Sacral Neuromodulation for Fecal Incontinence

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Klaus E. Matzel and Birgit Bittorf

Learning Objectives
- Understand the technique of sacral neuromodulation for the treatment of fecal incontinence
- Understand the indication and patient selection of SNM for FI
- Understand the outcome of SNM for FI
- Understand the role of SNM for FI in the current treatment algorithm of FI

40.1 Introduction

Sacral neuromodulation (SNM)/neurostimulation (SNS) is a minimally invasive treatment for functional disorders of the pelvic floor, particularly urinary and fecal incontinence. By stimulating sacral spinal nerves, central and peripheral neural control of these functions is affected, and residual anorectal function is recruited.

The introduction of SNM into clinical practice in coloproctology [1] represents a paradigm shift in the treatment of fecal incontinence: before this, any attempt to correct fecal incontinence aimed to modify sphincter function by narrowing the anal canal or reinforcing the anal sphincters. There was no possibility of affecting other physiological functions influencing continence. Also, SNM has the unique advantage over other techniques in that it offers a reliable trial stimulation that can identify patients who will respond to permanent stimulation therapy.

K. E. Matzel (✉) · B. Bittorf
Sektion Koloproktologie, Chirurgische Klinik der Universität Erlangen-Nürnberg, Erlangen, Germany
e-mail: Klaus.Matzel@uk-erlangen.de

40.2 Technique and Its Evolution

The procedure has evolved since its introduction. The original technique entailed a presacral incision to identify the sacral foramen for insertion of the electrode implant and suture fixation of the electrode to the periosteum under general anesthesia. The technique became less invasive with the introduction of a percutaneous Seldinger-like positioning for electrode placement, performed under fluoroscopy. This modified technique can be performed under either general or local anesthesia.

Recently the technique has been revisited, modified, and standardized with the objective of reducing the risk of suboptimal implants [2]. The current technique involves intraoperative imaging and the use of a curved stylet for electrode placement (Fig. 40.1). Fluoroscopy clarifies the location of electrode insertion by identifying the medial edges of the sacral foramina and the distal edges of the sacroiliac joint (H-sign) (Fig. 40.2). It helps to determine the depth of electrode insertion (Fig. 40.3) and the direction of placement. A curved, less rigid stylet adds another degree of electrode

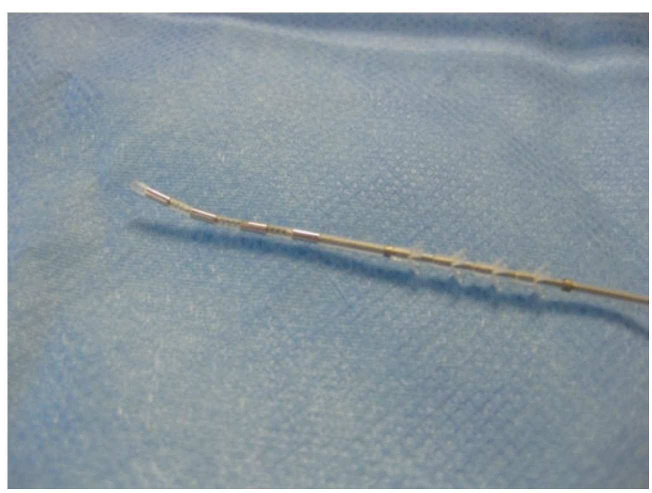

Fig. 40.1 Tined lead electrode with curved tip

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reach and facilitates placement along the natural path of the sacral spinal nerves in the pelvis. The positioning of the electrode is always determined by the pattern and intensity of a motor or sensory response to stimulation, the intensity of applied stimulation, and the radiographic appearance of the implanted electrode. Ideally, all four contacts of the electrode should be positioned close to and parallel with the target nerve, which runs in a caudolateral direction after exiting the ventral opening of the foramen. This offers the greatest number of programming options for permanent stimulation with the least energy consumption—and thus battery longevity and the lowest likelihood of negative side effects [2].

Fig. 40.2 Intraoperative use of fluoroscopy with lateral imaging of sacrum after a.p. marking of distal edge of ileosacral junction and medial edges of sacral foramina: “H“-sign foramen needle electrode inserted into S3 left

The SNM procedure consists of a test phase to determine clinical effectiveness and, in case of a successful test, chronic therapeutic stimulation. The test phase entails percutaneous nerve evaluation (PNE) with either temporary electrodes (one or more easily placed monopolar flexible electrodes (Medtronic InterStim® 3059, Medtronic Inc., Minneapolis, MN, USA)) or the so-called quadripolar tined lead [2] (Medtronic InterStim® 3889, Medtronic Inc., Minneapolis, MN, USA). The first option offers the possibility of testing more than one sacral spinal nerve and is less invasive and expensive. These electrodes are easily removable; however, if test stimulation is successful, insertion of a tined lead is required for chronic stimulation. The latter option, the tined lead, is less prone to dislodgement [3] and can remain and be connected to the fully implantable pulse generator (Medtronic InterStim® II, 3058, Medtronic Inc., Minneapolis, MN, USA), which will be implanted if during the test phase a 50% symptom improvement is achieved. For the test stimulation phase (typically 2 weeks), both types of electrode are connected to an external pulse generator (Fig. 40.4), and the patient documents bowel habits and incontinence frequency by diary. The indication for chronic therapeutic stimulation is based on the degree of symptom improvement.

For both test and chronic stimulation with the fully implanted system (Fig. 40.5), the parameters are set in cooperation with the awake patient. They are determined by the perception of stimulation, the required intensity, and the

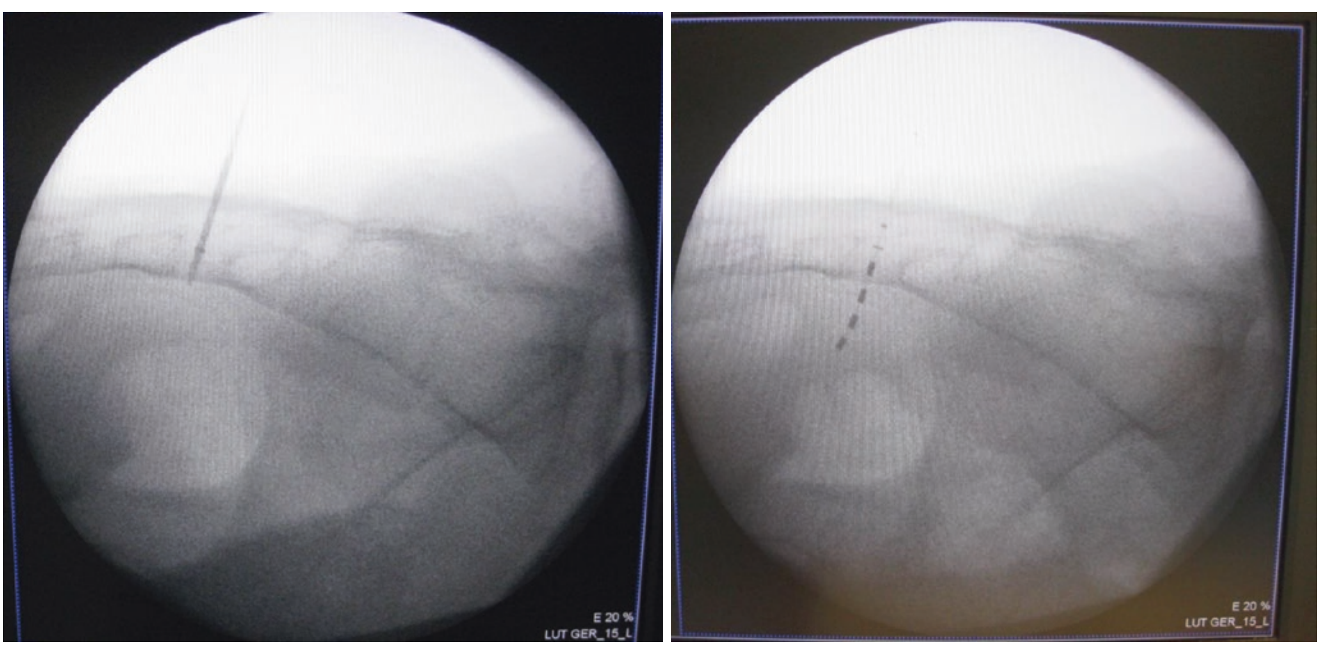

Fig. 40.3 Intraoperative imaging: (**a**) electrode introducer placement, (**b**) tined lead electrode placement

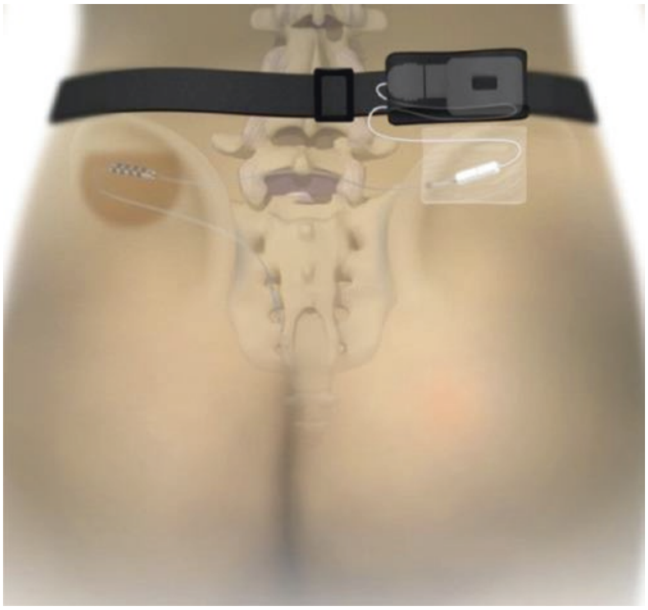

Fig. 40.4 Test stimulation phase: electrode connected to external pulse generator for continuous low-frequency stimulation (Medtronic)

Fig. 40.5 Sacral neuromodulation system (electrode and pulse generator) implanted

presence of side effects. The temporary electrodes allow only unipolar stimulation and the tined lead electrode only bipolar stimulation; chronic stimulation with an implanted tined lead and pulse generator can be uni- or bipolar. The stimulation setting should be comfortable and free of side effects. Most commonly, suprasensory threshold stimulation is used, although a subsensory threshold can also be effective [4]. Patients are able to adjust the parameters within a preset range with a handheld programmer. Adjustments to the programming parameters may be required.

Over time the implantable pulse generator has been reduced in size and its features improved, resulting in greater comfort and safer implantation, especially in underweight patients with thin subcutaneous tissue. The programmer has also improved in performance and ease of use.

40.3 Mechanism of Action

The mechanism of action of SNM is not yet entirely understood. It appears to modulate peripheral and central nervous functions. The original concept—that it worked predominately by improving anal sphincter function [5]—has not been confirmed [6]. A sphincter contraction can be induced by SNS during electrode placement, but this has been shown to be the result of a polysynaptic reflex rather than a direct activation of the alpha-motoneurons [7] and, when present, is not sufficient to fully explain the restored continence. Improved anorectal sensation seems to play a major role in the control of continence. An intact ascending neural pathway to the central nervous system (CNS) is also needed, as one of the contraindications for SNM is complete spinal cord injury [8]. To what extent colonic motor function is affected remains controversial, as the lack of consistent data does not permit a firm conclusion. Increasing evidence indicates that SNM's effect is not limited to the anorectum per se but that it appears to modulate areas of the CNS associated with storage and evacuation, most likely via stimulation of the afferent sensory nerve fibers [9]. The effects on the CNS have been investigated mostly in patients with urinary incontinence; positron emission tomography (PET) [10] has demonstrated that, via the spinal cord, SNS influences some brain areas involved in alertness and awareness, leading to a reduced excitability of some areas of the cortex [11].The effect of temporary stimulation on the CNS appears to differ from that of chronic stimulation [12].

40.4 Indications

No physiological predictors of outcome exist. Thus, the indications for implantation of the permanent device are based on the clinical outcome of test stimulation. Initially, SNM was limited to fecal incontinence in the presence of a morphologically intact anal sphincter. However, based both on the awareness that stimulation's effect is not limited to the sphincters and on the experience of a highly predictive positive test, a progressive broadening of the indications has occurred. Today a wide spectrum of causes of fecal incontinence is successfully treated with SNM. The procedure has also been extended to other pelvic organ/floor disorders, such as constipation [13]. A pragmatic trial and error concept—in which the indication for test stimulation is not based solely on specific pathophysiological or pathomorphological criteria—has demonstrated that SNM may be effective for fecal incontinence caused by external anal sphincter damage [14–16], radiation [17], rectal prolapse repair [18], Crohn's disease [19], partial spinal lesions [20], and cauda equina [21], several neurological diseases (such as muscular dystrophy and systemic sclerosis) [22, 23], and also low anterior resection syndrome (LARS) [24, 25]. The association of fecal incontinence with other pelvic floor dysfunctions such as urinary incontinence or retention is a further area for application [26, 27].

A placebo effect has been addressed in a double-blind randomized crossover trial [28].

Multiple guidelines and recommendations (National Institute for Health and Care Excellence [NICE] [29], American Society of Colon and Rectal Surgeons [ASCRS] [30], International Consultation on Incontinence [ICI] [31], French [32] and Italian [33]) confirm the clinical efficacy of SNM and consider it to be one of the first-line surgical interventions for fecal incontinence of varied etiology. The positioning of SNM in the treatment algorithm is central (Fig. 40.5 ICI Algo). A limited number of surgical alternatives such as sphincteroplasty exist, but they are suitable for a far more limited spectrum of etiologies (Fig. 40.6).

The list of specific contraindications for SNM is limited to conditions not allowing adequate electrode placement, such as anorectal/sacral malformations, complete spinal cord transection, septic conditions in the field of operation (pilonidal sinus), pregnancy, mental or physical inability to adhere to treatment, and the need for MRT (the current version of the implant is only conditionally safe for 1.5 T MRT head coil).

40.5 Prognostic Factors of Outcome

Any attempt to identify factors statistically predictive of a successful outcome to temporary and chronic stimulation has failed. At present no clinical factors (patient features, etiology of incontinence, motor or sensory response to test stimulation) or preoperative laboratory investigations (anal manometry, electrophysiological tests, etc.) have convincingly demonstrated prognostic value [34–37], either for the test phase or for chronic stimulation [38]. Recently, a retrospective study reported that patients with fecal incontinence and concomitant high-grade internal rectal prolapse (Oxford Grade 3 and 4) have a poorer clinical outcome to chronic SNM [39].

40.6 Outcome

Since the introduction of SNM in coloproctology [1], outcome reports have accumulated (Tables 40.1 and 40.2), some focusing on its long-term efficacy [40–44, 50, 61–63]. Most

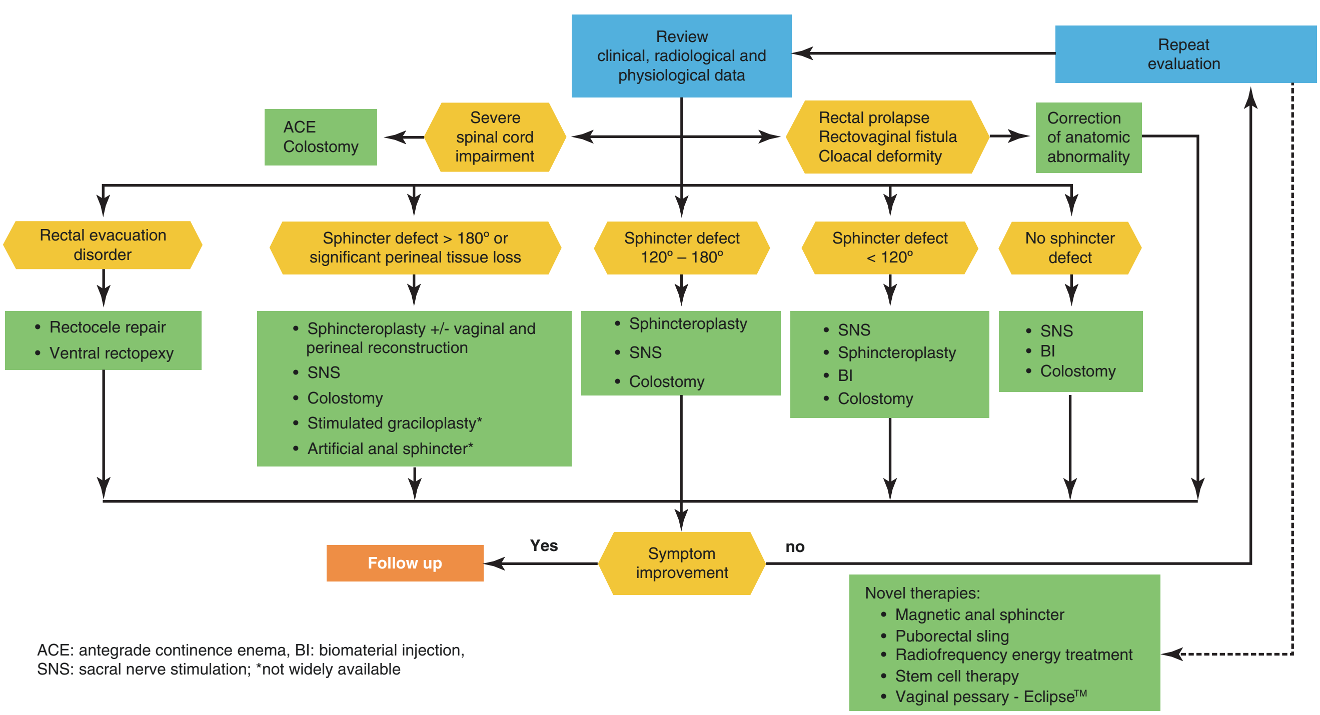

Fig. 40.6 Algorithm International Consultation on Incontinence (ICI): surgical treatment for fecal incontinence [31]

Table 40.1 Chronic sacral nerve stimulation (SNS) for fecal incontinence (FI): incontinence episodes, studies with at least 50 patients

Author	Year	Patients (*n*) PNE	Patients (*n*) (implants)	Patients (*n*) (follow-up)	Median follow-up (months)	Incontinence episodes/week median (range)		*P* value
						Baseline	Last follow-up	
Uludag et al. [40]	2004	63	50 (79%)	6	24[a]	8 (n.a.)	1 (n.a.)	n.a.
Melenhorst et al. [41]	2007	134	100 (75%)	6	60[a]	10 (n.a.)[b]	2 (n.a.)[b]	<0.001
Dudding et al. [42]	2008	60	51 (85%)	48	24	6 (0–81)	1 (0–59)	n.a.
Tjandra et al. [43]	2008	60	53 (88%)	53	12[a]	10 (13)[b]	3 (10)[b]	<0.001
Altomare et al. [44]	2009	94	60 (64%)	52	74[b]	4 (n.a.)[b]	1 (n.a.)[b]	0.004
Michelsen et al. [45]	2010	167	126 (74%)	49	12[a]	8 (n.a.)	1 (n.a.)	<0.001
Hollingshead et al. [46]	2011	113	86 (76%)	86	33	9 (7)[b]	1 (2)[b]	<0.001
Uludag et al. [47]	2011	n.a.	50	n.a.	60	8 (n.a.)	0 (n.a.)	<0.002
Duelund-Jakobsen et al. [48]	2012	n.a.	147	147	46	6 (n.a.)	1 (n.a.)	<0.001
Hull et al. [49]	2013	133	120 (90%)	76	>60	9 (n.a.)	2 (n.a.)	<0.0001
Altomare et al. [50]	2015	407	272 (67%)	228	84	7 (4–11)	0.3 (0–3)	<0.001
Janssen et al. [51]	2017	374	325 (87%)	?	7.1 years	5 (n.a.)[b]	1(n.a.)[b]	<0.001

Modified after Thin et al. [52]
n.a. not available
[a]Values at specific time point
[b]Mean

Table 40.2 Chronic sacral nerve stimulation (SNS) for fecal incontinence (FI): Cleveland Clinic Incontinence Score, studies with at least 50 patients

Author	Year	Patients (*n*) (baseline)	Patients (*n*) (follow-up)	Median follow-up (months)	Median score baseline (range)	Median score follow-up (range)	*P*-value
Tjandra et al. [43]	2008	53	53	12[a]	16 (1)[b]	1 (2)[b]	<0.001
Altomare et al. [44]	2009	60	52	74[b]	15 (4)[b]	5 (5)[b]	<0.001
Brouwer et al. [53]	2010	55	13	48[a]	15 (13–18)	6 (2–8)	0.008
Faucheron et al. [54]	2010	87	87	45	13 (6–19)[b]	8 (1–17)[b]	n.a.
Michelsen et al. [45]	2010	126	10	72[a]	20 (12–20)	7 (2–11)	<0.001
Gallas et al. [34]	2011	200	54	24[a]	14 (2–20)	7 (0–19)	0.001
Lim et al. [55]	2011	53	41	51§	12 (9–15)	8 (5–11)	0.001
Wong et al. [56]	2011	61	61	31	14 (n.a.)	8 (n.a.)	n.a.
Faucheron et al. [57]	2012	57	42	63	14 (4–19)	7 (1–16)	<0.001
Damon et al. [58]	2013	102	101	48[b]	14 (3)	9 (1)	<0.0001
Maeda et al. [59]	2014	108	101	60[a]	16 (6–20)	8 (0–19)	<0.0001
Altomare et al. [50]	2015	272	228	84	16 (13–18)	7 (4–12)	<0.001
Duelund-Jakobsen et al. [60]	2016	164	n.a.	22	15 (3–20)	9 (0–20)	<0.001

Modified after Thin et al. [56]
n.a. not available
[a]Values at specific time point
[b]Mean

patients treated with chronic SNM experience a sustained clinical improvement regardless of the underlying etiology [50], with reported follow-up of up to 18 years [61]. The long-term results are favorable when compared with those of other surgical techniques such as sphincteroplasty. The clinical benefit is not limited to symptom reduction or relief but also to quality of life: a significant improvement has been repeatedly demonstrated in short-, mid-, and long-term outcome studies that used both general health (SF-36) and disease-specific questionnaires such as the Fecal Incontinence Quality of Life Scale (FIQLS) [41, 44–46, 63–65].

40.7 Future Directions

SNM is a well-established treatment option for fecal incontinence. Its role in the current treatment is central. Future development will most likely include a modifications of the applied stimulation device (miniaturization) and its handling (programming, interface). With the availability of a test stimulation phase, which is highly predictive of the clinical effectiveness if it leads to a positive clinical outcome during the test phase, the spectrum will of application will expand further.

Take-Home Messages

SNM develop to be the central treatment modality for surgical therapy of fecal incontinence. A broad spectrum of etiologies leading to fecal incontinence can be treated successfully. The patient selection is pragmatic and based on the outcome of a timely limited test stimulation phase. The chronic stimulation results in long-term symptom improvement and improved quality of life.

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