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Title:	EVALUATION OF EXTRACORPOREAL MAGNETIC INNERVATION FOR THE
	TREATMENT OF FECAL INCONTINENCE

Aims of study:

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To assess the utility of the NEOCONTROL magnetic chair (Marietta, GA, USA) pelvic floor Extracorporeal Magnetic Innervation (EXMI) for treatment of female patients with fecal incontinence.

Methods:

Institutional Review Board approval was obtained to enrol thirty subjects in this ongoing study. Subjects were evaluated by colonoscopy, endoanal ultrasonography and anal manometry. Each subject received 16 treatments twice weekly lasting 20 minutes in 5 and 50 Hz frequencies (1). One subjective and two objective methods of evaluation were utilized. All subjects completed a validated fecal incontinence questionnaire every fourth treatment and a modified Wexner fecal incontinence score (0-24) was calculated (2). Pre-treatment and post-treatment pelvic magnetic resonance imaging (MRI), with three dimensional reconstruction and conventional reconstruction was used to assess levator ani volume in ten patients (3). Pre-treatment and post-treatment anal manometry for assessing anorectal function was performed in ten patients (4).

Results:

Forty-five patients with fecal incontinence were interviewed. Nineteen patients whose fecal incontinence etiology was either idiopathic or secondary to anal sphincter or levator ani muscle weakness received 298 treatment cycles from March to December 2000. Sixteen subjects have completed the study to date. The demographics are summarized in Table 1. Values are given as absolute numbers.

Table 1.	(N=16)				
Age	Body Mass Index (kg/m2)	Concurrent urinary urge incontinence	Prior hysterectomy	Vaginal vault prolapse	Prior anal injury
57	26	9	8	3	9

The modified Wexner fecal incontinence scores are summarized in Table 2. Values are given as mean \pm standard deviation.

Table 2. (N=16)	Solid	Liquid	Gas	Pad	Life style	Urgency	<u>Score (0-24)</u> 0 = Continent
Pre-treatment Post- treatment	1.6 <u>+</u> 0.9 1 <u>+</u> 0.7	1.6 <u>+</u> 0.9 1 <u>+</u> 0.7	2.4 <u>+</u> 0.8 2 <u>+</u> 0.7	1.3 <u>+</u> 1.3 1 <u>+</u> 1.3	1 <u>+</u> 1.6 0.1 <u>+</u> 0.4	1.6 <u>+</u> 1.3 1.9 <u>+</u> 1	10 <u>+</u> 3 7 <u>+</u> 2 (P < .05)

The MRI measurements are summarized in Table 3. Values are given as mean <u>+</u> standard deviation.

Table 3. (N=6)	Levator Ani Area (mm ²)	Levator Ani volume (mm [°])
Pre-treatment	467 <u>+</u> 172	16,836 <u>+</u> 4,158
Post-	410 <u>+</u> 112	17,147 <u>+</u> 5,255
treatment		

Three dimensional levator ani volume calculations and anal manometry measurements are not analyzed at this time, but will be available at the ICS meeting.

Conclusions:

The parameters determined by the Wexner score revealed statistically significant improvement in our study population. The best potential for the use of EXMI in treatment of fecal incontinence was seen in the patients with an intact anal sphincter and weak levator ani muscles. We did not find this response in subjects with an urge or diarrhea component. Since EXMI treatment did not result in increase of the levator ani volume, and all patients who had responded to treatments reported a rebound of symptoms after the cessation of treatments, EXMI may be exerting its transient effect by bypassing the interrupted innervation to intact pelvic floor muscles.

References:

Urology. 53(1999):1108-11. Gut. 44(1999):77-80. International Urogynecology Journal & Pelvic Floor Dysfunction. 10(1999):300-7. Digestive Diseases. 15 Suppl 1(1997):64-77. Funded in part by NEOTONUS Inc.