



# The Effect of Radiofrequency Therapy on Sexual Function in Female Cancer Survivors (Gynecologic and Breast) and Non-cancer Menopausal Women: A Single-Arm Trial

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## Abstract

**Introduction:** Up to 90% of postmenopausal women and female cancer survivors may be affected by the genitourinary syndrome of menopause (GSM), with a negative impact on sexual function and quality of life. A novel energy-based device among the treatment options for GSM is radiofrequency therapy (RFT). RFT is a treatment option that uses energy from radio waves to heat the tissue. The objective of this study was to assess the impact of RFT on sexual function in female cancer survivors (gynecologic and breast) and non-cancer menopausal women.

**Methods:** In a single-arm prospective trial, the efficacy of RFT in both female cancer survivors (gynecologic and breast) and non-cancer menopausal women with sexual dysfunction at a tertiary and referral center (Imam Hossein Medical Center, Tehran, Iran) was evaluated between April 2022 and December 2022. The study protocol consisted of 3 monthly RFT sessions. Examination was performed at baseline (T0) and 3 months after the last RFT session (T1). The primary outcome was sexual function, which was assessed using the Female Sexual Function Index (FSFI). In addition, adverse events were evaluated during treatment and at T1.

**Results:** A total of 37 female cancer survivors (mean [SD] age: 49.4 [8.9] years) and 37 non-cancer menopausal women (mean [SD] age: 53.8 [5.5] years) were enrolled. Patients exposed to RFT showed a significant improvement in FSFI scores when compared to baseline scores for both female cancer survivors (13.07, 95% CI: 12.27 - 13.86) and non-cancer menopausal women (13.18, 95% CI: 12.34 - 14.03). There was no difference in FSFI total score improvement between the two groups ( $t_{(72)} = 0.06$ ,  $P = 0.951$ ). There were no serious adverse events associated with RFT.

**Conclusion:** The efficacy of RFT as a treatment for sexual dysfunction has been demonstrated in both non-cancer menopausal women and female cancer survivors. In both groups, a significant improvement was confirmed.

**Keywords:** Radiofrequency therapy; Sexual function; Menopause; Gynecologic cancer; Breast cancer.



## Introduction

Breast cancer and gynecologic cancers are the most frequently diagnosed cancers in women, accounting for 24.5% and 15.2% of the newly diagnosed cancers in women worldwide, respectively.<sup>1</sup> Moreover, breast cancer is a major global health concern, given that it is currently the most commonly diagnosed cancer worldwide.<sup>1</sup> Advancements in timely detection and more effective therapies have contributed to a steady increase in the number of female cancer survivors, particularly breast cancer survivors.<sup>2,3</sup> Adjuvant therapy for gynecologic cancer and breast cancer (e.g., systemic chemotherapy

and endocrine therapy) can lead to undesirable symptoms that negatively impact on women's quality of life.<sup>4</sup> For example, GSM, previously known as vulvovaginal atrophy (VVA), is a pervasive side effect associated with female sexual dysfunction (FSD).<sup>5,6</sup> FSD refers to a problem that prevents women experiencing the satisfaction of sexual activity and affects approximately 40%-50% of all women and 66% of women with cancer.<sup>7</sup>

GSM is characterized by genital (e.g., vaginal dryness, irritation/burning/itching), urinary (e.g., urgency, dysuria), and sexual symptoms (e.g., decreased lubrication, dyspareunia, impaired function).<sup>5</sup> The GSM

is highly prevalent, affecting approximately 50% to 90% of post-menopausal women<sup>8-12</sup> and 35% to 91% of breast cancer survivors.<sup>13</sup> Vaginal dryness was the most prevalent GSM-related symptom reported in previous studies both in menopausal women and in breast cancer survivors, with a wide variety in the severity and frequency of the symptom.<sup>9, 12-14</sup> Despite its significant impact on sexual function and high prevalence, GSM is still under-recognized and undertreated.<sup>15</sup> The standard treatment for alleviating GSM-related symptoms includes both non-hormonal therapies, that is, vaginal lubricants and moisturizers, in addition to hormonal therapies, including topical estrogen.<sup>13,16</sup> In recent years, physical methods such as laser therapy and radiofrequency therapy (RFT) have been recruited to manage GSM, especially in women who have been advised against hormone therapy.<sup>16</sup>

Intravaginal laser therapy has emerged as a potential treatment modality for GSM and/or urinary incontinence. The fractional microablative CO<sub>2</sub> laser and the non-ablative erbium:YAG (Er:YAG) laser are the two main types of lasers utilized for treating symptoms related to GSM.<sup>16-19</sup> RFT is another modality to alleviate GSM-related symptoms, and its use has become more popular over the last years.<sup>16, 20</sup> There are various types of radiofrequency treatments available, categorized based on energy dissipation and the effect of the electromagnetic wave on tissue.<sup>21</sup> Among these, non-ablative monopolar radiofrequency is the most commonly used method.<sup>22</sup>

A systematic review by Sarmiento et al<sup>16</sup> evaluated the use of laser and radiofrequency physical therapies for GSM in pre- and postmenopausal women. They found that laser therapy is a safe and effective treatment for GSM and urinary incontinence in postmenopausal women. Similarly, another review and meta-analysis<sup>23</sup> found that although vaginal laser therapy has shown efficacy in treating GSM in breast cancer survivors in the short term, there is a lack of long-term safety and efficacy data. However, the efficacy and safety of RFT for the treatment of GSM have not been evaluated to the same extent. Considering the above-mentioned points, it is necessary to investigate the effectiveness of RF for the treatment of GSM because most studies only evaluate laser therapy use. In addition, the majority of studies have been conducted on menopausal women, and little is known regarding the efficacy of RFT on FSD among female cancer survivors. Given this background, the current study was performed to examine the effect of RFT in the treatment of FSD, as assessed using the FSFI,<sup>24</sup> in female cancer survivors (gynecologic/breast cancer) and non-cancer menopausal women, and to compare the efficacy of RFT in these two groups of women.

## Materials and Methods

### Study Design

The study is a single-arm prospective trial and evaluates

the efficacy of RFT in both female cancer survivors (Gynecologic and Breast) and non-cancer menopausal women with FSD at a tertiary and referral cancer center (Imam Hossein Medical Center, Tehran, Iran) between April 2022 and December 2022.

Inclusion criteria for the study were as follows: (1) female cancer survivors (Gynecologic Cancer and Breast Cancer), (2) self-reported FSD as defined by a baseline FSFI total score of less than 26.5, and (3) wishing to maintain an active sexual life. In addition, non-cancer menopausal women (at least 12 months after their last menstrual period and/or bilateral oophorectomy) with FSD participated in the study.

The following exclusion criteria were applied: (1) use of hormone replacement therapies, either systemic or local, (2) use of vaginal moisturizers or lubricants, (3) presence of active genital infection such as herpes genitalis or candida, (4) acute or recurrent urinary tract infection, (5) HIV positive status, (6) previous pelvic reconstructive surgery or use of an intrauterine device, (7) current pregnancy, (8) breastfeeding, and (9) presence of any skin disease.

### Therapeutic Procedure

All women included in the study were treated with a Physio Vag radiofrequency device, which is based on temperature-controlled transcutaneous radiofrequency that uses monopolar and bipolar modes. There are 4 frequencies (i.e., 420, 500, 720 and 1000 kHz) in this device. In this study, a frequency of 720 kHz was used for both monopolar and bipolar modes.

For the application, the women were placed in the lithotomy position. Each session was carried out using two handpieces, one for the external genitalia and another for the vaginal canal. In the external genitalia, the working time was about 10 minutes using an external probe with a frequency of 720 kHz and monopolar mode. In the vaginal canal, the working time was also about 10 minutes using an internal probe with a frequency of 720 kHz and bipolar mode. Each woman underwent three RFT sessions, with an interval of one month between them. Assessments were made at baseline (T<sub>0</sub>) and 3 months after the last RFT session (T<sub>1</sub>). The treatment was done by the same trained gynecologist.

### Primary Outcome

The primary outcome of the study was sexual function, which was evaluated using the FSFI.<sup>24</sup> The FSFI is a brief, 19-item self-administered questionnaire that measures female sexual function over the preceding four weeks. It evaluates sexual function across multiple domains, including desire, arousal, lubrication, orgasm, satisfaction, and pain, and it provides an overall score for sexual function. The FSFI total score ranges from 2 to 32. A total score of  $\leq 26.55$  on the FSFI is considered

to be indicative of possible FSD.<sup>25</sup> The Persian version of the FSFI has demonstrated adequate psychometric properties.<sup>26</sup>

### Secondary outcome (Side effects)

To examine safety, we considered the adverse events during the treatment and 3 months after the treatment.

### Sample Size

The sample size calculation was done using G\*Power version 3.1.9.2.<sup>27</sup> With an effect size of 0.7, a power of 0.8 and an alpha value of 0.05, 34 women would be necessary in each group. Assuming a potential dropout rate of 10%, 37 women were needed in each group.

### Statistical Analysis

We reported continuous variables as mean (standard deviation (SD)), and categorical variables were reported as frequency (percentage). Comparisons of mean scores from FSFI total score and its domain were performed using the paired-samples t-test. The independent-samples t-test was used to compare the improvement of FSFI total and its domain score between female cancer survivors and non-cancer menopausal women. Data analysis was performed using SPSS for Windows, version 16.0 (SPSS Inc., Chicago, IL, USA). Graphs with error bars were generated using GraphPad Prism, Version 8.0.1 (GraphPad Prism Software Inc., San Diego, CA, USA). The *P* value of less than 0.05 was considered statistically significant.

## Results

### Participants' Characteristics

All women in both groups completed the study, and none were dropped from the study. Table 1 shows the demographic and clinical data of the women. The mean age of the women was 51.58 (SD=7.68) years.

### Outcomes

#### Comparison Between Baseline and 3 Months After the Last RFT Session

As presented in Table 2, female cancer survivors reported a higher FSFI total score after the intervention (Mean=27.82, SD=2.13) compared to before the treatment (Mean=14.75, SD=2.22). A paired-samples t-test indicated this improvement; 13.07, 95% CI [12.27, 13.86] was statistically significant ( $t_{(36)} = 33.25, P < 0.001$ ). Similar results were observed for all FSFI domains among female cancer survivors (see Table 2).

In non-cancer menopausal women, the women's score of total FSFI increased significantly from baseline (M=14.31, SD=1.45) to post-intervention (M=27.94, SD=2.20) ( $t_{(36)} = 31.78, P < 0.001$ ). On average, the total FSFI scores 3 months after the last RFT session were 13.18 [95% CI: 12.34, 14.03] units more than the FSFI

**Table 1.** Baseline Characteristics of the Study Participants

	Total	Female Cancer Survivors	Non-cancer Menopause
Age, mean (SD), y	51.58 (7.68)	49.41 (8.94)	53.76 (5.46)
Gravidity, n (%)			
NG	3 (4.1)	2 (5.4)	1 (2.7)
G1	13 (17.6)	9 (24.3)	4 (10.8)
G2	25 (33.8)	16 (43.2)	9 (24.3)
G3	19 (25.7)	4 (10.8)	15 (40.5)
≥G4	14 (18.9)	6 (16.2)	8 (21.6)
Live birth, mean (SD)	2.34 (1.38)	2.11 (1.45)	2.57 (1.28)
Abortion, n (%)			
No	62 (83.8)	30 (81.1)	32 (86.5)
Yes	12 (16.2)	7 (18.9)	5 (13.5)
Type of Delivery, n (%)			
None	6 (8.1)	4 (10.8)	2 (5.4)
NVD	43 (58.1)	16 (43.2)	27 (73.0)
CS	14 (18.9)	10 (27.0)	4 (10.8)
NVD/CS	11 (14.9)	7 (18.9)	4 (10.8)

NVD, Natural vaginal delivery; CS, Caesarean section. Data are mean (SD) or n (%).

scores at baseline. Similar results were observed for all FSFI domains among non-cancer menopausal women (Table 2).

### Comparison Between Groups

A comparison of FSFI score improvement between female cancer survivors and non-cancer menopausal women is depicted in Figure 1. There was no difference in FSFI total score improvement between the two groups ( $t_{(72)} = 0.06, P = 0.951$ ). The same results were also obtained for Desire ( $t_{(72)} = 1.53, P = 0.129$ ), Arousal ( $t_{(72)} = 0, P = 1$ ), Lubrication ( $t_{(72)} = 0.06, P = 0.953$ ), Orgasm ( $t_{(72)} = 0.28, P = 0.780$ ), Satisfaction ( $t_{(72)} = 0.08, P = 0.933$ ), and Pain ( $t_{(72)} = 0.61, P = 0.543$ ).

### Side Effects

All women completed the trial and none was lost to follow-up. There were no serious and unexpected adverse events associated with RFT.

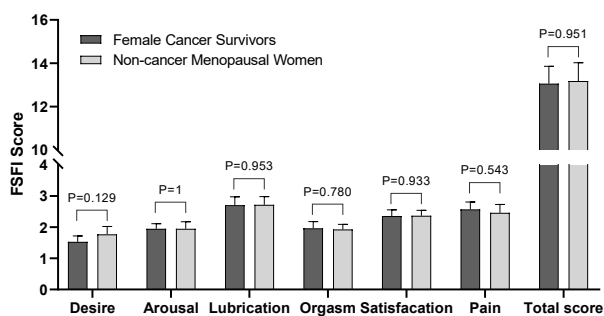
## Discussion

GSM in female cancer survivors is a critical and pervasive problem, resulting in FSD and impaired quality of life. However, the appropriate therapy for managing GSM in female cancer survivors is still an inadequately addressed issue. Several systematic reviews have demonstrated the feasibility and safety of laser therapy for treating GSM, as well as improvements in sexual function among both postmenopausal women and breast cancer survivors.<sup>13,17,28</sup> However, evidence regarding the support for the hypothesis of safety and effectiveness of RFT on

**Table 2.** FSFI Scores at Baseline and 3 Months After the Last RFT Session

	Time		Mean Differences (95% CI)	t <sub>(36)</sub> / t <sub>(72)</sub>	P
	Baseline	Three Months After Last RFT			
<b>Cancer survivors (n=37)</b>					
Desire	2.42 (0.39)	3.94 (0.62)	1.53 (1.34, 1.72)	16.24	<0.001
Arousal	2.36 (0.40)	4.31 (0.53)	1.95 (1.78, 2.11)	24.01	<0.001
Lubrication	2.38 (0.60)	5.09 (0.49)	2.71 (2.44, 2.97)	20.70	<0.001
Orgasm	2.63 (0.55)	4.59 (0.29)	1.96 (1.74, 2.18)	18.28	<0.001
Satisfaction	2.44 (0.52)	4.80 (0.42)	2.36 (2.16, 2.55)	24.42	<0.001
Pain	2.51 (0.50)	5.08 (0.55)	2.57 (2.33, 2.80)	22.01	<0.001
Total FSFI score	14.75 (2.22)	27.82 (2.13)	13.07 (12.27, 13.86)	33.25	<0.001
<b>Non-cancer menopause (n=37)</b>					
Desire	2.29 (0.34)	4.05 (0.70)	1.77 (1.51, 2.02)	14.13	<0.001
Arousal	2.21 (0.42)	4.15 (0.63)	1.95 (1.72, 2.17)	17.26	<0.001
Lubrication	2.38 (0.49)	5.10 (0.56)	2.72 (2.46, 2.98)	21.15	<0.001
Orgasm	2.58 (0.35)	4.51 (0.31)	1.92 (1.76, 2.09)	23.53	<0.001
Satisfaction	2.29 (0.38)	4.66 (0.44)	2.37 (2.20, 2.54)	28.30	<0.001
Pain	2.56 (0.44)	5.02 (0.64)	2.46 (2.19, 2.73)	18.48	<0.001
Total FSFI score	14.31 (1.45)	27.49 (2.20)	13.18 (12.34, 14.03)	31.78	<0.001
<b>Total subjects (n=74)</b>					
Desire	2.35 (0.37)	4.00 (0.66)	1.65 (1.49, 1.80)	20.86	<0.001
Arousal	2.28 (0.41)	4.23 (0.58)	1.95 (1.81, 2.08)	28.22	<0.001
Lubrication	2.38 (0.55)	5.10 (0.52)	2.71 (2.53, 2.90)	29.79	<0.001
Orgasm	2.61 (0.46)	4.55 (0.30)	1.94 (1.81, 2.08)	28.98	<0.001
Satisfaction	2.37 (0.46)	4.73 (0.44)	2.36 (2.24, 2.49)	37.24	<0.001
Pain	2.54 (0.47)	5.05 (0.60)	2.51 (2.34, 2.69)	28.53	<0.001
Total FSFI score	14.48 (1.86)	27.64 (2.34)	13.16 (12.60, 13.73)	46.48	<0.001

SD, Standard Deviation; CI, Confidence Interval; FSFI, Female Sexual Function Index. Data are mean (SD), unless otherwise specified.



**Figure 1.** The Improvement (Gain) Score From Baseline to Three Months After the Last Session of RFT in FSFI and its Domain Scores for Female Cancer Survivors and Non-cancer Menopausal Women. P values are based on the independent-samples t-test

GSM is rare.<sup>16</sup>

Our findings indicate that in women with GSM-related symptoms, either female cancer survivors or non-cancer menopausal women, RFT is effective in significantly improving 6 different domains of sexual function. These results are consistent with other studies that have also found RFT to improve sexual function. In a study

performed by Pinheiro et al<sup>22</sup> in Brazil, RFT improved sexual function in 72.7% of participants as assessed by the FSFI. A similar result was obtained in a randomized, single-blind, and sham-controlled study performed by Krychman et al,<sup>29</sup> in nine clinical centers located in Canada, Japan, Italy, and Spain.

Our study utilized three RFT sessions applied at a one-month interval for all women. In previous studies, the treatment protocol included three to five sessions.<sup>22,30-33</sup> There are no guidelines regarding the optimal number of sessions or the intervals between them. Future studies comparing different interval and session protocols might produce the best treatment approaches.

The present study found no serious adverse events associated with RFT during or after the treatment, indicating that RFT may be considered a safe and well-tolerated method for treating GSM. This finding is consistent with the previous studies.<sup>22,30-33</sup> Nevertheless, these results must be interpreted carefully, considering the lack of randomized controlled trials and follow-up on the long-term effect of this therapy.

In the present study, no differences in the efficacy of

RFT on sexual function were found between female cancer survivors and non-cancer menopausal women. Gittens and Mullen's study<sup>34</sup> supports the role of fractional microablative CO<sub>2</sub> laser therapy as an effective treatment for FSD in postmenopausal women and breast cancer survivors. However, the group size was too small to allow a direct comparison between postmenopausal women and breast cancer survivors. In a study conducted by Siliquini et al<sup>35</sup> using fractional a CO<sub>2</sub> vaginal laser, GSM symptoms improved slower in breast cancer survivors than in healthy women.

To date, most studies have examined the efficacy of only one physical method for the treatment of GSM. Further comparative research between different RF-based devices and other energy-based devices, such as laser and micro-focused ultrasound, may help establish more specific treatment protocols for GSM.<sup>36</sup>

The limitations of the study include a single-center study, the absence of a control group, and a short follow-up time of up to 3 months. In the present study, subgroup analysis was not designed, particularly due to the small number of subgroups. Further studies using longer follow-up assessments in larger and more diverse populations are useful. In addition, prospective trials to compare RFT with therapeutic alternatives are useful.

## Conclusion

RFT effectively treated the symptoms of FSD in gynecologic/breast cancer survivors as well as in non-cancer menopausal women, and no differences in the efficacy of the RFT were observed between the two groups.

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## Authors' Contribution

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**Resources:** Farah Farzaneh.

**Software:** Mahshid Vasef.

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**Writing – original draft:** Mahshid Vasef.

**Writing – review & editing:** Maliheh Arab.

## Data Availability Statement

The corresponding author can provide the data sets used and/or analyzed in the present study upon request in a reasonable manner.

## Ethical Approval

This study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences in Tehran, Iran (Ethics Code: IR.SBMU.RETECH.REC.1401.489). All participating women were fully informed about the study and provided their consent to participate. The trial was registered at www.irct.ir (identifier: IRCT20160531028187N2).

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