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**Title:** INTERIM ANALYSIS OF A MULTI-CENTER STUDY OF EXTRACORPOREAL MAGNETIC INNERVATION (ExMI) FOR THE TREATMENT OF URINARY INCONTINENCE FOLLOWING RADICAL PROSTATECTOMY

### **Aims of Study:**

Pelvic floor physiotherapy has been utilized extensively for the treatment of urinary incontinence (UI) in patients following radical prostatectomy (RP). Extracorporeal Magnetic Innervation (ExMI) is a non-invasive therapy utilizing a powerful, pulsed magnetic field to induce depolarization of the nerves in the pelvic floor and subsequent contraction of the pelvic floor musculature. ExMI has been reported to have efficacy in the treatment of urinary incontinence in females (1). The purpose of this study is to determine the effect of ExMI therapy on persistent UI symptoms in men who have undergone RP.

### **Methods:**

An ongoing multi-center, randomized, controlled, crossover study was designed to study men exhibiting persistent UI at least 3 months following RP. Eligible patients had not undergone prior anti-incontinence surgery and were using daily incontinence protection. All patients underwent urodynamics. Enrolled patients were randomized to sham or active treatment group. Both active and sham patients were treated twice weekly for 6 weeks, with each session consisting of intermittent stimulation at two intensities (5Hz and 50 Hz). For sham treatment, a magnetic shunt is inserted in the chair to direct the magnetic field away from the patient. The appearance and operation of the chair is the same for both groups. Those randomized to sham are crossed over after 6 weeks. Patients are evaluated with bladder diaries, standardized dynamic pad weight test, validated quality of life survey and detailed questionnaire. Outcome measures are repeated at baseline, 6 weeks, 8 weeks, 10 weeks and 18 weeks.

### **Results:**

To date, 33 of 60 patients are enrolled. 11 patients are available for interim data analysis. 45% of enrolled patients were randomized to sham. Pad weight was reduced from a mean of 3.36g at baseline to 0.88 at week 8 ( $p=0.01$ ). At week 6, patients in the active group had decreased UI during a standard exercise protocol as compared to sham ( $p=0.063$ ), and there was less leakage on vigorous provocation with repeated coughing in comparison to sham ( $p=0.13$ ). All sham patients leaked during this activity compared to 45% of active patients. No related adverse events have been reported.

### **Conclusions:**

Interim data analysis suggests that ExMI has a positive therapeutic effect in the treatment of patients with persistent UI following RP. To our knowledge, this is the first controlled study using ExMI therapy for post-prostatectomy incontinence. These are the early results, further updated findings will be presented. This study is being sponsored by Neotonus, Inc.

(1) Galloway N, El-Galley R, Sand P, Appell R, Russell H, Carlan S. (2000). Update on Extracorporeal Magnetic Innervation (ExMI) Therapy for Stress Urinary Incontinence. *Urology*, 56 (6A):82-86.

