ORIGINAL CONTRIBUTION

Evaluation of an Anal Insert Device for the Conservative Management of Fecal Incontinence

Emily S. Lukacz, M.D., M.A.S.[1] • Mark M. Segall, M.D.[2]
Steven D. Wexner, M.D., Ph.D. (Hon.), F.R.C.S., F.R.C.S. (Edinb.)[3]

1 Female Pelvic Medicine and Reconstructive Surgery, UC San Diego Health System, La Jolla, California
2 Mark M. Segall, Los Gatos, California
3 Digestive Disease Center, Department of Colorectal Surgery, Florida Atlantic University College of Medicine, Florida International University College of Medicine, Weston, Florida

BACKGROUND: Management of fecal incontinence remains challenging owing to the limited availability of consistently safe, effective, and/or tolerable treatment options.

OBJECTIVE: The aim of this study was to evaluate the efficacy, safety, and tolerability of an anal insert device for the conservative management of fecal incontinence.

DESIGN: This is a multicenter, prospective, open-label study of a single-arm cohort.

SETTING: Patients were recruited between November 2009 and June 2011 from 3 US clinical sites.

PATIENTS: Subjects who were ≥18 years old with incontinence severity scores ≥12 of 20, and at least weekly leakage of solid and/or liquid stool, were selected.

INTERVENTIONS: Patients underwent 12 weeks of continuous anal insert device use.

MAIN OUTCOME MEASURES: The primary outcomes measured were bowel diaries, incontinence severity, satisfaction, and adverse events. The percentage of reduction in leakage frequency and severity was assessed weekly. Sample size calculations predicted that 47 subjects would demonstrate that 70% of subjects would have ≥50% reduction of incontinence frequency. The paired *t* test and Wilcoxon tests were used as appropriate.

RESULTS: Seventy-seven percent of the 73 completers and 62% of the 91 intent-to-treat subjects achieved a ≥50% reduction in incontinence frequency. Median fecal incontinence frequency was reduced by 82% from 0.9 (mean 1.1 ± 0.9) at baseline to 0.2 (mean 0.3 ± 0.4) episodes of leakage per day at 12 weeks ($p < 0.001$). Mean fecal incontinence severity scores improved by 32.4% (16.2, ±2.1 vs 10.9, ±4.4 of 20, $p < 0.001$) and 78% of completers were very or extremely satisfied with the device with no serious adverse events related to device use.

LIMITATIONS: This study was limited by the nonvalidated modification of the severity score and the lack of randomization, control comparison group, blinded assessments, and quality-of-life measures.

CONCLUSIONS: The anal insert device provides a conservative, safe, and effective management strategy for individuals with fecal incontinence, with high patient satisfaction and low adverse event rates.

Funding/Support: Study development, implementation, data collection, and data analyses were fully funded by the study sponsor: Renew Medical, Inc.

Financial Disclosures: Dr Lukacz – Renew Medical, consultant; Pfizer, research support; American Medical Systems, consultant; Boston Scientific, research grant; Uroplasty, research grant; National Institutes of Health/NICHD, research support. Dr Segall – Renew Medical, consultant. Dr Wexner – Incontinence Devices, Inc., consultant; Mederi Therapeutics, consultant; Medtronic, Inc., consultant; Renew Medical, consultant; Salix Therapeutics, advisor.

Clinical Trial Registration: http://www.ClinicalTrials.gov. Identifier: NCT01475474.

Poster presentation at the joint meeting of the American Urogynecologic Society (AUGS) and the International Urogynecological Association (IUGA), Washington, DC, July 22 to 26, 2014.

Correspondence: Emily S. Lukacz, M.D., 9500 Gilman Dr, MC 0971, La Jolla, CA 92093-0971. E-mail: elukacz@ucsd.edu

Dis Colon Rectum 2015; 58: 892–898
DOI: 10.1097/DCR.0000000000000427

KEY WORDS: Accidental bowel leakage; Anal insert; Anal plug; Bowel incontinence; Bowel management; Fecal incontinence.

Fecal incontinence (FI) is a serious but rarely discussed medical condition that can have a devastating impact on quality of life.[1] Recent studies have

FIGURE 1. The Renew Insert Device.

reported the high prevalence of FI, and the importance of using accidental bowel leakage as the terminology preferred by patients to describe this condition.[2,3] Epidemiologic studies have reported alarmingly high rates of FI in up to 18% of community dwellers and up to 47% of nursing homes residents.[2,4–9] Treatment options for FI range from conservative therapy such as pelvic floor exercises with biofeedback, alteration of stool consistency through modification of diet and medication, and inflatable or expandable anal plugs.[10–12] Other approaches include the injection of bulking agents, radiofrequency energy sphincter reformation, neuromodulation, anal sphincter surgery, and neosphincter operations (artificial bowel sphincter, magnetic anal sphincter implantation, and stimulated or adynamic muscle transfers).[13–17] These treatments must be considered in the context of their morbidity and efficacy profiles and balanced with the individual patient's general health, severity of FI, and insurance coverage. We evaluated an alternate therapy for those who had FI and hypothesized that continuous use of the anal insert would result in significant reductions in FI frequency and severity.

MATERIALS AND METHODS

Design Overview

This was an institutional review board-approved, multicenter, prospective, nonrandomized, single-arm study of the Renew anal insert device (Renew Medical Inc., Foster City, CA) for the management of moderate to severe FI. The device is a single-use, soft silicone anal insert (Fig 1) that is self-inserted with the use of a fingertip applicator. The top disk of the anal insert forms a seal at the top of the anal canal and helps prevent leakage of solid and liquid stool. The device is available in 2 top disk diameters (22 mm and 28 mm) to accommodate variation in patient anatomy. The stem of the insert spans the anal canal, and the bottom disk remains outside the anus to help prevent displacement of the device upward into the anal canal or rectum. The anal insert is designed to be self-expelled during a voluntary bowel movement, but can also be manually removed by pulling on the bottom disk.

Setting and Participants

Participants for this study were recruited from 3 US clinical sites between November 2009 and June 2011: UC San Diego Health System, Cleveland Clinic Florida, and a private practice in Los Gatos, CA. Subjects ≥18 years of age with an FI severity score ≥12, and at least weekly leakage of solid and/or liquid type stool were included. Individuals with anorectal pathology (≥third degree hemorrhoids, rectal prolapse, anal fissure or stricture, perianal abscess or fistula, anismus, recent rectal surgery, fecal impaction, or clinically significant rectocele), need for rectal suppository use, IBD, immune suppression, spinal cord injury or neurologic disease, pregnancy/breastfeeding, or any major medical illnesses were excluded. Eligible participants signed informed consent and underwent a 4-week baseline evaluation including daily bowel diaries to confirm eligibility, followed by a 12-week treatment period of continuous device use. Fecal incontinence frequency and type at baseline were characterized by subject assessment into 4 categories: passive, urge, mixed with passive predominant, or mixed with urge predominant leakage. Subjects taking antidiarrheal medications were instructed to maintain their therapy and record frequency and dosage on daily diaries.

Outcomes and Follow-up

Overall frequency of FI was assessed by using daily bowel diaries that were completed by each subject to record bowel movement frequency, leakage, pad soiling, and insert usage. The nurse coordinators at each site reviewed these during regular in-person visits for 12 weeks. Nurse study coordinators also read and recorded responses to complete the severity scores, usability, tolerability, adverse

events, and satisfaction data sections. An FI severity score based on the Cleveland Clinic Fecal Incontinence/Wexner score was used to assess symptom severity.[18] The FI severity score modified the term "lifestyle alteration" to "quality of life impact" and frequency parameters from "always (≥1/day), usually (<1/day up to ≥1/week), sometimes (<1/week to ≥1/month), rarely (<1/month), never" to "daily, weekly, monthly, less than once per month, and never." Frequency of leakage with solid, liquid, and gas; pad usage; and impact on quality of life were assessed by using the Wexner system on a 0 to 4 scale, from never to daily for a maximum summed score of 20 representing full incontinence. Overall subject satisfaction was assessed only in patients who completed 12 weeks of treatment, using a 5-point Likert scale from "not at all satisfied" to "extremely satisfied." Ease of use, usability, and comfort were measured on 10-point scale from 1 representing "very difficult, demanding and unfriendly" to 10 representing "very easy, simple, and comfortable." Adverse events were assessed by subject report and/or digital and anoscopic examination at the time of occurrence, and at the12-week completion of the study or withdrawal. After completion of the 12-week treatment period, subjects were followed by using daily bowel diaries for an additional 4 weeks off treatment for return to baseline. For this article, the primary outcome of objective success was defined as ≥50% reduction in FI episodes, and subjective success was measured by reduction in FI severity score.

Statistical Analysis

Original sample size calculations determined that 76 subjects were necessary to detect at least a 10% reduction in FI frequency and severity with 90% power and 5% significance. A total of 95 subjects were recruited with a goal of attaining 76 subjects assuming a 20% dropout rate. In addition, a 2-subject margin of error was included to account for ineligibility and dropouts. A post hoc sample size calculation demonstrated that if 70% of our subjects were expected to meet a threshold of ≥50% reduction in FI frequency, then 47 subjects would be sufficient based on the χ^2 test with a 2-sided 0.05 level of statistical significance and a 0.80 level of statistical power.

Efficacy was assessed by using the intent-to-treat (ITT), completers, and modified ITT (mITT) cohorts, the latter being those subjects who entered treatment and completed at least 1 week of device use (Fig. 2). Safety was evaluated in the ITT cohort. In the ITT analysis, dropouts were considered as treatment failures. In the modified ITT analysis, all available valid data were analyzed. Paired *t* tests and Wilcoxon tests were used as appropriate to assess changes in comparison with baseline, and adverse events were reported using descriptive statistics. Mean and median percentage reduction in FI frequency and FI severity scores were used to describe changes from baseline with each subject acting as their own control.

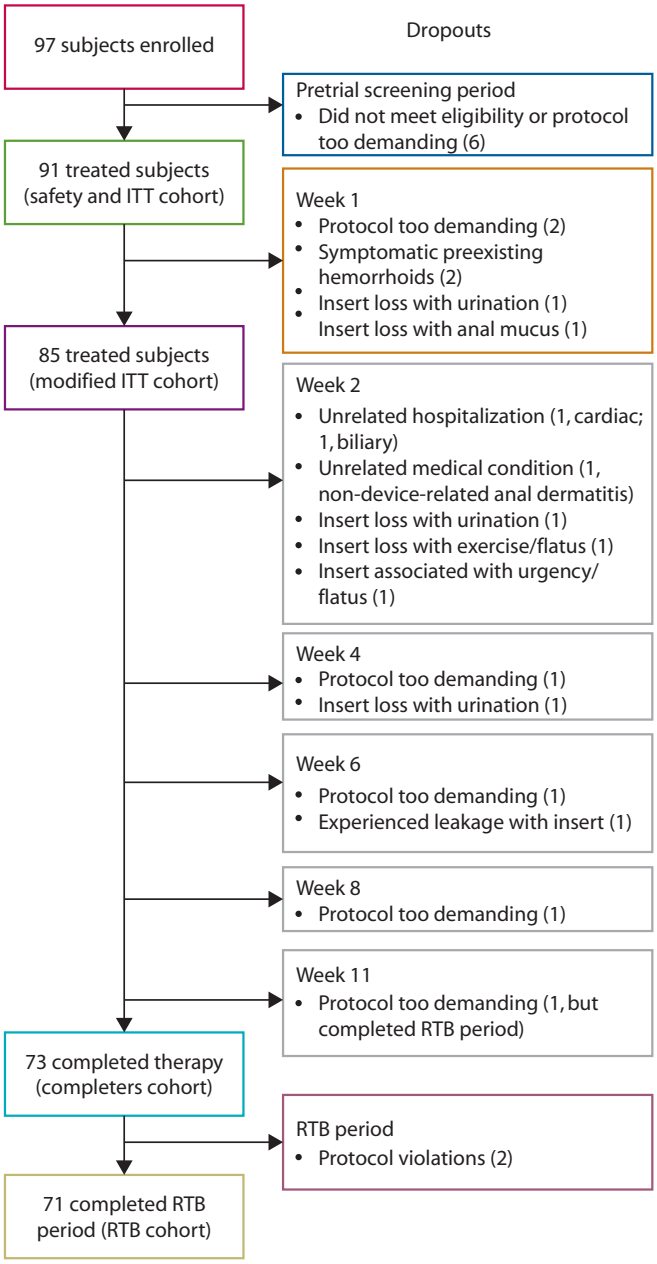

FIGURE 2. Disposition of study population and cohort definitions. ITT = intention to treat; RTB = return to baseline; FI = fecal incontinence.

RESULTS

Ninety-one of the 97 subjects enrolled remained eligible after the 4-week baseline evaluation (ITT cohort), 85 of whom completed at least 1 week of treatment (mITT cohort) and 73 completed all 12 weeks of treatment (completer cohort) (Fig. 2). Table 1 describes the characteristics of the ITT and completer cohorts who were mostly female and white. Those who dropped out were slightly older than those who completed the study, but were otherwise similar to the completers. A total of 18 subjects withdrew during the treatment phase of the study. The specific reasons for withdrawal are shown in Figure 2. Bowel incontinence type

TABLE 1. Characteristics of study subjects

	Intention-to-treat (n = 91)	*Completers (n = 73)*	*Dropouts (n = 18)*
Age, y, mean (SD)	68.6 (12.1)	67.2 (12.6)	74.3 (8.2)
Age, y [Range]	[33.9–88.9]	[33.9–88.9]	[55.2–85.2]
Mean BMI (SD), kg/m^2	27.2 (5.8)	27.4 (5.9)	26.5 (5.6)
Female sex, %	90	90	89
Male sex, %	10	10	11
Race, %			
White	91	92	89
Asian	5	4	11
Black	3	4	0
Ethnicity, %			
Hispanic or Latino	4	5	0
Non-Hispanic or non-Latino	90	92	83
Not specified	6	3	17
Incontinence type, %			
Passive	21	21	22
Urge	19	18	22
Mixed with passive dominant	33	32	39
Mixed with urge dominant	28	30	17
Fecal incontinence severity score at end of baseline			
Mean (SD)	16.2 (2.1)	16.3 (2.1)	16.2 (2.2)
Fecal incontinence episodes/day at end of baseline			
Mean (SD)	1.1 (0.8)	1.1 (0.8)	1.3 (0.9)
Median	0.9	0.8	1.0

was mixed with passive predominant (33%), mixed with urge predominant (28%), passive only (21%), and urge only (19%) in the ITT cohort. Antidiarrheal medication and enema use at baseline were 33% and 11%. During the course of the study, 8% initiated antidiarrheal medication and 4% enema use, whereas 5% and 9% discontinued antidiarrheal and enema use. An average of 2.6 inserts were used per day with 66% of them being expelled during defecation. Some inserts were expelled during urination (11%) or with gas or other FI episodes (5% each).

In the ITT cohort, 62% (95% CI, 51%–71%; 56/91) demonstrated ≥50% reduction in FI frequency. This success rate was 78% (95% CI, 68%–86%; 66/85) and 77% (95% CI, 66%–85%; 56/73) in the mITT and completer cohorts. As a secondary analysis, in the modified ITT cohort, the median FI frequency was reduced by 82% from 0.9 FI episodes (mean 1.1 ± 0.9) per day at baseline to a median of 0.2 FI episodes (mean 0.3 ± 0.4) per day at 12 weeks ($p < 0.001$). Only 3 subjects demonstrated an increased FI frequency: 2 associated with increased diarrhea from antibiotic use, and 1 with an upper respiratory infection causing increased FI associated with coughing. Figure 3 demonstrates FI frequency by week, with 77% reduction in the first week and 93% reduction by 4 weeks. After 4 weeks of return to baseline, FI frequency increased to a median of 0.5 FI episodes (mean 0.7 ± 0.7) per day in the 71 subjects. Although this was a statistically significant increase over the treatment period, it also was a 26% reduction in mean FI frequency in comparison with their baseline frequency (paired t test $p < 0.0001$; mean 1.1 ± 0.8, median 0.8). Mean FI severity scores improved by 32% (median 29%) after treatment (median 16, mean 16.2 ± 2.1 vs median 11, mean 10.9 ± 4.4; $p \leq 0.001$).

There were no serious adverse events and only 3 moderate adverse events (fecal urgency, soreness, and bleeding hemorrhoids) in 2 subjects during treatment from among the 91 subjects in the ITT cohort. Fifty-one percent (46/91) of the participants who reported any adverse event as probably or possibly related to device use, were primarily related to anorectal symptoms such as sensation of urge

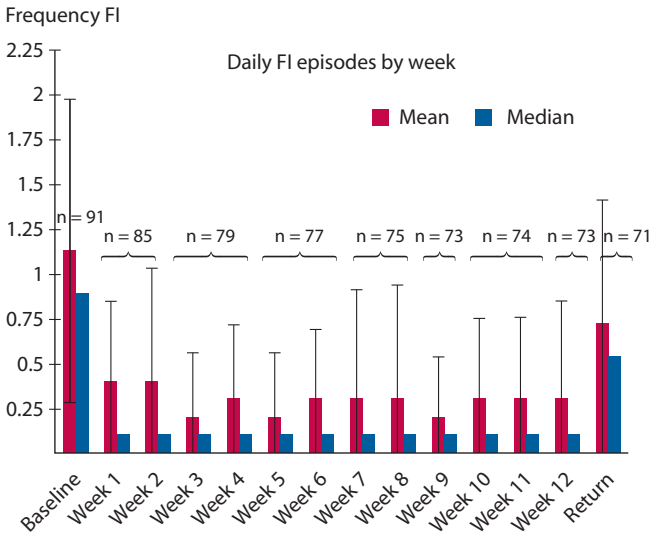

FIGURE 3. Mean and median frequency of daily incontinence episodes by treatment week. FI = fecal incontinence.

(26%, 24/91), irritation (13%, 12/91), pain (7%, 6/91), or soreness (6%, 5/91) in the anal area. All were deemed mild in severity with the exception of 3 moderate adverse events in 2 subjects (fecal urgency, soreness, and bleeding hemorrhoids). There were no serious adverse events related to insert use. Displacement of the device upward into the anal canal occurred in 24% of participants, but resolved with natural expulsion during bowel movements. Seventy of the 116 (60%) displacement events were reported by 2 subjects: one with displacement during exercise and the other with history of an anal sphincter tear and an asymmetric anal sphincter muscle bulk anteriorly. There were no anal or rectal injuries detected on anoscopic or digital examination related to continuous use of the device after 12 weeks.

Regarding patient satisfaction, 78% of the completers were very or extremely satisfied with the device and 91% of them rated the overall experience, comfort, and ease of insertion ≥8 on the 10-point scale (median 9.5) with mean and median experience scores above 8 at each weekly assessment throughout treatment. Eighty percent of the completers reported that they liked the inserts "quite well," "very well," or "extremely well." "Ease of use" and "effectiveness" were the leading reasons why subjects liked the anal insert (60% and 49%) when surveyed in the 12th week of treatment. The usability parameters, including comfort holding the applicator, ease of placement of the device, sensation during placement, and removal of the applicator after insert placement, all achieved mean scores above 7.6 of 10 throughout the treatment period.

DISCUSSION

Fecal incontinence is a highly prevalent condition with a profound negative impact on the quality of life.[1] Unfortunately, the majority of people with FI do not seek treatment or even discuss their condition with their health care providers.[19] There are many treatment options for FI, including pelvic floor exercises with biofeedback, alteration of stool consistency through the modification of diet and medication, inflatable or expandable anal plugs, injection of bulking agents, radiofrequency energy sphincter reformation, neuromodulation, anal sphincter surgery, and neosphincter procedures.[10–17,20] However, the morbidity and financial cost of each alternative are variable, must be balanced against long-term efficacy, and considered in the context of the individual patient's general health, degree of incontinence, and insurance coverage. Biofeedback and pelvic floor/anal sphincter muscle exercise therapy are designed to enhance sensory and motor capabilities to help patients improve control of the anal sphincter and have demonstrated 60% to 70% efficacy.[21,22] However, there are many obstacles to biofeedback/exercise therapy including the completion of therapy, the time needed to realize therapeutic benefit, and long-term compliance.[23] Because the anal insert device is a passive barrier to help prevent FI and provides immediate results, it has the potential to serve as a stand-alone therapy or work in conjunction with other conservative treatments including biofeedback, muscle exercise therapy, dietary modifications, and/or the use of antimotility agents.

Expandable and inflatable anal plugs are designed to treat FI by blocking the flow of solid and liquid stool from the rectum. Unfortunately, the adoption of anal plugs has been limited because current anal plug devices are considered intolerable or difficult to use by patients. The expandable device tested by Norton and Kamm[12] reported that 70% (14/20) of patients could not tolerate a plug owing to discomfort. Giamundo et al[10] reported that 61% (11/18) of patients did not complete the 14-day protocol because of hypersensitivity (3/18) or difficulty using the device (8/18). The anal plug described by Giamundo et al occupies 20 mL in the rectum, and that described by Norton and Kamm occupies approximately 8 mL (small plug) and 13 mL (large plug) in the rectum. The anal insert tested here is designed so that the section of the device that resides in the rectum has a volume of 0.5 mL (regular size) and 0.8 mL (large size), which is approximately 4% and 6% of the volume of the anal plug devices tested by Giamundo and colleagues and Norton and Kamm. As a result, we believe that the anal insert in this study does not stimulate the anal sensory system as much as other anal plugs, resulting in lower discontinuation rates than previously reported. Only 1% of subjects withdrew from our study owing to device-related urge and gas, and a further 6% of subjects withdrew because of insert loss or leakage around the insert, whereas, overall, 78% of completers were very or extremely satisfied with the anal insert.

Generally accepted surgical treatment approaches for FI include anterior or posterior repair of the anal sphincter, augmentation, replacement, stimulation, and diversion. During the 1990s short-term results of sphincter repair revealed success rates ranging from 55% to 93%, but more recent long-term studies revealed success rates generally ranging from 23% to 54%.[24–28] This clear attrition with time as demonstrated by Glasgow and Lowry[20] has led to a search for better alternatives.

Graf et al[13] report that the injection of dextranomer in stabilized hyaluronic acid in the anal canal achieves a ≥50% reduction in the number of incontinence episodes among 52% (71/136) of subjects in the active treatment group. Hull et al[29] report that sacral neuromodulation achieves ≥50% reduction in the number of incontinence episodes at 5+ years among 89% (64/72) of subjects available for follow-up; however, with the use of an ITT analysis, this rate drops to 52% (64/120). The anal insert in our study achieved ≥50% reduction in the number of incontinence episodes among 77% of the completers and 62% among the ITT cohort.

The strengths of this study include the multicenter, prospective study design including individuals with moderate to severe FI (severity scores ≥12/20), the use of daily bowel diary data to measure efficacy, and the return to baseline evaluations performed 4 weeks after the completion of therapy. Weaknesses of this study include the use of a nonvalidated modification to the FI severity score questionnaire wording, and the lack of a control comparison group, randomization, blinded assessments, and FI-related quality-of-life measures. The use of the 4-week return to baseline was used to control for some of the biases from an observational nonrandomized design; however, we are unable to speculate on the 26% mean reduction in FI frequency after the 4-week return to baseline relative to baseline for the completers cohort. We were only able to assess satisfaction with the device in those subjects who completed the study, thus potentially skewing this result to the positive. The low number of men enrolled in this trial limits the generalizability of these results. Future studies should include a larger proportion of men and possibly a longer duration of treatment phase to test acceptance and any potential long-term effects from this treatment modality. This study indicates that additional larger-scale, randomized comparative studies to other standard-of-care therapies using validated patient-centered outcome measures (including quality of life) should be undertaken. Because this is the first study reporting on the utility of this device, we expect that future studies will be directed to determine the role of this therapy in the treatment algorithm for FI. We believe that the benefit of this device falls somewhere between pads, behavior, dietary modification, and more invasive therapies such as radiofrequency, bulking, or sacral nerve stimulation. As such, comparative effectiveness trials against any of these would be valuable. Future studies should also be aimed at characterizing optimal subject selection with more detailed demographic, patient history, and physiological testing.

CONCLUSION

This study has shown promising efficacy, safety, and satisfaction with a new anal insert device. Although it is possible that the anal insert may be considered as a first-line therapy for the management of FI, or as an adjunctive therapy for patients achieving unsatisfactory results with other surgical or nonsurgical FI treatments, future studies are warranted.

ACKNOWLEDGMENTS

The authors thank Lisa Carmel, Victoria Mackinnon, Ajit Shah, and Dari Shalon of Renew Medical for study development and implementation, and Peter Shabe of Advance Research Associates, Inc. for statistical support.

REFERENCES

1. Brown HW, Wexner SD, Segall MM, Brezoczky KL, Lukacz ES. Quality of life impact in women with accidental bowel leakage. *Int J Clin Pract*. 2012;66:1109–1116.
2. Brown HW, Wexner SD, Segall MM, Brezoczky KL, Lukacz ES. Accidental bowel leakage in the mature women's health study: prevalence and predictors. *Int J Clin Pract*. 2012;66:1101–1108.
3. Sung VW, Rogers RG, Bann CM, et al; Pelvic Floor Disorders Network. Symptom outcomes important to women with anal incontinence: a conceptual framework. *Obstet Gynecol*. 2014;123:1023–1030.
4. Sharma A, Marshall RJ, Macmillan AK, Merrie AE, Reid P, Bissett IP. Determining levels of fecal incontinence in the community: a New Zealand cross-sectional study. *Dis Colon Rectum*. 2011;54:1381–1387.
5. Macmillan AK, Merrie AE, Marshall RJ, Parry BR. The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Dis Colon Rectum*. 2004;47:1341–1349.
6. Tobin GW, Brocklehurst JC. Faecal incontinence in residential homes for the elderly: prevalence, aetiology and management. *Age Ageing*. 1986;15:41–46.
7. Nelson R, Furner S, Jesudason V. Fecal incontinence in Wisconsin nursing homes: prevalence and associations. *Dis Colon Rectum*. 1998;41:1226–1229.
8. Madoff RD, Parker SC, Varma MG, Lowry AC. Faecal incontinence in adults. *Lancet*. 2004;364:621–632.
9. Gorina Y, Schappert S, Bercovitz A, et al. Prevalence of incontinence among older Americans. National Center for Health Statistics. Vital Health Stat. 2014;3(36):1–33.
10. Giamundo P, Welber A, Weiss EG, Vernava AM 3rd, Nogueras JJ, Wexner SD. The procon incontinence device: a new nonsurgical approach to preventing episodes of fecal incontinence. *Am J Gastroenterol*. 2002;97:2328–2332.
11. Herbert J. Use of anal plugs in faecal incontinence management. *Nurs Times*. 2008;104:66–68.
12. Norton C, Kamm MA. Anal plug for faecal incontinence. *Colorectal Dis*. 2001;3:323–327.
13. Graf W, Mellgren A, Matzel KE, Hull T, Johansson C, Bernstein M; NASHA Dx Study Group. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. *Lancet*. 2011;377:997–1003.
14. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, et al. SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. *Dis Colon Rectum*. 2008;51:355–359.
15. Lim JT, Hastie IA, Hiscock RJ, Shedda SM. Sacral nerve stimulation for fecal incontinence: long-term outcomes. *Dis Colon Rectum*. 2011;54:969–974.
16. Nandivada P, Nagle D. Surgical therapies for fecal incontinence. *Curr Opin Gastroenterol*. 2014;30:69–74.
17. Wong MT, Meurette G, Stangherlin P, Lehur PA. The magnetic anal sphincter versus the artificial bowel sphincter: a comparison of 2 treatments for fecal incontinence. *Dis Colon Rectum*. 2011;54:773–779.
18. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum*. 1993;36:77–97.
19. Brown HW, Wexner SD, Lukacz ES. Factors associated with care seeking among women with accidental bowel leakage. *Female Pelvic Med Reconstr Surg*. 2013;19:66–71.
20. Glasgow SC, Lowry AC. Long-term outcomes of anal sphincter repair for fecal incontinence: a systematic review. *Dis Colon Rectum*. 2012;55:482–490.

21. Terra MP, Dobben AC, Berghmans B, et al. Electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence: a cohort study of 281 patients. *Dis Colon Rectum*. 2006;49:1149–1159.
22. Byrne CM, Solomon MJ, Young JM, Rex J, Merlino CL. Biofeedback for fecal incontinence: short-term outcomes of 513 consecutive patients and predictors of successful treatment. *Dis Colon Rectum*. 2007;50:417–427.
23. Jodorkovsky D, Dunbar KB, Gearhart SL, Stein EM, Clarke JO. Biofeedback therapy for defecatory dysfunction: "real life" experience. *J Clin Gastroenterol*. 2013;47:252–255.
24. Bravo Gutierrez A, Madoff RD, Lowry AC, Parker SC, Buie WD, Baxter NN. Long-term results of anterior sphincteroplasty. *Dis Colon Rectum*. 2004;47:727–731.
25. Halverson AL, Hull TL. Long-term outcome of overlapping anal sphincter repair. *Dis Colon Rectum*. 2002;45:345–348.
26. Mevik K, Norderval S, Kileng H, Johansen M, Vonen B. Long-term results after anterior sphincteroplasty for anal incontinence. *Scand J Surg*. 2009;98:234–238.
27. Karoui S, Leroi AM, Koning E, Menard JF, Michot F, Denis P. Results of sphincteroplasty in 86 patients with anal incontinence. *Dis Colon Rectum*. 2000;43:813–820.
28. Zutshi M, Tracey TH, Bast J, Halverson A, Na J. Ten-year outcome after anal sphincter repair for fecal incontinence. *Dis Colon Rectum*. 2009;52:1089–1094.
29. Hull T, Giese C, Wexner SD, et al; SNS Study Group. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. *Dis Colon Rectum*. 2013;56:234–245.