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TOPIC HIGHLIGHT

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# **Current management of fecal incontinence: Choosing amongst treatment options to optimize outcomes**

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# Abstract

The severity of fecal incontinence widely varies and can have dramatic devastating impacts on a person's life. Fecal incontinence is common, though it is often underreported by patients. In addition to standard treatment options, new treatments have been developed during the past decade to attempt to effectively treat fecal incontinence with minimal morbidity. Non-operative treatments include dietary modifications, medications, and biofeedback therapy. Currently used surgical treatments include repair (sphincteroplasty), stimulation (sacral nerve stimulation or posterior tibial nerve stimulation), replacement (artificial bowel sphincter or muscle transposition) and diversion (stoma formation). Newer augmentation treatments such as radiofrequency energy delivery and injectable materials, are minimally invasive tools that may be good options before proceeding to surgery in some patients with mild fecal incontinence. In general, more invasive surgical treatments are now reserved for moderate to severe fecal incontinence. Functional and quality of life related outcomes, as well

as potential complications of the treatment must be considered and the treatment of fecal incontinence must be individualized to the patient. General indications, techniques, and outcomes profiles for the various treatments of fecal incontinence are discussed in detail. Choosing the most effective treatment for the individual patient is essential to achieve optimal outcomes in the treatment of fecal incontinence.

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Key words: Fecal incontinence; Treatment; Sacral nerve stimulation; Sphincteroplasty; Artificial bowel Sphincter; Biofeedback

Core tip: An increasing number of treatment options for the management of fecal incontinence have been developed. In addition to traditional options such as sphincteroplasty and colostomy, non-surgical options such as biofeedback and dietary modification may be considered for mild incontinence. Injectable materials and radiofrequency energy delivery are two newer treatments for mild incontinence. Surgical options for moderate to severe incontinence include sacral nerve stimulation, artificial bowel sphincter implantation, muscle transposition, antegrade continence enemas, sphincteroplasty, and colostomy formation. Treatment for fecal incontinence (repair, stimulation, replacement, augmentation, or diversion) must be individualized to the patient, considering the underlying cause and impact on guality of life of the fecal incontinence.

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# INTRODUCTION

Fecal incontinence is a common problem; one that is likely underreported in the general population. The prevalence of fecal incontinence varies in the literature, with one study of over 4000 surveyed American adults finding a prevalence of  $8.3\%^{[1]}$ . The much larger and more recent Mature Women's Health Study of over 5800 American women found an even higher incidence of accidental bowel leakage of almost 20%<sup>[2]</sup>. Incontinence to liquid or solid stool, mucous, or flatus occurs with varying frequency and can have a range of impact on daily function<sup>[1]</sup>. The Mature Women's Health Study found that nearly 40% of women with accidental bowel leakage have severe symptoms impacting their quality of life, even though less than one third of women sought medical care for their bowel leakage<sup>[3,4]</sup>. While there can be many etiologic factors contributing to its development, there are some common risk factors. Age, diarrhea or frequent bowel movements, nocturnal bowel movements, other bowel disorders, and the presence of urinary incontinence are commonly associated with fecal incontinence<sup>[1,4,5]</sup>. In women, internal sphincter injury and reduced perineal descent related to obstetrical trauma independently predict the development of fecal incontinence<sup>[6]</sup>. Other risk factors include neurological disorders, congenital anorectal malformations, trauma, iatrogenic injury during anorectal procedures, and chronic diseases such as diabetes<sup>[6-9]</sup>.

It is necessary to complete a physiological and anatomical assessment of the pelvis and colon in order to choose the most appropriate treatment option for a patient's fecal incontinence. This caveat is especially important since many women with fecal incontinence have associated genital and urinary anatomical or functional problems<sup>[10]</sup>. A rectal examination may identify a sphincter defect or decreased rectal tone. This finding may be helpful to identify potential etiologies and treatments for a patient's fecal incontinence. Though not all investigations are required for every patient, options include anal or pelvic ultrasound, anal manometry, defecography, magnetic resonance imaging, and electromyography with pudendal nerve terminal motor latency testing. Anatomical imaging can help identify sphincter defects and associated pelvic floor disorders such as rectocele or prolapse, which may be contributing to the severity of incontinence $^{[11,12]}$ . A physiology lab is helpful for the assessment of incontinence and other pelvic floor disorders.

The impact of fecal incontinence varies and can greatly alter a person's ability to perform daily activities. One may alter timing of meals or eating habits, and possibly avoid all social occasions for fear of embarrassment<sup>[8]</sup>. While fecal incontinence is not a normal part of aging it may be perceived as such, and older people may not seek treatment until symptoms are severe. Treatment options for fecal incontinence range from dietary modification and physical therapy to major surgery, such as colostomy formation. In recent decades, many new treatments for fecal incontinence have been developed with

good success, adding to traditional options of sphincteroplasty and ostomy formation. These alternatives include biofeedback, radiofrequency, injectable materials, and surgical approaches such as sacral nerve stimulation, the artificial bowel sphincter, and muscle transposition. A recent Cochrane review concluded that there is insufficient evidence to allow for quality comparisons to be made among the various surgical approaches to fecal incontinence<sup>[13]</sup>. The decision among these options is multifactorial and the severity of the incontinence, patient anatomy, and patient wishes must all be carefully considered. The aim of this article is to review current options for the management of fecal incontinence, their indications, and reported outcomes. The treatments most commonly offered by the authors, from the five available categories of repair, stimulation, replacement, augmentation, and diversion, are discussed.

# DIETARY MODIFICATION AND MEDICATION

Modifiable diet and lifestyle factors may be identified which can provide simple interventions to try to improve symptoms. Smoking and sedentary lifestyle are associated with fecal incontinence<sup>[14]</sup>. Weight loss has been shown to improve fecal incontinence in obese women<sup>[15]</sup>. Medications should be reviewed with the help of a pharmacist to identify potentially incriminating medications. Low fiber and high fat diets may be contributory to loose stools. Loose stools and diarrhea often precipitate symptoms of fecal incontinence and may be improved with dietary and medication alterations. Other factors may be identified that may suggest the need for further testing or anatomical causes of fecal incontinence. For example, cholecystectomy may lead to persistent diarrhea and flatulence which may amplify symptoms of fecal incontinence; cholestyramine may help relieve these symptoms<sup>[16,17]</sup>.

The addition of a daily fiber supplement should be advocated in fecal incontinence. It acts as a bulking agent to allow for more solid stool and adds little to no morbidity to the patient. A randomized, blinded, placebo controlled study found that fiber improved fecal incontinence and stool consistency within 1 mo in the community living population<sup>[18]</sup>. In addition to fiber, medications with a constipating effect may be useful for patients with fecal incontinence with loose stools. These pharmacologic agents include loperamide, diphenoxylate and atropine, and codeine. Loperamide is most commonly used and may also have beneficial effects on anal sphincter resting tone<sup>[19]</sup>. Unfortunately, studies comparing various medications are lacking and trials of medications for the treatment of fecal incontinence include very heterogeneous populations and treatments<sup>[20]</sup>. A Cochrane review conducted in 2013 concluded that there is insufficient evidence to guide the decision between medications for the treatment of incontinence in various clinical situations<sup>[20]</sup>. Clearly, no medication will cure moderate to severe fecal incontinence, but it should certainly be utilized in mildly

| Table 1         Success of biofeedback for fecal incontinence |      |              |  |   |                                      |  |  |  |  |  |
|---|------|--------------|--|---|--------------------------------------|--|--|--|--|--|
| Ref.  | Year | Patients (n) | Significant reduction in incontinence (percentage of patients) | Improvement in quality of life (percentage of patients) | Adjuncts to traditional biofeedback  |  |  |  |  |  |
| Keck et al <sup>[33]</sup>                                    | 1994 | 15           | 73%  | NR  | None                                 |  |  |  |  |  |
| Solomon et al <sup>[28]</sup>                                 | 2003 | 102          | 70%  | 69%   | Anal manometry, transanal ultrasound |  |  |  |  |  |
| Terra et al <sup>[34]</sup>                                   | 2006 | 239          | 60%  | NR  | EMG, electrostimulation              |  |  |  |  |  |
| Naimy et al <sup>[30]</sup>                                   | 2007 | 49           | None   | None  | Electrostimulation                   |  |  |  |  |  |
| Byrne et al <sup>[32]</sup>                                   | 2007 | 385          | 70%  | 87%   | None                                 |  |  |  |  |  |
| Heymen et al <sup>[27]</sup>                                  | 2009 | 45           | 76%  | NR  | None                                 |  |  |  |  |  |
| Schwandner et al <sup>[29]</sup>                              | 2010 | 158          | 50%  | NR  | EMG, electrostimulation              |  |  |  |  |  |
| Bartlett et al <sup>[26]</sup>                                | 2011 | 72           | 86%  | 100%  | None                                 |  |  |  |  |  |
| Jodorkovsky et al <sup>[31]</sup>                             | 2013 | 12           | 80%  | NR  | None                                 |  |  |  |  |  |

NR: Not reported; EMG: Electromyography.

symptomatic patients where indicated.

# BIOFEEDBACK

Biofeedback is a form of physical therapy and muscle re-training offered to patients refractory to medical treatment of fecal incontinence. There are numerous regimens, most of which involve many weeks of treatment lead by a physical therapist. Numerous studies have attempted to define the most effective regimen and most responsive patient population, but overall there are few high quality studies showing a definitive impact of biofeedback on fecal incontinence<sup>[21]</sup>. It has been suggested by some authors that biofeedback should be offered to all patients who have not responded to medical interventions of fecal incontinence because it is safe, inexpensive, and effective long term<sup>[22]</sup>. Older patients with normal defecation physiology appear to respond well<sup>[23]</sup>. Advanced anorectal physiology tests such as manometry, defecography, pelvic magnetic resonance imaging, and pudendal nerve terminal motor latency testing do not seem to predict who will respond best to biofeedback<sup>[24]</sup>. Patients with mild or moderate fecal incontinence who have not responded well to medical treatments are likely the best candidates for biofeedback<sup>[25]</sup>.

The technique of biofeedback may include monitored or home sessions, pelvic floor exercises, digital feedback, electrical stimulation, balloons, and manometric or ultrasound monitoring of response. Pelvic floor exercises alone have been shown to improve fecal incontinence scores and quality of life<sup>[26]</sup>. In one study of pelvic floor exercises, no differences in treatment effect were found between the different regimens, but symptoms improved in both groups<sup>[26]</sup>. The addition of biofeedback using manometry is more effective than pelvic floor exercises alone to improve fecal incontinence scores and achieve more physiologically normal defecation<sup>[27]</sup>. Biofeedback with digital feedback alone may be just as effective as manometry and ultrasound guided treatment, providing enough feedback to guide re-training, as found in a randomized controlled trial of different methods of biofeedback<sup>[28]</sup>. Some literature suggests that electrical stimulation leads to more effective results over biofeedback alone, while others have found that biofeedback alone is

adequate to improve patient symptoms<sup>[29,30]</sup>. A multicenter randomized and blinded trial found that the combination of electrical stimulation with extended treatment duration (longer than 3 mo) achieved the best results<sup>[29]</sup>. Such treatment regimens may not be available in many centers, but access to a trained biofeedback therapist who is aware of the various treatment modalities may be invaluable to the population with fecal incontinence.

Biofeedback requires the patient and therapist to commit to treatment for a number of weeks to months. One study found that only 44% of patients with fecal incontinence who were recommended to undergo biofeedback therapy completed the treatment<sup>[31]</sup>. This finding was largely due to lack of insurance coverage and distance to treatment centers<sup>[31]</sup>. It is important to note that in this study those patients who did undergo biofeedback reported an 80% positive response to the treatment<sup>[31]</sup>. Other studies have confirmed improvement in over 70% of patients when fecal incontinence scores and quality of life scores were assessed<sup>[32,33]</sup>. Table 1 summarizes the success of biofeedback. Physiologic parameters such as squeeze pressure and maximum tolerated volume have also been reported to improve with biofeedback<sup>[34]</sup>. Improvements in fecal incontinence scores are durable over at least 1 year, but some patients may require additional sessions to boost the effect<sup>[35]</sup>. Pelvic floor training with biofeedback is likely beneficial to many patients with fecal incontinence long term, but patients and therapist must be willing to devote the time to a complete set of sessions to see maximum benefit. In those able to do so, biofeedback may achieve improvement in symptoms without invasive procedures.

#### REPAIR

#### Sphincteroplasty

Sphincteroplasty has long been the standard of care of the management of fecal incontinence related to anal sphincter injury<sup>[36]</sup>. The vast majority of patients who undergo sphincteroplasty have a history of vaginal delivery<sup>[37]</sup>. However, only about one third of women who have had a known sphincter injury related to vaginal delivery develop fecal incontinence over time<sup>[36]</sup>. Pudendal nerve injury, failed prior sphincteroplasty, multiple



| Table 2 Success o | f overlappin | ng sphincteroplasty |  |
|-------------------|--------------|---------------------|--|
|-------------------|--------------|---------------------|--|

| Ref.                             | Year | No. of patients with follow-up | Mean<br>follow-up<br>(mo) | Success <sup>1</sup><br>(percentage of<br>patients) |
|----------------------------------|------|--------------------------------|---------------------------|---|
| Karoui et al <sup>[52]</sup>     | 2000 | 74                             | 40                        | 28%   |
| Halverson et al <sup>[40]</sup>  | 2002 | 49                             | 69                        | 46%   |
| Bravo Gutierrez                  | 2004 | 130                            | 120                       | 41%   |
| et al <sup>[39]</sup>            |      |                                |                           |   |
| Barisic et al <sup>[49]</sup>    | 2006 | 65                             | 80                        | 48%   |
| Maslekar et al <sup>[55]</sup>   | 2007 | 64                             | 84                        | 80%   |
| Oom <i>et al</i> <sup>[50]</sup> | 2009 | 120                            | 111                       | 60%   |
| Mevik et al <sup>[51]</sup>      | 2009 | 25                             | 84                        | 53%   |
| Zutshi et al <sup>[53]</sup>     | 2009 | 31                             | 129                       | 0%  |
|                                  |      |                                |                           |   |

<sup>1</sup>Success variably defined in studies. Good, excellent or complete continence included as success.

vaginal deliveries, history of third of fourth degree tear, and instrument-assisted vaginal deliveries are all factors which may predispose to fecal incontinence associated with sphincter defect and impact the success of sphincteroplasty<sup>[38]</sup>. It is important to note that the majority of recent studies indicate that pudendal nerve injury as demonstrated by prolonged pudendal nerve terminal motor latency does not independently predict the success of sphincteroplasty<sup>[39-41]</sup>. Many women who undergo sphincteroplasty have associated pelvic floor injuries, which do not seem to impact the success of sphincteroplasty<sup>[42]</sup>. In addition, the combination of internal and external anal sphincter defect repair can lead to successful and equivalent outcomes when compared to external anal sphincter defect repair, alone<sup>[43]</sup>.

While various techniques for sphincteroplasty have been described, the most commonly performed procedure is the anterior overlapping sphincteroplasty. A curvilinear incision is made on the perineum and dissection proceeds until the edges of the external anal sphincter are identified and isolated. Care is taken to not dissect too far laterally to avoid nerve injury. The ends are overlapped and sutured together, providing new bulk to the sphincter complex and an intact circumferential ring of sphincter. Separate attention to the imbrication of the internal anal sphincter does not seem to add to the overall durability of the sphincteroplasty if the internal sphincter is not injured<sup>[44]</sup>. Post-operative manometry shows significant increases in the length of the high pressure zone and resting and squeeze pressures<sup>[37]</sup>. A diverting stoma is not required to achieve optimal outcomes in early repair of third and fourth degree tears during vaginal delivery<sup>[45]</sup>. Delayed repair is associated with higher overall cost in this situation, but may still achieve good long term outcomes and may be the safer option depending on the clinical scenario<sup>[45,46]</sup>.

Posterior sphincter repair is rarely needed, given that most sphincter injuries are associated with traumatic vaginal delivery. However, posterior repair may be occasionally utilized for neurogenic fecal incontinence, multifocal sphincter defects, or after failed anterior sphincteroplasty in order to avoid any significant scar tissue in the area. A similar technique is used as in the anterior technique, with a curvilinear posterior incision being used for access to the external anal sphincter. Some surgeons may proceed with a combined anterior and postanal approach, though this combination is not common. The success rate of the postanal approach is likely equivalent or less durable compared to anterior sphincteroplasty<sup>[47,48]</sup>. In the absence of a specific iatrogenic posterior sphincter injury or excessive anterior scar tissue, the anterior sphincteroplasty should be considered the preferred approach.

The long term functional outcomes following anal sphincteroplasty are not ideal. The Wexner fecal incontinence score is commonly used to assess for incontinence following sphincteroplasty. In the short term, good results are achieved in over 70% of patients and excellent results in over half of patients<sup>[49]</sup>. However, the long term outcomes which have been reported in numerous retrospective studies reveal a consistent decrease to 15% to 60% good long term continence<sup>[39-40,50-56]</sup>. Interestingly, there is poor correlation between long term quality of life scores and fecal incontinence scores, with one study reporting that 95% of patients were satisfied with their operation a mean of 7 years following sphincteroplasty<sup>[39,53]</sup>. A summary of long term outcomes is found in Table 2. Age has long been felt to be a predictor of success of sphincteroplasty, with many studies reporting that older patients do not have as durable long term outcomes compared to younger patients<sup>[39,53,56]</sup>. However, a recent large review of 321 women who underwent sphincteroplasty showed that age is not a predictor of long term incontinence scores<sup>[57]</sup>. A review of both sphincteroplasty and sacral nerve stimulation concluded that sphincteroplasty remains a good option for the management of incontinence due to sphincter defect, despite new technologies<sup>[58]</sup>. Patients must be chosen after appropriate preoperative evaluation to achieve optimal outcomes.

# STIMULATION

#### Sacral nerve stimulation

For many patients and practitioners, sacral nerve stimulation has revolutionized the treatment of moderate to severe fecal incontinence. Adapted from its use in urinary incontinence, it may provide effective relief from fecal incontinence without any direct intervention on the anal sphincter complex. Interestingly, one study found that the only positive predictors of successful treatment with sacral nerve stimulation were loose stools and low stimulation intensity during the test phase of the procedure<sup>[59]</sup>. Conversely, age, gender, etiology of fecal incontinence, and physiology study results did not impact the efficacy of sacral nerve stimulation<sup>[59]</sup>. Though sacral nerve stimulation and sphincteroplasty have not been directly compared in the literature, numerous studies have shown that patients with sphincter defects can have excellent results with sacral nerve stimulation<sup>[60-64]</sup>. The success of sacral nerve stimulation in these patients also does not appear to be correlated to the degree of sphincter defect<sup>[63]</sup>. Pa-

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| Table 3         Studies of outcomes of sacral nerve stimulation |      |                 |  |   |  |  |  |
|---|------|-----------------|--|---|--|--|--|
| Ref.  | Year | Patients<br>(n) | Significant reduction<br>in incontinence<br>scores and<br>incontinent episodes | Significant<br>increase in<br>quality of life |  |  |  |
| Leroi et al <sup>[73]</sup>                                     | 2005 | 27              | Y  | Y   |  |  |  |
| Boyle <i>et al</i> <sup>[63]</sup>                              | 2009 | 15              | Y  | NR  |  |  |  |
| Brouwer et al <sup>[64]</sup>                                   | 2010 | 55              | Y  | Y   |  |  |  |
| Wexner et al <sup>[79]</sup>                                    | 2010 | 120             | Y  | Y   |  |  |  |
| Hollingshead<br>et al <sup>[76]</sup>                           | 2011 | 18              | Y  | NR  |  |  |  |
| Lim et al <sup>[78]</sup>                                       | 2011 | 41              | Y  | Y   |  |  |  |
| Mellgren et al <sup>[81]</sup>                                  | 2011 | 83              | Y  | Y   |  |  |  |
| George et al <sup>[77]</sup>                                    | 2012 | 23              | Y  | Y   |  |  |  |
| Devroede<br>et al <sup>[83]</sup>                               | 2012 | 78              | Y  | Y   |  |  |  |
| Hull et al <sup>[75]</sup>                                      | 2013 | 76              | Y  | Y   |  |  |  |
| Damon et al <sup>[82]</sup>                                     | 2013 | 92              | Y  | Y   |  |  |  |

Y: Yes; NR: Not reported.

tients known to have pudendal nerve injuries or previous sphincteroplasty can have good responses to sacral nerve stimulation<sup>[64]</sup>.

The mechanism by which sacral nerve stimulation improves fecal incontinence is not well defined, as it is multifactorial. A systematic review found that sacral nerve stimulation likely works in 3 ways: stimulation of a somato-visceral reflex, direct effect on the anal sphincter complex, and afferent nerve modulation<sup>[65]</sup>. It is postulated that sacral nerve stimulation may induce a change in anal sphincter muscle type from fast to slow twitch, thus reducing muscle fatigue, though this has not been definitively demonstrated in the sacral nerve stimulation population<sup>[66]</sup>. Sensory changes include the sensation of rectal filling and urge to defecate at higher rectal volume<sup>[67]</sup>. Sacral nerve stimulation alters colonic transit by inducing retrograde colonic propagating sequences, activity which may slow transit in the setting of fecal incontinence<sup>[68]</sup>. In an animal model, sacral nerve stimulation was found to increase activity in the central cerebral cortex<sup>[69]</sup>. The effects of sacral nerve stimulation are well beyond local effect on the anal sphincter complex.

There are two approaches to the implantation of the sacral nerve stimulator. Some surgeons introduce a peripheral nerve stimulator wire in the office, guided by anatomical landmarks. The patient is tested for response for a period of 1-2 wk and if good response is achieved, the permanent tined lead and stimulator device are implanted in the same setting in the operating room. The authors' preferred approach is a two-stage operative technique. The first stage is the insertion of the tined lead into the S3 foramen in the operating room with careful fluoroscopic and patient-directed guidance. Local anesthetic injections and light sedation allow the patient to signal when stimulation is felt in the perianal, perineal, or saddle regions during lead electrostimulation. In addition, sphincter bellows and plantar flexion of the great toe on the side of lead placement are used to further indication stimulation of the sacral nerve. Once a good response is achieved the lead is tunneled into position. A temporary device is used during a 2 wk test phase. If a good response is achieved during the test phase, the patient undergoes a second procedure to implant the permanent device which is attached to the tined lead. This approach is associated with very little lead migration during the test phase but does require two operations. A test phase is important in both approaches, as not all patients will have a good response to lead placement<sup>[70]</sup>. Each permanent device is programmed to the individual's response pattern. Successful strategies to prolong the durability of the device battery beyond the average of six years include cyclical stimulation and subsensory stimulation<sup>[71,72]</sup>.

Results of the first randomized multi-center study of sacral nerve stimulation were reported in 2005, showing that fecal incontinence was improved when the sacral nerve stimulator was activated<sup>[73]</sup>. Longer term results are now available. Compared to medical treatment of fecal incontinence, sacral nerve stimulation is significantly more effective<sup>[74]</sup>. A recent report from the SNS Study Group showed that in patients followed for at least 5 years, 89% have significant continued reduction in fecal incontinence and 36% had a complete response to sacral nerve stimulation<sup>[75]</sup>. Numerous other studies from around the world have demonstrated significant long term reduction in fecal incontinence scores<sup>[75-79]</sup>. Table 3 summarizes the results of studies of outcomes of sacral nerve stimulation. Furthermore, in women who have undergone sacral nerve stimulation for fecal incontinence; urinary, sexual, and vaginal symptoms also improve with a global benefit on pelvic floor health<sup>[80]</sup>. Quality of life scores are also improved in the short and long term after sacral nerve stimulation<sup>[79,81-84]</sup>.

There are potential morbidities with sacral nerve stimulation including a 5% risk of lead displacement associated with the percutaneous lead testing technique<sup>[85]</sup>. Pain at the surgical site and paresthesias are the most commonly reported complaints<sup>[81]</sup>. Infection of the permanent device or surgical site occurs in 10%, with about half of those infections requiring surgical management<sup>[81,85]</sup>. Overall, about one third of patients required surgical manipulation of the device in a study of long term outcomes<sup>[75]</sup>. Despite potential morbidity associated with the device, sacral nerve stimulation has been shown to be cost-effective in the treatment of fecal incontinence<sup>[86,87]</sup>. When balancing the effectiveness, morbidity profile, and cost-effectiveness of the technique, sacral nerve stimulation is a very valuable tool for the treatment of fecal incontinence, especially in its more severe forms.

# REPLACEMENT

#### Artificial bowel sphincter

The artificial bowel sphincter is considered only for patients with severe fecal incontinence. It is an effective device, but requires long term follow up and a motivated patient. The use of an artificial bowel sphincter requires both manual dexterity and mental capacity to operate the device<sup>[88]</sup>. Due to the high incidence of adverse events,



| Table 4         Outcomes of        | artificial b | owel sphincter |                       |  |  |
|------------------------------------|--------------|----------------|-----------------------|--|--|
| Ref.                               | Year         | Patients (n)   | Explanted devices (n) | Success (percentage of patients), intention to treat | Complications                                    |
| Lehur <i>et al</i> <sup>[93]</sup> | 2000         | 24             | 7                     | 83%  | Obstructed defecation                            |
| Altomare et al <sup>[94]</sup>     | 2001         | 28             | 3                     | 75%  | Obstructed defecation, infection, device erosion |
| Devesa et al <sup>[95]</sup>       | 2002         | 53             | 10                    | 65%  | Perforation, infection, sepsis, device erosion,  |
|                                    |              |                |                       |  | pain, impaction                                  |
| Wong et al <sup>[97]</sup>         | 2002         | 112            | 41                    | 53%  | Infection, pain                                  |
| Lehur et al <sup>[101]</sup>       | 2002         | 16             | 4                     | 69%  | Erosion  |
| Parker et al <sup>[96]</sup>       | 2003         | 45             | 18                    | 49%  | Infection, pain                                  |
| O'Brien et al <sup>[98]</sup>      | 2004         | 14             | 1                     | NR as percentage                                     | Obstructed defecation, non-healing of wound      |
| Melenhorst et al <sup>[103]</sup>  | 2008         | 33             | 7                     | NR as percentage                                     | Pain, perforation, infection, obstructed defeca- |
|                                    |              |                |                       |  | tion   |
| Ruiz Carmona et al <sup>[99]</sup> | 2009         | 17             | 11                    | 53%  | Infection, erosion                               |
| Wexner et al <sup>[90]</sup>       | 2009         | 51             | 31                    | NR as percentage                                     | Infection, malfunction, erosion, pain            |
| Wong et al <sup>[100]</sup>        | 2011         | 52             | 14                    | 67%  | Perforation, cuff leak                           |

NR: Not reported.

other treatment options should be considered and attempted before proceeding to artificial bowel sphincter<sup>[89]</sup>. Contraindications include Crohn's disease, local sepsis, prior radiation, poor quality of the perineal tissues, severe constipation, and incontinence associated irritable bowel syndrome<sup>[89]</sup>. Disruption of the anal sphincter complex due to trauma, severe obstetrical injury, and imperforate anus are common indications<sup>[89,90]</sup>. Sacral nerve stimulation and the artificial bowel sphincter have largely replaced muscle transposition and dynamic graciloplasty for the treatment of severe fecal incontinence, with better functional outcomes and quality of life parameters<sup>[91,92]</sup>. Patients must be carefully selected and extensively counselled on the risks and benefits of the artificial bowel sphincter, as discussed below.

Meticulous sterile technique and thorough bowel preparation are essential to reduce the risk of infection associated with the artificial bowel sphincter. The 3 components of the artificial bowel sphincter are connected via tubing and compose the sphincter cuff, the reservoir balloon, and control pump. These components are inserted via perineal, Pfannenstiel, and labial or scrotal incisions, respectively. The cuff itself is chosen for size based on circumferential length around the rectum and width. It is inserted first and great care is taken to ensure there is adequate tissue bulk distal to the cuff, in an attempt to avoid device erosion and infection. The balloon holds approximately 40 mL of liquid and is left filled with the device deflated at the end of the procedure after testing the control pump. The device is not activated for four to six weeks to allow for complete healing. The patient is taught how to fill and empty the cuff by using the implanted control pump.

Patients who retain the artificial bowel sphincter long term have reported very good functional and qualitative results. Manometry results show that the artificial bowel sphincter achieves normal resting tone when the cuff is filled<sup>[93]</sup>. Improved continence is achieved in over 75% of patients, with one series reporting normal continence in two-thirds of patients<sup>[94,95]</sup>. Though adverse events are

significant, patients who retain the device have excellent responses to artificial bowel sphincter implantation based on incontinence scores<sup>[93-100]</sup>. Quality of life scores are also markedly improved after successful treatment of fecal incontinence with the artificial bowel sphincter<sup>[96,98,99,101]</sup>. A systematic review of the safety of the artificial bowel sphincter noted that functional outcomes and quality of life scores for those patients who do not retain a functioning device are not reported in the literature<sup>[102]</sup>.

Complications following artificial bowel sphincter implantation unfortunately remain high and often lead to device explantation, mitigating the overall population benefit in fecal incontinence. Unfortunately, these complications continue to accrue long term<sup>[90]</sup>. The rate of revision of the device has been reported to be up to 50%, with infection and device failure the most common reasons<sup>[100]</sup>. About 25%-40% of artificial bowel sphincters become infected over time<sup>[90,100,103]</sup>. Erosion of the cuff or control pump and post-operative constipation may also occur<sup>[92,104,105]</sup>. The outcomes and complications associated with the artificial bowel sphincter are included in Table 4. In summary, a balanced consideration of potential benefits and adverse events is important and artificial bowel sphincter may still be the optimal treatment consideration for select patients with severe fecal incontinence.

#### Muscle transposition

Muscle transposition is a technique used to physically replace the sphincter with *in vivo* muscle bulk. It is most often used in the setting of a traumatic or iatrogenic disruption of the anal sphincters to recreate a wrap of muscle around the anus. A substantial congenital or posttraumatic defect is indicated to consider muscle transposition. The two muscles widely described in the literature for transposition are the gluteus maximus and gracilis muscles. These are useful because of their proximity to the anus, sizeable muscle bulk, and nerve locations which are amenable to preservation upon transposition. In addition, the gluteus maximus was thought to be a good

| Table 5 Outcomes of graciloplasty |      |                       |                 |  |  |  |  |
|-----------------------------------|------|-----------------------|-----------------|--|--|--|--|
| Ref.                              | Year | Type of graciloplasty | Patients<br>(n) | Success<br>(percentage of<br>patients) |  |  |  |
| Kumar et al <sup>[114]</sup>      | 1995 | Unstimulated          | 9               | 100%                                   |  |  |  |
| Eccersley et al <sup>[113]</sup>  | 1999 | Unstimulated          | 8               | 100%                                   |  |  |  |
| Madoff et al <sup>[109]</sup>     | 1999 | Stimulated            | 128             | 66%                                    |  |  |  |
| Wexner et al <sup>[110]</sup>     | 2002 | Stimulated            | 115             | 62%                                    |  |  |  |
| Bresler et al <sup>[112]</sup>    | 2002 | Stimulated            | 24              | 79%                                    |  |  |  |
| Rongen et al <sup>[111]</sup>     | 2003 | Stimulated            | 200             | 72%                                    |  |  |  |
| Thornton et al <sup>[117]</sup>   | 2004 | Stimulated            | 38              | 73%                                    |  |  |  |
| Hassan et al <sup>[107]</sup>     | 2010 | Stimulated            | 31              | 71%                                    |  |  |  |

choice for transposition given that involuntary gluteal contraction occurs with the strong urge to avoid involuntary defecation<sup>[106]</sup>.

The surgical technique of muscle transposition is complex and requires significant experience to gain expertise. Three main options exist: gluteoplasty, graciloplasty, and dynamic (or stimulated) graciloplasty. Gluteoplasty is performed with the patient in the prone position with the table flexed at the hips. Bilateral incisions over the gluteus are made and two tongues (one from each side) of the lower 10% of the muscle are raised with care taken to preserve the neurovascular bundles<sup>[106]</sup>. The mobilized muscle is then tunnelled and delivered through separate bilateral curvilinear incisions around the anus. The contralateral mobilized segments are sutured together to create a ring of muscle.

In a graciloplasty procedure, the patient is placed in the modified lithotomy position. Two or three incisions are made along the longitudinal access of the gracilis muscle on the chosen side to harvest the entire length of the gracilis. The neurovascular bundle is preserved through its identification during medial dissection. The muscle is released distally and tunneled medially. A perineal incision is made and the gracilis is wrapped circumferentially around the anus. In the dynamic graciloplasty technique, an electrode is placed in the gracilis muscle and an implantable device similar to that used for sacral nerve stimulation is implanted in the abdominal wall. Modified approaches to dynamic graciloplasty include temporary stimulation with an external stimulator for muscle retraining, similar to biofeedback<sup>[107]</sup>. It must be noted that the stimulator and leads for dynamic graciloplasty are not currently approved for use in North America.

Much like the artificial bowel sphincter, muscle transposition has fairly good functional outcomes but high rates of complications and re-operation; graciloplasty has largely replaced gluteoplasty. The largest and most recent study of gluteoplasty reported a good functional outcome in 59% of patients<sup>[108]</sup>. Successful functional outcomes for gracilplasty, dynamic and unstimulated, is consistently reported to be about 60%-75%, with earlier success of unstimulated graciloplasty being even higher<sup>[107-114]</sup>. Table 5 lists the published success rates of graciloplasty. If a patient has a stoma at the time of the graciloplasty, eventual outcomes are equivalent to those

who do not have a stoma, but are delayed in achieving them<sup>[110]</sup>. Complications of the procedure are common, and include surgical site infections, pain, rectal injury, and erosion of the device in the case of dynamic graciloplas-ty<sup>[112,115,116]</sup>. In addition, constipation due to obstructed defecation is commonly reported in as many as 50% of patients<sup>[115-117]</sup>. There are no studies directly comparing muscle transfer to other surgical treatments of fecal incontinence. Graciloplasty followed by artificial bowel sphincter implantation may be the best combination option for adult patients with fecal incontinence attributable to congenital imperforate anus<sup>[118]</sup>.

# DIVERSION

#### Antegrade continence enema

The antegrade continence enema was first described by Malone et al<sup>[119]</sup> in 1990. It is used to control fecal soiling in both adults and children, but is most commonly used and reported in the pediatric population. Neurogenic conditions, such as spina bifida, resulting in neurogenic bowel and urinary symptoms are the most common indications in children. While the antegrade continence enema may be helpful in pure fecal incontinence, most often patients who undergo this procedure have the combination of constipation or colonic dysmotility with associated overflow fecal incontinence. Patients also commonly undergo urological procedures at the same time to control neurogenic bladder symptoms, with good results for these combined indications<sup>[120]</sup>. In adults, good functional outcomes are better in this setting, when compared to those patients who undergo the procedure for constipation alone<sup>[121]</sup>. While an antegrade continence enema does not alter anorectal physiology or anatomy, it provides a mechanism to empty the colon in a controlled fashion, allowing the patient to perform their daily activities with little worry of fecal soiling or incontinent episodes.

Since Malone's original description, various techniques have been described for the creation of an antegrade continence enema. The appendix, ileum, cecum, and left colon may be used successfully as the access point for irrigation<sup>[122-124]</sup>. The appendix is most commonly used, where it is inverted and fixated to the skin at the umbilicus or right lower quadrant. This can be performed open or laparoscopically with good results<sup>[124]</sup>. The access point is left intubated with a catheter for about 3 wk after the operation before intermittent intubations begin. Patients or their caregivers then intubate the bowel daily to every few days and perform colonic irrigation with tap water or an electrolyte or bowel cleansing solution. Both tap water and commercial products have good irrigation results, with solution irrigants achieving slightly better continence rates<sup>[125]</sup>. The volume of irrigation is gradually increased over time after the procedure and the timing and frequency of irrigation through the site may be largely patient directed. In the pediatric patient population, the operation is performed around the age of 10 years.

Few studies report on outcomes of antegrade con-



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| Table 6    | Outcomes | of | antegrade | continence | enema | in |
|------------|----------|----|-----------|------------|-------|----|
| incontinen | t adults |    |           |            |       |    |

| Ref.                                  | Year | Patients using<br>antegrade<br>continence enema<br>on follow-up | Percentage<br>of patients<br>achieving<br>continence | Complication<br>rate |
|---------------------------------------|------|---|--|----------------------|
| Gerharz et al <sup>[121]</sup>        | 1997 | 8   | 100%   | 44%                  |
| Teichman et al <sup>[120]</sup>       | 1998 | 7   | 86%  | 71%                  |
| Teichman et al <sup>[128]</sup>       | 2003 | 4   | 75%  | 67%                  |
| Lefevre et al <sup>[127]</sup>        | 2006 | 18  | 94%  | 33%                  |
| Poirier <i>et al</i> <sup>[126]</sup> | 2007 | 14  | 78%  | 67%                  |

tinence enemas in adults. Overall, functional results are very good, with about 75% of adults achieving continence with the procedure<sup>[126-128]</sup>. Quality of life improves in adult patients with antegrade continence enemas, although not all patients continue to use their antegrade continence enema in the long term<sup>[127,128]</sup>. See Table 6 for a summary of antegrade continence enema study results. In children, full continence is achieved in 65%-100% of patients<sup>[122,125,129-133]</sup>. Even though the amount of time devoted to bowel care may not significantly change, satisfaction and quality of life scores improve for most children and parents<sup>[131,134-137]</sup>. Persistent leakage, stoma stenosis, and surgical site infections are common complications, with one study quoting a 13% chance of requiring stoma revision due to stoma complications<sup>[130,131,138]</sup>. While the antegrade continence enema is not commonly performed in adults, the patients who have grown to adulthood require long term follow up and attention to these possible complications.

### Fecal diversion

The creation of a colostomy or ileostomy provides definitive control of fecal incontinence. An ileostomy may be considered in patients with colonic transit abnormalities but the colostomy is the standard ostomy utilized in the treatment of fecal incontinence. In many patients the ostomy can be created using a laparoscopic approach to improve recovery time. While a colostomy is not without short and long term risks, such as bleeding, anesthesia related cardiac or respiratory morbidities, and parastomal hernia, it is a safe and effective treatment of severe fecal incontinence. It is generally only offered if other treatment modalities have failed. Patients are usually understandably very resistant to the idea of a permanent colostomy, fearing it will be difficult to manage and have great impact on self-image and social interactions.

When patients who had undergone colostomy creation for fecal incontinence were surveyed, general quality of life and fecal incontinence quality of life scores were actually higher in the colostomy group when compared to other patients with fecal incontinence<sup>[139]</sup>. Another study found that patients generally reported high satisfaction levels with their stomas for fecal incontinence, with over 80% of patients stating that they would likely or definitely choose to undergo the procedure again<sup>[140]</sup>. Compared to other surgical treatments of sever incontinence (dynamic

# Table 7 Outcomes of radiofrequency energy treatments

| Ref.                                       | Year | Patients<br>(n) | Significant<br>improvement in<br>incontinence scores<br>after treatment | Significant<br>improvement<br>in quality of<br>life |
|--|------|-----------------|---|---|
| Efron et al <sup>[143]</sup>               | 2003 | 50              | Y   | Y   |
| Felt-Bersma et al <sup>[147]</sup>         | 2007 | 11              | Y   | NR  |
| Takahashi-Monroy<br>et al <sup>[142]</sup> | 2008 | 19              | Y   | Y   |
| Lefebure <i>et al</i> <sup>[144]</sup>     | 2008 | 15              | Y   | Ν   |
| Kim <i>et al</i> <sup>[148]</sup>          | 2009 | 8               | Ν   | Ν   |
| Ruiz et al <sup>[145]</sup>                | 2010 | 24              | Y   | Y   |
| Abbas et al <sup>[146]</sup>               | 2012 | 27              | Y   | NR  |

Y: Yes; N: No; NR: Not reported.

graciloplasty and artificial bowel sphincters), a British study found colostomy to be most cost effective in terms of quality adjusted life years<sup>[92]</sup>. While fecal diversion is not required in the majority of patients presenting for treatment of fecal incontinence, it is a viable, definitive, and well-tolerated treatment which offers good quality of life.

# AUGMENTATION

#### Radiofrequency energy

There is a gap between medical and surgical treatment options in fecal incontinence<sup>[141]</sup>. Radiofrequency energy delivery and injectable materials are becoming increasingly popular as minimally invasive procedural treatments that may bridge this gap. The delivery of radiofrequency energy to the internal anal sphincter, known as the SECCA<sup>®</sup> procedure, is proposed to induce local restructuring of collagen, leading to a more robust internal anal sphincter and better continence. It can be used for patients with mild or moderate fecal incontinence who are unwilling or not candidates to undergo surgical treatment after failing medical management. It may also be applied to patients with idiopathic or sphincter defect-associated fecal incontinence.

The technique of radiofrequency energy delivery is simple. It is done with conscious sedation and local anesthesia on an outpatient basis in endoscopy or the operating room. A commercial device is utilized and the procedure takes about 30 min. The device resembles a clear plastic anoscope with four retractable needles. The needles are electrodes which are deployed into the anorectal mucosa to deliver radiofrequency energy to the internal anal sphincter, starting just distal to the dentate line and moving proximally. The device delivers radiofrequency while simultaneously monitoring the temperature and impedance of the tissues to avoid burning. The device is activated four or five times per quadrant of the anorectum, moving 5 mm more proximal before each activation in a quadrant. The machine provides constant feedback on the contact with the tissues, temperature and impedance during the device activation, and the timing of each activation, giving visual and sound cues to the surgeon



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| Table 8 Outcomes of dextranomer in hyaluronic acid gel for fecal incontinence |      |                 |  |   |  |  |  |  |
|---|------|-----------------|--|---|--|--|--|--|
| Ref.  | Year | Patients<br>(n) | > 50% reduction<br>in fecal incontinence<br>episodes (percentage<br>of patients) | Significant<br>quality of life<br>improvement |  |  |  |  |
| Dodi et al <sup>[150]</sup>   | 2010 | 115             | 64%  | Yes   |  |  |  |  |
| Graf et al <sup>[161]</sup>   | 2011 | 136             | 52%  | Yes   |  |  |  |  |
| Schwandner et al <sup>[159]</sup>   | 2011 | 21              | 56%  | Yes   |  |  |  |  |
| Danielson et al <sup>[160]</sup>  | 2012 | 34              | 76%  | Yes   |  |  |  |  |
| La Torre <i>et al</i> <sup>[156]</sup>  | 2013 | 83              | 63%  | Yes   |  |  |  |  |

throughout the procedure.

Reports of the success of radiofrequency energy treatment are generally, though not universally, positive and are summarized in Table 7. Numerous studies have reported long term improvement in fecal incontinence scores<sup>[142-145]</sup>. The cohort with the longest reported follow-up showed a durable reduction in mean Wexner fecal incontinence scores from 14 to 8 and found that most participants had a greater than 50% improvement in symptoms after 5 years<sup>[142]</sup>. Similarly, patient satisfaction and quality of life scores show improvement after radiofrequency energy treatment<sup>[142-145]</sup>. Another study with a higher average baseline fecal incontinence score compared to other trials found that only 22% of patients had sustained treatment benefits at an average follow up of 40 mo<sup>[146]</sup>. Despite the overall favorable outcomes of radiofrequency energy delivery, anal manometry testing does not show any significant change in physiologic parameters<sup>[143,147,148]</sup>. No major adverse events have been reported following radiofrequency energy delivery, though there have been reports of infection, hematoma, minor bleeding, and anal pain<sup>[145,147,148]</sup>.

### Injectable materials

Various injectable materials have included trialed for local injection of the sphincter complex to treat fecal incontinence. Benefits of this approach are that it is an outpatient procedure with little discomfort that has low morbidity. The materials used have included collagen, silicone, autologous fat, glutaraldehyde, carbon-coated beads, dextranomer in hyaluronic acid gel, and others<sup>[149]</sup>. Dextranomer in hyaluronic acid gel (NASA/Dx) has received the most extensive recent investigation and attention in the literature. Injectables may be used in patients who have failed medical treatment and have fecal leakage or mild to moderate fecal incontinence<sup>[149]</sup>. The bulking effect may not be permanent and may require repeat injections at subsequent office visits.

The technique of injection is relatively simple. The open-label multicenter trial of NASHA/Dx involved four quadrant injections of 1 mL of NASA/Dx into the deep submucosa of the anal canal<sup>[148]</sup>. This was performed through an anoscope and done with the patient in the prone jack-knife or lithotomy positions. The injections were placed at a 30 degree angle 5-10 mm proximal to the dentate line<sup>[150]</sup>. The needle was kept in place for

up to 30 s so that the gel would not leak from the site<sup>[150]</sup>. There are very few comparative trials amongst injectable materials. A small study of 40 patients found that silicone was more effective than carbon-coated beads to reduce incontinence<sup>[151]</sup>. No published studies have compared NASHA/Dx with other injectables. One randomized controlled trials comparing NASHA/Dx to biofeedback and found no significant difference in functional outcomes<sup>[152]</sup>. Biofeedback, however, certainly requires more dedication and long term commitment from the patient. The effect of injectables on manometry parameters are an increase in the length of the high pressure zone and asymmetry index<sup>[153]</sup>. The impact on resting pressure is variable in the literature, ranging from improvements in resting pressure to no effect<sup>[153,154]</sup>.

There are no long term outcomes reported yet for NASHA/Dx, the most popular injectable. The longest reported outcomes are at 2 years<sup>[155,156]</sup>. A Cochrane review published in 2013 noted the absence of long term studies, making definitive conclusions about the utility of injectables difficult<sup>[157]</sup>. See Table 8 for a summary of cohort studies investigating the utility of NASHA/Dx gel. A good response is considered a 50% reduction in the number of reported incontinence episodes, which is reported to occur in over 50% of patients who have been treated with injectables<sup>[150,154,156,158-161]</sup>. In addition, the majority of patients have good quality of life improvement, as reported on both global quality of life and fecal incontinence quality of life scores<sup>[150,155,156,158]</sup>. Morbidity from the use of injectables is low, with fever and proctalgia being the two most common adverse events and bleeding, abscess, and pain being other rare reported events<sup>[150,156,160,161]</sup>. Though many patients with fecal incontinence may be candidates for the use of injectables, the ideal candidate is one who has seepage or mild to moderate incontinence who has failed medical management but is not yet ready to pursue surgical treatment. Prior use of an injectable such as NASHA/Dx does not preclude future surgical treatments such as sacral nerve stimulation, sphincteroplasty or artificial bowel sphincter.

### CONCLUSION

Successful treatment of fecal incontinence requires careful consideration of the individual patient's severity of incontinence. Treatments range from inexpensive medications and physical therapy to complex surgical procedures such as artificial bowel sphincter implantation and muscle transposition. In general, more invasive treatments are required for more severe incontinence or after less invasive treatments have failed. A careful history including obtaining an incontinence score, physical examination, bowel diary, and adjunctive anal physiology tests should be utilized to define the nature of the fecal incontinence. Minimally invasive approaches including biofeedback, radiofrequency energy, and injectables have moderate long term success. Sphincteroplasty remains an acceptable option for patients with documented sphincter defects. Be-

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cause initially adequate functional outcomes decline over time, quality of life improvement after sphincteroplasty is not robust long-term. Sacral nerve stimulation is very effective in managing moderate to severe fecal incontinence and has had a great impact on the treatment of fecal incontinence. In the very long-term, patients will require additional procedures to change the battery of the sacral nerve stimulator but the procedure has excellent reproducible long term functional and quality of life outcomes. The artificial bowel sphincter has similar outcomes in those patients who retain the device, but further studies aimed at reducing infection, erosion, and device failure must be undertaken. Fecal diversion remains a good option for severe fecal incontinence and actually provides the patient with satisfying quality of life. Knowledge of these currently used treatments is essential to honest and thorough counseling of the patient with fecal incontinence to improve treatment success. Together with the patient, the surgeon can then best select treatment from the five available categories of repair, replacement, augmentation, stimulation, and diversion.

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