

Sphincter repair or Sacral Nerve Modulation: Still debatable?

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ABSTRACT

Fecal incontinence (FI) is a debilitating condition with negative consequences to patients. It is recognized as a “quality of life” illness. Sphincter tears resulting often from difficult childbirth or from surgical trauma, are well-identified causes of FI. When conservative measures fail to resolve FI symptoms, a surgical treatment is recommended on the basis of a comprehensive pelvic floor work-up. A sphincter tear is frequently found on endoanal ultrasonography. The best way to surgically approach a patient with FI related/associated with a sphincter lesion is still debatable. International guidelines are inconsistent regarding the role of either sacral neuromodulation (SNM) or anal sphincteroplasty (anal sphincter repair) (AS) in patients with anal sphincter defect. Decision making for an individual patient often relies on expert opinion and personal experience due to the poor quality of the few published studies. Currently the presence of a sphincter defect is no longer considered a contraindication for sacral nerve modulation (SNM) which has several advantages. SNM is a minimally invasive procedure with very low morbidity, its results can be accurately predicted with a test phase, and are sustained with long-term placement of the implant. Nevertheless, AS has clearly a role to play, for instance in young female patients reluctant to get an implanted nerve stimulator early in life and/or in case of a cloacae-like deformity as a sequela of a post-obstetrical 4th degree tear. While waiting for prospective studies directly comparing SNM and AS for various types of FI, we propose in this paper a pragmatic treatment algorithm based on the most recently published studies and recommendations for the management of sphincter defect related/associated FI.

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Introduction

Functional disorders of the anorectum that mainly encompass rectal prolapse syndrome, outlet obstruction, and fecal incontinence (FI), belong to a specific and rather complex field in proctology. Over the recent years, new knowledge has been gained in epidemiology, diagnosis, and management of these conditions that often have multiple origins and are caused by various mechanisms, that usually coexist and intermingle. Currently, based on a better understanding of the underlying pathophysiology, we can offer more adapted treatment strategies to improve patients' symptoms.

FI, also referred to as “accidental bowel leakage” (ABL), is highly representative of the functional anorectal disorders in its complexity to be managed especially in its most severe types.¹ Defined as a recurrent and chronic loss of the ability to control anal sphincters and bowel movements, it results in leakage of feces. FI is a debilitating condition with devastating consequences on both the physical and psychosocial wellbeing of afflicted individuals that often leads to social isolation and decreased self-esteem. It is therefore recognized

as a “quality of life” (QoL) illness and should be addressed on these grounds.^{2,3}

Recommendations for treating FI have been recently updated.^{4,5} It is widely accepted that conservative management is the first treatment approach that can resolve the symptoms of approximately 50% of patients. It includes dietary and behavioral modifications, pelvic floor training and biofeedback, and the use of medications to regulate bowel emptying and stool consistency. In some more difficult situations, retrograde colonic enemas are worth a trial. When conservative measures fail after a sufficient time trial, surgical therapies become an option based on a detailed FI assessment. A “bowel habits” diary recording normal bowel movements and fecal leaks classified as minor (staining on pads or underwear) and major (need a change) on a daily basis for a 3–4-week period is an objective assessment tool. Report of the incapacitating “stool urgencies” is documented. FI is considered as “severe” or refractory when ABL occurs at least once a week during a period of 3 consecutive weeks. Infrequent leaks but several urgencies per day or week impairing greatly daily life activities have to be considered similarly in the decision to treat. At that stage, a careful history taking (including past obstetrical and gynecological history) and clinical examination along with specialized investigations are required to identify the underlying FI mechanisms and causes.

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One of the well-identified causes of FI relates to sphincter tear originating from perineal trauma. It often results from a difficult childbirth or from surgical trauma following fistula surgery or complicated hemorrhoidectomy. Traditionally the sphincter “barrier” was considered as essential to maintain (anal) continence and as a consequence the surgical repair of identified sphincter tears was the first and for many years and in many centers, the only option to restore a better function. We know today that while sphincteric alteration is still relevant to the development of FI, it is only one of the multiple factors involved in the complex dysfunction leading to FI.⁶ There is a determinant role of the sensory components in the anal canal and rectum and conscious modulation by the central nervous system to maintain continence. The effectiveness of sacral nerve modulation (SNM)¹ to control FI despite lack of improvement of anal pressures and/or voluntary contractions reinforces the message that the presence of a sphincter tear does not preclude a return to a (nearly) normal fecal continence.^{5,7}

With regard to the increasing use of SNM as the first surgical option for FI regardless of the anal sphincters integrity, is there still a place today for anal sphincteroplasty (AS)²? And on which basis should we decide which procedure to offer to an individual patient? In absence of strong clinical trial-based evidence and/or high-quality comparative studies, the question is still pending especially given the greatly variable clinical situations among the population suffering from FI.

This paper aims to give some answers by reviewing the most recent and relevant published literature and current expert recommendations in the field, through a debate of pro and con arguments for these two therapeutic options.

In favor of sacral nerve modulation

Sacral nerve modulation is indicated whatever the structural aspect of the anal sphincters

In a recent statement of the International Continence Society, SNM is defined as “a technique that electrically stimulates a sacral spinal nerve root to *modulate* a neural pathway with the aim of treating bladder and/or bowel dysfunction”.⁷ First described for use in urinary incontinence it was adapted for use in FI in the 1990’s. The mechanism of action of SNM is still poorly understood but experimental and clinical data favor the hypothesis of an effect on local anal and colorectal reflexes and on the sensory cerebral cortex by a modulation of ascending spinal sensory pathways.^{5,6}

Sacral nerve modulation is a standardized procedure

The SNM procedure is a two-stage process. First, a *screening* phase aims at identifying responders to the treatment (about 80–90% of tested patients in the majority of published series). In this testing phase, also called peripheral nerve evaluation (PNE) test, a stimulating electrode is inserted through the S3 foramen in close proximity of the sacral root under fluoroscopic guidance, the patient lying on prone position under local or general anesthesia. The electrode placement technique has been recently “optimized” to obtain a stimulation at low threshold (less than 2 Volts) on the 4 electrode poles that would allow for more programming options and a longer duration of

¹ Sacral nerve modulation, “SNM”, is now the recommended term that has superseded the previous acronym of “SNS” for sacral nerve stimulation as the former is closer the exact mechanism of action as mentioned in the definition of the procedure.⁷

² the term “Anal Sphincteroplasty” (AS) refers to the delayed reconstruction of the anal sphincter muscle for a defect that has either not been recognized at the time of the injury or has not been adequately repaired primarily.⁵ However, the term “Sphincter repair” which theoretically is dedicated to the repair of an acute lesion of the anal sphincters, most commonly following a traumatic childbirth, the classic obstetrical anal sphincter injury (OASI) is frequently employed as a synonym in the literature⁸

the battery.⁹ A unilateral phasic stimulation of the S3 and S4 sacral roots triggers a ‘bellow response’ of the pelvic floor (also referred to the “anal wink sign”) and a plantar flexion of the great toe (only for S3). These are the expected motor responses that confirm the correct positioning of the lead, which is thereafter tunneled subcutaneously and out to an external portable temporary stimulator.

Following this initial operative step, the patient undergoes a 2 to 3-week trial period of stimulation and carefully fills out a bowel diary that is compared to the baseline one. Patients who significantly improve during the screening phase with a reduction of fecal leaks by at least 50% and improved time to defer a bowel movement, are then eligible for the second *therapeutic* phase, the implantation of the permanent programmable stimulator. Under local anesthesia, the stimulator is placed into a small pocket prepared under Scarpa’s fascia, superficial to the gluteal muscles and connected to the lead (Fig. 1A and B). Activation and stimulation parameters are set by telemetry and recorded.

The current results of sacral nerve modulation for sphincter defect related fecal incontinence

All indications considered, SNM is a feasible, minimally invasive, safe, reversible, and effective procedure to manage FI with an excellent predictability of the screening phase. A recent Finnish study reported national results of 432 patients with FI, a majority of them were women, tested for SNM from 1999 to 2017. A permanent stimulator was implanted in 72.5% of the patients. After a mean follow-up of 2.4 years, a successful outcome (defined as a 50% symptom improvement) was reported by 59.3% of the patients.¹⁰ Longer term sustainable results have been shown in a European study of 228 patients. For those patients with an implanted stimulator, i.e. the responders to the screening phase, improvement was observed in 71% at a median follow-up of 84 (70–113) months with 50% of the patients regaining full continence. The number of weekly ABL fell from 7 to 0.25 and the Cleveland Clinic incontinence score improved from 16 to 7 ($p < 0.001$ for both parameters).¹¹ However, *on an intention to treat basis*, i.e. when the non-responders to the test phase are taken into account, full continence was achieved in 33% of patients. In another expert-center study, the long-term efficacy of SNM was analyzed in 101 patients after 5 years of therapy. Sixty of them reported a favorable outcome, whereas 41 were not significantly improved, 24 of which had their implant deactivated or removed.¹² Predictors of success were an improvement in urgency during the screening stage and a good outcome at 6 months.¹²

Initially considered a contraindication, FI with coexisting anal sphincter defect is now effectively treated with SNM.^{13,14} Even though this population of patients is not always clearly distinguished when reporting results of patients’ cohorts treated with SNM, its use is clearly supported by several studies summarized in a systematic review.^{5,15} Of 119 patients described in 10 articles, the reported test phase success rate was 89%. During a follow-up period ranging from

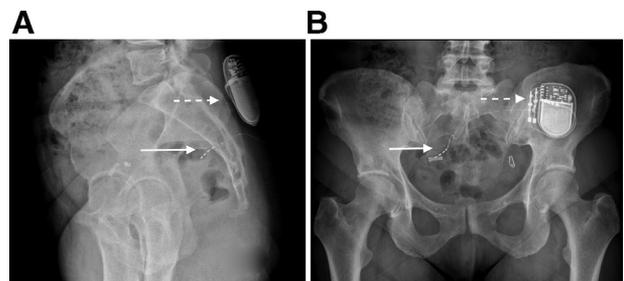


Fig. 1. Sacral nerve modulation (SNM) on X-rays: Anteroposterior (A) and lateral (B) views of the lead through S3 sacral foramen and the implanted programmable stimulator.

4 to 48 months, the average number of ABL per week decreased from 12.1 to 2.3 and the Cleveland Clinic incontinence score improved from 16.5 to 3.8, with a significant improvement in quality of life in the 4 series assessing it.¹⁵ More recently the response to PNE was assessed in a group of 75 female patients suffering from FI secondary to OASI (3rd and 4th degree tear; 25 and 38 patients, respectively). It was observed that the extent of the sphincter defect did not affect outcome, whereas a higher BMI, concomitant urinary incontinence (positive effect), and pain during PNE (negative effect), did.¹⁶ In another study based on the previously mentioned national Finnish database, out of 237 patients treated for FI with SNM and examined with endoanal ultrasound (EAUS), a sphincter defect was found in 128. 33 patients had a history of a previous delayed sphincter repair. Similar to other reports, the outcome of SNM in this study, did not differ among patients with an EAUS documented defect, patients who had undergone sphincter repair, or patients with intact sphincters, both for response to the test phase as well as at the end of the follow-up after permanent implantation of SNM. The authors concluded that “a delayed sphincter repair prior to SNM treatment initiation for FI is not necessary”.¹⁷

The trend nowadays to consider SNM more frequently than AS in patients suffering from FI with a coexisting sphincter lesion is well illustrated in a study from New York State in which the authors analyzed longitudinally, the variation in utilization of both procedures from 2008 to 2014 (AS) and from 2011 (FDA-approval of SNM) to 2014.¹⁸ This population-based survey identified a 4-fold increase in the number of SNM procedures as well as in the number of surgeons performing it grew from 13 to 45. Progression from test to implant in the SNM group was 80.2% for the colorectal surgeons and 77.0% for non-colorectal surgeons. In the meantime, AS procedures decreased from 91 in 2008 to 68 in 2014 as did the number of surgeons performing it (from 52 in 2008 to 41 in 2014). Interestingly, 38% of those shifted their practice exclusively to SNM by 2014.¹⁸

In favor of anal sphincteroplasty still playing a role

Considering a growing body of evidence in favor of SNM, is there any reason to support AS as a useful treatment for FI patients? SNM undoubtedly has distinct advantages over AS, but are there circumstances in which the indication to perform an AS as the initial modality remains preferable?

Anal sphincteroplasty is a more complex procedure

Anal sphincteroplasty refers to a secondary (delayed) repair of the anal sphincter muscles. Anterior AS for sequelae of an OASI [Fig. 2A] is the most common type of reconstruction performed.

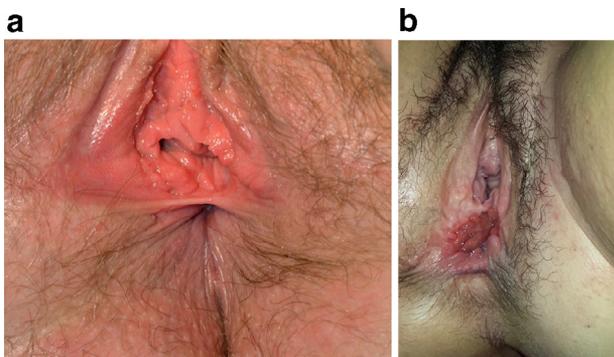


Fig. 2. Sequelae of 4th degree obstetrical anal sphincter injury (OASI) resulting in loss of perineal integrity (A) or cloacae-like deformity of the perineum (B).

In overlapping sphincteroplasty, both the external and internal sphincters have been traditionally included in the repair.^{5,8} Separation and individual repair of these 2 muscles is not thought to confer any benefit. Under general anesthesia with the patient either in prone jack-knife or lithotomy position, an inverted V incision is made between the anus and the vaginal introitus. The scarred muscle ends are identified laterally and dissected from the rectum posteriorly and the vagina anteriorly. An adequate mobilization is necessary to ensure a tension-free wrap. The scar tissue is then divided transversely and preserved to hold the sutures. The two ends are overlapped over the midline and stitched with 2/0 mattress U-shaped monofilament sutures. A levatorplasty can be added, taking great care not to narrow the vagina excessively to avoid dyspareunia. A skin T shaped closure with interrupted absorbable sutures is often feasible. A small opening in the center of the wound is left open or a Penrose drain is inserted. Importantly, preoperative counseling should highlight the risk of postoperative wound infection and delayed healing as the most common complication.⁵

Although well described in the textbooks and apparently a straightforward procedure, the AS is prone to multiple variations based on indications and techniques. Considering the size of the defect, AS is generally advised for defects of at least 90° of circumference but no more than 180°. When it comes to surgical technique, there are significant variations in the extent of dissection performed, the amount of tension applied on the repair, or the type of sutures used (absorbable or not). In addition, the experience of the surgeon remains variable between centers but most likely tends to decrease especially in Western countries as less AS are performed, in part thanks to the improvement in delivery methods which have limited the number of severe OASIs. This is an important point as technique and expertise have probably more impact on the outcome of AS than with SNM which is a highly standardized procedure, although no predictive technical factors have been identified.

The available data for anal sphincteroplasty

There are significantly less recent reports focusing on AS compared to SNM. Based on a full review of the literature in 2016, it was stated with a suboptimal grade of evidence that “the majority of patients have significant improvement in continence following AS with an average of 66% excellent or good results in the short term. Early failure is associated with a persisting defect that may be amenable to a further attempt at repair. Continence outcomes deteriorate with long-term follow-up, decreasing to 30–80% at 80 months”.⁵ A systematic review of 16 studies analyzed the long-term results in over 900 AS beyond 5 years (1991 to 2010).⁸ It is interesting to note that all articles reported high overall patient satisfaction even if continence declined with time or adaptive measures were needed. The authors concluded that correlation between quality of life and the severity of FI was poor with most patients remaining satisfied with their surgical outcome post-AS despite worsening results over time.⁸ Along that line, a recent French study of AS, interestingly from a gynecological department, reported on 23 patients who were followed up to 7 years.¹⁹ 85% of the patients declared to be satisfied even if only 60% were continent and 50% had impaired sexual life. Other favorable results have been published when the sphincter repair is conducted for cloacae-like deformities [Fig. 2B] of the perineum as a result of a fourth-degree tear.²⁰ In a small retrospective study, the authors observed that although long-term complete anal continence was difficult to achieve (53% of cases), good quality of life and low symptom severity were maintained at a mean 7 years follow-up after surgery.

Making meaningful recommendations in 2019 for a patient suffering of FI with a demonstrated sphincter defect

Considering the lack of strong evidence from comparative studies, a balanced decision-making based on pros and cons of each procedure is proposed in Table 1.

Clear indications for sacral nerve modulation

The most evident indication for SNM is a common clinical scenario in daily practice: a female patient older than 50 years with progressively increasing symptoms of FI and a prior history of traumatic childbirth. The work-up, namely an EAUS complementing the clinical examination, identifies a sphincter tear of various extent in height and circumference. The conservative treatment has failed. Looking at the pathophysiology behind that case, we know that vaginal deliveries impair much more than the anal sphincters alone. Structural “stretch-induced” damage of the pelvic floor muscles well demonstrated on 3-D computer models contributes to a deterioration of continence. Neural damage associated with traumatic childbirth is attributed to the second stage of childbirth during which the perineal descent and straining leads to an excessive stretch of nerves innervating the anal sphincter beyond the threshold known to cause permanent damage.^{21,22} Under such scenario which pertains to a majority of patients referred for FI in clinical practice, SNM confers significant advantages: its effect against sensory dysfunction through a modulation of afferent activity from peripheral nerve to brain centers, is particularly useful to improve bowel control, and even more if there is a concomitant urinary incontinence.^{6,15,16} Even more so, if the sphincter lesion concerns only the internal sphincter with isolated or multiple defects secondary to internal sphincterotomy or anal dilation either from a surgical procedure or from a sexual assault, SNM is the first and only option to help the patient as bulking agents have failed to demonstrate substantial efficacy.⁵

Strong indication for anal sphincteroplasty

A typical clinical scenario where AS plays a role, is in a young patient with a clinically recognized, recent (less than 2–5 years) sphincter tear, usually anterior based and as a consequence of a complicated delivery with forceps or vacuum-assisted, a large birth weight, and a prolonged second stage of labor. When there is severe loss of perineal tissue, AS can improve both anal function and sexual comfort (Fig. 2A, B).^{4,5,19,20} Clinical assessment of the sphincters and perineal body with EAUS or MRI imaging is essential prior to intervention. There is no sense to repair small external sphincter defect (<90°) and isolated internal sphincter tears that are not surgically amenable to repair.

Complex clinical scenarios

Several clinical scenarios can be listed where decisions are more debatable. For instance, it is not currently clear of what to

Table 1
An expert opinion-based comparison of the 2 options to treat fecal incontinence with an associated anal sphincter defect.

| | AS | SNM |
|---|------|-----|
| Concomitant pelvic disorders (urinary incontinence) | – | +++ |
| Short term outcome | +++ | +++ |
| Long term outcome | – | ++ |
| Patient satisfaction | ++ | ++ |
| Safety | + | +++ |
| Maintenance* | ++ | – |
| Cost | ++++ | – |

Adapted from K. Matzel, personal communication.

AS: Anal sphincteroplasty, SNM: Sacral neuromodulation.

* Includes programming and battery changes.

do with patients who are initially considered as good candidates for SNM but who eventually fail the PNE test. Current recommendations advise to redo the test by stimulating another root: contralateral S3 or any S4.^{7,9} The same has been recommended in case of loss of efficacy in the medium–long term after an initially successful SNM. On the opposite side of the spectrum are cases of AS failure, either shortly after the repair or in the long run. Some authors advocate a redo anal sphincteroplasty although the results of a redo appear to be poor.²³ There is an emergent consensus nowadays to opt in such circumstances for SNM. Furthermore, after a successful AS we instruct patients with a long-term loss of efficacy to consider the SNM option.

Extensive loss of sphincter muscles (>160–180°) represents a challenge to restore continence. AS is rarely efficient in such cases and we believe that it is worth suggesting a test of SNM to those patients, just as we do for other extreme deformities related to anorectal malformations.²⁴ In the case of loss of perineal coverage, a graciloplasty could be a helpful option. However, the stimulating device for the gracilis muscle wrap, necessary to avoid muscle atrophy, is no longer commercially available. Furthermore, the artificial bowel sphincters (ABS or magnetic anal sphincter) were unfortunately pulled out of the market. In such “end-stage” situations, detailed information has to be given on stoma, an alternative to regain a better quality of life even if patient acceptance is usually low at a first encounter.^{4,5}

Limitations in decision-making

Deciding between SNM and AS in patients with FI and a sphincter defect is still largely based on expert opinions more than scientific evidence. Without being as categorical as Rydningen et al. who stated that “the presence of a sphincter defect does not preclude PNE and that SNM should be considered as first-line treatment for all women with FI following OASI, regardless of the extent of sphincter defect and in the absence of other indications for perineal reconstruction”, we agree that SNM today has clearly a prominent role to play in the treatment of FI associated with a sphincter defect.¹⁶ Its use is supported by the underlying mechanism of action on sensory dysfunction as well as its significant practical advantages. However, this technique is not free of complications as reported in a series from an expert center: at a median follow-up of 33 months, 17.6% of patients have required explanation of the device or discontinued treatment entirely.²⁵ Furthermore, not all patients respond favorably to PNE. They have to be informed that it can yield dramatic improvement in some of them, and yet provide no benefit in others. Finally, SNM is an expensive therapy at the time of initial implantation but also during the long-term as it requires active programming with the support of a dedicated team, battery exchanges or replacement, and in some cases removal of the device. The need for battery replacement has to be taken into account specially if the first implantation is done early in life as many changes will be required long-term.²⁶

AS on the other hand, has probably been used in excess in the past mainly due to lack of other options before introducing SNM. Technically AS is less standardized and less reproducible than SNM and a loss of expertise in performing AS in the future may limit its use. Centralizing this complex surgery to specially trained surgeons should be suggested. This holds also true for SNM when considering the wide variation in progression rates from stage 1 (PNE) to stage 2 (long-term treatment).¹⁸ A non-conversion to a definitive implantation could be related to patient's factors, but also to an inadequate lead positioning making stimulation inefficient. Caseload and the availability of a support team for optimal programming are essential for the full success and cost-effectiveness of SNM.

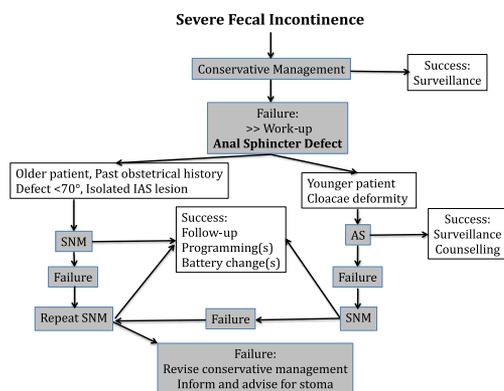


Fig. 3. Decision making strategy – Severe fecal incontinence and anal sphincter defect.
Note: SNM (sacral nerve modulation), AS (anal sphincteroplasty), IAS (internal anal sphincter).

Conclusions

To eventually close an on-going debate, we should not think of a decision “AS or SNM” to manage FI associated with a sphincter defect, but much more “AS and SNM” to help patients affected by a severe “chronic” condition to improve their debilitating symptoms. In Fig. 3 we propose a treatment algorithm that can be helpful to surgeons treating FI. SNM has distinctive advantages if done properly by well-trained providers. A blanket approach to neglect the sphincter status and to go straight to SNM is probably not a wise decision for all patients, especially in some patients such as those with cloacae-like defects. We need to understand that FI is a chronically progressing disorder, varying over time, and that all available therapeutic tools have to be embraced in a pragmatic and combined fashion to help patients find a good QoL.

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