

When Everything Fails: Prevention and Therapy of Treatment Failures

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15.1 Introduction

Surgery for fecal incontinence (FI) is very challenging and associated a high failure rate, particularly as far as the long-term success rate is concerned.

Traditionally, all the treatments proposed over the last 50 years, from the anal wire according to Thiersch to artificial anal sphincters, were aimed at repairing, reinforcing or replacing a damaged, functionally insufficient or even absent anal sphincter. However, in the last 25 years, the extension on the indication of sacral nerve modulation to FI, proposed by Klaus E. Matzel, has revolutionized the treatment algorithm for this common functional disturbance, making some of the traditional treatments obsolete [1].

The prevention and treatment of failures of the most frequent surgical approaches to FI are discussed in this chapter.

15.2 Sphincteroplasty with or Without Postanal Repair

Overlapping anal sphincteroplasty remains one of the milestones in the treatment of FI even if its indication is limited to cases with an overt lesion of the external anal sphincter, which represents a minority of the causes of FI in Italy. The success rate of this operation is reported to be around 50% in the long term [2], and several prognostic factors have been considered to prevent treatment failure, including the presence of pudendal neuropathy [3].

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Nevertheless, the success rate of the operation cannot be easily predicted. An excessively large sphincter defect ($>90^\circ$) and the occurrence of postoperative wound infection can strongly influence the outcomes. The utility of a protective colostomy to prevent wound contamination has been investigated by several authors, but no consent has been reached [4]. On the other hand, morbidities related to stoma formation and closure discourage its use in routine clinical practice.

15.2.1 What to Do when Sphincteroplasty Fails?

One possible reason for unsuccessful sphincteroplasty may be an early or late disruption of the overlapping sutures on the muscle stumps. In these cases, a re-do sphincteroplasty has been demonstrated to be useful, with a success rate comparable with the first sphincteroplasty attempt [5].

Another possible option in the case of failure of the sphincteroplasty is to test sacral nerve stimulation (SNS), which has been shown to be successful even in selected cases of untreated sphincter lesions [6]. The unexpected result of SNS in these cases has been explained by considering the multiple and still unknown neurological effects of SNS on the mechanisms involved in the physiological control of continence.

15.3 Injectable Anal Bulking Agents

The proposal to treat minor or passive FI by creating a passive obstacle to the passage of feces through the injection of bulking agents into the submucosa or deeper into the anal canal has been an attractive mini-invasive surgical option in recent decades, and several materials have been experimented, including autologous fat, silicone, collagen, carbon-coated microbeads, polyacrylamide gel, and NASHA/Dx (dextranomer in non-animal stabilized hyaluronic acid) gel [7–17].

While the experience of the proponents of these techniques was successful in most of the cases, colorectal surgeons have lost interest in the injection of anal bulking agents despite the advantages of its minimal invasiveness and easy procedure because none of these treatments have stood the test of time or the comparison with other treatments, mainly SNS. In fact, the few studies addressing the middle/long-term outcome of these procedures failed to confirm the utility of these materials [18] and those comparing anal bulking agents against SNS show a clear advantage of SNS [9].

On the other hand, the procedure was not free of possible complications including anal abscesses or bleeding and, in rare cases, hemospermia (personal experience). Nowadays, injection of anal bulking agents is seldom performed in clinical practice.

Patients reporting unsatisfactory outcome are usually treated by biofeedback/physiotherapy or, in the case of more severe FI, by SNS.

15.4 Adynamic Anal Sphincter Reinforcement by Prosthetic Implants

Other surgical options to control the passive passage of feces involve the use of implantable adynamic prosthetic devices.

15.4.1 Gatekeeper and Sphinkeeper

The Gatekeeper and the newer Sphinkeeper involve the ultrasound-guided transanal implantation of 4–12 nonresorbable prostheses able to increase their volume by absorbing fluids from the interstitial spaces, thereby narrowing the anal canal and creating passive control to the loss of feces. This technique has been shown to be effective in about 50% of cases, even in the long-term follow-up [19–22].

Possible complications include anal abscess, migration of the prosthesis (possible in up to 50% of patients), mucosa ulceration and expulsion of the prosthesis. These complications could be prevented by careful monitoring of correct placement of the prostheses by transanal three-dimensional ultrasound guidance and wide spectrum antibiotic prophylaxis.

In cases of failure or distal migration, the procedure could be repeated if the distance between the prostheses allows for further transanal implants, or the patients could undergo SNS if the FI severity justifies that expensive procedure.

15.4.2 Fenix Device

Another surgical option involving adynamic prosthetic implants is the Fenix device. This magnetic sphincter augmentation (MSA) device consists of a flexible band of interlinked titanium beads with magnetic cores of variable length placed around the anal canal. The passive attraction of the magnetic beads keeps the anal canal narrow, but the voluntary passage of feces can open the anal canal allowing defecation [23].

Very few colorectal centers have experienced this device and therefore there is little information on its potential complications and true effectiveness. A randomized controlled trial versus SNS was stopped prematurely because of the very low success rate (about 10%) reported in both groups [24].

15.4.3 Silastic Band

The use of anal encirclement by a silastic band is actually an evolution of the Thiersch anal wire and was proposed by a German surgeon in 1991 [25] and recently reconsidered by Devesa et al. [26]. This simple, inexpensive surgical option could be considered in several patients after failure of more complex and expensive procedures including artificial bowel sphincter, SNS, sphincteroplasty and injectable

bulking agents. Careful preparation of the tunnel around the anal canal to host the elastic band is the only critical point of this operation because of the risk of rectal/vaginal perforation.

15.5 SECCA Radiofrequency Treatment

The SECCA procedure was designed to create deep thermal necrosis of segments of the internal anal sphincter by using a modified anoscope equipped with special needles to deliver radiofrequency energy, in order to produce anal scars able to narrow the anal canal thus preventing episodes of FI [27]. Despite some positive reports [28], this procedure has been abandoned owing to the great perplexity of most colorectal surgeons to further damage a weak anal sphincter [29]. A SNS test could be considered for patients not responding to this technique.

15.6 Dynamic Anal Neosphincters

15.6.1 Dynamic Graciloplasty

This fascinating and skill-demanding operation has been reserved for many years for the worst cases of FI or patients with anal malformation or after a perineal colostomy following a Miles operation for rectal cancer [30]. Nevertheless, the long-term success rate of this operation is unsatisfactory. One of the most recent reports on the long-term outcome of electro-stimulated graciloplasty concluded that “the individual patient can expect a 16% chance of normal fecal continence at 5 years with at least one surgical morbidity”, with 27% of them converted to an end colostomy [31]. As a consequence, this surgical option has been virtually abandoned, particularly after the company Medtronic decided to stop the production of the needle electrodes used to electro-stimulate the gracilis muscle. In fact, despite some recent reports on the use of adynamic graciloplasty [32], the unstimulated muscle becomes atrophic without electrostimulation, losing the ability to contract and therefore making the operation useless.

15.6.2 Artificial Bowel Sphincters

The great enthusiasm of about 20 years ago for the use of artificial sphincters, following the success of the urinary artificial sphincter, was replaced by a profound skepticism about its possible role in helping these patients when several papers addressing long-term effectiveness and outcomes became available in the literature [33, 34]. The excessive number of postoperative complications (mainly infections and skin/mucosal erosion), malfunction of the system components and the

long-term inefficacy of the device convinced the industry to stop its production worldwide, and all the other later attempts to produce artificial anal sphincters—such as the soft anal band, the prosthetic anal sphincter (PAS) [35], the German anal sphincter system (GASS) [36], the artificial anal sphincter system (AASS) [37]—remained in their early experimental phase.

Patients who have failed an operation with an artificial bowel sphincter or dynamic graciloplasty have very few chances to cure their incontinence. Nowadays, before considering an end colostomy or procedures for pseudocontinence, a last option could be a SNS test, although there is very little experience on this indication.

15.7 Sacral Nerve Stimulation

In the last 20 years, SNS has replaced most of the other surgical options to treat FI since the indication for this technique has greatly expanded, including incontinence due to sphincter lesions, incontinence after anterior resection of the rectum [38] and many other challenging conditions (but excluding patients with spinal lesions).

Few complications have been reported after SNS and most of them, like infection or malposition of the pacemaker, can be prevented by rigid observance of antisepsis and antibiotic prophylaxis and by correct positioning of the pulse generator in a subcutaneous pocket of the gluteal region. Correct positioning of the pacemaker is also necessary to prevent pain and skin erosion. Another rare but possible complication is liquor spillage during electrode positioning in patients with spina bifida (personal observation). In this case, prolonged compression and bed rest is sufficient to overcome the problem.

A major problem with SNS is the loss of efficacy in the long term. Several reports indicate that the long-term success rate is about 50% [39–41], making the management of the remaining patients very difficult because of the shortage of other surgical options.

15.8 Last Options for Patients Unsuccessfully Treated for Fecal Incontinence

The severe distress of untreatable fecal incontinence still needs to be managed to improve the quality of life of these patients. Some procedures such as the Peristeen enema or the Malone antegrade enema can help by maintaining the rectum empty and giving a pseudocontinence which can help to prevent episodes of incontinence [42, 43]. Finally, after full discussion and information with the patients, an end colostomy, could be considered the last option in selected cases of FI, since its management is easier than uncontrolled bowel movements and quality of life may be improved.

15.9 Conclusions

Critical revision of the outcomes of several surgical treatments have restricted our toolbox for treating patients with FI, relegating some of the traditional treatments to the annals of surgical history. Many surgical options such as artificial bowel systems, injectable bulking agents, the SECCA procedure, dynamic graciloplasty, adynamic artificial sphincters, initially presented with great enthusiasm and with very high success rates, did not stand the proof of time and repeatability of the initial experiences.

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