFD

The damage to the pelvic floor tissue during pregnancy and childbirth often leads to female PFD and various clinical symptoms. However, the pelvic floor tissue is composed of a variety of muscles and fascia, and there are many muscles directly related to sexual function, such as the bulbocavernosus muscle, the deep transverse perineal muscle, and the levator ani muscle [12]. Studies have shown that pregnancy and childbirth can lead to various abnormal conditions such as perineal pain, urinary incontinence, depression and changes in sexual function in women. Therefore, pelvic floor tissue damage will also have adverse effects on the female sexual function. As for the exact relationship between FSD and PDF, there is no conclusion yet. Some studies believe that PFD and FSD have no obvious correlation. Other studies have shown that women suffering from PFD affect the quality of life and cause anxiety and other adverse emotional states, thereby increasing the occurrence of FSD. It is closely related [13–15].

In summary, both FSD and PFD have a certain correlation with changes in the female pelvic floor structure. Many treatment methods for PFD, while improving the relaxation and injury of pelvic floor structure, promote the blood supply of tissues near the clitoris, improve female vaginal relaxation, and stimulate glandular secretion, and thus improve their quality of sexual life [16]. Therefore, the occurrence of FSD and PFD are closely related to a certain pathogenic mechanism, and the research on PFD is relatively mature. Based on clear principle and safe application, we can explore whether PFD treatment method can achieve ideal therapeutic effect when applied to FSD treatment.

Feasibility of the application of the temperature-controlled radiofrequency technology in FSD

The temperature-controlled radio frequency technology uses high-frequency alternating electromagnetic waves generated by radio frequency to act on the electrons and ions in the target tissue of the human body, causing them to move in a directional manner and produce a thermal effect. Through constant temperature control, it can promote the regeneration of collagen and elastic fibers in the human body and improve blood circulation without causing tissue damage, to achieve the purpose of non-invasive physical therapy for the treatment of diseases. When applied to FSD, it can promote the regeneration of vaginal collagen and elastic fibers and promote the overall blood circulation of the pelvic cavity, so as to reduce the symptoms of vaginal relaxation, vaginal dryness, and sexual pain in FSD. Relevant basic research shows that after percutaneous temperature-controlled radiofrequency treatment of the vulvovagina, vaginal mucosal sections showed that the treatment promoted the regeneration of collagen, and regeneration of blood vessels and small nerve fibers [17]. The temperature-controlled radiofrequency technology has been gradually applied to the treatment of PFD, and it

has achieved good results in the treatment of vaginal relaxation and urinary incontinence [18, 19]. Previous study found that radiofrequency can improve the maximal pelvic muscle contraction [4]. Some European and American countries have applied the temperature-controlled radiofrequency technology to the treatment of FSD in a small scale and achieved certain results [20]. Therefore, applying the temperature-controlled radio frequency technology to the treatment of FSD has certain rationality and considerable exploration value. At the same time, with its non-invasive treatment characteristics, it can relieve the pain of patients, improve the treatment experience, and relieve the psychological burden of FSD patients.

CONCLUSIONS

In this study, the mean FSFI score, mean surface myoelectric potential of the patients' type I and II muscle fibers of the pelvic floor and mean peak myoelectric potential of the sexual function test were improved after treatment, indicating that the application of temperature-controlled radio frequency technology has a certain therapeutic effect on FSD. Applying the objective evaluation index of PFD to the assessment of the condition of the FSD patients can reflect the treatment effect to a certain extent and improve the patients' subjective feelings.

Article information and declarations

Data availability statement

The datasets used or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics statement

This study is approved by the Ethics Committee of Peking University Shenzhen Hospital, NO. [2020](001A). Signed informed consent were also obtained from all participants.

Author contributions

We declare that all the listed authors have participated actively in the study and all meet the requirements of the authorship. Dr. NW designed the study and wrote the paper, Dr. HL managed the literature searches and analyses, contributed to the correspondence. All authors reviewed the manuscript.

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None.

Conflict of interest

The authors declare that they have no conflict of interest.

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