

Novel Approaches in the Treatment of Fecal Incontinence

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Fecal incontinence (FI) usually is defined as the involuntary loss of bowel control, which normally allows the passage of gas or stool at a socially acceptable time and place. Normal continence results from an integrated activity of the anal sphincters, pelvic floor muscles, and adequate neural input. It also is influenced by stool consistency, rectal capacity and compliance, the anorectal sampling reflex, normal resting anal tone, and normal anorectal sensation. Failure of any of those factors may result in FI [1]. The tremendous physical, emotional, social, and even economic adverse effects of FI are well documented [2–5]. Owing to the social stigma that is associated with FI, this condition is usually underreported and probably underestimated. The true incidence and prevalence of FI are unknown; one community-based survey of nearly 7000 individuals reported that 2.2% of those surveyed had FI [6], although a more recent meta-analysis reported significantly higher rates ranging from 11% to 15% [7]. FI is the second leading cause of nursing home placement with up to 45% of patients in nursing homes having some form of FI [8]. The major risk factors for FI are anal sphincter and pudendal nerve injuries occurring during vaginal deliveries [9], making FI significantly more prevalent in women.

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When planning a treatment regimen, it is extremely important to make the subjective complaints and symptoms of FI somewhat more objective. To accomplish that goal several scoring systems have been designed and validated, the Cleveland Clinic Florida FI (CCF-FI; Wexner) score being the most popular and widely cited [10]. This scale measures the frequency of incontinence to gas, liquid, and solid stool; the degree of alteration in lifestyle; and the use of protective devices (0 = total control, 20 = complete incontinence). In one of several validation studies of this scoring system it has been demonstrated that a score greater than 9 is associated with a significant alteration in quality of life and can be used as an indication for surgical therapy [11].

Because diarrhea is one of its most common aggravating factors, the mainstay of the medical management of FI is control of diarrhea through dietary modifications and a wide variety of antidiarrheal medications. Strengthening and retraining of the pelvic floor and sphincter muscles with biofeedback may be used as an adjunct to the medical treatment. The decision of which surgical modality should be undertaken is usually straightforward, depending on the condition of the anal sphincters. Patients who have obvious sphincter defects normally should undergo an overlapping sphincteroplasty; conversely, other modalities should be pursued in patients who have intact sphincters.

Injectable bulking agents

For decades, a wide variety of materials have been used successfully as bulking agents of the urinary sphincter in women who have urinary incontinence. The materials that are currently approved by the United States Food and Drug Administration (FDA) for that indication are autologous fat [12], glutaraldehyde cross-linked (GAX) collagen [13], and carbon beads [14]. These materials, when injected adjacent to the bladder neck, provide additional bulk to the malfunctioning urinary sphincter, thus improving its function. Following the success of this treatment modality, it was only a matter of time until this concept was attempted for patients who have FI. Shafik [15] provided the first report of successful short-term outcomes of treatment of FI with submucosal injection of polytetrafluoroethylene (Teflon or Polytef; DuPont, Wilmington, DE) in 1993, and similar outcomes with the use of autologous fat in 1995 [16]. Additional materials that have been used as bulking agents for the anal sphincters with varying degrees of success include GAX collagen (Contigen; Brad, Covington, GA) [17] and injectable-silicone – PTQ implants (formerly known as Bioplastique; Uroplasty BV, Geleen, The Netherlands) [18,19]. The long-term results are less encouraging than the initial results of these small pilot trials, however. The slow deterioration in fecal continence following the initial improvement was attributed to migration or flattening of the bulking material, sometimes necessitating additional injections. There are several other bulking agents that are commonly used in the fields of urology and plastic surgery, but there are limited published reports regarding their use for the treatment of FI.

Carbon-coated beads are another compound that initially has been used as a bulking agent for treating urinary incontinence and recently applied for FI also. Durasphere FI (formerly known as ACYST; Carbon Medical Technologies, Inc., St. Paul, MN, distributed by Boston Scientific Corporation, Boston, MA) is composed of pyrolytic, carbon-coated, zirconium oxide beads suspended in a water-based carrier gel containing β -glucan (Figs. 1–3). The beads have a dimension of 212–500 μm , which has been designed specifically to be nonmigratory, nonabsorbable, and biocompatible, and the gel is approximately 97% water and 3% β -glucan. Durasphere FI is manufactured in 1 mL or 3 mL sterile syringes, and may be injected either submucosally in the anal canal and distal rectum adjacently to the anal sphincter or in the intersphincteric space.

Weiss and colleagues [20] from Cleveland Clinic Florida presented their experience with Durasphere FI. A total of 10 patients (7 women) who had severe FI were enrolled in a prospective, open-label pilot trial. The patients who were included in the trial had all failed previous attempts at standard, nonsurgical treatment of FI, and all had intact external anal sphincters. In all patients the procedure was performed as an outpatient, office-based procedure under local anesthesia. Durasphere FI was injected in the submucosal space 0.5 to 1 cm distal to the dentate line, typically 45° apart. Eight of the 10 patients (80%) experienced symptomatic improvement. The CCF-FI score decreased from an average of 13 at baseline to 10 at 3 months after the injection ($P = .012$), and to 9.3 after 6 months. Davis and coworkers [21] used Durasphere FI in a slightly different manner. The authors treated 18 incontinent patients who had internal anal sphincter defects and injected the compound submucosally only adjacently to the area of the disrupted sphincter until the regularity of the anal canal was restored. The CCF-FI score decreased from a baseline of 11.89 to 8.07 at 12 months ($P = .002$), with no reduction of the effect over time. The authors demonstrated a strong correlation between the number of sites that were injected and the degree of improvement in the incontinence scores. In both trials [20,21] there was a significant improvement in FI quality-of-life scores in addition to the symptomatic improvement.

The effects of Durasphere FI were evaluated recently in a large multicenter trial in the United States in which the investigators noted that intersphincteric

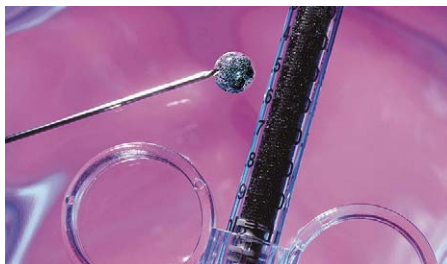


Fig. 1. Durasphere® FI. Courtesy of Carbon Medical Inc., St. Paul, Minnesota.

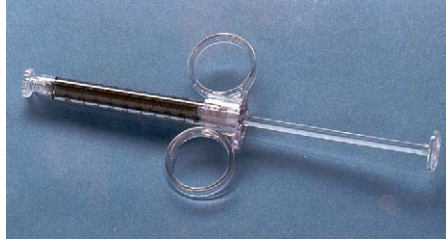


Fig. 2. Durasphere® FI. Courtesy of Carbon Medical Inc., St. Paul, Minnesota.

injection of the bulking agent may achieve significant and durable improvement with fewer mucosal complications, such as erosion or migration (EG Weiss, personal communication, 2004), and thus may provide an attractive alternative to submucosal injection. There are several potential mechanisms in which Durasphere FI achieves its effect: the bulk provides additional resistance to the passage of stool and allows for improved sensation and discrimination, the physical filling of sphincter defects restores the normal contour of the anal canal, and the continuous fibrosis adds further volume to the sphincter muscles. This procedure has proven to be a safe, simple, inexpensive, and effective technique in the treatment of moderate to severe FI.

Radiofrequency

Physicians have used thermal energy for treating a wide variety of medical conditions; electricity by far is the most prevalent energy source for generating thermal energy. For decades electrocautery has replaced cautery for cutting tissue and controlling bleeding by coagulating blood vessels. The radiofrequency (RF) device deploys energy by generating heat through a high-frequency alternating current that is delivered to the tissue, causing frictional movement of ions and heat. The immediate result is contraction

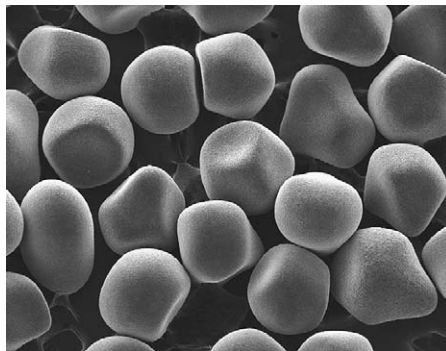


Fig. 3. Durasphere® FI: carbon-coated micro-beads. Courtesy of Carbon Medical Inc., St. Paul, Minnesota.

of collagen fibers, with subsequent healing and remodeling processes that cause shortening of the fibers and tightening of the tissue [22]. This specific effect of RF energy has been applied for treating gastroesophageal reflux disease (GERD) [23–25], benign prostatic hypertrophy [26], joint capsule instability [27], and even obstructive sleep apnea syndrome and snoring [28–30]. Temperature-controlled RF is a modification of the technology in which a constant temperature monitoring and feedback is used to control the amount of energy delivered to the treated tissue, with a simultaneous cooling that minimizes the damage to the surface. The Stretta procedure (Curon Medical, Sunnyvale, CA) was approved by the FDA in April 2000 for treating GERD. In view of its efficacy, Curon Medical developed a similar procedure for treating FI, the Secca procedure, which was approved by the FDA in March 2002. The system consists of a central control module, a four-channel radiofrequency generator, and an anoscopic handpiece (Figs. 4 and 5). Four titanium needle electrodes that are located at the handpiece (Fig. 6) deliver the energy to the tissue. Thermocouples at the tip and base of each needle constantly monitor the temperature of the treated tissue and mucosal surface; the current is automatically interrupted if the temperature reaches the preselected target of 85°C. The procedure is typically performed in an ambulatory setting, either in the endoscopy suite or in the operating room. The patient is positioned in the prone-jackknife position, and intravenous sedation, local anesthesia, and prophylactic antibiotics are administered. The handpiece is inserted under direct visualization into the anal canal to the level of the dentate line (Fig. 7) and the four needle electrodes deliver the RF energy for 90 seconds at that level. Additional applications in all four quadrants are administered in 5-mm increments proximal to the dentate line for a total of 16 to 20 application sites depending on the height of the anal sphincter (Fig. 8).



Fig. 4. The Secca® handpiece. *From* Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum* 2003;46(12):1606–18; with permission.



Fig. 5. The Secca® control module. *From* Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum* 2003;46(12):1606–18; with permission.

Takahashi and colleagues [31] reported the results of the first trial that assessed the efficacy of the procedure for treating FI with a subsequent report of the results at 2-year follow-up [32]. The investigators treated 10 female patients with the Secca procedure and observed a significant reduction in the CCF-FI score from 13.5 at baseline to 5 after 12 months ($P < .001$); the average CCF-FI score after 2 years was 7.3 ($P = .002$), which further emphasizes the procedure's long-term durability. Efron and coworkers [33] treated 50 patients with the Secca procedure in a multicenter trial in the United States. The average CCF-FI score decreased from 14.5 at



Fig. 6. Four titanium needle electrodes in the operating head of the handpiece. *From* Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum* 2003;46(12):1606–18; with permission.



Fig. 7. Placement of the Secca® handpiece into the anal canal. From Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum* 2003;46(12):1606–18; with permission.

baseline to 11.1 after 6 months ($P < .0001$). Again, in both studies a significant improvement in quality of life was demonstrated. A multi-institutional single-blinded randomized prospective trial comparing the Secca procedure to a sham intervention has been completed recently and its results are pending.

Stimulated graciloplasty

The concept of substituting the anal sphincter with another muscle was attempted more than a century ago by Chetwood [34], who used the gluteus maximus muscle to replace the sphincter. A skeletal muscle that is considered as a potential candidate for this task should have a relatively negligible role in

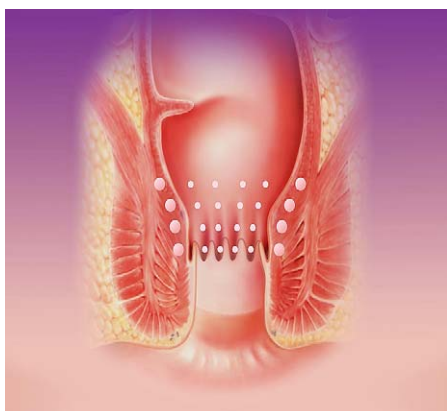


Fig. 8. Location of the RF lesions in the anal canal and distal rectum. Courtesy of Curon Medical, Inc., Fremont, California.

movement or posture, should be large enough to provide sufficient bulk, and should have a neurovascular pedicle that will allow simple handling in the process of mobilization and transposition. Since Chetwood's first experiment, several modifications to his technique of using the gluteus maximus have been made [35,36]. Although the gluteus maximus is theoretically a good option because of its strength and proximity to the anus, harvesting it for treating FI may result in significant impairment in performing simple daily activities, such as standing up or climbing stairs. The sartorius muscle has been used successfully in dogs [37], but its mobilization in humans may be complicated because of a segmental vascular supply that can be compromised easily during mobilization. The gracilis muscle is the smallest and most superficial adductor of the thigh. It has a relatively consistent proximal neurovascular pedicle and it has an insignificant role in movement. Like any other skeletal muscle, the gracilis is comprised mainly of type II fast-twitch fibers, which are prone to fatigue after prolonged contraction. Conversely, the external anal sphincter has approximately 80% type I, slow-twitch fibers, which are relatively fatigue resistant [38]. Transforming type II fibers to type I may be achieved by application of a constant low-frequency electrical current, a process that was termed muscle conditioning [39]. The technique used by most surgeons today was described initially by Pickrell and colleagues [40] in 1952, and the principle of conditioning with an electrical stimulator was independently reported in the same issue of *The Lancet* in 1991 by Baeten and coworkers [41] and Williams and coworkers [42]. The technique involves the transposition of the gracilis muscle from the thigh to form a muscular ring around the anus with the distal tendon anchored to the contralateral ischial tuberosity (Fig. 9). There are two phases in this procedure, with the number of required operations depending on whether the surgeon elects to create a protective stoma. The first phase usually consists of transposition of the muscle and implantation of the stimulator and electrodes (Medtronic Inc., Minneapolis, MN), and the second phase involves 8 weeks of muscle conditioning with increasing levels of neuromuscular

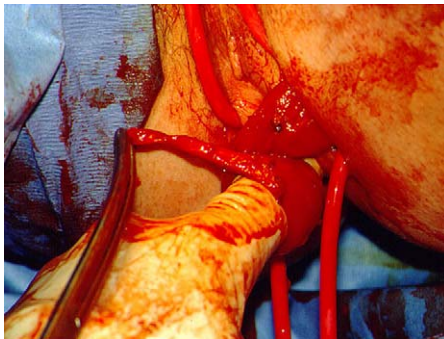


Fig. 9. The patient's left gracilis is wrapped around the surgeon's index finger. *From* Person B, Wexner SD. Advances in the surgical treatment of fecal incontinence. *Surg Innov* 2005;12(1): 7-21; with permission.

stimulation. The use of a diverting stoma requires additional operative intervention for creation and subsequent closure. On completion of the second phase, the patients can control continence with the aid of an external magnet that turns the stimulator off to allow evacuation and back on to resume muscular contraction and continence.

The Dynamic Graciloplasty Therapy Study Group conducted the largest prospective multi-national trial that assessed this procedure and produced both short-term and long-term data [43,44]. In the initial report [43], 60% of the patients had significant improvement in continence and quality of life; the long-term durability of the procedure was demonstrated by showing that at 2-year follow-up 62% of the patients had significant improvement in continence and quality-of-life parameters [44]. Nevertheless, stimulated graciloplasty is technically demanding with considerable morbidity; a systematic review of the literature on the subject of stimulated graciloplasty [45] demonstrated that every patient had an average of 1.12 complications, with the most common being infection (28%), malfunctioning stimulator or electrodes (15%), and leg pain (13%). Efficacy ranged from 42% to 85%, and the rate of re-operation ranged from 0.14 to 1.07 per patient. Even though the complication rates of this procedure were high, most complications, with the exception of major infections, could be treated successfully without adversely affecting functional outcome.

Sadly, although this option is the best one for patients who have severe perineal tissue loss, the Medtronic Corporation decided not to pursue FDA approval and thus this beneficial procedure is no longer performed in the United States; fortunately, the stimulated graciloplasty remains a viable option in other parts of the world.

Artificial bowel sphincter

Another concept that was adapted from the field of urology is the use of synthetic material to replace a malfunctioning sphincter. Artificial sphincters have been used to treat urinary incontinence since 1973 [46], and the first report of their use for treating FI was in 1987 [47]. The current version of the artificial bowel sphincter (ABS), the Acticon Neosphincter (American Medical Systems, Minnetonka, MN), consists of three silastic components: an inflatable cuff, a pressure-regulating balloon, and a control pump that allows activation or deactivation of the device (Fig. 10). The inflatable cuff is implanted around the anus and is connected by silastic tubing to the control pump placed in the scrotum of men or in the major labia of women, on the side of the patient's dominant hand. The control pump also is connected to the pressure-regulating balloon, which is implanted in the space of Retzius (Fig. 11). The pressure-regulating balloon constantly maintains the cuff pressure, keeping the cuff inflated and the anus closed. By manual activation of the pump, the fluid leaves the cuff into the balloon, thus deflating the cuff and allowing evacuation. The fluid subsequently



Fig. 10. The Acticon® neosphincter. Courtesy of American Medical Systems, Inc., Minnetonka, Minnesota.

returns into the cuff by the pressure that is created in the balloon. This maneuver may be repeated if evacuation is incomplete.

The Acticon Neosphincter was approved by the FDA in 1999. The largest case series to date that assessed its safety and efficacy was reported by Wong and colleagues [48] in 2002. A total of 112 patients were enrolled in a prospective multicenter nonrandomized cohort trial. At 1-year follow-up 75 of these 112 patients (67%) had a functional device; of these, 85% had significant

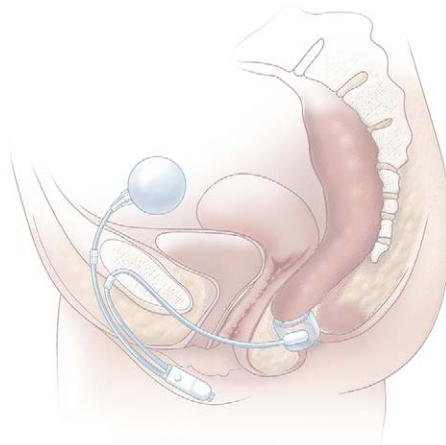


Fig. 11. The final position of the ABS in a female patient. Courtesy of American Medical Systems, Inc., Minnetonka, Minnesota.

improvement in incontinence scores and quality-of-life parameters. The overall intention to treat success rate was 53%. Ninety-nine patients (88%) had a total of 384 complications related to the ABS; 41 patients (37%) had their ABS completely explanted, and the overall infection rate that led to surgical interventions was 25%. In a recent prospective comparison of eight cases of dynamic graciloplasty and eight implantations of the ABS followed for more than 3 years, there was no difference in complications, wound healing problems, or explantation rates, all of which were considerably high in both groups, although the ABS was found to be more effective in lowering the FI scores [49]. A systematic review of the literature about ABS [50] demonstrated that approximately one third of patients have their ABS explanted by the end of the follow-up period; this number approaches 50% in series with the longest follow-up (5 years), which may be an indirect indicator of the lifespan of the device. There are no reported data on the outcomes of patients in whom the ABS was explanted. Because these patients represent a substantial percentage of all those treated by ABS, and the condition of these patients may have deteriorated following the explantation, these data may be crucial to fully appreciate the true efficacy and safety of the device. Recent modifications to the perioperative antibiotic treatment regimens resulted in a significant reduction in the rates of infectious complications to approximately 9% (unpublished data).

Despite these numerous drawbacks, ABS remains one of only a few available surgical treatment modalities for patients who have end-stage FI who otherwise would require a permanent stoma; however, it has limited or no usefulness in patients who have major perineal tissue loss. In these individuals, a nonstimulated graciloplasty before implantation of an ABS may prove beneficial as a means of bulking or replenishing the lost tissue, or a stimulated graciloplasty may be considered.

Sacral nerve stimulation

The latest and most innovative modality in the armamentarium available for treating FI is sacral nerve stimulation (SNS). Once again the concept was initially implemented for treating urinary incontinence, and subsequently the technology has been adopted by the colorectal community also. Patients who were treated by SNS for urinary incontinence and had FI also soon noted a significant improvement in both symptoms. This observation prompted investigators to attempt SNS in patients who had isolated FI. Matzel and colleagues [51] published the first report of successful outcomes in three patients who were treated with SNS in 1995; in the decade since that initial report, several hundred patients have been treated with SNS for FI in Europe; in the United States, SNS is currently under investigation in a multicenter trial.

The innervation of the pelvic floor musculature and anal sphincter apparatus is derived from both the somatic and autonomic nervous systems. Terminal nerve fibers of both nervous systems reach the target organs in the pelvis by way of the sacral plexus. The rationale behind SNS is that direct

stimulation of the sacral nerves potentially will result in recruitment and arousing of additional, inactive motor units. SNS also has a beneficial effect on the sensory and autonomic components of the sacral nerves as demonstrated by improvement in rectal sensory threshold and improved balloon expulsion time [52] and an increase in the resting anal pressure and rectal blood flow [53].

The technique of SNS is unique in the sense that it includes an extremely strict patient selection process, which is an integral part of the procedure sequence itself. This selection process allows choosing patients with the best potential to benefit from the procedure. The hardware for the procedure (stimulator and electrodes) is supplied by Medtronic Inc, Minneapolis, MN. SNS is a staged procedure that consists of two stages: percutaneous nerve evaluation (PNE, the diagnostic stage), and the permanent implant (the therapeutic stage). The PNE consists of two steps: in the acute phase the feasibility of SNS is determined and the sacral nerve that elicits the best muscular response is selected; in the subchronic phase of this stage SNS is performed with an external stimulator for a period of 2 weeks, during which the therapeutic effect is assessed. The patient is placed in the prone position and local anesthesia is administered; the sacral foramina are identified using bony landmarks and the needle electrodes are inserted into the foramina with fluoroscopic guidance. Correct placement of the electrodes is determined by intermittent electrical stimulation until visual muscular contraction is obtained. Typical muscular responses include contraction of the perineal muscles and external rotation of the leg (S2), contraction of the levator ani and external sphincter with a plantar flexion of the first and second toes—the “bellows response” (S3), and contraction of the external sphincter without movement of any part of the leg (S4). When satisfactory response is achieved, the subchronic phase of the PNE is initiated. This phase involves placement of a temporary stimulator lead into the same position as the testing needle. This lead is left in place for a trial period of 2 weeks to allow evaluation of functional response. The decision to proceed from temporary to permanent stimulation is made on the basis of 50% functional improvement in either the number of episodes or incontinence-free days. Patients who experience such an improvement are offered a permanent implant. The permanent stimulator (Model 3023 InterStim implantable pulse generator; Medtronic Inc., Minneapolis, MN) (Fig. 12) is implanted in the subcutaneous tissue in the buttock; the patients may deactivate the stimulator or modulate the delivered energy with a hand-held device.

Most of the reports that assessed the efficacy of SNS for FI included small numbers of patients and had relatively short follow-up periods. A recent systematic review of SNS for the treatment of FI [54] evaluated six studies. A total of 266 patients underwent PNE, of whom 149 (56%) had a permanent stimulator implanted; follow-up periods ranged from 1 to 99 months. Complete continence was reported in approximately 55% of patients, with 90% having more than 50% improvement in incontinence; there was no deterioration of the effect of SNS over time. The reported complications were minor and

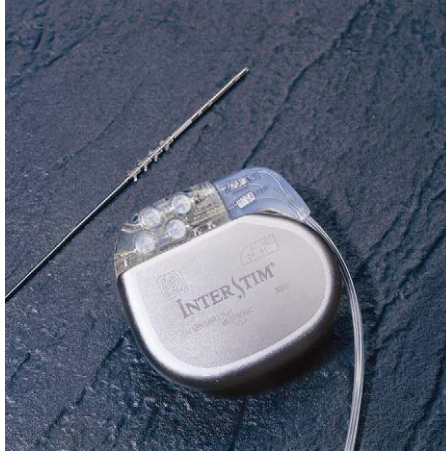


Fig. 12. The Interstim® neurostimulator. Reprinted with the permission of Medtronic, Inc., © 2003.

rare with lead migration being the most common, accounting for 8 of the 19 adverse events, and infection necessitating explantation of the stimulator occurred in 3 patients. The remaining complications were attributed mostly to pain originating either in the stimulator or leads.

The excitement surrounding SNS results from its relative simplicity, high efficacy, and safety. The procedure offers numerous advantages over almost any other surgical treatment modality for FI: it is the only modality in which the patient selection and screening process is incorporated in the procedure itself, which inevitably results in high success rates; it is a minimally invasive procedure that is usually performed in an outpatient setting and does not require mechanical bowel preparation; it does not involve physical manipulation of the rectum, anus, or the pelvic floor anatomy, and therefore has significantly fewer complications; repeat operations, explantations, and revisions following SNS are relatively simple procedures that do not necessarily obligate the patient to a stoma. It is an exciting treatment option in a population in whom conservative measures have failed and other surgical approaches may be conceptually questionable, have limited success, or are considered too risky. Again, unlike the stimulated graciloplasty, SNS has no role for patients who have significant muscle loss.

Choice of procedure

As for any other condition for which several treatment options are available, choosing the appropriate procedure for treating end-stage FI is a complicated process that depends on several factors, including patient-related comorbidities and risk factors, procedure-specific risks and

contraindications, and the cause of FI. Our suggested decision-making algorithm is illustrated in Fig. 13.

Patients in poor general health who have significant comorbidities and who are poor surgical candidates, and individuals who refuse more invasive therapy, may benefit most from the least-invasive procedure, which is injection of a bulking agent. The Secca procedure and SNS are also considered minimally invasive, but they are performed in a monitored setting under some form of anesthesia, and require sophisticated instrumentation. Another patient-related aspect that needs to be addressed when planning a surgical intervention is the patient’s mental capacity. ABS, SNS, and stimulated graciloplasty all are extremely high-maintenance procedures that mandate that the patients have complete appreciation of the complexity of the hardware, basic knowledge in pelvic and anorectal anatomy, and full commitment to daily operation and maintenance of the devices; they should also be educated as to the high rates of complications, be able to recognize the early signs of failure, and be mentally prepared for re-operations, including the possibility of the need for a stoma. Conversely, injectable bulking agents and RF do not require any maintenance or routine follow-up and thus may be more suitable for patients who have impaired mental capacity.

Injectable bulking agents and RF cause an increase in the physical barrier to the passage of stool through the anal canal. This feature of both procedures makes them potentially suitable for treatment of mild FI regardless of cause. SNS has been used successfully for various causes also, but it requires an intact neuromuscular architecture of the sphincter mechanism, which should be demonstrated adequately by preoperative electromyography and pudendal nerve terminal motor latency testing. Patients who

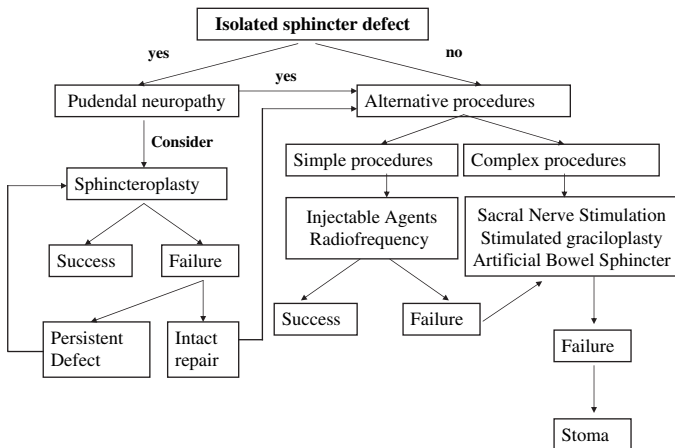


Fig. 13. Suggested algorithm for treatment of FI.

have substantial sphincter muscle loss may not benefit from SNS and should be considered as candidates for sphincter replacement techniques.

Injectable bulking agents, the Secca procedure, stimulated graciloplasty, and ABS implantation require direct manipulation of the perianal area, anal canal, or distal rectum. Consequently, any local pathology—abscesses, fistulae, fissures, perianal inflammatory bowel disease, or anorectal cancer—is a contraindication for attempting these modalities. Patients who have cardiac pacemakers or implantable defibrillators should not undergo SNS or the stimulated graciloplasty because of the obvious interference of the electrical stimulators. ABS is the most complicated and most invasive procedure currently available in the United States for treating FI. It usually is reserved for patients in whom other treatment modalities have failed. ABS requires highly motivated patients who are physically able to undergo multiple potential subsequent interventions, overcome severe infections, and be mentally prepared to live with a permanent stoma, because this is the almost inevitable consequence of failure of ABS. Implantation of an ABS may not be optimal in patients who have an artificial urinary sphincter or inflatable penile prosthesis; however, we have successfully implanted the ABS in these settings.

Summary

The availability of novel techniques to treat end-stage FI gives hope for a better quality of life in patients who were traditionally treated by a permanent stoma. The diversity of causes of FI and the different modes of action of the various treatment modalities mandate a tailored, individualized approach in each case. A meticulous preoperative evaluation process is imperative in the course of the decision-making of which procedure to perform, with full awareness that a stoma still may be the best option for some patients who have end-stage FI.

References

- [1] Mavrantonis C, Wexner SD. A clinical approach to fecal incontinence. *J Clin Gastroenterol* 1998;27(2):108–21.
- [2] Madoff RD, Parker SC, Varma MG, et al. Faecal incontinence in adults. *Lancet* 2004; 364(9434):621–32.
- [3] Deutekom M, Terra MP, Dobben AC, et al. Impact of faecal incontinence severity on health domains. *Colorectal Dis* 2005;7(3):263–9.
- [4] Miner PB, Jr. Economic and personal impact of fecal and urinary incontinence. *Gastroenterology* 2004;126(1, Suppl 1):S8–13.
- [5] Mellgren A, Jensen LL, Zetterstrom JP, et al. Long-term cost of fecal incontinence secondary to obstetric injuries. *Dis Colon Rectum* 1999;42(7):857–65.
- [6] Nelson R, Norton N, Cautley E, et al. Community-based prevalence of anal incontinence. *JAMA* 1995;274(7):559–61.

- [7] Macmillan AK, Merrie AE, Marshall RJ, et al. The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Dis Colon Rectum* 2004;47(8): 1341–9.
- [8] Whitehead WE, Wald A, Norton NJ. Treatment options for fecal incontinence. *Dis Colon Rectum* 2001;44(1):131–42.
- [9] Madoff RD, Williams JG, Caushaj PF. Fecal incontinence. *N Engl J Med* 1992;326(15): 1002–7.
- [10] Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum* 1993;36(1):77–97.
- [11] Rothbarth J, Bemelman WA, Meijerink WJ, et al. What is the impact of fecal incontinence on quality of life? *Dis Colon Rectum* 2001;44(1):67–71.
- [12] Haab F, Zimmern PE, Leach GE. Urinary stress incontinence due to intrinsic sphincteric deficiency: experience with fat and collagen periurethral injections. *J Urol* 1997;157(4):1283–6.
- [13] Monga AK, Robinson D, Stanton SL. Periurethral collagen injections for genuine stress incontinence: a 2-year follow-up. *Br J Urol* 1995;76(2):156–60.
- [14] Lightner D, Calvosa C, Andersen R, et al. A new injectable bulking agent for treatment of stress urinary incontinence: results of a multicenter, randomized, controlled, double-blind study of Durasphere. *Urology* 2001;58(1):12–5.
- [15] Shafik A. Polytetrafluoroethylene injection for the treatment of partial fecal incontinence. *Int Surg* 1993;78(2):159–61.
- [16] Shafik A. Perianal injection of autologous fat for treatment of sphincteric incontinence. *Dis Colon Rectum* 1995;38(6):583–7.
- [17] Kumar D, Benson MJ, Bland JE. Glutaraldehyde cross-linked collagen in the treatment of faecal incontinence. *Br J Surg* 1998;85(7):978–9.
- [18] Malouf AJ, Vaizey CJ, Norton CS, et al. Internal anal sphincter augmentation for fecal incontinence using injectable silicone biomaterial. *Dis Colon Rectum* 2001;44(4):595–600.
- [19] Kenefick NJ, Vaizey CJ, Malouf AJ, et al. Injectable silicone biomaterial for faecal incontinence due to internal anal sphincter dysfunction. *Gut* 2002;51:225–8.
- [20] Weiss EG, Efron JE, Noguera JJ, et al. Submucosal injection of carbon coated beads is a successful and safe office based treatment for fecal incontinence. *Dis Colon Rectum* 2002;45: A46–7 [abstract].
- [21] Davis K, Kumar D, Poloniecki J. Preliminary evaluation of an injectable anal sphincter bulking agent (Durasphere) in the management of faecal incontinence. *Aliment Pharmacol Ther* 2003;18(2):237–43.
- [22] Gustavson KH. On the chemistry of collagen. *Fed Proc* 1964;23:613–7.
- [23] Richards WO, Scholz S, Khaitan L, et al. Initial experience with the stretta procedure for the treatment of gastroesophageal reflux disease. *J Laparoendosc Adv Surg Tech A* 2001;11(5): 267–73.
- [24] Triadafilopoulos G, Dibaise JK, Nostrant TT, et al. Radiofrequency energy delivery to the gastroesophageal junction for the treatment of GERD. *Gastrointest Endosc* 2001;53(4): 407–15.
- [25] Triadafilopoulos G, DiBaise JK, Nostrant TT, et al. The Stretta procedure for the treatment of GERD: 6 and 12 month follow-up of the US open label trial. *Gastrointest Endosc* 2002; 55(2):149–56.
- [26] Dawkins GP, Harrison NW, Ansell W. Radiofrequency heat-treatment to the prostate for bladder outlet obstruction associated with benign prostatic hyperplasia: a 4-year outcome study. *Br J Urol* 1997;79(6):910–4.
- [27] Hecht P, Hayashi K, Lu Y, et al. Monopolar radiofrequency energy effects on joint capsular tissue: potential treatment for joint instability. An in vivo mechanical, morphological, and biochemical study using an ovine model. *Am J Sports Med* 1999;27(6):761–71.
- [28] Powell NB, Riley RW, Troell RJ, et al. Radiofrequency volumetric tissue reduction of the palate in subjects with sleep-disordered breathing. *Chest* 1998;113(5):1163–74.

- [29] Steward DL. Effectiveness of multilevel (tongue and palate) radiofrequency tissue ablation for patients with obstructive sleep apnea syndrome. *Laryngoscope* 2004;114(12):2073–84.
- [30] Said B, Strome M. Long-term results of radiofrequency volumetric tissue reduction of the palate for snoring. *Ann Otol Rhinol Laryngol* 2003;112(3):276–9.
- [31] Takahashi T, Garcia-Osogobio S, Valdovinos MA, et al. Radio-frequency energy delivery to the anal canal for the treatment of fecal incontinence. *Dis Colon Rectum* 2002;45(7):915–22.
- [32] Takahashi T, Garcia-Osogobio S, Valdovinos MA, et al. Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the Secca procedure). *Dis Colon Rectum* 2003;46(6):711–5.
- [33] Efron JE, Corman ML, Fleshman J, et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum* 2003;46(12):1606–16.
- [34] Chetwood CH. Plastic operation for restoration of the sphincter ani with a report of a case. *Med Rec* 1902;61:529.
- [35] Pearl RK, Prasad ML, Nelson RL, et al. Bilateral gluteus maximus transposition for anal incontinence. *Dis Colon Rectum* 1991;34(6):478–81.
- [36] Devesa JM, Vicente E, Enriquez JM, et al. Total fecal incontinence - a new method of gluteus maximus transposition: preliminary results and report of previous experience with similar procedures. *Dis Colon Rectum* 1992;35(4):339–49.
- [37] Konsten J, Baeten CG, Havenith MG, et al. Canine model for treatment of faecal incontinence using transposed and electrically stimulated sartorius muscle. *Br J Surg* 1994;81(3):466–9.
- [38] Konsten J, Baeten CG, Havenith MG, et al. Morphology of dynamic graciloplasty compared with the anal sphincter. *Dis Colon Rectum* 1993;36(6):559–63.
- [39] Pette D, Vrbova G. Adaptation of mammalian skeletal muscle fibers to chronic electrical stimulation. *Rev Physiol Biochem Pharmacol* 1992;120:115–202.
- [40] Pickrell KL, Broadbent TR, Masters FW, et al. Construction of a rectal sphincter and restoration of anal continence by transplanting the gracilis muscle; a report of four cases in children. *Ann Surg* 1952;135(6):853–62.
- [41] Baeten CG, Konsten J, Spaans F, et al. Dynamic graciloplasty for treatment of faecal incontinence. *Lancet* 1991;338(8776):1163–5.
- [42] Williams NS, Patel J, George BD, et al. Development of an electrically stimulated neoanal sphincter. *Lancet* 1991;338(8776):1166–9.
- [43] Baeten CG, Bailey HR, Bakka A, et al. Safety and efficacy of dynamic graciloplasty for fecal incontinence: report of a prospective, multicenter trial. Dynamic Graciloplasty Therapy Study Group. *Dis Colon Rectum* 2000;43(6):743–51.
- [44] Wexner SD, Baeten C, Bailey R, et al. Long-term efficacy of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2002;45(6):809–18.
- [45] Chapman AE, Geerdes B, Hewett P, et al. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg* 2002;89(2):138–53.
- [46] Scott FB, Bradley WE, Timm GW. Treatment of urinary incontinence by implantable prosthetic sphincter. *Urology* 1973;1(3):252–9.
- [47] Christiansen J, Lorentzen M. Implantation of artificial sphincter for anal incontinence. *Lancet* 1987;2(8553):244–5.
- [48] Wong WD, Congioli SM, Spencer MP, et al. The safety and efficacy of the artificial bowel sphincter for fecal incontinence: results from a multicenter cohort study. *Dis Colon Rectum* 2002;45(9):1139–53.
- [49] Ortiz H, Armendariz P, DeMiguel M, et al. Prospective study of artificial anal sphincter and dynamic graciloplasty for severe anal incontinence. *Int J Colorect Dis* 2003;18(4):349–54.
- [50] Mundy L, Merlin TL, Maddern GJ, et al. Systematic review of safety and effectiveness of an artificial bowel sphincter for faecal incontinence. *Br J Surg* 2004;91(6):665–72.

- [51] Matzel KE, Stadelmaier U, Hohenfellner M, et al. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 1995;346(8983):1124–7.
- [52] Ganio E, Masin A, Ratto C, et al. Short-term sacral nerve stimulation for functional anorectal and urinary disturbances: results in 40 patients: evaluation of a new option for anorectal functional disorders. *Dis Colon Rectum* 2001;44(9):1261–7.
- [53] Kenefick NJ, Emmanuel A, Nicholls RJ, et al. Effect of sacral nerve stimulation on autonomic nerve function. *Br J Surg* 2003;90(10):1256–60.
- [54] Jarrett ME, Mowatt G, Glazener CM, et al. Systematic review of sacral nerve stimulation for faecal incontinence and constipation. *Br J Surg* 2004;91(12):1559–69.