11 Treatment for Fecal Incontinence: Nonsurgical Approaches

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Case Scenario

A 68-year-old woman presents to the office with complaints of urgency and inability to hold her bowel movements. She reports that she has soiled undergarments intermittently during the past 2 months, prior to which time, she had no bowel control problems. She notes that her stools have been more irregular and less formed. She has had two vaginal deliveries in her early 30s and no previous anorectal surgeries. She denies urinary incontinence or inability to control flatus.

Introduction

Fecal incontinence (FI) is the uncontrolled passage of feces or gas in an individual age ≥4 years old who has previously attained control, lasting for greater than 1 month [1]. The reported rates of fecal incontinence vary, depending upon the population that is examined. In the general population, the rates of fecal incontinence range between 1.4% and 18%, with the rates being higher in the elderly and in institutionalized populations. In the elderly, the prevalence is approximately 15%, whereas incontinence may affect up to 50% of institutionalized patients [2–7]. In addition, fecal incontinence is more prevalent among individuals with inflammatory bowel disease, celiac disease, irritable bowel syndrome, or diabetes than people without these disorders [7]. The largest household survey revealed that 18% of adult women had experienced at least one episode of fecal incontinence during the year prior to the survey [8].

Fecal continence is a complex condition. It requires coordinated interplay among rectal capacity, sensation, and neuromuscular function. Alterations in factors such as stool consistency, stool volume, rectal distensibility, colonic transit, anorectal sensation, anal sphincter function, and anorectal reflexes can all contribute to the development of fecal incontinence [9]. Because of this complexity, when evaluating a patient for fecal incontinence, risk factors for fecal incontinence should be elucidated. Risk factors include pregnancy, chronic diarrhea, diabetes, smoking, previous anorectal surgery, obesity, urinary incontinence, neurologic disease [2, 10]. Obstetric history is important to determine if there has been injury to the sphincters, which is overtly identified in 10% of vaginal deliveries. Up to 35% of vaginal deliveries will have occult

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injuries to the anal sphincters. Often times, there will be a long delay between onset of symptoms and the injury due to compensatory mechanisms [1, 11].

Classification of Fecal Incontinence

Many scoring systems have been developed to describe and measure the type, amount, frequency, and impact the incontinence has on a patient. The use of these scoring systems or grading scales is to help to quantify the severity of the incontinence and to select patients for treatment as well as to measure response to treatment. The authors utilize the validated Cleveland Clinic Florida Fecal Incontinence Score (CCF-FIS) [12]. The CCF-FIS factors in frequency as well as type of incontinence (liquid, sold, or gas), the impact on the patient's lifestyle, and whether the patient wears a pad (Table 11.1). It has been validated in multiple languages and is the most widely cited FI score in the world's literature. In addition, there is statistically significant correlation between the CCF-FIS and quality of life [13, 14].

In addition to scoring systems, fecal incontinence can be stratified based upon etiology of the disease in order to better understand and treat the fecal incontinence. These two groups are as follows: (1) fecal incontinence with normal pelvic floor, and (2) fecal incontinence with abnormal pelvic floor (Table 11.2) [9].

Patients with fecal incontinence who have a normal pelvic floor include elderly patients. The mechanism of incontinence is usually a chronic history of straining with subsequent injury to the pudendal nerve. Neurogenic cause of fecal incontinence is due to disturbance of motor and sensory nerve innervation of the sphincters and rectum, in the case of CNS or spinal cord disorders resulting from congenital, traumatic, or infectious causes. In patients with idiopathic incontinence, who have no structural abnormalities, it is also thought that neurologic damage results in abnormal sensation in the anal canal and rectum, causing incontinence [15, 16]. Patients with gastrointestinal diseases such as chronic diarrhea, inflammatory bowel disease, infectious colitis, and laxative abuse general also have a normal pelvic floor. Incontinence develops due to interference from these diseases in the sphincter function as well as loss of reservoir function of the rectum. History of pelvic radiation may also result in proctitis and reduced reservoir function of the rectum, leading to fecal incontinence. Patients with overflow incontinence due to fecal impaction and seepage of liquid stool around the impacted stool also fall under this category of normal pelvic floor.

Patients with fecal incontinence who have an abnormal pelvic floor tend to have a structural abnormality, whether it is congenital, due to trauma, due to prolapse or previous anorectal surgery. For example, patients with imperforate anus and subsequent surgical repair can develop fecal incontinence. Patients with previous anorectal surgeries such as lateral internal sphincterotomy, hemorrhoidectomy, or fistula surgery may have sphincter damage, resulting in incontinence. Trauma from childbirth or other source can disrupt the sphincter mechanism, leading to incontinence. Full-thickness rectal prolapse can also cause internal and external sphincter damage due to chronic dilation, as well as pudendal nerve injury.

Table 11.1 Cleveland Clinic Florida FecalIncontinence Score (CCF-FIS)

Type of incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle modification	0	1	2	3	4

Never, 0; Rarely, < 1/mo; Sometimes, < 1/d, ≥ 1/mo; Usually, <1/d, ≥ 1/wk; Always. > 1/d

Table 11.2 Stratification of fecal incontinence patients

Fecal incontinence	
With normal pelvic floor	With abnormal pelvic floor
Aging	Anorectal surgery
Gastrointestinal pathologies	Childbirth
Irradiation	Trauma
Neurogenic causes	Congenital abnormalities
Overflow incontinence and soiling	Procidentia
Idiopathic incontinence	

Approaches to Fecal Incontinence

Nonoperative Management

Medical Management

A large component of nonoperative management is medical management geared at efforts to improve stool frequency and consistency, provide skin protection, strengthen the pelvic floor and the sphincters as well as improving sensation. Appropriate medical management can improve symptoms in many patients, potentially avoiding surgical intervention.

Fecal seepage and soilage can be detrimental to the perianal skin. Wearing pads with polymers can provide skin protection by wicking moisture away from the skin as well as protection for clothing [17]. Skin irritation from fecal soilage can also be tempered with barrier creams such as zinc-oxide-containing agents such as calmoseptine [18].

Fecal incontinence may be directly related to stool consistency, such as in patients with chronic diarrhea. The treatment in this case is to treat the underlying cause (in the case of inflammatory bowel disease or infectious causes) and modify the stool consistency (when other causes have been ruled out). Patients should be instructed to use a diary in order to identify and eventually avoid triggers and aggravating factors for their fecal incontinence. This detailed log and systematic changes can impact their bowel function and thereby fecal control. Example of dietary components that are often culprits with regard to diarrhea include caffeine, lactose, and sugar substitutes [19]. Fiber supplementation such as psyllium can be used as a bulking agent for the stool, in addition to antidiarrheal agents once other causes have been ruled out. Loperamide is often preferred as the first-line antidiarrheal treatment, because it does not have an effect on the central nervous system [20–22]. Diphenoxylate and codeine can also be added as stronger antidiarrheal agents but have central nervous system effects. These treatments decrease intestinal fluid secretion and slow down the colonic transit time, allowing for increased water absorption [23, 24]. In the case of patients with irritable bowel syndrome that causes diarrhea, bile acid sequestrants such as colestipol or colesevelam may be helpful. This is based upon observations that a subset of these patients has bile acid malabsorption [25]. Tricyclic antidepressants are also known to inhibit intestinal motility as well as inhibit sphincter relaxation [26]. More recently, clonidine has been used in fecal incontinence as it is thought to reduce rectal sensation and urgency [27, 28].

In patients with overflow incontinence associated with fecal impaction, management is with disimpaction and colonic cleansing. Subsequently, a consistent bowel regimen needs to be implemented to prevent recurrence. The patient needs scheduled defecation with the addition of fiber supplementation, regular sufficient water intake as well as stool softeners and laxatives, such as docusate, polyethylene glycol, and bisacodyl.

Behavioral modification is another cornerstone of medical management. Manometric or electromyography (EMG) – assisted biofeedback – is a specialized technique geared at strengthening the external anal sphincter muscle as well as the puborectalis, much like Kegels exercises, but in addition to muscle strengthening, the patient works toward enhancing rectal sensation so that progressively smaller volumes of distension will trigger the threshold of rectal sensation and shorten the response time between perception of rectal distension and voluntary contraction of the external anal sphincter [18]. Data from a randomized controlled trial suggests that manometric biofeedback is superior to Kegels exercises alone [29].

Many patients with fecal incontinence do respond well to medical management with phar-

macologics, lifestyle modification, and biofeedback therapy. However, further evaluation is needed with the more invasive interventions outlined below for patients who do not respond to these conservative approaches,

Augmentation

Methods for augmentation are described in Chap. 14.

Inserts

Insertable devices have been developed to aid in the treatment of fecal incontinence. The vaginal bowel control device is a vaginal inflatable balloon and pump system that is fitted to each woman. The vaginal insert is a dynamic, low-risk, reversible, patient-controlled device that is deflated to allow for bowel movements and inflated to prevent stool leakage. A small multicenter prospective study of 61 patients showed a 50% reduction in episodes and no adverse events, with 41% of patients achieving complete continence [30–33]. Currently, there is an ongoing multicenter trial to evaluate the durability and long-term safety of the device.

Anal insert devices have also been used to aid in the treatment of fecal incontinence. Their use is limited as it is often difficult to tolerate [34]. A multicenter prospective study with a single arm cohort showed a 50% improvement in continence, with minor adverse side effects including sensation of urge 26%, displacement up into rectum 24%, irritation 13%, pain 7%, and soreness 6% [35]. Long-term efficacy data and comparative data to other modalities of treatment are still needed.

Overview of Surgical Interventions for Fecal Incontinence

Neuromodulation

Percutaneous Tibial Nerve Stimulation (PTNS) and Transcutaneous Tibial Nerve Stimulation (TTNS)

Given the success of SNS in the treatment of FI with modulation of the S3 nerve root, peripheral tibial nerve stimulation (PTNS and TTNS) has been investigated for treatment of fecal incontinence. The tibial nerve has afferent and efferent fibers originating from L4-S3 nerve roots. Therefore, it is thought that tibial nerve modulation may lead to alterations in anorectal neuromuscular function, much like SNS. TNS is nonsurgical and thereby less invasive than SNS. There are two main methods of delivering outpatient TNS treatments: percutaneous and transcutaneous. With PTNS, a needle is placed superior to the medial malleolus near the tibial nerve in the ankle and electrical stimulation is given via the needle. TTNS involves two pad electrodes placed above the medial malleolus over the tibial nerve. Outpatient treatment protocols for both PTNS and TTNS can vary in frequency and duration. Studies have shown that although TTNS resulted in improvements in some outcome measures for fecal incontinence, it is not superior to sham simulation in a large adequately powered randomized control trial [36]. With regard to PTNS efficacy, results of studies are equivocal with only one study showing statistically significant improvement in incontinence at 6 months, whereas other trials show no difference between the sham and PTNS groups when treated for shorter periods of time [3–39]. Data from the Control of Fecal Incontinence using Distal Neuromodulation Trial demonstrated no significant clinical benefit of percutaneous tibial nerve stimulation (PTNS) compared to sham stimulation in patients with fecal incontinence (FI) much like TTNS. However, reanalysis of the primary outcome excluding patients with obstructive defecation symptoms resulted in a significant clinical effect of PTNS compared to sham (48.9% vs. 18.2% response, $P = 0.002$; multivariable OR, 4.71; 95% CI, 1.71–12.93; $P = 0.003$) [40]. These data suggest that patient selection may be a key factor in the successful implementation of tibial nerve stimulation for fecal incontinence.

Fecal Diversion

In patients who have failed alternative therapies for fecal incontinence, fecal diversion with a well-created stoma at an optimal site is a surgical option. Studies show that the majority of patients

who underwent stoma creation for fecal diversion for fecal incontinence had a significant improvement in their quality of life [41, 42].

Injectables

Bulking agents in the form of biomaterial injectables may be a viable option for the above patient with minor FI in order to augment passive outlet resistance. The method of injection is dependent on the agent of choice; final sites of implantation may include submucosal, intersphincteric, or intrasphincteric and the route of injection may be transmucosal, transsphincteric, or intersphincteric. Local anesthetic and/or endorectal ultrasound may be used to assist in the injection of the agent.

The use of injectable polytetrafluoroethylene was initially described in the 1990s when traditional bulking agents such as carbon, collagen, and fat demonstrated poor long-term results. Newer agents such as NASHA Dx, PTQ™ (a biocompatible silicone implant), and Durasphere™ (carbon-coated beads) are the most common injectables used worldwide; however, only NASHA Dx or Solesta® is FDA approved for use in FI in the USA [32]. NASHA Dx or nonanimal stabilized hyaluronic acid/dextranomer has been used for years as a bulking agent for urological procedures. The injection is typically performed in the office, with the patient either in left lateral or prone position. The anal canal is divided into four quadrants and using an anoscope, 1 mL of the bulking agent is injected into the deep submucosa of each of the quadrants. After injection, the needle is retained within the submucosa space for 10 seconds in order to avoid leakage through the puncture site. The use of NASHA Dx has been shown to reduce the number of FI episodes by at least 50% in 52% of patients versus a similar reduction rate in only 31% of the placebo group [43]. NASHA Dx was used in patients with moderate FI and the 36-month follow-up demonstrated a sustained reduction with significant improvement in quality-of-life measures. The percentage of patients who experienced complete continence doubled from 6% at 6 months to 13.2% at 36 months [44]. The authors contend that these results are due to the durable composition of NASHA Dx and the lack of migration resulting from its particle size.

Complications with injectable bulking agents are generally minimal and short-lived. Pertaining to NASHA Dx injections, the most commonly reported adverse events include proctalgia, rectal bleeding, diarrhea, constipation, and fever. Rare and serious adverse events include abscess development. Though these results are encouraging and are supported by other prospective trials, it should be noted that repeat injections were necessary in most patients in order to achieve such outcomes [31, 44–47]. As such, other agents are currently being explored in order to improve long-term outcomes and include stem cells and the use of self-expandable agents.

One such self-expandable agent being investigated is the Gatekeeper™ prosthesis. It is made of the inert polymer resin polyacrylonitrile and was originally intended for use to bulk the lower esophageal sphincter in the setting of gastric reflux. For FI, the material is implanted in six locations circumscribing the intersphincteric space using a specially designed delivery system. The resin material reshapes to its environment by water absorption over time and thus is purported as an ideal bulking agent. One multicenter observational study performed in Europe demonstrated greater than 75% improvement in all FI parameters at 12 months, with 13% of patients reporting full continence during the same timeframe [48]. Another observational study noted that those of whom responded to the treatment initially will likely sustain a response and demonstrate greater than 50% improvement in FI scores from baseline at least at the one-year interval [49]. The primary issue with this product is prosthesis migration with reported rates ranging from 5% to more than 50%. One small study demonstrated by endorectal ultrasound at 3 months after injection that more than half of the implanted material had migrated, though they noted no significant clinical change in their patients' FI [50]. Other risks associated with this product include pain, infection that may require removal, and dislodgement

that may require extraction and/or replacement. Unfortunately, the Gatekeeper™ is currently not an available option in the USA.

Radio-frequency Tissue Remodeling

Radio-frequency tissue remodeling is a therapeutic option for mild-to-moderate FI with intact or limited sphincter defect (less than 30°) who failed conservative management and are seeking less invasive treatments. Using the SECCA® anoscope containing nickel-titanium needles, radio-frequency energy is delivered into the internal anal sphincter to approximately 85 °F in order to induce higher passive outlet resistance through remodeling in collagen deposition and thickening of the muscularis propria. Needle insertion is repeated at several levels within the upper anal canal. The specialized anoscope can detect impedance and self-thermoregulates so that it does not induce burning. This is a minimally invasive outpatient procedure that can be performed either in the operating room or in the endoscopy suite. Complications may include pain, bleeding/hematoma, infection, diarrhea, and mucosal ulceration. Though extremely rare, it also has the potential to cause rectovaginal fistula due to anterior penetration of the thermoneedle in females, especially in the presence of rectocele. Patients who have undergone biomaterial injections are excluded from radio-frequency tissue remodeling. The mechanisms of action have been elegantly delineated.

Efron et al. published the initial prospective multicenter study in the US of 50 patients (43 women) with long-standing FI who underwent radio-frequency tissue remodeling [51]. At 6 months, the mean CCF-FIS significantly improved from 14.5 to 11.1. Whereas the FI of 11.1 is considered moderate in severity, patients experienced significant improvement in quality of life. While the above study remains the largest study to date, there were other smaller sample studies on the use of radio-frequency tissue remodeling in the late 2000s through early 2010s [52–55]. Most report significant improvement in FI scores at 6-month or 12-month follow-up with the exception of one study [54]. Three of the four studies assessed for whether improvement in incontinence affected quality of life and were split in terms of whether it actually did or not [53–55]. Interestingly, one study reported that while there was a significant improvement in FI, there was no significant change in the anal manometry and rectal compliance of these patients at 3 months [52]. They suggested that there may be a tendency toward increased rectal sensitivity related to urge and the maximal tolerated volume, as a potential contributor to improvements in reported scores. Reported long-term results were variable, in terms of duration of the improvement in FI. Despite an initial response of 78% to treatment, Abbas et al. reported that over 50% of the patients required or were waiting for additional intervention at a mean follow-up time of 40 months. Another study noted that only 6% of their patients maintained their results in the same time interval [56, 57]. The longest follow-up to date was at 5 years by Takahashi-Monroy et al. and they noted significant clinical improvement in FI scores that persisted to 5 years, as well as improvements in quality-of-life measures especially in the social functioning and mental components [58]. More recently, a small study comparing radio-frequency tissue remodeling versus sham control showed no difference in quality-of-life scores and anorectal function at 6 months [59]. Table 11.3 depicts the results of different studies. Despite these varying outcomes, radio-frequency tissue remodeling may still be a worthwhile procedure for those who have failed other options, given its low rate of serious complications.

Case Discussion (Fig. 11.1)

The first step in evaluation of our patient is a detailed history of her incontinence episodes, diet, medications, comorbidities, obstetric history, and bowel habits. A digital rectal exam is performed, taking note of whether there is fecal impaction, and her resting sphincter tone and ability to squeeze. If there is no anorectal pathology on examination, such as rectal prolapse, anal

Table 11.3 Outcomes for SECCA

Author	*n*	Follow-up (months)	Fecal incontinence	Improvement
Takahashi [60]	10	12	CCF: – 13.5–5	80%
Takahashi [61]	10	24	CCF: 13.8–7.8	70%
Efron [51]	50	6	CCF: 14.6–11.1	60%
Felt-Bersma, [52]	11	12	Vaizey 18.8–11.5	55%
Takahashi, [58]	19	60	CCF: 14.3–8.26	84%
Lefebure [53]	15	12	14–12.3	13%
Kim [54]	8	6	CCF: 13.6–9.9	–
Walega [62]	20	6	CCF: 12.1–9.3	68%
Ruiz [55]	16	12	CCF: 15.6–12.9	37.5%
Abbas [56]	27	40	CCF: 16–11	22%

CCF Cleveland Clinic Incontinence score

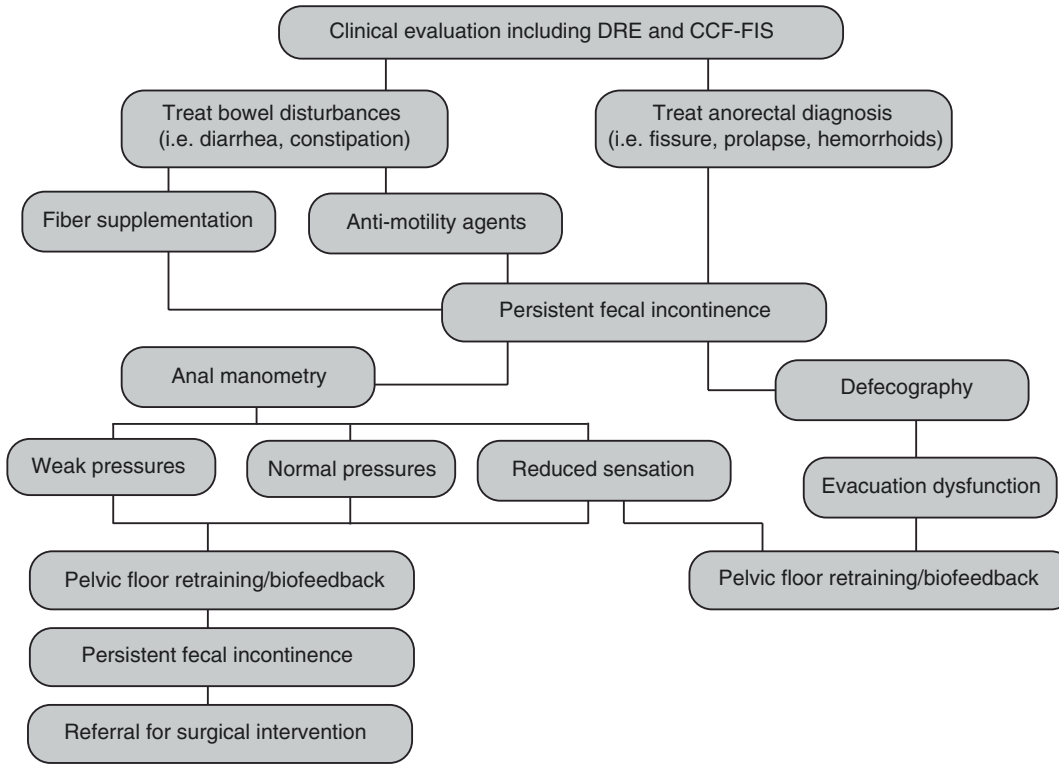

Fig. 11.1 Flow chart for nonoperative management of fecal incontinence

fissure, or significant hemorrhoids, the next step would be to treat her bowel disturbance, which is loose stools. If she has not under gone a recent colonoscopy with biopsies, she should undergo a colonoscopy with biopsies as part of her work-up to rule out microscopic colitis. Stool studies should be sent to exclude infectious diarrhea.

She can proceed with the addition of fiber supplementation such as psyllium and ensure adequate water intake daily. She should also start a diary to chart any aggravating factors to her loose stools, paying close attention to caffeine intake, lactose, and sugar alternatives.

If the diary does not identify any modifiable factors, and the fiber supplementation does not improve her continence, the next step would be to add pharmacologic modulators for her loose stools, as long as her stools studies are negative

for an infectious cause and the biopsies from her colonoscopy do not reveal a gastrointestinal disease process such as inflammatory bowel disease. She can start with loperamide to slow down her bowel transit and secretions, prior to escalating to more robust agents such diphenoxylate and codeine. If IBS-D is suspected, she can also be treated with bile acid binders, tricyclic antidepressants as well as clonidine.

If after treatment with pharmacologic therapy, she has persistent fecal incontinence, she should then be referred for biofeedback pelvic floor retraining therapy.

Commentary

Tracy L. Hull

Fecal incontinence (FI) as outlined in this chapter is not uncommon. The etiology is multifactorial, and treatment is individualized for each patient. Therefore, a comprehensive history is the first step in caring for this group of patients. Physical exam further refines treatment possibilities [63].

Some FI results from inflammatory conditions like ulcerative colitis. Treatment of the primary inflammatory process is the initial therapy. Otherwise, most treatment recommendations begin with a combination of nonsurgical approaches, which are discussed in detail in this chapter. The goal should aim toward total continence. Many studies determine successful results as 50% reduction in incontinent episodes. While a 50% reduction may be an improvement, any accidental episodes of FI can be humiliating and demoralizing.

Loose stools are a factor for many patients with FI, and strategies to minimize diarrhea are part of most recommendations. As mentioned, anal skin care with protective barrier creams is sometimes a forgotten component of treatment [64]. Physical therapy utilizing auditory and/or visual feedback emphasizes retraining for improved anal strength, pelvic coordination, and optimization of rectal sensitivity. This therapy can be operator dependent and time intensive to produce an acceptable outcome. Enemas or rectal washout is also a treatment strategy that may be successfully utilized for selected patients who are motivated to use this therapy [65, 66]. As outlined in the chapter, a combination of these treatments is part of the individual approach.

To further optimize quality of life, other nonsurgical approaches may be considered. While insertion of devices into the vagina in women or anal inserts seem like attractive options to prevent stool from being expelled at unwanted times, both success and tolerance have been suboptimal [66].

With the success of sacral nerve modulation, percutaneous tibial nerve stimulation seems like an attractive less invasive treatment that should stimulate similar nerve pathways. Results have not been straightforward, but as discussed in the chapter, selective patients may benefit [67].

Nonsurgical therapies are overall safe and do not burn bridges for other therapies. For patients who have failed all treatment options or are not candidates for other therapies, fecal diversion allows patients the ability to leave home, work, and attend social functions. A stoma should not be viewed as a failure, but instead as a means to improve quality of life in this group of patients [66].

As mentioned in this chapter, critical examination of studies regarding FI is essential when determining efficacy of therapy. As with many areas of pelvic floor research, patient selection for studies may not appropriately compare like patients, especially those with FI. FI is difficult to treat. Appraisal of the characteristics of patient included in studies and the primary aim should be scrutinized before fully dismissing a treatment with minimal risk to patients with FI.

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