MULTI-CENTER STUDY OF EXTRACORPOREAL MAGNETIC INNERVATION (EXMI™) FOR TREATMENT OF URINARY INCONTINENCE FOLLOWING RP

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Introduction and Objectives: Pelvic floor therapy is used extensively for treating urinary incontinence (UI) in patients following radical prostatectomy (RP). ExMI is a non-invasive therapy using a powerful, pulsed magnetic field to induce contractions of the pelvic floor muscles. ExMI is proven effective in treating female urinary incontinence. The purpose of this study is to determine the effect of ExMI therapy on persistent UI symptoms in men who have undergone RP.

Methods: A multi-center, randomized, controlled crossover study was designed to study men with UI at least 3 months following RP. Eligible patients had not undergone anti-incontinence surgery and were using daily incontinence protection. Patients underwent urodynamics and were randomized to sham or active treatment group. All patients were treated twice weekly for 6 weeks. For sham treatment, an insulator is inserted in the chair. The appearance and operation of the chair is the same for both groups. Sham patients were crossed over after 6 weeks. Patients are evaluated by bladder diaries, dynamic pad weights, validated IQOL survey and questionnaire.

Results: 34 patients were enrolled at 5 sites, but one site was dropped due to lack of follow-up. Analysis was conducted on 27 patients (16 sham, 11 active). Pad changes in the active group reduced from baseline of 1.41 to 0.53 pads / day, a 62% reduction (p> 0.04). Six of nine in the treated arm reported 0 pad use at the end of treatment and were cured. Pad changes in the sham arm increased. Sham patients that later crossed over to active treatment had pad changes reduced from 1.89 to 1.17 pads / day. Episodes of leakage in the treatment arm were reduced from 3.42 episodes / day at baseline to 0.91 at week six, a 73% reduction (p> 0.01). Dynamic pad weight was reduced from a mean of 4.81g at baseline to 3.81g at week 8 (p> 0.03). Sham reported no significant changes in pad weights, but patients that crossed over to treatment had pad weights reduced from 5.78g to 1.5g (p >0.05). IQOL scores in the treatment arm showed positive trends. There were no adverse events. Patients reported subjective improvement according to questionnaire and supporting data.

Conclusions: ExMI has a positive therapeutic effect in the treatment of patients with persistent UI following RP. Objective measures all showed significant improvement versus placebo. Patients tolerated the therapy well with no adverse side effects. The ExMI therapy has shown promising results in treating UI following RP.