Sacral Nerve Stimulation

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Klaus E. Matzel

Introduction

Fecal incontinence is a socially disabling problem that is underestimated but widespread. Approximately 2% of the general population suffer from the inability to control bowel emptying [1], and this rate rises with age: up to 11% of men and 26% of women over age 50 [2]. Its impact on society is substantial. Only a small portion of this population has to be treated surgically.

With better diagnostic methods, understanding the physiology and pathophysiology of the continence organ components has improved in recent years. Maintenance of fecal continence is an integrated result of the reservoir system of the rectum and the distal colon, outlet resistance of the sphincteric complex, and the sensory lining of the anal canal. Their functional interaction is attained by a convergence of somatomotor, somatosensory, and autonomic innervation mediated by fibers traveling with the sacral spinal nerves. Sacral nerve stimulation (SNS) potentially affects all of these functions.

The concept of recruiting residual function of an inadequate anorectal continence organ by electrostimulation of its peripheral nerve supply, i.e., the sacral spinal nerves, was adapted from the field of urology in the early 1990s. The rationale for applying SNS to fecal incontinence was based on both clinical observations and anatomic considerations (from the former, the beneficial effect on bowel habits and anorectal continence function and increased anorectal angulation and anal canal closure pressure seen in urologic patients; from the latter, the demonstration by dissection of a dual peripheral nerve supply of the striated pelvic floor muscles that govern these functions) [3]. It was thought that because the sacral spinal nerve site is the most distal common location of this dual nerve supply, stimulation there could both enhance physiologic function [3] and improve the symptoms of fecal incontinence. Subsequently, in 1994, SNS was first applied for the treatment of fecal incontinence [4] in patients with functional deficits of the anal sphincter but no morphologic defect. Patients were selected because conservative treatment had failed, traditional surgical options such as sphincter repair were conceptually questionable, or the benefit of sphincter-replacement procedures, such as artificial bowel sphincter and dynamic graciloplasty, with their high morbidity, would not outweigh the risk in this population [5, 6].

Since then, the technique has undergone continuous development, the patient selection process has been modified, and the spectrum of indications has expanded. Today, the treatment can be considered part of the armamentarium for treating fecal incontinence; however, our knowledge and understanding of its underlying mechanism of action is only slowly improving.

Patient Selection and Indications

Today, fecal incontinence from a variety of causes can be treated with SNS. The current spectrum of applications reflects the evolution and expansion of the initial indication. Initially, SNS was confined to patients with deficient function of the striated anal sphincter and levator ani but with no morphologic defect [4], as residual function of the continence organ would be recruited by electrical stimulation. Thus, initial patient selection for the SNS protocol was based on clinical and physiologic finding of reduced or absent voluntary sphincteric function but existing reflex activity, indicating an intact nerve–muscle connection (confirmed by intact anocutaneous reflex activity or by muscular response to pudendal stimulation with the St. Mark's electrode) [7]. In this group of patients, the causes varied and covered a spectrum from postoperative sphincteric weakness consequent to anal and rectal procedures to total lack of voluntary sphincteric control as a sequela of cauda syndrome secondary to lumbar spine fracture. The latter suggested the potential use of SNS in neurogenic incontinence (Table 1) [6]. The common denominator of the heterogeneous etiologies addressed was reduced function and intact morphology.

Table 1. Sacral nerve stimulation for fecal incontinence: clinical results

Report	Patients	Prestimulation	Stimulation		Follow-up (months)	
			Temporary	Permanent[a]		
Frequency of incontinence episodes to solid or liquid stool over a 7-day period						
Initial concept						
Matzel [7]	6	9 (2–19)	1.5 (1–5)	0 (0–1)	59 (5–70)	
Leroi [8]	6	2 (1–7)	0 (0–4)	0.5 (0–2)	6 (3–6)	
Ganio [9]	5	3(2–14)	0	0	14 (5–37)	
Ganio [10]	16	5.5 (1–19)	–	0. (0–1)	10.5 (3–45)	
Matzel [11]	34	8.3 (1.7–78.7)	–	0.75 (0–25)	23.9 (1–36)	
Modified Concept						
Vaizey [12]	9	8 (2–58)	0 (0–10)	–	–	
Malouf [13]	5	(see Cleveland Clinic Incontinence Score)				
Current Concept						
Rosen [14]	16	2 (1–5)	–	0.7 (0–5)	15 (3–26)	
Kenefick [15]	15	11 (2–30)	0 (0–7)	0 (0–4)	24 (3–80)	
Ripetti [16]	4	12[b]	–	2[b,c]	24	
Uludag [17]	50	7.5 (1–18)	0.67(0–4)	0.8(0–5)[c]	12.0[b]	
Altomare [18]		14	14 (11–14)[d]	–	0.5 (0–2)[d]	14 (6–48)
Jarrett [19]	46	7.5 (1–78)	–	1 (0–39)	12 (1–72)	
		Cleveland Clinic Incontinence Continence Score[e]				
Malouf [13]	5	16 (13–20)	–	2 (0–13)	16	
Matzel [20]	16	16 (12–19)	–	2 (0–7)	32.5(3–99)	
Rasmussen [21]	10	19.5 (14–20)	–	5.5 (0–20)	4.5 (1–12)	
Altomare [18]		14	15 (12.5–17.5)	–	5.7 (2–6)[d]	14 (6–48)

Data presented as median value unless otherwise indicated, – Not available, [a]Data at last follow-up, [b]Median value, standard deviation (SD) and range not available, [c]Follow-up value: median of values at published follow-up intervals, [d]Median values during a 2-week period, [e]Cleveland Clinic Incontinence Score [30]: 0 continent, 20 incontinent

This initial spectrum of indications and the positive clinical outcome were confirmed by single-center reports [6, 8, 10, 22] and recently in a prospective multicenter study (Table 2) [11]. Clinical symptoms, measured as number of episodes with involuntary loss of stool, were significantly improved during permanent stimulation. Approximately 90% of patients experienced a substantial (>50%) improvement, and 50% of patients gained full continence. In a recently published prospective multicenter trial, not only was the number of incontinent episodes or days with incontinence improved during the period of observation, but the ability to postpone defecation intentionally was significantly increased [7, 11, 23].

Recording anorectal activity during temporary

Table 2. Permanent sacral nerve stimulation for fecal incontinence, clinical results; quality of life

Report	Patients	Short Form (SF)-36	Fecal Incontinence Quality of Life			
		Categories improved	Lifestyle coping/behavior		Depression/self–perception embarrassment	
Malouf [13]	5	SF, RE, MH, RF	–	–	–	–
Rosen [14]	16	–	Increased[a]	Increased[a]	Increased[a]	Increased[a]
Kenefick [15]	15	All[a] except HT	–	–	–	–
Ripetti [16]	4	SF[a], RE[a], PF[a]	–	–	–	–
Matzel [20]	16	–	Increased[a]	Increased[a]	Increased[a]	Increased[a]
Altomare [18]	14	–	Increased[a]	Increased[a]	Increased[a]	Increased[a]
Matzel [11]	34	SF[a], MH, RE, RP, BP	Increased[a]	Increased[a]	Increased[a]	Increased[a]

SF 36: *RE* role–emotional, *GH* general health, *MH* mental health, *BP* bodily pain, *RP* role–physical, *SF* social function, *V* vitality, *HAT* health transition, *PF* physical functioning, – Not available, [a]Significant, (adapted from [7])

Table 3. Permanent sacral spinal nerve stimulation for fecal incontinence: anorectal physiologic findings

Report	Patients	Resting Pressure	Squeeze Pressure	Threshold Volume	Urge Volume	Maximal Tolerable Volume
Malouf [13]	5	No effect	No consistent change	No effect	No effect	Increased
Matzel [7]	6	No effect	Increased[a]	No effect	No effect	No effect
Ganio [9]	16	Increased	Increased	Decreased	Decreased	–
Leroi [8]	6	No effect	No consistent change	–	–	Decreased
Rosen [14]	16	Increased[a]	Increased[a]	Decreased	Decreased	No effect
Uludag [17]	50	No effect	No effect	–	–	–
Kenefick [15]	15	No effect	Increased[a]	Decreased[a]	No effect	Decreased
Ripetti [16]	4	Increased	Increased	Decreased	No effect	–
Matzel [20]	16	No effect	Increased[a]	Decreased	No effect	Increased
Altomare [18]	14	No effect	No effect	No effect	Decreased	No effect
Ganio [10]	16	Increased[a]	Increased[a]	Decreased	Decreased[a]	–

– Not available, [a]Significant, (adapted from [7])

testing suggested that the effect of SNS was not limited to the striated sphincter muscle [12]. Subsequently, indications for permanent SNS were expanded to patients suffering from fecal incontinence owing to a deficiency of the smooth muscle internal anal sphincter, to limited structural defects, and to functional deficits of the external and internal sphincters. As with the initial group of patients, the causes varied widely and included scleroderma, degeneration or disruption of the internal anal sphincter with or without concomitant external anal sphincter dysfunction, and idiopathic causes of sphincteric weakness. The symptomatic improvement in these patients was comparable with the outcome in the initial group (Table 1) [13, 15].

During the initial work, it became apparent that the two-step selection of patients with two phases of diagnostic stimulation–acute and temporary–was highly predictive of the therapeutic effect of permanent SNS [7, 23]. Consequently, patient selection was no longer based on a conceptual consideration of the potential mechanism of action but on a more pragmatic, trial-and-error approach. Test stimulation was indicated not by an underlying physiologic condition but by the existence of an anal sphincter and residual sphincteric or reflex function. Contraindications included pathologic conditions of the sacrum preventing adequate electrode placement (such as spina bifida), skin disease at the area of implantation, anal sphincter damage amenable to direct repair or requiring a sphincter substitute (e.g., artificial bowel sphincter, dynamic graciloplasty), trauma sequelae with micturition disorders or low bladder capacity, pregnancy, bleeding complications, psychological instability, low mental capacity, and the presence of a cardiac pacemaker or implantable defibrillator.

This pragmatic, trial-and-error selection process resulted in numerous publications [7, 23]. Most studies have represented patients with very heterogeneous pathophysiologic conditions, thus outlining the range of patients who might benefit from SNS. In only one study is a more defined patient population described: 75% of participants suffered from fecal incontinence of neurologic origin [14].

Most commonly, clinical outcome is reported as an improvement in incontinent episodes or days with incontinence during the observation period and in quality of life. The studies vary with regard to design and number of patients, but there is general agreement regarding the two-step stimulation for permanent implant selection. The short- and long-term effects of SNS have been demonstrated in multiple single- and multicenter trials (Table 3). The favorable clinical outcome data (Table 3) confirm this pragmatic selection process.

Technique

Because no other predictors of SNS outcome exist at present, patients are uniformly selected for operative implantation of a permanent neurostimulation device on the basis of clinical improvement during test stimulation, which is documented with standardized questionnaires and diaries. The testing procedure is most commonly considered therapeutically effective if the frequency of fecal incontinence episodes documented by a bowel-habit diary is alle-

viated by at least 50% and if the improvement is reversible after discontinuation.

The method of choice for permanent stimulation is unilateral implantation of a foramen electrode on the spinal nerve site demonstrated to be therapeutically effective during the test stimulation phase. Bilateral foramen electrodes can be considered if unilateral stimulation is insufficient and bilateral test stimulation reveals acceptable results [24].

Technical Evolution

The technique has been described extensively [25]. In short, after successful acute stimulation with needle electrodes placed at the target nerve(s) through the sacral foramen, electrodes are placed temporarily to test the clinical benefit of low frequency. Two technical options are used for subchronic percutaneous nerve evaluation (PNE): a temporary, percutaneously placed, test stimulation lead (or multiple leads) (Medtronic model 041830, temporary screening lead; Medtronic, MN, USA) that will be removed at the end of this phase or operative placement of a quadripolar lead, the so-called foramen electrode (Medtronic model 3886). Recently, a less invasive technique that uses a foramen electrode with a modified anchoring device, the so-called tined lead, placed through a trocar (Medtronic model 3550-18), has been increasingly used [26]. Both types of leads are connected to an external pulse generator for screening (Medtronic Screener 3625), the latter with a percutaneous extension cable.

Percutaneous placement of temporary test stimulation leads can be done on just one sacral spinal nerve or on multiple spinal nerves to offer the option of testing the effect of stimulating different sides and levels or of synchronous stimulation of multiple nerves in an awake patient [27]. Placement of the foramen electrode or tined lead is usually limited to one site.

At the end of the screening phase, the percutaneously placed temporary test stimulation lead is removed. If placement was successful, a permanent system consisting of an electrode, connecting cable, and pulse generator is implanted. The operatively placed foramen electrode is either removed if unsuccessful or connected to an implanted pulse generator (so-called two-stage implant [28]) if successful, offering the advantage of identical positioning of the electrode during screening and therapeutic stimulation. Bilateral placement of foramen electrodes, if performed, is based either on improved outcome of bilateral stimulation during the screening phase [24] or on conceptual considerations [29].

Stimulation parameters applied are those from the use of SNS in urology, sometimes with slight modifications. The combination most effective with regard to required voltage and the patient's perception of perineum and anal sphincter muscle contraction is commonly chosen for permanent stimulation: pulse width, 210 μs; frequency, 15 Hz; on/off, 5–1 s; or continuous stimulation. Stimulation level is usually adapted to be above the individual patient's perception of muscular contraction or perianal sensation and adjusted if necessary.

Results

As noted above, in most studies, quantitative measures are used to describe the clinical benefit, such as days with incontinent episodes/period of observation, absolute numbers of incontinent episodes/period of observation, ability to postpone defecation (in minutes), and percentage of improvement. Even though published reports differ with regard to patient population, a general pattern of outcome can be observed (Table 1). Results of the screening phase are reproduced with the permanent implant. When compared with baseline status, the clinical outcome is highly significant.

The complication rate is relatively low [7, 23]. These have comprised pain at the site of the electrode or pulse generator, electrode dislodgement or breakage, infection, loss of effect, or deterioration in bowel symptoms. In only approximately 5% has discontinuation of treatment with device removal been necessary because of loss of effect, deterioration of symptoms, pain, lead dislocation, or infection. When infection has necessitated removal, reimplantation at a later date has been successful [13].

As with indications, outcome assessment has also evolved. Initially, the usual measures were the number of incontinent episodes or days with incontinence during a set observation period (based on bowel-habit diary). Subsequently, aspects of quality of life were added to the evaluation: Cleveland Clinic Incontinence Score (CCIS) [30], Short Form-36 (SF-36) [31], and the Fecal Incontinence Quality of Life (FIQL) index [32]. The therapeutic impact of SNS is most evident when disease-specific quality-of-life instruments are applied. The disease-specific FIQL showed highly significant improvement in all four categories–lifestyle, coping/behavior, depression/self–perception, embarrassment-in both single- and multicenter studies (Table 2) [7, 23].

Anorectal Physiology

Numerous efforts have been made to correlate the clinical outcome of SNS with results of anorectal

physiology studies, but the effect of chronic stimulation varies greatly among published reports (Table 3) [7, 23]. Data are in part contradictory, inconclusive, and sometimes not reproducible. The most common finding was an increase in striated muscle function, expressed as improved squeeze pressure. In one study, the duration of voluntary contraction was shown to be increased [33]. The effect on resting pressure and rectal perception is inconsistent, although a trend toward decreased sensory and urge thresholds is apparent. Rectal hyposensitivity improved during chronic stimulation [34].

Rectal manometry (24 h) has indicated that the effect of SNS is not limited to sphincteric function and rectal perception. Reduction of spontaneous rectal motility complexes [12, 17] and spontaneous anal sphincter relaxation [33] are qualitative changes in anal and rectal motility. Changes in blood flow recorded by rectal Doppler flowmetry during stimulation give further indication that SNS affects distal bowel autonomic function [35]. Improvement in anal sensory function and sensibility of the perianal and perineal skin during SNS has been reported in one study [14]. Recently, it has been demonstrated that the physiologic changes induced by SNS can be observed not only on the target organ but also in the central nervous system [36, 37].

Thus, the clinical effect of SNS is likely multifactorial based on multiple physiologic functions. Understanding of the relative importance of each of these functions and their dependence on pathophysiologic preconditions is unclear. It may simply be that SNS works differently in different patients. The number of studies with a homogenous patient population is limited, and most studies represent a heterogeneous aggregation of patients with a wide variety of underlying pathophysiologic conditions selected by pragmatic means; thus, any firm conclusion regarding the underlying mechanism of action is unreasonable. A potential placebo effect is unlikely, and long-term benefit has been shown to be sustainable. Patients who experienced clinical deterioration had their therapeutic benefit restored after technical problems with the neurostimulator, of which they were not aware, were corrected; and lastly, the clinical effect has been confirmed in double-blind trials [11, 38].

Future Directions

The future direction of SNS in the context of anorectal dysfunction is in part already outlined by current research. Various interrelated clinical and technical issues are addressed by ongoing research efforts aimed at increasing our knowledge of the appropriate use of SNS and its mechanism of action.

A broad spectrum of patients is today successfully selected by the current pragmatic approach. Recently, some small case series and individual case reports have investigated the effect of SNS in groups of patients presenting with distinct conditions or well-defined anorectal physiologic findings, e.g., muscular dystrophy [39], a history of rectal resection and neoadjuvant chemoradiation [40], a sphincteric gap requiring surgical repair [41], neurologic dysfunction [42], rectal prolapse repair [43], and rectal resection for cancer [44]. Initial results are promising but need to be confirmed in large prospective trials. This approach hopes to pinpoint clinical predictors of responders, potentially obviating test stimulation; also, by focusing on a distinct pathophysiologic condition, it may be helpful to our understanding of how SNS works.

By applying SNS to patients with sphincteric disruption [42] in whom surgical repair is planned, and thus potentially avoiding repair, the current treatment algorithm for fecal incontinence is challenged. This is of special interest, as we have learned in recent years that the short-term benefit of sphincteric repair deteriorates over time; indeed, after 5 years, it has been shown to be less favorable [45, 46]. However, data of the long-term efficacy and durability of SNS are themselves limited.

Not only are surgical treatment options challenged by SNS, the role of SNS in the treatment algorithm needs to be reconsidered. It is currently viewed as an option if conservative therapy has failed. However, because test stimulation is a highly predictive diagnostic procedure with very limited morbidity, it is used much more liberally to explore potential future patient groups. It will be worthwhile to compare the very early use of SNS in the treatment algorithm with results of conservative treatment.

Electrostimulation of the sacral nerve depends on appropriate placement of the electrode to the target nerve, and anatomic pathophysiology may prevent this. This problem could be overcome with stimulation at the pudendal nerve level with a minimally invasive microstimulator [47]. Although further research is required to prove the efficacy and reliability of pudendal stimulation for anorectal dysfunction, recent work indicates that an even more peripheral stimulation, i.e., tibial, may be beneficial [48].

To increase its efficacy, SNS has been applied bilaterally in only a few patients. It remains to be determined whether bilateral stimulation per se leads to an improved and more durable clinical response. The observed increased effectiveness of bilateral SNS or unilateral stimulation of more than one nerve may depend on the patient's individual innervation pattern [49]. The validity, accuracy, and reproducibility of electrophysiologic testing, whether during treatment to monitor functional changes or during the

initial operation to optimize electrode placement, must continue to be investigated to further improve outcome and longevity of the pulse generator.

It is noteworthy that the stimulation parameters, especially subsensory threshold stimulation, are also under investigation. Not only may variations therein increase efficacy by prolonging the battery life of the stimulator; they may provide insight into the clinical effect of SNS, which may in some patients not be dependent on the perception of stimulation [50]. However, a placebo effect is not likely [38].

Outcome has been measured quantitatively by focusing separately on frequency of fecal incontinence episodes and quality–of–life parameters. The indication for a permanent implant has only been based on the clinical effect on incontinence during test stimulation, not on the impact of SNS on quality of life. It is hoped that integrating the effect of SNS on incontinence and quality of life into the decision-making process in a defined manner will be a valid option.

The indications for SNS have been expanded beyond the field of fecal incontinence to slow-transit constipation and outlet obstruction. Preliminary data indicate that it may be beneficial [51] and that this benefit is unlikely to be a placebo effect [52]. Based on these findings, a prospective multicenter trial is ongoing. Not only is the effect of SNS on functional disorders of the colorectum and anus of interest, in the future, its interaction with the anterior and middle compartment of the pelvis and pelvic floor will be important to identify further conditions in which SNS can be of clinical value.

The use of SNS has constantly evolved since its first application for the treatment of fecal incontinence. From selection based on conceptual physiologic considerations, it became a technique applied by a pragmatic approach. Based on the positive outcome, the technique established its place in the current treatment algorithm and is–by exploring new indications with the help of the minimally invasive test stimulation, which can be considered a diagnostic investigation–not only expanding it, but also challenging some paradigms of traditional surgical thinking. However, despite its very positive clinical outcome, increased use, and broadened acceptance, further distribution is hampered by economic considerations. Proof of cost effectiveness is varied [53].

Our knowledge of its mechanism of action remains limited. Further research should be performed on patient selection (based on defined morphologic and physiologic conditions), new indications (with the staged diagnostic approach) and new techniques, long-term outcome, increased efficacy (either by technical modifications or an individualized approach based on physiologic findings), and further determination of the role of SNS in the treatment algorithm. This is a dynamic process with a relatively new treatment concept, and we must constantly reconsider our understanding of anorectal physiology and neurostimulation in the treatment of anorectal functional disorders.

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Invited Commentary

Franc H. Hetzer

Sacral nerve stimulation (SNS) was developed and initially used in patients with urinary bladder dysfunction by Prof. Tanagho et al. during the 1980s [1, 2]. However, in 1990, to Prof. K. Matzel's great credit, the technique was adapted for use in patients with severe anal incontinence [3]. After anatomical considerations and clinical observations, he applied SNS successfully in patients with functional sphincter deficit [4].

Initially, SNS was a treatment for a highly select group of patients with no morphological defect of the sphincter, a deficit also known as idiopathic fecal incontinence [5]. However, in recent years, indications for its use have dramatically increased. This evolution was possible due to the development of the minimally invasive and highly predictive test stimulation. I agree with Prof. Matzel that patient selection is no longer based on morphological and physiological findings or conceptual considerations; it is a trial and error approach.

Due to the minimally invasive technique and the predictive test stimulation, SNS has become a very early option in the algorithm of surgical treatment of fecal incontinence. Complicated neosphincter procedures, such as dynamic graciloplasty or artifical bowel sphincter, have nearly vanished because of SNS. Even the classic sphincter repair, with its moderate long-term results, is being replaced by SNS. Additionally, an ongoing study evaluates SNS use for moderate fecal incontinence and compares it with the best conservative treatment (diet, medication, biofeedback, and pads) (personal communication by Prof. J.J. Tjandra, 2005).

In my opinion, there are a few things that need to be considered: First, I agree with Prof. Matzel that most new indications (e.g., muscular dystrophy, fecal incontinence after low anterior rectum resection and radiotherapy, and multiple sclerosis) are either based on case reports or single-center studies and have to be confirmed in larger series. Second, SNS is still a young technique without long-term follow-up. This lack of knowledge about long-term results makes a comparison with, for example, overlapping sphincter repair difficult. However, to my knowledge, there is also no randomized study available comparing SNS to classic sphincter repair or to a neosphincter procedure. Third, new medical treatments or technical approaches for fecal incontinence must not only prove their efficiency and safety but show cost-effectiveness. All studies label SNS as a highly safe treatment. The published complication rate is about 20% [6], and most of these complications are minor (e.g., test electrode dislodgement or a break of an extension during test stimulation). On the other hand, SNS is a costly treatment due to the expensive neurostimulator (6,200 euros) and electrode (1,800 euros). Additionally, complications such as an infection at the stimulator pocket can dramatically increase costs. This infection is normally not life threatening, but the infected stimulator and the electrode have to be removed immediately. Fortunately, a couple of weeks after successfully treating the infection, a new devise can be implanted.

As part of the expanded indications, the technique of SNS has changed, as described by Prof. Matzel. Recently, a new, smaller-sized neurostimulator (InterStim II model 3058, Medtronic) has become available, which simplifies implantation and increases patient acceptance. The slightly modified permanent electrode (white marker tip on an all–tinned lead, which provides for correct connection with the neurostimulator) can now be directly connected to the new stimulator. A special extension is no longer needed. Also, to vary the implantation position of the stimulator (e.g., gluteally or abdominally), different lengths of the permanent electrode (28-, 33-, or 41-cm leads, models 3093 and 3889, Medtronic) are available. Furthermore, there is a new patient programmer available (InterStim iCon Patient Programmer, Medtronic) that comes with an easy to read liquid crystal display (LCD) and allows to store four preset programs of stimulation. The patient is able to change those programs if necessary. However, in my experience, the more complicated the electronic tool, the more confusion there is for these, most often, elderly patients. Also, it needs

to be considered that whereas it may be reasonable and useful in patients with urinary bladder dysfunction, the benefit of switching between different stimulation patterns is questionable in patients with fecal incontinence.

In addition, a great improvement was accomplished through the development of a new introducing kit by Spinelli et al. [7]. Therefore, I would like to highlight the minimally invasive technique and the advantage of this two-stage procedure. Despite the fact that the tinned lead electrode (model 3889, Medtronic; 1,800 euros) is more expensive than the conventional screening electrode (model 30576SC, Medtronic; 130 euros), published data shows that the success rate of the screening phase is significantly improved, between 30% and 90%, when using the tinned lead [7–9] compared with 26% and 71% when using the conventional test electrode [10, 11]. Two aspects of the electrode may explain these findings: First, the tinned lead electrode is designed for both screening and permanent stimulation; therefore, a change of electrode is no longer necessary at the time of neurostimulator implantation. The electrode position is precisely the same as where it achieved positive screening results, thus, failures after permanent implantation are avoided. Second, the quadripole tinned lead allows for changing the location (pole) of the stimulation during the screening test to correct slight dislocations that may occur in the first days after introducing the electrode. This ability prevents false negative screening tests and increases the success rate of the first stage.

Due to the minimally invasive technique, the implantation of the permanent electrode can be easily performed under local anesthesia. General anesthesia may simplify the procedure for the surgeon but it increases costs. Additionally, we were able to demonstrate that the test electrode placement is more precise in awake patients, as they can report sensitive responses during the procedure. In addition to the visualization of the pelvic floor contraction, patients under local anesthesia were able to tell us intraoperatively if the response was symmetric and whether or not disturbing sensations in the lower extremities were present [8]. The conversion to general anesthesia was rare in our series (3 out of 41 electrode implantations). Limiting factors for the use of local anesthesia are small sacral foramina, which makes the introduction of the foramen needle (model 141828, Medtronic) or the electrode (model 3889, Medtronic) painful. The danger of sacral-root blockade does not allow the injection of local anesthesia in the foramen itself. Both the use of local anesthesia and a tinned lead electrode for the screening process allowed the SNS procedure to be performed in an outpatient setting.

SNS is now a confirmed therapy option in fecal incontinence. Its use in other bowel dysfunctions, such as outlet obstruction and slow-transit constipation, are under evaluation. Complex pelvic floor deficits arise as new targets of chronic stimulation. Urinary and fecal incontinence are often combined symptoms in patients older than 50 years (women ~9% and men ~6%) [12]. Other authors found a double incontinence in up to 25% of patients [13, 14]. For those patients, SNS is a promising therapy option because no other surgical treatment is similarly effective for both forms of incontinence. In the future, the challenge will be to assess pelvic floor disorders and select patients who may benefit from SNS. To do this, an interdisciplinary approach, as that found in pelvic-floor centers, is warranted. Additionally, by concentrating the treatment of SNS in such centers, the success and cost-effectiveness of the procedure will be guaranteed.

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