The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Fecal Incontinence

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The American Society of Colon and Rectal Surgeons (ASCRS) is dedicated to ensuring high-quality patient care by advancing the science and prevention and management of disorders and diseases of the colon, rectum, and anus. The Clinical Practice Guidelines Committee is composed of society members who are chosen because they have demonstrated expertise in the specialty of colon and rectal surgery. This committee was created to lead international efforts in defining quality care for conditions related to the colon, rectum, and anus and develop clinical practice guidelines based on the best available evidence. Although not proscriptive, these guidelines provide information on which decisions can be made and do not dictate a specific form of treatment. These guidelines are intended for the use of all practitioners, health care workers, and patients who desire information on the management of the conditions addressed by the topics covered in these guidelines. These guidelines should not be deemed inclusive of all proper methods of care nor exclusive of methods of care reasonably directed toward obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician considering all the circumstances presented by the individual patient.

STATEMENT OF THE PROBLEM

Fecal incontinence (FI) is generally defined as the uncontrolled passage of feces for a duration of at least 3 months in an individual who previously had control.[1,2] The prevalence of FI varies widely depending on the specific definition used and the population surveyed, ranging between 1.4% and 18% in women.[3–8] A study of bowel function in a primary care network found the incidence of FI to be 12.5%, with many patients reporting moderate to severe FI (Vaizey score more than 8).[9] The Mature Women's Health Study administered an online survey to 5817 women aged >45 years with an 86% response rate and found that nearly 20% of women reported FI.[10] Although many women with FI have coexisting pelvic floor disorders, the most bothersome symptoms are most often related to their FI.[11] FI in men is not as common and is most commonly because of evacuatory dysfunction and rectal hyposensitivity.[12] The highest incidence of incontinence is reported in nursing home populations, in which rates of FI can reach as high as 50%; FI is the second leading cause of nursing home placement in the United States.[5]

The management of FI is challenging and needs to be individualized according to the severity of symptoms,

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cause, and coexisting pathology.[2,13–17] Aside from conservative and supportive measures, several surgical interventions are available to treat FI with variable efficacy. This practice guideline reviews the medical and surgical options currently available for the management of patients with FI. Treatments for FI that are not currently approved for use in the United States by the Food and Drug Administration (FDA), have become unavailable in the United States, or lack clinical data to support their use are beyond the scope of this guideline.

METHODOLOGY

These guidelines are based on the previous ASCRS Clinical Practice Guidelines for the Treatment of Fecal Incontinence published in 2015.[18] An organized search of MEDLINE, PubMed, Scopus, Cochrane Database of Collected Reviews, Embase, and Web of Science was performed from January 1, 2014, through September 22, 2022. Key word combinations included "fecal incontinence" AND ("fecal OR anal OR stool"), AND ("physical therapy OR rehabilitation OR biofeedback"), AND ("sphincteroplasty" OR "implants" OR "bowel sphincter" OR "artificial sphincter" OR "radiofrequency" OR "sacral nerve stimulation" OR "injectable"). The 2289 screened articles were evaluated for their level of evidence, favoring clinical trials, meta-analyses/systematic reviews, comparative studies, and large registry retrospective studies over single institutional series, retrospective reviews, and peer-reviewed observational studies. Additional references identified through embedded references and other sources as well as practice guidelines or consensus statements from relevant societies were also reviewed. A final list of 182 sources was evaluated for methodological quality, the evidence base was analyzed, and a treatment guideline was formulated by the subcommittee for this guideline (Fig. 1).

Certainty of Evidence

The final grade of recommendation and level of evidence for each statement were determined using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system.[19] The certainty of evidence reflects the extent of our confidence in the estimates of effect. Evidence from randomized controlled trials (RCTs) start as high certainty, and evidence derived from observational studies start as low certainty. For each outcome, the evidence is graded as

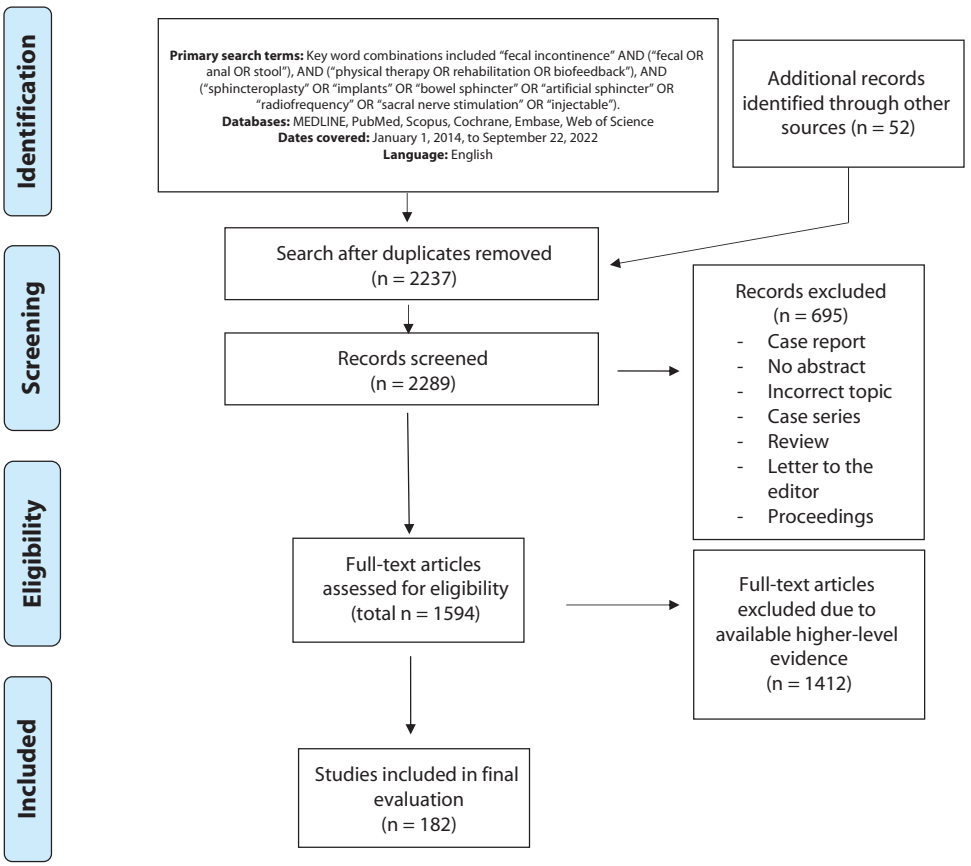

FIGURE 1. PRISMA literature search flow chart. PRISMA = Preferred Reporting Item for Systematic Reviews and Meta-Analysis.

high, moderate, low, or very low (Table 1). The evidence can be rated down for risk of bias, inconsistency, indirectness, imprecision, and publication bias. The certainty of evidence originating from observational studies can be rated up when there is a large magnitude of effect or dose–response relationship. As per GRADE methodology, recommendations are labeled as "strong" or "conditional" (Table 2). When agreement was incomplete regarding the evidence base or treatment guideline, consensus from the committee chair, vice chair, and 2 assigned reviewers determined the outcome. Recommendations formulated by the subcommittee were reviewed by the entire Clinical Practice Guidelines Committee. The submission was then approved by the ASCRS Executive Council and peer-reviewed in *Diseases of the Colon and Rectum*. In general, each ASCRS Clinical Practice Guideline is updated approximately every 5 years. No funding was received for preparing this guideline and the authors have declared no competing interests related to this material. This guideline conforms to the Appraisal of Guidelines for Research and Evaluation checklist.

EVALUATION

A History Should Be Obtained to Help Determine the Cause of Incontinence and Should Include Specific Risk Factors for Incontinence and Characterize the Duration and Severity of Symptoms

Maintaining continence depends on the complex interplay of multiple factors, including anal sphincter and pelvic floor musculature, rectal reservoir function (eg, capacity and compliance), stool consistency, and neurologic function (eg, colonic transit and motility, mental cognition, and sensorimotor function). Although conditions that alter these factors may result in FI, the cause of FI may be multifactorial, and the relative contribution of each factor may be difficult to ascertain. Independent risk factors for FI identified in population-based studies include older age, smoking, obesity, limited physical activity, white race, neurologic disease, diabetes mellitus, frequent and loose stools, and having multiple chronic comorbidities.[4,14] FI is more prevalent among those with Crohn's disease, ulcerative colitis, celiac disease, irritable bowel syndrome, or concomitant constipation.[4,7,20,21]

TABLE 1. Summary and strength of GRADE recommendations

	Summary	*Recommendation strength*	*GRADE quality of evidence*
1	A history should be obtained to help determine the cause of incontinence and should include specific risk factors for incontinence and characterize the duration and severity of symptoms.	Strong	Expert opinion
2	Measures that assess the nature and severity of incontinence and the impact of incontinence on quality of life should be used as a part of the assessment of FI.	Conditional	Low
3	A physical examination is an essential component of the evaluation of patients with FI.	Strong	Expert opinion
4	Anorectal physiology testing (manometry, anorectal sensation, volume tolerance, and compliance) can be considered to help define the elements of dysfunction and guide management.	Conditional	Very low
5	Endoanal ultrasound may be useful to evaluate sphincter anatomy when planning a sphincter repair.	Conditional	Very low
6	Pudendal nerve terminal motor latency testing is not routinely recommended.	Strong	Very low
7	Endoscopy should be performed according to established screening guidelines and in patients presenting with symptoms that warrant further evaluation (ie, changes in bowel habits, bleeding).	Strong	Moderate
8	Dietary and medical management are recommended as first-line therapy for patients with FI.	Strong	Low
9	Bowel training programs can improve rectal evacuation in selected patients.	Conditional	Very low
10	Biofeedback may be considered for patients with FI.	Conditional	Low
11	Vaginal mechanical inserts are not routinely recommended for FI.	Conditional	Very low
12	Anal mechanical insert devices are not routinely recommended for FI.	Conditional	Very low
13	Anal sphincteroplasty may be considered in patients with a defect in the external anal sphincter, but clinical results often deteriorate over time.	Conditional	Low
14	Repeat anal sphincter reconstruction after a failed overlapping sphincteroplasty should generally be avoided.	Conditional	Very low
15	Sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with or without sphincter defects.	Conditional	Low
16	Injection of biocompatible bulking agents into the anal canal is not routinely recommended for the treatment of FI.	Conditional	Low
17	Application of temperature-controlled radiofrequency energy to the sphincter complex is not recommended to treat FI.	Conditional	Very low
18	Antegrade colonic enemas can be considered in highly motivated patients who are seeking an alternative to a stoma.	Conditional	Very low
19	Colostomy is an option for patients who have failed or do not wish to pursue other therapies for FI.	Conditional	Very low

FI = fecal incontinence.

TABLE 2. Interpretation of strong and conditional recommendations using the GRADE approach

Recommendation	*Interpretation*
Strong	Most individuals should receive the intervention. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.
Conditional	Different choices will be appropriate for individual patients consistent with their values and preferences. Use shared decision-making. Decision aids may be useful in helping patients make decisions consistent with their individual risks, values, and preferences.
GRADE certainty rankings	
High	The authors are confident that the true effect is similar to the estimated effect.
Moderate	The authors believe that the true effect is probably close to the estimated effect.
Low	The true effect might be markedly different from the estimated effect.
Very low	The true effect is probably markedly different from the estimated effect.

GRADE = Grades of Recommendation, Assessment, Development, and Evaluation.

Obstetric-related sphincter injury is clinically recognized in approximately 4% to 10% of all vaginal deliveries, but occult sphincter damage may be present in up to 21% to 35% of women after vaginal delivery.[6,22] Among patients with a birthing injury, clinically relevant FI is more commonly observed in multiparous women and in patients who had instrument-assisted deliveries.[23] Some women develop delayed FI, which can make it difficult to determine whether the FI is associated with prior, sometimes remote, sphincter injury or with other factors such as menopause, pelvic organ prolapse, internal intussusception, obesity, or aging.[16] Additional causes of FI include sphincter injury from anorectal procedures (eg, hemorrhoidectomy, sphincterotomy, fistula surgery),[14,24–27] hysterectomy, pelvic surgery, or transanal surgery, or after surgical or nonsurgical treatment for rectal cancer.[12,28–30]

Patients with FI frequently have coexisting pelvic floor disorders and may benefit from a multidisciplinary evaluation.[31] For example, patients with concurrent constipation represent a specific phenotype of FI that may be related to pelvic organ prolapse or internal rectal intussusception.[16,32] Addressing the FI alone in this subgroup may not significantly improve patients' quality of life.

A detailed history goes beyond simply accounting for prior obstetric injury, anorectal surgery, or perineal trauma. For example, assessing changes in stool consistency and potential causative factors, dietary modifications, changes in medications and supplements, food intolerances, and allergies may help elucidate the underlying cause of FI. Operations such as cholecystectomy and gastric bypass can alter stool consistency and frequency and should also be considered when evaluating patients.[1]

Measures That Assess the Nature and Severity of Incontinence and the Impact of Incontinence on Quality of Life Should Be Used as a Part of the Assessment of FI

A number of instruments have been developed to describe the type, frequency, and degree of incontinence as well as the impact of FI on quality of life. FI severity has been assessed most commonly with the Fecal Incontinence Severity Index,[33] the St. Marks Fecal Incontinence Score (Vaizey Score),[34] and the Cleveland Clinic Florida Fecal Incontinence Score (Wexner Score),[35] although other measures of FI also have been reported.[36–40] Using objective measures of severity can help establish baseline scores for a particular patient, measure response to treatment over time, and permit comparisons among groups of patients treated with different strategies.[41]

A Wexner score of 9 or higher indicates a significant impairment of quality of life and is the threshold at which patients will commonly seek medical care.[40] The Fecal Incontinence Quality-of-Life Scale[39] is an incontinence-specific quality-of-life measure commonly used in conjunction with more general quality-of-life measures such as the Short Form 36 and is more commonly used in the research setting.[42] A recent review by the ASCRS Pelvic Floor Disorders Consortium suggested that standardizing measurements would be beneficial in streamlining clinical care and research regarding patients with FI and recommended the routine use of a combination instrument labeled "IMPACT" (Initial Measurement of Patient-Reported Pelvic Floor Complaints Tool) that combines the Wexner and the Vaizey scores while limiting the number of questions patients are asked.[43]

All of these instruments are based on patients' subjective experience of FI. A bowel diary that documents the daily number and severity of FI episodes may help clinicians quantify disease severity before and after therapeutic intervention. A cutoff of 50% or more reduction in the number of episodes per week has been used in recent FI studies as an objective measure of clinical improvement after an intervention. Although this is the most commonly used measure of success in industry-sponsored trials, it has not been validated against other measures.

A Physical Examination Is an Essential Component of the Evaluation of Patients With FI

Elements of a focused clinical examination include external inspection and digital rectal examination.[14] The perianal skin should be evaluated for stool staining, skin irritation or excoriation, surgical scars, trauma, the presence of a patulous anus on spreading the buttocks, or

other pathology such as an external fistula opening or rectal prolapse.[44] The thickness of the perineal body should be noted as well. Examining patients during a Valsalva maneuver or when straining on the commode may demonstrate a mucosal or full-thickness prolapse.[45] Digital examination may provide rough estimates of anal resting tone, squeeze pressure, muscle coordination (including the use of accessory gluteal muscles), and sphincter integrity. Furthermore, it is important to exclude the presence of a distal rectal mass, stricture, or fecal impaction, which would suggest other causes of incontinence. Anoscopy and proctoscopy can be useful for identifying pathology, including hemorrhoids, proctitis, or neoplasia that may be contributing to incontinence.

Anorectal Physiology Testing (Manometry, Anorectal Sensation, Volume Tolerance, and Compliance) Can Be Considered to Help Define the Elements of Dysfunction and Guide Management

An evaluation of pelvic floor function can be considered in patients who fail to respond to conservative therapy. However, anorectal physiology testing does not routinely influence management and debate persists as to which tests are considered helpful. Anorectal manometry can provide detailed information regarding anal sphincter and puborectalis motor function as well as rectal sensation. Anorectal physiology (ARP) testing consists of a number of elements that measure the resting and squeeze pressures of the anal sphincter, determine the length of the high-pressure zone and the pressure profile of the anal canal, and assess anorectal sensation, rectal capacity, and rectal compliance.[45–55] Consensus statements have recommended standardizing definitions for various manometric variables to facilitate both clinical care and research.[53,54] A meta-analysis of 13 studies, including 2981 patients with FI and 1028 controls, indicated that the number of appropriately controlled studies evaluating anorectal manometry is small and that the risk of bias within the literature was high.[56]

Although manometric profiles would ideally provide objective findings to guide optimal treatment, evidence describing the clinical value of ARP is generally lacking.[47,57,58] For example, ARP cannot reliably differentiate patients who would benefit from sacral neuromodulation therapy or colostomy creation or reversal.[59,60] The unsupported utility of ARP may be explained, in part, by the lack of standardization of manometry techniques and/or the broad spectrum of FI phenotypes observed in clinical practice.[61] A notable exception to the general narrative regarding ARP testing is that manometry may be useful to guide biofeedback therapy in patients with obstructed defecation.[62,63] Patients with combined obstructive defecation and FI may benefit from dynamic imaging such as defecography as well.

Endoanal Ultrasound May Be Useful to Evaluate Sphincter Anatomy When Planning a Sphincter Repair

Endoanal ultrasound is a useful and sensitive tool to investigate a sphincter defect in the setting of FI, especially when there is a history of vaginal delivery or when a surgeon considers performing a sphincter repair. Although ultrasound can reliably identify internal and external sphincter defects, the presence of a sphincter defect alone is not sufficient to predict symptomatic FI.[23,64] Some older studies using 2-dimensional ultrasound suggested a correlation between sphincter defects on ultrasound and lower pressures measured on anal manometry.[65,66] However, a 2011 study of 61 patients using 3-dimensional ultrasound demonstrated lower maximum squeeze pressure (66.9 versus 99.7 mm Hg; $p = 0.009$) in patients with external sphincter defects on ultrasound but no difference in Wexner incontinence scores (12.5 versus 11.5).[67] Patients with delayed FI years after vaginal delivery are frequently found to have sonographic evidence of a sphincter defect, but the size of these defects does not necessarily correlate with the severity of their FI.[57,67]

The addition of advanced dynamic endoanal ultrasound and perineal pelvic floor ultrasound can identify additional causes of FI, which can coexist with anal sphincter defects, including levator ani injuries and internal rectal intussusception, but these imaging techniques are not widely available.[68–70] Alternative imaging modalities such as dynamic MRI and fluorodefecography should be considered when endoanal ultrasound imaging is not available or when an endoanal ultrasound reports a normal sphincter complex in appropriately selected patients.[71,72]

Pudendal Nerve Terminal Motor Latency Testing Is Not Routinely Recommended

Pudendal nerve terminal motor latency (PNTML) testing is no longer routinely recommended.[73] Although a number of reports have correlated clinical symptoms or manometry testing with the degree of PNTML impairment,[72,74–78] the presence or absence of pudendal neuropathy does not reliably predict outcomes after a sphincter repair or sacral neuromodulation.[77–83] However, severe denervation and pudendal nerve damage have been reported in some patients who remain incontinent after an otherwise successful sphincter repair.[78–86] It is unclear as to whether this finding is clinically relevant or whether the pudendal nerve conduction delay is only a marker for other conditions related to pelvic floor damage, including perineal descent, levator hiatus injury or distortion, or internal intussusception. Given the lack of clinical utility, PNTML testing is not routinely recommended in patients with FI. No studies have been published in support of this testing modality since 2013, and the 2 more recent studies did not support this test for clinical decision-making.[73,87]

Endoscopy Should Be Performed According to Established Screening Guidelines and in Patients Presenting With Symptoms That Warrant Further Evaluation (ie, Changes in Bowel Habits, Bleeding)

Although colonoscopy rarely contributes to the diagnosis and management of FI, diarrhea is commonly observed in women with late-onset incontinence, and endoscopic evaluation may be warranted under these circumstances to rule out other pathology.[85,88] Other symptoms of concern include bleeding, urgency, tenesmus, and mucus drainage that may be because of incontinence, colorectal cancer, or other serious pathology. General screening recommendations should be followed for all other patients to exclude concomitant colorectal pathology that might require attention.[89]

NONOPERATIVE MANAGEMENT

Dietary and Medical Management Are Recommended as First-Line Therapy for Patients With FI

Conservative management is considered first-line therapy because 22% to 54% of patients with FI report improved symptoms after behavior modification regarding dietary habits and fluid management and changes to medications.[90–92] An evaluation of patients' dietary habits combined with information collected via a bowel diary regarding the frequency of bowel movements, the degree of incontinent episodes, and the consistency of incontinent stools may be helpful when adjusting patients' medical management regimen. The goal of this process is to identify, modify, and avoid triggering aggravating factors in patients' daily routines.[86] Specific attention should be directed toward the use and effects of caffeine, artificial sweeteners, lactose, gluten, and dietary supplements or prescription medications that may trigger fecal urgency or diarrhea in a particular patient.

Generally, medical management of FI focuses on slowing colonic motility and optimizing stool consistency.[93] Pharmacologic treatments have been used to slow colonic transit, decrease intestinal fluid secretion, increase absorption, and reduce sphincter relaxation.[94,95] Much of the variability in stool consistency may be addressed by fiber supplementation, which will ideally thicken and optimize stool consistency. A RCT comparing 39 patients who were treated with either fiber supplementation or placebo showed that patients in the fiber supplementation group decreased their percentage of incontinent stools to less than half of that in the placebo group and had an improvement in stool consistency.[90]

Other medical treatments for FI are supported by less robust evidence and mainly focus on the management of diarrhea and urgency. A Cochrane review analyzed 16 randomized trials (558 pooled patients) that used medications other than fiber to address FI and noted that antidiarrheal drugs such as loperamide or diphenoxylate-atropine may decrease episodes of FI in patients with preexisting diarrhea.[96] Common medications used in these circumstances include adsorbents (eg, Kaopectate and Pepto Bismol), which absorb excess fluid in the stool. A trial of cholestyramine may be reasonable in patients with suspected urgency from bile salt diarrhea after cholecystectomy or ileocolonic resection.[95] Symptomatic management of FI should also include supportive measures that provide advice on skin care, protective (barrier) ointments (eg, zinc oxide), gentle soaps, wipes, deodorants, and pads.

Bowel Training Programs Can Improve Rectal Evacuation in Selected Patients

Bowel management programs vary from simply training patients to facilitate emptying by using scheduled enemas or suppositories to more complex regimens involving the instillation of larger volumes of either water or cathartic enema solutions into the rectum and the descending colon (techniques referred to as transanal irrigation [TAI] or retrograde colonic irrigation). High-volume irrigations require specific devices (eg, Foley catheter, stopcocks, tubing) and education on how to administer high-volume hydrotherapy. There is a commercially available device for TAI, and this has been studied most closely in the pediatric population and patients with spinal cord injury. Although TAI has been most commonly described in pediatric populations,[97,98] it has been evaluated in small studies in patients with FI caused by low anterior resection syndrome (LARS) or neurological injuries.[99–101] The success rate of high-volume irrigation, namely TAI, is typically evaluated as the proportion of patients continuing TAI because they perceive a benefit. Success has been reported in 80% of patients initially, with 50% continuing long-term TAI.[99] Those who choose to discontinue TAI may eventually pursue alternative interventions such as sacral neuromodulation.[100–102]

Biofeedback May Be Considered for Patients With FI

Biofeedback training, also called pelvic floor rehabilitation, is a noninvasive treatment option for patients with FI who have not responded adequately to dietary modification, medications, counseling, and other supportive measures. The goals of a comprehensive biofeedback program are to improve sensation, coordination, and strength and to provide supportive counseling and practical advice regarding diet, bowel habits, behavior modification, and skin care.[103,104] The reported utility of biofeedback in the setting of FI has substantial variability, and outcomes appear to be affected by the degree of presenting symptoms, disease cause, and unique patient factors.[104–112] Although nonrandomized, prospective, and retrospective case series report 64% to 89% improvement in FI related to biofeedback, many of the smaller studies have

methodological weaknesses that make it difficult to draw definitive conclusions regarding the utility of biofeedback.[104–106,108,109,111–114] Interestingly, randomized trials have compared biofeedback to different treatment approaches such as pelvic floor exercise, counseling, and education, but there are no RCTs comparing biofeedback to sham therapy.[90,106,108,110,111,113,115–119] Standardized treatment protocols and larger, well-designed studies are needed to determine the efficacy of this treatment modality.[120,121]

Vaginal Mechanical Inserts Are Not Routinely Recommended for FI

The vaginal bowel-control system is a soft, inflatable vaginal pessary that can be inflated in the vagina in such a way as to occlude the rectum and provide a barrier to the fecal stream to improve FI symptoms. In a multicenter, prospective trial including 110 women, 61 patients (55%) achieved a successful device fit and were treated for FI. After 1 month of treatment, 78.7% of treated patients achieved 50% or more reduction in weekly FI episodes.[122] In a subsequent multicenter prospective trial of 73 patients, the clinical success of 50% or more reduction in weekly FI episodes was achieved in 73% of patients at 3 months of follow-up ($p < 0.001$). At 12 months of follow-up, major FI episodes per 2 weeks decreased from a baseline of 5.0 to 1.2 ($p < 0.001$), and Vaizey scores decreased from 16.5 to 9.8 ($p < 0.001$).[123] Although these results are encouraging, the available clinical evidence suggests that only 55% to 80% of patients are able to achieve a good clinical fit with this device and additional clinical evidence is needed to further evaluate device efficacy.[123,124] Of note, there have been no new clinical studies of this device published since 2016.

Anal Mechanical Insert Devices Are Not Routinely Recommended for FI

Anal inserts for the treatment of FI have been studied in small series that reported modest improvements in FI; the most common adverse events reported were discomfort and device slippage.[125,126] The largest prospective study evaluating this approach reported that 62% of 91 patients achieved a 50% or more reduction in FI episodes. This study had no comparison group and did not report any quality-of-life metrics.[127] A recent pilot study randomly assigned 50 patients to treatment either with an anal insert (n = 25) or with percutaneous tibial neuromodulation and reported a 50% or more reduction in FI episodes in 19 patients (76%) treated with an anal insert compared to 12 patients (48%) treated with tibial nerve stimulation ($p = 0.04$).[128] Although these data provide some insight, studies of a number of various anal insert devices during the past 20 years have reported limited long-term tolerability or efficacy beyond 3 months; the utility of these devices for treating FI remains unclear.[127,129–134]

SURGICAL MANAGEMENT

Anal Sphincteroplasty May Be Considered in Patients With a Defect in the External Anal Sphincter, but Clinical Results Often Deteriorate Over Time

Anal sphincteroplasty is typically performed to treat injuries to the anterior anal sphincter because of a complicated vaginal delivery. Although sphincteroplasty repairs of obstetric injuries have been historically associated with good to excellent short-term results in up to 85% of patients, many studies did not use uniform criteria to define functional success, making it difficult to compare various series and different procedures.[114,135–137] The major limitation of anal sphincter reconstruction is that the clinical results often worsen over time. After 5 years, as few as 10% to 14% of patients have a sustained improvement in function, suggesting that FI after obstetric injury is multifactorial.[114,119,138,139] Single-center case series have shown improvement in Wexner scores in the short term after sphincteroplasty, but these results typically diminish to baseline by 3 years.[135–137,140,141] Given the potentially short-lived benefits, some authors have questioned the utility of sphincteroplasty, especially in women who develop incontinence decades after their obstetric trauma, and have recommended considering other approaches such as sacral neuromodulation.[60,79,140,142–145] Population data showed a 7-fold decrease in the number of anal sphincteroplasty operations performed in the United States from 2009 to 2015.[146] In a retrospective review that compared 26 patients with an external sphincter defect who underwent sphincteroplasty (n = 13) versus sacral neuromodulation (SNM; n = 13), patients who had SNM had a decrease in their Wexner score at 3 months (baseline 15.9–8.4; $p = 0.003$), whereas patients who underwent sphincteroplasty did not experience a significant improvement in Wexner score at 3 months (16.9–12.9; $p = 0.078$).[147]

Repeat Anal Sphincter Reconstruction After a Failed Overlapping Sphincteroplasty Should Generally Be Avoided

Deterioration in function after overlapping sphincteroplasty over time occurs commonly.[114,119] In patients without a specific factor responsible for failure of their first repair, such as recurrent sphincter injury because of repeat vaginal delivery, repeat sphincteroplasty is unlikely to be successful. Older studies evaluating repeat sphincteroplasty reported subjective outcomes without long-term follow-up. A single-center retrospective review of 56 patients who underwent repeat sphincteroplasty for FI showed poor long-term success. Although the mean Wexner score decreased from 16.5 to 11.9 ($p < 0.001$) after repeat sphincteroplasty, it is important to recognize that patients with a Wexner score more than 9 are considered to have severe FI, and patients with this range of scores typically seek medical care.[40] Not surprisingly, 21.4% of the

patients in this study underwent further procedures for FI and 5.4% underwent colostomy creation. Furthermore, after 74 months of follow-up, only 28.6% of patients subjectively reported a "good" result.[148]

Sacral Neuromodulation May Be Considered as a First-Line Surgical Option for Incontinent Patients With or Without Sphincter Defects

SNM was approved by the FDA in 2011 for fecal and urinary incontinence.[149–154] With this approach, patients undergo a 2-week evaluation after placing a test lead in the operating room or a 1-week evaluation with percutaneous leads placed in the office setting; patients with at least a 50% improvement in FI episodes during their evaluation period are offered full system implantation.[155] In a pooled analysis of 61 SNM studies, a median of 79% of patients experienced 50% or more improvement in weekly FI episodes in the short term (ie, 0–12 mo), and a median of 84% of patients experienced 50% or more improvement at >36 months follow-up.[150] In a prospective, nonrandomized, multicenter study of 120 patients with SNM treated at 14 centers across the United States, Canada, and Australia,[156] of the 76 patients who were followed for at least 5 years, 27 (35.5%) required at least 1 revision, replacement, or explant, highlighting the need for long-term patient follow-up.[156] Rechargeable devices and devices with up to 15 years of battery life are now available and may theoretically decrease the frequency of revisions required because of battery life issues, but clinical studies will need to determine whether this leads to fewer device revisions in the future.[157,158] One small prospective study of 15 patients treated with the rechargeable device implanted in a single stage indicated 50% or more improvement in FI in 13 patients (87%) at 4 weeks. This response was sustained at 6 months.[157,158]

The best predictor of success with SNM is a successful trial of test stimulation. Meanwhile, clinical factors such as the presence of a sphincter defect or pudendal neuropathy or a history of a previous sphincter repair do not accurately predict outcomes of SNM.[79] For example, in a retrospective study of 237 patients treated for FI with SNM, the 128 patients who had a sphincter injury on endoanal ultrasound demonstrated similar responses to SNM compared to the 109 patients with an intact sphincter.[159] Another retrospective study evaluating the impact of a sphincter injury on the success of SNM compared 54 patients with ultrasound-confirmed external sphincter muscle defect (mean defect size = 105 degrees) to 91 patients without a sphincter defect. In this study, patients with an external sphincter defect improved from a baseline median Cleveland Clinic Florida Fecal Incontinence Score (CCF-FIS) score of 15 to 2.5 at 12-month follow-up, which was comparable to the patients without a sphincter defect who improved from a baseline median CCF-FIS score of 14 to 3 at 12 months.[144] Furthermore, a systematic review of 10 studies including 119 SNM patients with a sphincter injury demonstrated a decrease in the weighted average Cleveland Clinic Florida Fecal Incontinence Score (CCF-FIS) score from 16.5 to 3.8.[160] Success of SNM has been reported in patients with sphincter defects of up to 120 degrees.[149,161] SNM may also improve FI symptoms in patients with LARS. A pooled analysis of 10 studies in patients with LARS found a significant reduction in FI after SNM implantation (mean LARS score difference 11.23; 95% CI, 9.38–13.07; $p < 0.001$).[162]

Meanwhile, a single retrospective study from 2015 indicated that temporary test stimulation for SNM to treat FI was successful in 69% of patients with high-grade internal intussusception diagnosed on defecography and in 86% of patients without high-grade intussusception.[163] Although intriguing, these data have not been reproduced.

The efficacy of SNM for FI may be better in women than men. In a single-center retrospective study comparing 31 men and 321 women, the 1-, 3-, and 5-year cumulative successful treatment rates were 88.6%, 63.9%, and 43.9% in men and 92.0%, 76.8%, and 63.6% in women, respectively.[164] Another prospective study of 360 patients treated with SNM at 7 French centers reported that at 10 years, 94 patients (26.1%) required SNM explantation because of a variety of reasons such as loss of efficacy (n = 83; 23.1%) or infection (n = 28; 7.8%), and male sex appeared predictive of less favorable outcomes (HR: 1.98 [1.09– 3.61]; $p = 0.02$). The relatively worse outcomes in men may be partly because of differences in pathophysiology of FI as men with FI in these studies were more likely to have had previous anorectal surgery or low anterior resection, whereas women with FI were more likely to have had prior obstetric trauma.

Although there is mounting evidence demonstrating long-term success of SNM, there are only a few studies comparing SNM to other treatments or other surgical approaches.[165] Another randomized trial that used CCF-FIS scores compared SNM (n = 60) with a medically managed control group (n = 60) and reported 100% continence in 41.5% of SNM patients and that 90% of patients had at least a 50% improvement; meanwhile, there was no significant functional improvement in the control group.[149]

Injection of Biocompatible Bulking Agents Into the Anal Canal Is Not Routinely Recommended for the Treatment of FI

In 2011, the FDA approved a nonanimal stabilized hyaluronic acid dextranomer gel (NASHA Dx) for submucosal injection in patients with passive FI. The largest series evaluating this approach at the time was a randomized, double-blinded, placebo-controlled, multicenter trial of 206 patients from Europe and the United States.[166] In this study, at 6-month follow-up, 52% of patients in the

NASHA Dx group reported 50% or more reduction in FI episodes, compared to 31% of patients in the placebo arm ($p = 0.008$). A subsequent 36-month follow-up indicated that 57% of study patients still had 0% or more improvement in FI episodes compared to baseline, but median Wexner scores in this group of patients only decreased from 14 at baseline to 11 at 36 months ($p < 0.001$), indicating fairly significant persistent FI.[167] Additionally, most patients whose function improved in this trial had 2 separate injections of the bulking agent. In a retrospective study with long-term follow-up of 19 patients treated with an injectable for FI, ultrasound evaluation indicated that less than 14% of the injected substance was still present after 5 years, and the Wexner scores of these patients had returned to pretreatment baseline.[168] Given the limited improvement over placebo, diminishing long-term results, and cost, injectable bulking agents are not considered first-line treatment for FI.

Application of Temperature-Controlled Radiofrequency Energy to the Sphincter Complex Is Not Recommended to Treat FI

The application of radiofrequency energy for FI was adapted from the treatment for gastroesophageal reflux disease and was FDA approved for this indication in 2002. Meanwhile, the evidence supporting this approach for the management of FI is relatively sparse and has relevant limitations. Early studies regarding this technology, mostly single-center series without long-term follow-up, reported modest improvement in FI.[169–175] One series considered 55% to 80% of patients responders at 12 months based on having had some improvement in CCF-FIS scores, but most series did not meet a threshold of demonstrating 50% or more improvement in incontinence episodes.[175] A 2017 placebo-controlled trial of 40 patients treated with either radiofrequency energy or a sham procedure reported that the mean Vaizey scores decreased from 16.8 to 14.3 in the treatment group and from 15.6 to 13.2 in the sham group, and there was no statistically significant improvement in quality of life at 6 months.[176] Another retrospective study of 10 patients treated with radiofrequency energy with 15 years of follow-up showed no improvement in the Wexner scores (12.4 from 13.8; $p = 0.24$) or quality-of-life scores compared to baseline.[177] Based on the available data, radiofrequency energy delivery is not recommended for the treatment of FI. Additionally, no new studies evaluating this modality have been published since 2014.

Antegrade Colonic Enemas Can Be Considered in Highly Motivated Patients Who Are Seeking an Alternative to a Stoma

Historical data regarding the use of antegrade enemas via an appendicostomy (Malone) or a cecostomy tube have been mostly limited to the pediatric population. A systematic review by Patel et al, published in 2015, analyzed several case series evaluating antegrade enema therapy for the treatment of constipation or incontinence in adults. In this review, most of the patients had FI because of spinal cord injury, anorectal malformation, or prior anorectal surgery; the primary outcome was the percentage of patients still irrigating with antegrade enemas at the end of the study. Of the 134 patients with FI included in the study treated with antegrade enemas, 78% to 100% were still using antegrade enemas at 22 to 48 months of follow-up.[178] Only 1 retrospective telephone survey of 75 patients used a validated scoring system and found a significant decrease in the Wexner score (14.3–3.4; $p < 0.001$) at a median follow-up of 48 months.[179]

Colostomy Is an Option for Patients Who Have Failed or Do Not Wish to Pursue Other Therapies for FI

When alternative therapies are not appropriate or have failed, a colostomy may allow patients with FI to resume normal activities and may improve their quality of life.[180,181] In a questionnaire study comparing 39 patients with FI treated with a colostomy to 71 patients with FI without diversion, responders who had a colostomy reported better scores in various Fecal Incontinence Quality-of-Life Scale domains such as coping (2.7 versus 2.0; $p = 0.005$), embarrassment (2.7 versus 2.2; $p = 0.01$), and lifestyle (3.2 versus 2.7; $p = 0.14$), and had depression scores comparable to the control group (3.1 versus 2.9; $p = 0.62$).[182] Similarly, in another survey of 69 patients with FI treated with colostomy, 83% of patients reported a significant improvement in lifestyle and 84% of patients stated that they would choose to have the stoma created again.[181] Patients who described persistent restrictions because of their stoma reported needing to be conscious of the location of toilets, having travel restrictions, feeling self-conscious about stoma-related noises or odors, and being concerned about the possibility of appliance or anal leakage.

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