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**Abstract**

**TITLE:** Long-term Symptom Improvement in Women after Fecal Incontinence Treatments: A Multicenter Cohort Study of the Pelvic Floor Disorders Network

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**ABSTRACT BODY: Objective:** Fecal incontinence (FI) can be surgically and non-surgically treated with behavioral therapy, medications, pelvic floor muscle exercises and biofeedback. Few long-term treatment outcomes exist in women seeking FI treatment. The aims of this study were to characterize women with at least monthly FI and measure improvements in FI severity and quality of life (QoL) 3 and 12 months after treatment.

**Methods:** In this preplanned secondary analysis of a multicenter trial to measure adaptive behaviors in women with FI, 133 women with a primary complaint of liquid, solid stool, or mucus FI, occurring at least monthly for 3 consecutive months and planning to have additional or new treatment for FI were recruited from referral-based specialty clinics. We excluded women with prior rectal or colon cancer, inflammatory bowel disease, pelvic irradiation, a current or prior rectal fistula(e), removal of any portion of the colon/rectum, rectal prolapse, or severe neurological conditions. Sociodemographics, medical history, prior FI treatments, and body mass index (BMI) were obtained. A central facility conducted phone interviews at baseline, 3- and 12-months after treatment per usual care (decided by treating provider). Validated questionnaires administered to measure QoL and FI symptoms were: the Fecal Incontinence Severity Index (FISI), Modified Manchester Health Questionnaire (MMHQ—condition specific QoL), Pelvic Floor Disorders Inventory's Colorectal and Anal Distress Inventory (CRADI), Pelvic Floor Impact Questionnaire's Colorectal and Anal Impact Questionnaire (CRAIQ), Medical Outcomes Study Short-Form (SF-12), and the Patient Global Impression of Improvement (PGI-I). Questionnaire score changes from baseline were compared at 3- and 12-months following treatment.

**Results:** Of the 133 women enrolled, 83 women completed the 3-month visit and 71 completed the 12-month visit. Women who completed questionnaires at 12 months were older ( $59.6 \pm 13.3$  vs  $55.0 \pm 14.6$  years,  $p=0.05$ ) than non-completers without any statistical differences observed for parity, BMI, race, insurance status, education, or prior FI treatments. Treatments included: surgery (anal sphincter repair, 22%) and combinations of nonsurgical treatments [medications (43%), pelvic floor muscle exercises (43%), biofeedback (11%), and other (eg, electrical stimulation, 7%)]. FISI scores, MMHQ, CRADI, and CRAIQ scores significantly improved 3-months after surgical and nonsurgical treatments without significant changes in scores from 3-months to 12-months post-treatment (Table). Overall, 81% reported symptom improvement on the PGI-I at 3- and 12-months after treatment.

**Conclusions:** FI severity, colorectal symptoms, and condition-specific QoL significantly improved within the first 3-months after treatment and were maintained up to 12-months after treatment among women

seeking care primarily for FI.

### Changes in Questionnaire Scores 3 and 12 Months Post-Treatment for FI

	Score changes from baseline to 3-months post-treatment*			Score changes from 3-months to 12-months post-treatment*		
	N	Mean (SD)	p-value	N	Mean (SD)	p-value
FISI-patient weights, range 0-54	83	-8.8 (12.0)	<0.001	71	1.4 (10.5)	0.26
CRADI, range 0-400	83	-52.7 (70.0)	<0.001	69	-3.0 (71.9)	0.73
CRAIQ, range 0-400	76	-60.6 (90.0)	<0.001	64	-3.4 (77.6)	0.73
MMHQ, range 0-100 (higher scores represent greater impact on QoL)	66	-12.6 (19.2)	<0.001	56	-1.4 (17.9)	0.56
SF-12 Physical, range 0-100 (lower scores represent greater impact of QoL)	78	4.2 (9.4)	0.001	70	-1.2 (10.0)	0.30
SF-12 Mental, range 0-100 (lower scores represent greater impact of QoL)	78	0.3 (8.7)	0.80	70	2.5 (9.2)	0.03

\*At least one FI treatment: surgery, medication, exercises, biofeedback, or other