EFFICACY OF THE Eros CLITORAL THERAPY DEVICE FOR THE TREATMENT OF SEXUAL DYSFUNCTION IN WOMEN WITH CERVICAL CANCER TREATED WITH RADIATION THERAPY: PRELIMINARY RESULTS

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Introduction and Purpose:

Cervical cancer is diagnosed in approximately 12,800 women a year in the United States. Many are treated with radiation therapy (RT). Sexual dysfunction is very common in these women and causes considerable distress. Symptoms range from mild vaginal dryness to severe dyspareunia due to marked physical changes to the pelvic organs. To date, treatment has focused on use of dilators and lubricants to prevent vaginal stenosis and allow for intercourse to occur and sex counseling to help these women adjust to persistent, compromised sexual function for the rest of their lives. Recently, promising results have been seen with the use of the *Eros-CTD*™ Treatment (UroMetrics, Inc.) in women with sexual dysfunction. The *Eros-CTD* is designed to increase blood flow to the clitoris, enhance clitoral engorgement, and ultimately improve arousal in women with Female Sexual Dysfunction (FSD). The purpose of this study was to evaluate the therapeutic role of the *Eros-CTD* in the treatment of sexual dysfunction in cervical cancer patients treated with RT.

Methods:

Eligible patients are those with a history of cervical cancer treated with RT who have been without evidence of disease for a minimum of 1 year and have symptoms of sexual arousal and/or orgasmic disorder. At the initial visit, a complete medical history is taken and a physical exam including a pelvic exam is performed. Subjects also complete a baseline sexual function questionnaire, the Female Sexual Function Index (FSFI©), that rates domains of desire, arousal, lubrication, orgasm, satisfaction and pain with a full scale score range of 2 - 36; a baseline relationship questionnaire, the Dyadic Adjustment Scale; and are interviewed about their sexual history and current function using the Derogatis Interview For Sexual Functioning - Females (DISF-F). Subjects are instructed in the use of the *Eros-CTD*. Patients use the device 4 times weekly for 3 months in self-stimulation and sexual foreplay. Patients complete a Treatment Diary and the Female Intervention Efficacy Index (FIEI) every two weeks. Outcome evaluation is performed at 3 months.

Results:

Since 1/01, 9 women (of a total planned 30) have been enrolled. Patient #1 is a 52 year old African American woman, who was treated for a Stage IB cervical cancer with definitive RT (4500 cGy to the whole pelvis followed by an additional 4000 cGy via vaginal intracavitary brachytherapy) a year prior to enrollment. Her symptoms included post-coital bleeding, dyspareunia, vaginal dryness, decreased genital sensation, orgasmic disorder and pelvic pain. Her baseline FSFI full-scale score was 17. A Pap smear was unsatisfactory due to excess blood and exudates. Significant cervical ulceration and telangiectasias were noted on pelvic exam. On Week 3, the patient and her spouse noted increased lubrication, genital sensation and decreased post-coital bleeding. By the completion of the trial, she noted no post-coital bleeding and pelvic pain as well as resolution of sexual dysfunctions. Outcome FSFI full scale score was 34.2 attaining the best scores possible for all domains except desire. Her personal, marital and family relationships were markedly improved. Pelvic exam revealed decreased cervical ulceration. A satisfactory Pap smear was also obtained with only benign cellular changes noted. The remaining 8 patients have also noted similar improvements in sexual function.

Conclusions:

The *Eros-CTD* is a promising treatment for female sexual dysfunction in women with cervical cancer following RT. Additional patients with longer follow-up are needed to evaluate the full potential of this approach.