

Title: A Prospective Trial To Assess **B**reast Cancer Survivors **A**nd **V**aginal Atrophy Treatment **O**utcomes **(BRAVO)**

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Introduction: Estrogen suppression, often used as part of multimodal treatment for hormone-sensitive breast cancer survivors, can reduce the likelihood of a breast cancer recurrence. However, regardless of age or pre-existing menopausal status, the estrogen suppression can either exacerbate existing menopausal symptoms or induce medical menopause in otherwise premenopausal women. Like many other women, hormone-sensitive breast cancer survivors can experience a myriad of symptoms known as genitourinary syndrome of menopause (GSM) which includes pain, changes in lubrication and arousal and even urinary incontinence as a result of estrogen suppression related to age or hormone suppression therapy. The prevalence of GSM in breast cancer patients is over 60% and the impact of GSM on sexual morbidity has been well established. Additionally, breast cancer patients can experience vaginal laxity (VL) similar to non-breast cancer women as VL is associated with expansion from vaginal childbirth and loss of rugation and tone from changes in hormones. Treatments for symptoms of vaginal atrophy vary depending upon the area affected, severity of condition, and reduction in quality of life. This study aims to investigate the efficacy of a non-invasive, non-surgical cryogen-cooled monopolar radiofrequency (CMRF) treatment for vaginal atrophy in this patient population.

Objective: This pilot study is investigating a non-invasive, non-surgical treatment for symptomatic vaginal atrophy in hormone-sensitive breast cancer survivors.

Methods: This study will enroll ten (10) women with self-reported sexual dysfunction and vaginal laxity who are stage 0-2 breast cancer survivors, are cancer-free for at least 6 months, and currently taking tamoxifen for estrogen suppression. Women meeting all of the inclusion and exclusion criteria will be enrolled in the study and receive one CMRF treatment. Follow-up visits are scheduled for 1, 3, and 6 months post-treatment. At the screening visit and each timepoint beginning at Month 1, subjects will complete the following validated subjective patient reported outcome measures: vaginal laxity questionnaire (VLQ), female sexual function index (FSFI), female sexual distress scale – revised (FSDS-R), and the day-to-day impact of vaginal aging (DIVA). Additionally, safety assessments will be completed at each study visit.

Results/Conclusions: This study is currently enrolling and interim data is expected by early 2019.