

PRESENTATION: E-POSTER

<https://doi.org/10.29289/259453942025V36S10890>

890 – Restoring vaginal health after breast cancer: a randomized sham-controlled trial of microablative fractional radiofrequency for genitourinary syndrome of menopause

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Introduction: Genitourinary syndrome of menopause (GSM) is common among breast cancer survivors and may significantly impair quality of life. Because hormonal therapies can be contraindicated or avoided in this population, non-hormonal vaginal energy-based therapies warrant rigorous evaluation.

Objective: This study evaluated the safety and efficacy of vaginal microablative fractional radiofrequency (MAFRF) compared with sham treatment in breast cancer survivors with GSM.

Methods: This prospective, single-blind, randomized, sham-controlled clinical trial was conducted from March to December 2025. Eligible breast cancer survivors with GSM were randomized to vaginal MAFRF or sham treatment. Outcomes were assessed at baseline and one month post-intervention. The primary outcome was GSM symptom severity measured by a visual analog scale. Secondary outcomes included vaginal pH, the Vaginal Health Index (VHI), dyspareunia, dysuria, vaginal dryness, and sexual function measured by the Female Sexual Function Index (FSFI). Within-group changes were tested using paired Student's t-tests, effect sizes were calculated using Cohen's d, and statistical significance was set at $p < 0.05$.

Results: Sixty women were included, with a mean age of 49.6 years (standard deviation ± 6.9); 75% had treatment-induced menopause and 83.3% had luminal breast cancer. In the MAFRF group, significant improvements were observed in vaginal pH, VHI, dyspareunia, vaginal dryness (all $p < 0.001$), and dysuria ($p = 0.004$), while FSFI did not change significantly ($p = 0.132$). In the sham group, modest improvements were observed in FSFI ($p = 0.002$), dyspareunia ($p < 0.001$), dysuria ($p < 0.001$), and vaginal dryness ($p = 0.007$), with no significant changes in vaginal pH ($p = 0.083$) or VHI ($p = 0.625$). Between-group comparisons favored MAFRF for objective vaginal health outcomes (vaginal pH and VHI). According to Cohen's criteria, the MAFRF group showed improvements with large effect sizes for VHI ($d = -1.48$), vaginal dryness ($d = 1.29$), dyspareunia ($d = 0.92$), and vaginal pH ($d = -0.82$).

Conclusion: Vaginal MAFRF was a safe and effective non-hormonal therapy for improving GSM-related symptoms and vaginal health in breast cancer survivors, representing a promising management option.

Ethics: Research Ethics Committee Approval (CAAE 81973618.2.0000.5292).

Registry: Brazilian Registry of Clinical Trials (ReBec): RBR-2ntr3yd.

Keywords: breast neoplasms; cancer survivors; menopause; atrophy; radiofrequency therapy.