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**Surgical Interventions and the Use of Device-Aided Therapy for the Treatment of Fecal
Incontinence and Defecatory Disorders**

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Running Title: Devices and Surgery for FI

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Abstract

Description: The purpose of this clinical practice update expert review is to describe the key principles in the use of surgical interventions and device-aided therapy for managing fecal incontinence (FI) and defecatory disorders.

Methods: The best practices outlined in this review are based on relevant publications, including systematic reviews and expert opinion (when applicable).

Best practice advice 1: A stepwise approach should be followed for management of FI.

Conservative therapies (diet, fluids, techniques to improve evacuation, a bowel training program, management of diarrhea and constipation with diet and medications if necessary) will benefit approximately 25% of patients and should be tried first.

Best practice advice 2: Pelvic floor retraining with biofeedback therapy is recommended for patients with FI who do not respond to the conservative measures indicated above.

Best practice advice 3: Perianal bulking agents such as intraanal injection of dextranomer may be considered when conservative measures and biofeedback therapy fail.

Best practice advice 4: Sacral nerve stimulation should be considered for patients with moderate or severe FI in whom symptoms have not responded after a 3 month or longer trial of conservative measures and biofeedback therapy and who do not have contraindications to these procedures.

Best practice advice 5: Until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI in clinical practice.

Best practice advice 6: Barrier devices should be offered to patients who have failed conservative or surgical therapy, or in those who have failed conservative therapy who do not want or are not eligible for more invasive interventions.

Best practice advice 7: Anal sphincter repair (sphincteroplasty) should be considered in postpartum women with FI and in patients with recent sphincter injuries. In patients who present later with symptoms of FI unresponsive to conservative and biofeedback therapy and evidence of sphincter damage, sphincteroplasty may be considered when perianal bulking injection and sacral nerve stimulation are not available or have proven unsuccessful.

Best practice advice 8: The artificial anal sphincter, dynamic graciloplasty, may be considered for patients with medically-refractory severe FI who have failed treatment or are not candidates for barrier devices, sacral nerve stimulation, perianal bulking injection, sphincteroplasty and a colostomy.

Best practice advice 9: Major anatomic defects (e.g., rectovaginal fistula, full thickness rectal prolapse, fistula in ano, or cloacalike deformity) should be rectified with surgery.

Best practice advice 10: A colostomy should be considered in patients with severe FI who have failed conservative treatment and have failed or are not candidates for barrier devices, minimally invasive surgical interventions, and sphincteroplasty.

Best practice advice 11: A magnetic anal sphincter device may be considered for patients with medically refractory severe FI who have failed or are not candidates for barrier devices, perianal bulking injection, sacral nerve stimulation, sphincteroplasty or a colostomy. Data regarding efficacy are limited and 40% of patients had moderate or severe complications.

Best practice advice 12: For defecatory disorders, biofeedback therapy is the treatment of choice.

Best practice advice 13: Based on limited evidence, sacral nerve stimulation should not be used for managing defecatory disorders in clinical practice.

Best practice advice 14: Anterograde colonic enemas are not effective in the long-term for management of defecatory disorders.

Best practice advice 15: The STARR and related procedures should not be routinely performed for correction of structural abnormalities in patients with defecatory disorders.

Fecal Incontinence: Definition, Prevalence, and Impact on Quality of Life

Fecal incontinence (FI) is the recurrent uncontrolled passage of liquid or solid stool. FI affects 7 to 15% of community-dwelling women and men^{1,2}. The prevalence of FI is higher among care-seeking populations, home-care populations, and adults in long-term care settings³.

FI can have a devastating impact on daily life^{2,4,5}, underscoring the need to manage the symptoms effectively. In addition to a loss of confidence, self-respect, modesty, and composure⁶, there is a social stigma attached to FI. Thus, many people with FI do not share the condition with their friends or physicians. Hence, physicians should routinely screen patients who may be at risk for symptoms of FI.

Having made the diagnosis of FI, the management is guided by the severity of FI, its impact on quality of life and the risk factors for FI.

Symptom Severity and its Relationship with Quality of Life

In clinical trials, severity is primarily evaluated by the frequency of FI using daily diaries; a 50% reduction in the number of episodes or days with FI is considered to be clinically significant improvement^{7,8}. Alternatively, the severity can be evaluated with questionnaire-based instruments such as the Wexner and Modified Manchester Health Questionnaires, the Fecal Incontinence Severity Score, previously known as the Fecal Incontinence Constipation Assessment (FICA) FI symptom severity instrument and the Fecal Incontinence Severity Index (FISI) to name a few^{9,8}. All of the available instruments incorporate the frequency and type of leakage. Some also incorporate the volume of leakage and rectal urgency, which contribute to the burden of FI. So assessed, the severity of FI is strongly correlated with its impact on quality of life⁵.

Risk Factors for Fecal Incontinence

Patients with FI have anorectal dysfunctions and/or bowel disturbances, typically diarrhea. In community surveys, bowel disturbances, particularly diarrhea, the symptom of rectal urgency, and burden of chronic illness rather than obstetric history (e.g., forceps use, complicated episiotomy) are by far the most important independent risk factors for FI in older women⁹. Specifically, in a community-based cohort of 176 randomly selected women with and 176 without FI, independent risk factors for FI were diarrhea (odds ratio, OR=53 [95% CI=6.1–471], cholecystectomy (OR=4.2 [95% CI=1.2–15]), current smoking (OR=4.7 [95% CI=1.4–15]), history of rectocele (OR=4.9 [95% CI=1.3–19]), stress urinary incontinence (OR=3.1 [95% CI=1.4–6.5]), and higher BMI (per unit increase, OR=1.1 [95% CI=1.004–1.1])¹⁰. Other conditions associated with FI include advanced age, disease burden (co-morbidity count, diabetes), anal sphincter trauma (obstetrical injury, prior surgery), and decreased physical activity⁹. FI may be secondary to diseases that cause anorectal inflammation (e.g., inflammatory bowel disease), peripheral neuropathy (e.g., diabetes), iatrogenic anal sphincter injury, or neurological disorders (e.g., dementia, stroke, spinal cord injury or disease).

Medical Management of FI

Before considering surgical therapy or devices, all patients must be managed with conservative therapies that are tailored to the symptoms and rigorously implemented for an adequate duration. These measures, which are detailed elsewhere, include dietary modification, fiber supplements, fluids, techniques to improve evacuation such as scheduled toileting, a bowel training program, pelvic floor exercises to strengthen musculature, and medications to manage diarrhea and constipation⁷. The next step is pelvic floor retraining with biofeedback therapy in which patients may work with their therapists using electronic and mechanical devices to improve pelvic floor strength, pelvic floor sensation and contraction, rectal sensation and

tolerance of rectal distention¹¹⁻¹³. In our experience, many incontinent patients who are considered refractory to conservative therapy have, indeed, not received an optimal trial of conservative therapy, which includes one or more of the following measures as appropriate: (i) A meticulous characterization of the bowel habits, circumstances surrounding FI (e.g., relationship to meals and activity), and prior treatment for FI¹⁴, (ii) Among patients with diarrhea, a careful dietary history to identify ingestion of poorly absorbed sugars (e.g., sorbitol, fructose) and/or caffeine followed by a trial of elimination, (iii) For diarrhea, we recommend starting with loperamide (2 mg) generally starting with 1 tablet taken 30 minutes before breakfast and titrated as necessary up to 16 mg daily. Fiber supplementation can be used to improve stool consistency and reduced diarrhea-associated FI¹⁵. Because bile-salt malabsorption is common in patients with idiopathic diarrhea, cholestyramine or colesevelam may be helpful. Anticholinergic agents and clonidine¹⁶ are alternative options for patients with diarrhea and FI. (iv) Laxatives and anorectal testing to identify evacuation disorders are recommended for patients with constipation¹⁷. In particular, patients with fecal seepage suffer from evacuation disorders with overflow of retained stool in the rectum¹⁸. These conditions can be effectively managed with pelvic floor biofeedback therapy directed at addressing the underlying rectal evacuation disorder. Alternatively or in addition, rectal cleansing with a small enema or tap water reduces the likelihood of stool leakage. Patients who are truly refractory to conservative measures should undergo anorectal testing, starting with anorectal manometry, followed if necessary by anorectal imaging (**Figures 1 and 2**)^{19,20}. These patients are eligible for surgical therapy or devices.

Anorectal testing

Anal manometry is a simple test that can identify several anorectal dysfunctions (i.e., anal weakness, reduced or increased rectal sensation, and impaired rectal balloon expulsion) which

are associated with FI and amenable to pelvic floor biofeedback therapy¹⁹. Anal imaging with ultrasound or MRI can identify anal sphincter defects, atrophy, and a patulous anal canal^{19,21,22}. Imaging should be considered, in particular prior to surgery or devices. It is easier to visualize internal sphincter tears with endoanal ultrasound than MRI²². By contrast, MRI is superior for visualizing external sphincter defects and atrophy and a patulous anal canal^{19,21,22}.

Perianal bulking injection

Perianal injection of biocompatible bulking agents is used to treat FI. Dextranomer microspheres in non-animal stabilized hyaluronic acid (NASHA Dx) is the only Food and Drug Administration (FDA)-approved product for FI²³. While the implied mechanism of action is to enhance the seal of the anal canal, dextranomer did not significantly increase anal resting or squeeze pressures nor was it superior to biofeedback therapy²⁴. In a randomized, double-blind sham-controlled study in adults who had failed conservative therapies, 71/136 (52%) patients in the active treatment group vs. 22/70 (31%) in the sham group had a treatment response ($\geq 50\%$ improvement from baseline in the number of FI episodes) at 6 months (OR: 2.36; $P = 0.0089$)²⁵ (**Table 1**). A second injection was given to 112 (82%) patients in the NASHA Dx group, and a sham injection in 61 (87%) patients in the sham group. At 6 months, compared with the sham group, patients in the NASHA Dx group had significantly more incontinence-free days, and improved FIQOL coping, and behavior but not lifestyle, depression and self-perception, or embarrassment scores. The most common adverse events with NASHA Dx were proctalgia (14%), fever (8%), and rectal bleeding (7%); no apparent migration, protrusion, or leakage of NASHA Dx was observed during bowel movements. At 12 and 24 months, 64.0% of 86 patients and 62.7% of 83 patients were responders in the NASHA Dx and sham groups, respectively ($\geq 50\%$ improvement from baseline in number of FI episodes)²⁶.

Sacral nerve stimulation for FI

Sacral nerve stimulation (SNS) involves continuous pulsed electrical stimulation of the sacral nerves with a battery-operated stimulator. Initially, stimulation is provided by an external electrical stimulator for 2-3 weeks. If the frequency of FI declines by 50% or more, stimulator is permanently implanted beneath the skin.

In the pivotal, uncontrolled, US multicenter trial, 90% of 133 patients proceeded from temporary to permanent stimulation²⁷. Among 76 of 120 patients (63%) with 5-year follow up data, 36% reported complete continence, and 89% were deemed a therapeutic success²⁸. There are few controlled studies. Two parallel-group RCTs compared SNS to medical treatment and percutaneous tibial nerve stimulation (PTNS).^{29,30} (**Table 1**). In these studies, SNS was significantly better than medical treatment but not significantly better than PTNS.

Most trials were limited to patients with a structurally intact anal sphincter or a defect smaller than 120°. Although a few studies have suggested that SNS may be beneficial irrespective of the degree of sphincter injury^{31,32}, larger prospective trials are needed to confirm these findings. Hence, the efficacy of SNS in patients with larger external sphincter defects is unknown. Batteries must be replaced after approximately 7 years. The most common adverse events are pain and infection at the insertion site which occurs in up to 10% of patients²⁷. These data suggest that SNS is an effective surgical option for selected patients with FI.

In six crossover studies of SNS for FI, patients experienced equal symptoms with the stimulator on or off³³. The discrepancy between symptom-improvement and relatively minor effects on anorectal functions is puzzling³⁴. Perhaps improved continence is explained by SNS-induced colonic retrograde propagated sequences, which may be anticipated to delay colonic transit³⁵.

Percutaneous tibial nerve stimulation

The posterior tibial nerve can be stimulated via a skin-surface electrode (transcutaneous stimulation) or a needle (percutaneous tibial nerve stimulation, PTNS). In, predominantly uncontrolled, studies, 52% to 82% of patients reported a 50% or greater reduction in frequency of FI with PTNS³⁶. In a small randomized trial of 30 patients with FI, a 50% or greater reduction in FI episodes was observed in 9 of 11 patients (82%) with percutaneous, 5 of 11 (45%) with transcutaneous, and 1 of 8 (13%) with sham transcutaneous stimulation³⁷. Thereafter, a large, multicenter RCT observed that transcutaneous stimulation was not significantly better than sham stimulation, provided by a needle inserted to 2 mm but no electrical stimulation³⁶. However, during that study, loperamide use was reduced by 29% of patients on PTNS but only 11% in the placebo group; differences were not significant ($p=0.06$).

Barrier devices for FI

A Cochrane review identified four randomized crossover or parallel studies of anal plugs or barrier devices, none of which are available in the United States. This review observed that while anal plugs might be helpful in some patients, they are poorly tolerated, with a dropout rate ranging from 12.5% to 68% across the four studies³⁸. More recently, a new anal insert device (Renew Medical Inc., Foster City, CA), which is designed to be better tolerated than other plugs has become approved by the Food and Drug Administration in the United States. In an open label study, 62% of patients reported a 50% or greater reduction in FI frequency; 78% of users were extremely satisfied with the device. There were no serious adverse events and only three moderate adverse events (i.e., fecal urgency, soreness, and bleeding hemorrhoids)³⁹. Another device, a vaginal insert and pressure-regulated pump was also assessed in a prospective open-label study in women with FI. Of 110 participants, 61 completed successful fitting of the device

of whom 78.7% achieved treatment success, defined as $> 50\%$ reduction of incontinent episodes at 1 month⁴⁰. Secondary analysis of bowel function also showed reduction in stool frequency, urgency, liquid stool and incomplete evacuations⁴¹. Additional randomized studies of longer duration will be needed to fully assess the utility of novel barrier devices, as they may be an effective treatment option for patients who fail standard conservative or surgical therapy.

Anal sphincteroplasty

Sphincteroplasty for surgical repair of anal sphincter defects may be performed using an “end-to-end” repair or an “overlap” repair. Post-operative complication rates are generally low. Rates for the most commonly reported complication of wound infection range from 6 to 35%⁴². Success rates decline with time after the procedure. For example, only 28% were continent at 40 months in one study⁴³ and predicted median time to relapse of FI after sphincteroplasty is five years⁴⁴. Given these data, anal sphincteroplasty is primarily reserved for women with postpartum FI. Technical and patient-related factors influencing prognosis after sphincteroplasty are not clearly established. Age, gender, extent of sphincter injury, etiology of sphincter injury, duration of FI, presence or absence of pudendal neuropathy, and surgical technique have all been considered as potential factors. However, none of these factors has consistently demonstrated a clear correlation with outcomes^{45, 46, 47}. There is also little data comparing sphincteroplasty to newer approaches such as SNS, though one retrospective comparison of sphincteroplasty to SNS did not clearly demonstrate superiority of either intervention³². Given these limitations, newer modalities with minimally invasive approaches may soon be considered the preferred first-line surgical approach to treatment of FI except in those with recent or acute sphincter injuries.

Artificial bowel sphincter (ABS) and dynamic graciloplasty for FI

ABS is comprised of an inflatable cuff that acts as a new sphincter, a control pump, and a balloon that regulates the pressure and also acts as a fluid reservoir⁴⁸. The inflated cuff helps to maintain continence, and the deflated cuff facilitates evacuation. Comparisons of its efficacy are confounded by the different scales used to define improvement²³. The largest single-center study published ($n = 52$ patients and 85 devices; mean follow-up, >5 years) showed that full continence is seldom achieved, 14% had device-related infections and 32% required explantation⁴⁸. Others have reported higher rates of complications and explantations²³.

Graciloplasty uses the patient's gracilis muscle to encircle the anus and form a new sphincter. Dynamic graciloplasty consists of implanting an electrical stimulator in the abdominal wall to sustain the tone of the graciloplasty and thereby maintain continence.⁴⁹ In a multicenter international trial of dynamic graciloplasty, success, defined as a $\geq 50\%$ reduction in incontinent episodes, was reported in 47 of 76 (62%), 37 of 67 (55%), and 35 of 62 (56%) patients at 12 months, 18 months, and 2 years post-treatment, respectively⁴⁹. A systematic review reported dynamic graciloplasty success rates of 42% to 85%, with the most common AEs being infection (28%), stimulator malfunction (15%), and leg pain (13%)⁵⁰. Very few reports and no clinical trials of this procedure have been published during the last few years, suggesting that treatment is not routinely performed.

Secca

This procedure involves delivering temperature-controlled radiofrequency energy (465 kHz, 2-5 W) to the anorectal junction with a goal of remodeling, scarring and causing contraction of the collagen tissues in anal region. Manometry and endoanal ultrasound tests did

not reveal any changes⁵¹. In a 5-year follow-up of 19 patients, sustained improvements in FI symptoms and FIQOL were reported when compared to baseline⁵². Other studies have also reported modest improvements in one or both of these measures, albeit over a shorter time duration⁵³⁻⁵⁵. In a review of 10 Secca studies comprising 220 patients, FI improved in 55 to 80% of patients,; complications occurred in 20% of patients. Most studies included small numbers of patients and most were conducted over 8 years ago. There are no randomized controlled trials, but it has been FDA-approved since 2002 for patients who have failed conservative therapy for FI.

Colostomy

Fecal diversion through creation of a colostomy or ileostomy offers definitive therapy for FI in patients who have failed or are not suitable for standard conservative or surgical treatments. Despite its curative potential, colostomy is not commonly used due to concerns for poor quality of life, particularly in the domains of psychologic and social function^{56,57}. However, in one cross-sectional survey study⁵⁸ patients with colostomy formation reported higher social function scores on the SF-36 as well as higher coping, embarrassment, lifestyle and depression scores on the FIQOL compared to patients with FI. Another survey found 84% of patients who had a colostomy for FI would choose to have it again⁵⁹. However, generalizability of these findings may be limited due to patient selection. Mortality rates for colostomy are approximately 2%⁵⁰ and associated complications may include bleeding, cardiopulmonary events related to anesthesia, and parastomal hernia²³. Major long-term stomal problems may also include rashes, leakage and ballooning⁶⁰.

Magnetic anal sphincter

The magnetic anal sphincter comprises a series of interlinked titanium beads with internal magnetic cores that form a flexible ring, encircling the EAS and creating a barrier. During defecation, the beads separate, allowing stool to pass. In a prospective, non-randomized matched study ($n = 20$) FI severity and FIQOL scores improved significantly after implantation of a magnetic or artificial anal sphincter⁶¹. No significant differences in early postoperative complications were observed, but surgical time (62 vs. 97 min) and hospital stay (4.5 versus 10 days) were shorter for the magnetic sphincter group than the artificial sphincter group. The device is approved in several European countries (e.g., United Kingdom and France) and, through the humanitarian device exemption (HDE) process, by the United States FDA agency.

The FDA approval, which is based on a report of 35 patients, is for patients with FI “who are not candidates for or have previously failed conservative treatment and less invasive therapy options (e.g., injectable bulking agents, radiofrequency ablation, sacral nerve stimulation)⁶².” This approval considered a dataset in which all patients had completed follow up at 36 months with partial follow up at 48 and 60 months. At 36 months, 57% of patients reported a $\geq 50\%$ reduction in FI episodes. Seven patients (20%) had the device explanted for infection, erosion, or lack of effect and another patient required a stoma for relieve obstructed defecation. Including other complications (e.g., pain and bleeding), 40% of patients had moderate or severe complications.

Costs of treatment

The costs of conservative treatment in 2010 dollars adjusted for 2013 dollars was \$2584 (\$2067 - \$3101)⁶³. For other treatments, the costs in 2013 dollars are as follows⁶³. For biofeedback therapy, the cost for a 3 month trial was \$796 (\$638 – \$955). Dextranomer, mean (range) physician and procedure costs were \$5181 (\$3165 – \$7197). For SNS, corresponding figures were \$35,818 (\$28,654 – \$42,982).

Defecatory Disorders

Defecatory disorders (DD) are defined by symptoms of chronic constipation or constipation-predominant IBS associated with anorectal tests indicative of impaired rectal evacuation.²⁰ These disorders are common in the community with a prevalence of 22 [versus 5.8 for Crohn’s disease] per 100,000 person years⁶⁴. In patients with chronic constipation unresponsive to laxatives, anorectal testing is necessary to identify DD^{17, 65}. Dyssynergic defecation should be managed by biofeedback therapy, which is not widely available⁶⁶. When patients do not respond to an adequate trial of pelvic floor retraining with biofeedback therapy, options include: (i) ongoing medical management with an emphasis on suppositories and enemas,

(ii) evaluation for pelvic floor structural abnormalities (e.g., clinically significant rectoceles or enteroceles) with appropriate surgical management for the same, (iii) management of colonic motor dysfunction (e.g., prokinetic agents), and (iv) surgery or devices for defecatory disorders. This category includes anal sphincter injection of botulinum toxin, sacral nerve stimulation, and the STARR procedure.

Sacral nerve stimulation (SNS) for defecatory disorders

In addition to several retrospective reports⁶⁷, three prospective studies have evaluated SNS for chronic constipation. In a multicenter European trial published in 2010, 45 of 62 patients with constipation refractory to medical management proceeded from temporary to permanent SNS⁶⁸. Of 62 patients, 81% had slow colon transit and 18% had “normal transit constipation with impaired evacuation”. Bowel symptoms (frequency, straining, and incomplete evacuation) and QOL improved significantly after a median follow up of 28 months (range 1-55 months). The effects of SNS on colonic transit and rectal evacuation were only evaluated in a subset of patients; some parameters improved. By contrast, in a prospective, 18-week randomized, double-blind, placebo-controlled, two-phase crossover study, neither sub- nor supra-sensory SNS increased the proportion of complete bowel movements compared to sham SNS in 55 patients with medically-refractory slow transit constipation and normal anorectal functions evaluated with manometry, rectal balloon expulsion, and proctography⁶⁹. Hence, although small studies suggest that SNS may improve rectal sensation in patients with DD and rectal hyposensitivity⁷⁰ and induce colonic propagating sequences⁷¹, there is no evidence that SNS improves bowel symptoms or rectal evacuation in defecatory disorders.

Anterograde colonic enema procedures for defecatory disorders

Malone described a surgically-created appendicostomy for delivering antegrade colonic enemas in children with constipation or FI⁷². In adults, where the appendix is not always available or stenosed, Malone antegrade continence enemas have been used in patients with medically-refractory severe DD⁷³. This report provided follow up data in 17 of 20 patients; 13 patients were satisfied with the outcome; the outcome of two patients was unchanged and one patient was worse. Enemas can be delivered via a button cecostomy device created by a colonoscopy and percutaneous technique^{73,74}. In these small series, follow up was short, and success rates were lower in adults (approximately 50%) than children (80%). Long-term complications such as stoma stenosis or leakage, or failure to effectively treat symptoms commonly (> 50% at 3 years) require revision, reversal or conversion to a formal stoma⁷⁴. Moreover, this procedure does not address the primary dysfunction, i.e., pelvic floor dysfunction. Hence, in our opinion, this is not an effective long term solution for adults with DD.

Stapled transanal rectal resection and ventral rectopexy for DD

Some patients with DD may have rectoceles and/or rectal intussusception (occult rectal prolapse). Because these structural abnormalities may at least partly result from excessive straining and/or pelvic floor dysfunction, they are primarily managed with pelvic floor biofeedback therapy. Surgical options, which can be transanal (STARR and Contour transtarTM) or transabdominal approaches (i.e., ventral rectopexy) are considered for clinically significant rectoceles (e.g., large defects, those that fill preferentially and/or fail to empty on a defecating proctogram) and symptomatic rectoceles (e.g., when patients recourse to vaginal stenting during defecation).

These procedures aim to cure symptoms by excluding the redundant rectal mucosa associated with a rectocele and intussusception. A prospective, multicenter trial randomized 119

patients with rectal intussusception or a rectocele, size not specified, to STARR or biofeedback therapy⁷⁵ (**Table 1**). It is unclear how many, if any, patients had impaired rectal evacuation at baseline. Thirteen patients withdrew before treatment. At one year, 44 of 54 (82%) STARR patients versus 13 of 39 (33%) biofeedback patients reported a greater than 50% reduction in the obstructed defecation scores; 25% of biofeedback patients (13/52) withdrew before the end of treatment. The constipation-related QOL also improved significantly in both groups. However, 8 (15%) STARR patients had adverse events (i.e., infection, pain, incontinence, bleeding, UTI, or depression), occasionally severe and requiring further surgery, while only one biofeedback patient experienced anal pain. Other complications after STARR procedure include fistula, peritonitis, and bowel perforation⁷⁶⁻⁷⁸.

The correlation between symptoms and rectocele size is weak⁷⁹. The correlation between improvement in symptoms and anatomy after the STARR procedure is also weak; symptoms may improve despite modest effects on anatomic disturbances^{78, 80, 81} and vice versa⁸². It is quite probable that anatomic abnormalities, such as intussusception and complete rectal prolapse, are actually caused by the underlying disorder of function (impaired pelvic floor relaxation and excessive straining), which is not corrected by the procedure. Finally, the long-term outcomes of patients even ideally suited for STARR are somewhat disappointing⁸³. The operation has failed to gain widespread acceptance in the United States.

Surgery for rectal prolapse

Asymptomatic Grade 1-2 rectal prolapse does not require surgery, and should be managed with conservative and/or biofeedback therapy to correct underlying dyssynergia. However, in addition to these measures, patients with symptomatic grade 3-4 prolapse require surgery, using either an abdominal approach (i.e., resection, rectopexy, or both) or perineal resection. A

Cochrane review that included 12 randomized trials with 380 patients concluded that “there is insufficient data to say which of the abdominal and perineal approaches has a better outcome. Division, rather than preservation, of the lateral ligaments was associated with less recurrent prolapse but more postoperative constipation. Laparoscopic rectopexy was associated with fewer post-operative complications and shorter hospital stay than open rectopexy. Bowel resection during rectopexy was associated with lower rates of constipation⁸⁴.” However, bowel resection should be avoided in patients with preexisting diarrhea and/or incontinence as these symptoms may worsen with resection.

In practice, the perineal approach is more frequently used in clinical practice, has lower perioperative morbidity, and a higher recurrence rate. In general, elderly patients, those with significant medical comorbidities, or those with contraindications for abdominal surgery are often the best candidates for a perineal procedure, generally a perineal proctosigmoidectomy (Altemeier procedure)⁸⁵. This may be combined with transperineal levatoroplasty which may help to reduce the risk of recurrence⁸⁶.

Recurrence rates for transabdominal rectopexy are low (0–8%); however, after posterior rectopexy 50% of patients complain of severe constipation^{87,88}. Perineal procedures have a recurrence rate of 5-21% with similar incidence of constipation⁸⁸.

Pouch of Douglas protrusion, which is often confused with rectal intussusception and full-thickness rectal prolapse, is best addressed with sacrocolpopexy and is usually performed in conjunction with other gynecologic procedures in patients with pelvic floor abnormalities such as cystoceles, rectoceles, and enteroceles and vaginal vault prolapse.

Conclusions

Surgical options may be considered in patients with FI and DD who have failed conservative therapy. Our experience suggests that many patients undergo surgical therapy without a rigorous trial of conservative therapy (e.g., biofeedback therapy for DD or antidiarrheal agents in patients with diarrhea and FI). Among surgical procedures, sacral nerve stimulation is a safe and effective option for FI. There is less evidence to support the routine use of other surgical procedures sans a colonic stoma for FI. For some emerging surgical options (e.g., magnetic anal sphincter), limited evidence suggests modest efficacy and the potential for severe side effects. In our experience, surgery is necessary in a very small fraction, perhaps < 5% of patients with DD, generally patients with considerable pelvic organ and/or rectal prolapse. There is a critical need for clinical trials comparing various surgical procedures and conservative with surgical therapies.

Figure Legends

Figure 1. Algorithm for the diagnosis and management of fecal incontinence.

Figure 2. Surgical Devices and Procedures for Managing Fecal Incontinence

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Table 1. Systematic Review of Randomized Controlled Trials of Surgery or Devices for Fecal Incontinence and Defecatory Disorders^a

Author	Year, Countries	Study Design	Treatments (n)	Findings ^b
FI				
Tjandra ²⁹	2008, Australia	Parallel-group RCT	SNS (60) and medical treatment (60)	At 12 months, a $\geq 50\%$ reduction in FI frequency observed in 71% of 53 patients receiving permanent SNS (data not provided for medical treatment). Episodes of incontinence were significantly lower at 12 months with SNS than with medical treatment (MD -6.30 , 95% CI -10.34 to -2.26)
Thin ³⁰	2015, United Kingdom	Investigator-blinded parallel-group RCT	SNS (23) and PTNS (17)	At 6 months, a $\geq 50\%$ reduction in FI frequency observed with SNS (11 of 18, 61%) and PTNS (7 of 15, 47%); differences were not significant
George ³⁷	2013, United Kingdom	Single-blind, parallel-group, RCT	PTNS (11), Transcutaneous (11), Sham	At 6 weeks, a $\geq 50\%$ reduction in FI frequency was significantly greater for PTNS (82%) than

			(8) stimulation	transcutaneous (45%) or sham (13%) stimulation. Improvements were maintained over 6 months.
Knowles ³⁶	2015, United Kingdom	Double-blind, multicenter, pragmatic, parallel-group, RCT	PTNS (115) or sham stimulation (112) of tibial nerve once per week for 12 weeks	For $\geq 50\%$ reduction in FI frequency at 12 weeks, differences between PTNS (39 of 103, 38%) and sham (32 of 102, 31%) were not significant.
Graf ²⁵	2011, Multicenter (USA, Europe)	Double-blind RCT	Dextranomer (136) or sham (70)	At 6 months, a $\geq 50\%$ reduction in FI frequency was significantly greater for dextranomer (52%) than sham (31%)
DD				
Lehur ⁷⁵	2008, France, Italy, United Kingdom	RCT	STARR (54) Biofeedback (52)	Bowel symptoms improved in 44 (82%) STARR vs. 13 (33%) evaluable biofeedback patients.

RCT = randomized controlled trial

^a This Table does not include crossover studies

^b For proportions, the denominator is the number of patients for whom evaluable data were reported in the trial

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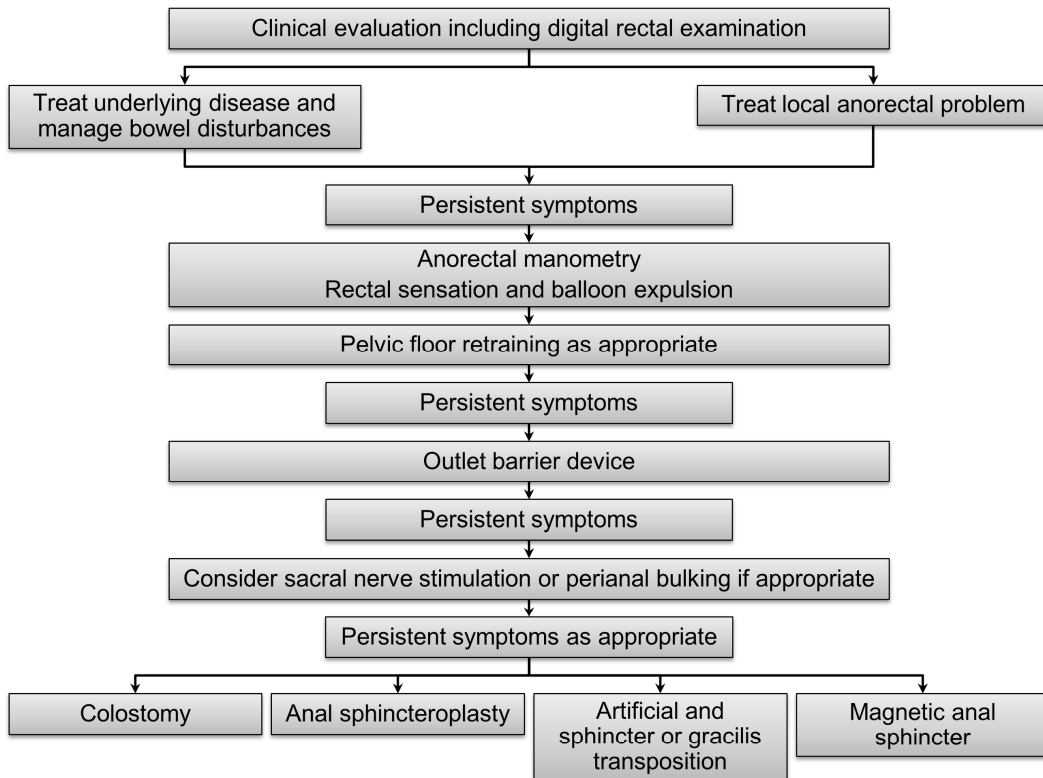
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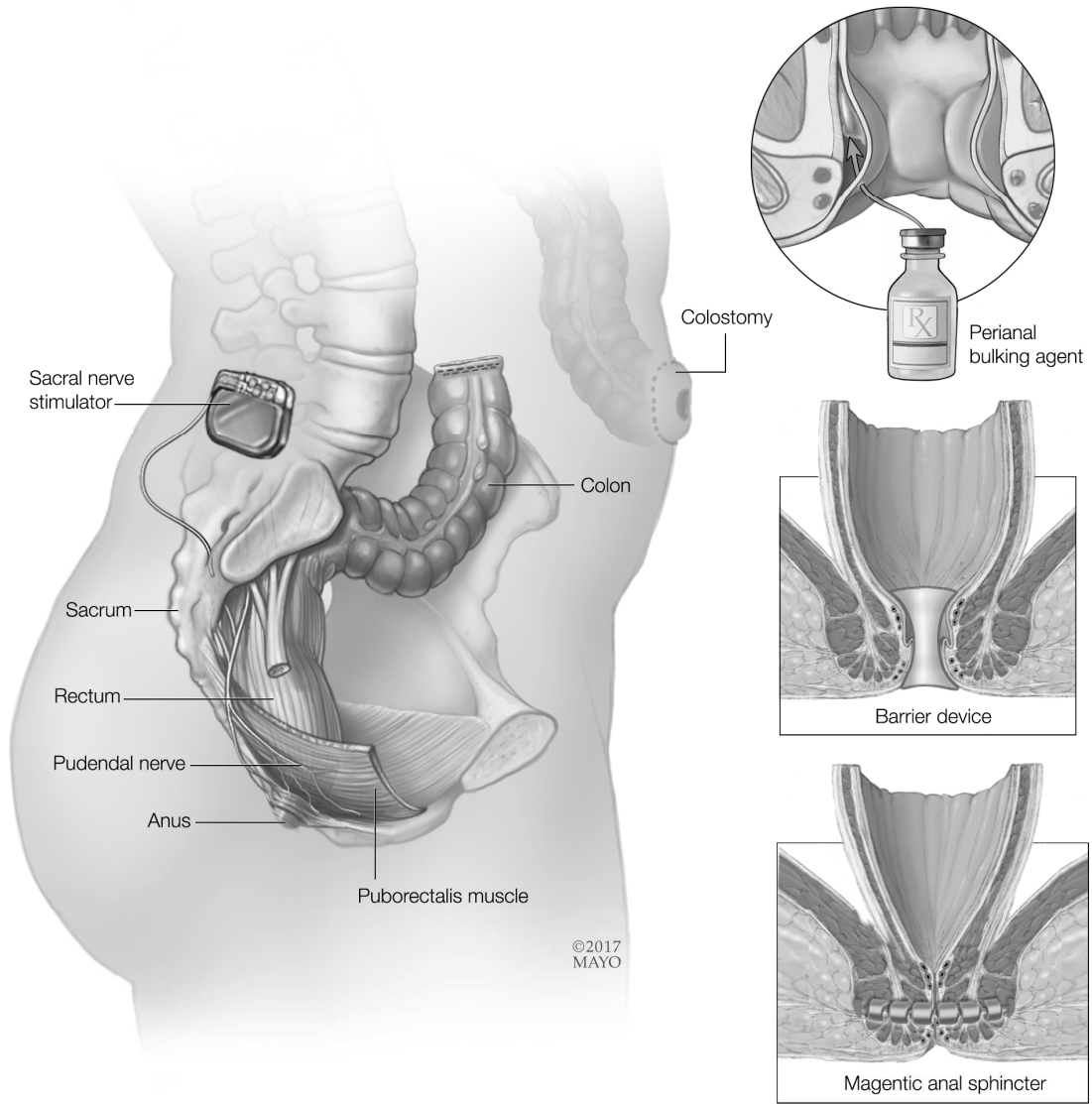
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