

# Sacral nerve stimulation in the treatment of severe faecal incontinence: long-term clinical, manometric and quality of life results

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## Abstract

**Background** Faecal incontinence (FI) is a complex and multifactorial health problem. Treatment has to be individualised, analysing the aetiology and gravity in every case. Sacral nerve stimulation (SNS) has been shown to effectively improve treatment of FI.

**Methods** Fifty patients with severe FI treated with SNS between March 2002 and December 2010 were analysed. Preoperative assessment included physical examination, anorectal manometry and anal endosonography. Anal continence was evaluated using the Wexner continence grading system. Quality of life was evaluated using the Fecal Incontinence Quality of life Scale (FIQLS). Follow-up appointments were scheduled at 1, 6 and 12 months and annually thereafter. Wexner score, FIQLS and the ability to defer defecation were assessed at each visit.

**Results** Fifty patients underwent a permanent implant. The overall mean follow-up period was  $55.52 \pm 31.84$  months. After 6 months, SNS significantly improved FI and positively impacted quality of life, as evidence by significant improvements in all 4 scales of the FIQLS. Anorectal manometry showed a trend towards an increase in maximum resting pressure and maximum

pressure. After the first assessment at 6 months, Wexner score and FIQLS remained stable. Ability to defer defecation was also maintained. During follow-up, 3 patients (6 %) experienced implant site pain and episodes of extremity pain and paresthesias that were refractory to medical management and required device explantation. The implant site infection rate was 2 %.

**Conclusions** Analysis of our long-term results confirms the safety and effectiveness of SNS in the management of patients with FI.

**Keywords** Faecal incontinence · Sacral nerve modulation · Long-term follow-up

## Introduction

Faecal incontinence (FI) is a complex, multifactorial health problem [1], and it provokes awkward situations that few people can tolerate. FI is defined as the partial or total loss of the ability to voluntarily control gas and stool expulsion. The severity of FI is evaluated principally by determining the frequency and type of incontinence [2, 3].

The neuromuscular integrity of the pelvic floor, rectum and anus contribute to normal anorectal functioning, continence and defecation. The cause of incontinence is often multifactorial. Many diseases influence faecal consistency, rectal sensations, rectal compliance and sphincteric mechanisms and provoke anorectal dysfunction and consequent FI.

There are many studies reporting the incidence of FI [3–12]. All these studies report that the prevalence of FI increases with age [5–11] and that it is more frequent in women [12]. The individuals with the highest risk of developing this condition include the elderly, patients with

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previous anal surgery, women with obstetric trauma and neurological patients.

The treatment of FI is based on a careful clinical evaluation of the patients. In order to determine the correct treatment, it is important to identify the cause(s) of the incontinence. The treatment has to be individualised, with the aetiology and severity being analysed in every case.

Recently, sacral nerve stimulation (SNS) has been shown to effectively improve the treatment of FI. Studies have generally reported high success rates and low morbidity rates [13].

The purpose of this study was to evaluate the long-term clinical, manometric and quality of life results of SNS for FI.

## Materials and methods

We conducted a prospective study on 52 patients with FI treated with SNS in the Coloproctology Unit of the University General Hospital of Elche between March 2002 and December 2010. Ethics Committee approval was obtained, and the patients gave written informed consent. Inclusion criteria were as follows: inadequate response to conservative treatment including drugs, constipating diet and bio-feedback physiotherapy for at least 2 years and a Wexner score >12 [14]. Exclusion criteria included pregnancy, age younger than 18 years, local acute–chronic infection, coagulopathy, major sphincter defect (>180°), pacemaker or cardiac arrhythmia, cancer, colostomy bag and psychiatric disorders that would prevent adherence to the protocol. Patients who refused to provide consent were also excluded.

The preoperative assessment included a physical examination, anorectal manometry (SmartGI Anorectal Manometry System) and anal endosonography (Pro Focus Ultrasound Scanner model 2202 with a 360° rotating transducer model 2050). The data were collected according to a standardised SNS protocol designed specifically for the present study. Anal continence was evaluated using the Wexner continence grading system [14] (Table 1), and the score was calculated after the patients completed a daily questionnaire. A score of 0 corresponded to full continence, whereas a score of 20 was indicative of total incontinence. Quality of life was evaluated using the Fecal Incontinence Quality of Life (FIQL) scale [15]. In addition, the ability to delay defecation was classified as a <1 min, between 1 and 5 min, between 5 and 10 min, between 10 and 15 min and >15 min.

The physical examination and anal endosonography were intended to detect sphincter lesions. Anal endosonography findings were classified as normal (when there were no pathological findings), internal sphincter injury,

**Table 1** Wexner score

	Never	Rarely <1/month	Sometimes >1/month, <1/week	Usually >1/ week, <7/ week	Always >1/day
Flatus	0	1	2	3	4
Liquid stools	0	1	2	3	4
Solid stools	0	1	2	3	4
Wears pad	0	1	2	3	4
Alteration in lifestyle	0	1	2	3	4

external sphincter injury, internal and external sphincter injury and thinning (thickness of the sphincter lower than 0.5 mm). Anorectal manometry was performed using a low-compliance water perfusion system equipped with a filled 6-lumen catheter and radially arranged ports throughout the cross section. The pressure was recorded by pressure transducers that were located within each infusion line and connected to a chart recorder. In particular, the maximum resting pressure (MRP) and maximum squeeze pressure (MSP) were recorded. The mean  $\pm$  SD of pressures obtained from 30 healthy patients in our laboratory of anorectal physiology was used as a reference (MRP = 76  $\pm$  22 mmHg and MSP = 178  $\pm$  58 mmHg).

Antithrombotic prophylaxis (enoxaparin 40 mg subcutaneously) and antibiotic prophylaxis (piperacillin–tazobactam 4/0.5 g intravenously) were administered.

## Surgical technique

The technique for SNS has been previously described in detail [16]. A quadripolar electrode (Medtronic Model 3889) was placed under local anaesthesia at the S3 or S4 foramen based on the best sensory or motor response during the peripheral nerve evaluation (PNE) and connected via a percutaneous extension kit (Medtronic Model 3550-05) to an external test stimulation (Medtronic Model 3625). A conventional X-ray confirmed the position of the electrode during the procedure. The patients completed a bowel habit diary during the ambulatory stimulation period of 3 weeks. The patients were eligible for a definitive SNS implant when a reduction of at least 50 % of the number of incontinence episodes or days with incontinence was observed. The electrode was connected to a pulse generator (Medtronic Model 3023 InterStim I) with an extension kit (Medtronic Model 3095) after removing the percutaneous extension kit or connected directly to the pulse generator (Medtronic Model 3058 InterStim II) and placed in a subcutaneous pocket created in the ipsilateral gluteal area.

## Follow-up

The follow-up visits for the patients with permanent implants were scheduled at 1, 6 and 12 months and annually thereafter. In the controls, the Wexner score, ability to delay evacuation and quality of life score were determined, and variations in the voltage were examined. In the 6th month, anorectal manometry was performed. These parameters were compared with the values obtained before therapy.

## Statistical analysis

Statistical analysis was performed using Student's *t* test or the Wilcoxon signed-rank test for nonparametric samples in SPSS 20.0 (SPSS, Chicago, IL, USA). The data are shown as the mean value with the range or with the standard error of the mean (SEM), when stated. Statistical significance was set at  $p < 0.05$ .

## Results

From March 2002 to December 2010, 52 patients, including 42 women, who were an average of 63.5 years of age (range 22–77 years) were included in the present study. All patients had already undergone conservative treatment, including drugs, a constipating diet and biofeedback physiotherapy for at least 2 years. The aetiologies of FI were idiopathic ( $n = 22$ ), post-surgery ( $n = 17$ ), obstetric trauma ( $n = 5$ ), post-radiotherapy ( $n = 2$ ), scleroderma ( $n = 2$ ), congenital (anal atresia and Hirschsprung disease) ( $n = 2$ ), neuropathic ( $n = 1$ ) and paraplegia ( $n = 1$ : patient with partial spinal cord injury after traffic accident).

Eight of the patients had already undergone surgery for FI [sphincteroplasty ( $n = 5$ ) and post-anal repair ( $n = 4$ )]. Other previous surgical procedures are shown in Table 2. Eighteen patients had associated urge urinary incontinence (34.6 %). Patient characteristics are shown in Table 2. The duration of the symptoms was  $9.73 \pm 7.11$  years (range 2–36 years).

The results of the anal endosonography are shown in Table 3. On anal manometry, the MRP was  $49.67 \pm 16.421$  mmHg and the MSP was  $73.79 \pm 31.687$  mmHg.

Fifty-two patients underwent the PNE testing. The electrode was positioned in the S3 foramen in 27 patients (13 right and 14 left) and S4 in 25 patients (14 right and 11 left). In 2 patients (4 %), there was no sensory or motor response in any foramen, and we could not perform the temporary stimulation PNE test. A total of 50 patients (96 %) underwent t PNE testing with a temporary stimulation period of 3 weeks. All these patients had a reduction of at least 50 % of incontinence episodes or days with

**Table 2** Patient characteristics

Age	63.5 years (range 22–77 years)
Sex (male/female)	10/42
Duration symptoms (years)	2–36
Deliveries	2 (range 0–8)
Previous surgery	
Sphincteroplasty	5
Post-anal repair	4
Anterior resection	4
Hemorrhoidectomy	4
Fistulotomy and sphincter reconstruction	10
Internal sphincterotomy	3
Hysterectomy	12
Uterine prolapse	1
Rectal prolapse	2
Prostatectomy	2

**Table 3** Results of anal endosonography

Normal	27
Internal sphincter injury	6
External sphincter injury	7
Internal and external sphincter injury	0
Thinning	12

Sphincter defects less than 180°. Thinning of the sphincter <0.5 mm

incontinence, at which time they received a permanent implant of the pulse generator (Medtronic Models 3023 InterStim I or 3058 InterStim II).

The mean post-operative stay was 0.67 days (range 0–1 days) after the PNE test and 0.65 days (range 0–1 days) after the permanent implant.

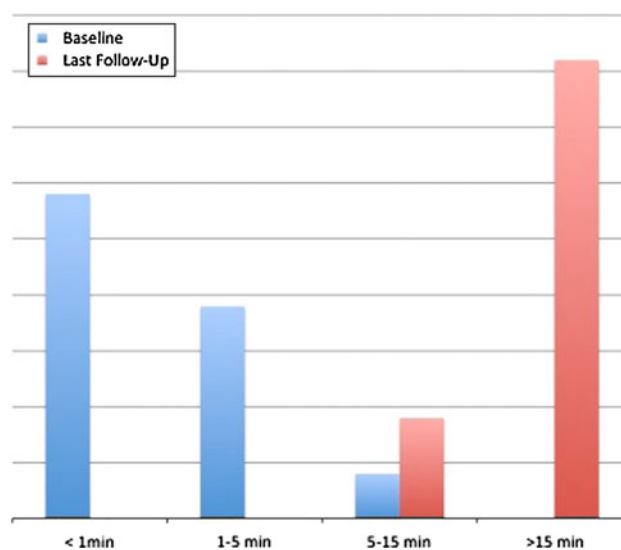
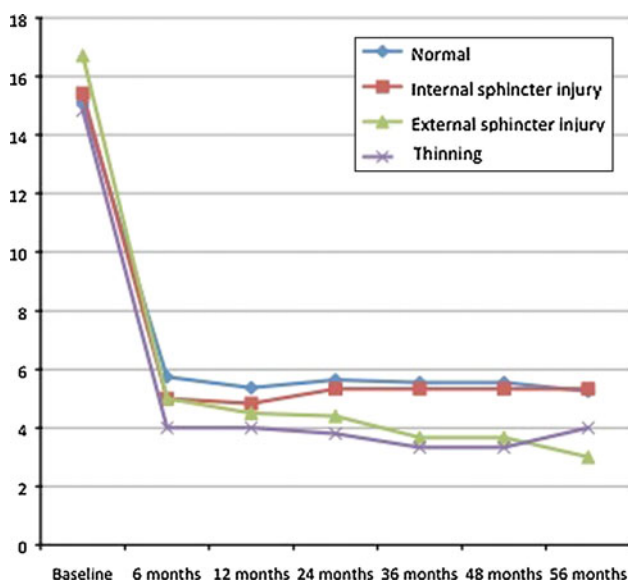
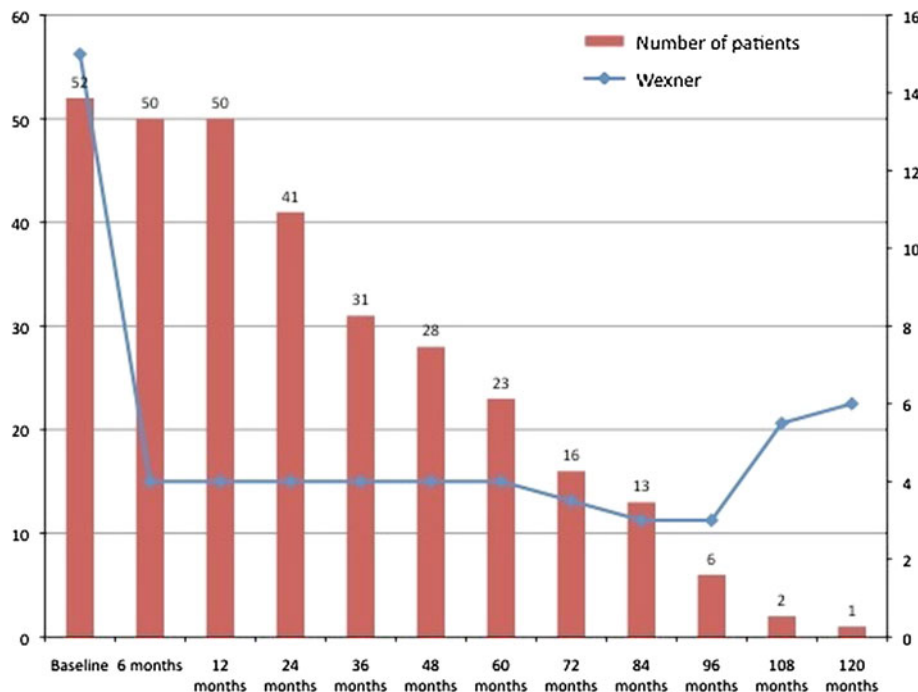
None of the patients were lost to follow-up. The overall mean follow-up period was  $55.52 \pm 31.84$  months (range 12–121 months). Twenty-three patients (46 %) completed 5 years of follow-up, 16 (32 %) completed 6 years, 13 (26 %) completed 7 years, 5 (10 %) completed 8 years, 2 (4 %) completed 9 years and 1 (2 %) completed 10 years.

## Effect on faecal incontinence

Sacral nerve stimulation improved FI in all the patients. The mean Wexner score decreased significantly from a median of 15 (13–20) (preoperative) to 4 (0–7) (6-month revision) ( $p < 0.001$ ). The Wexner scores are shown in Fig. 1.

Statistical analysis revealed that the endosonography findings were not significantly associated with a lower likelihood of treatment success compared to subjects with no sphincter defects (Fig. 2).

**Fig. 1** Wexner score during follow-up. All paired test comparing follow-up to baseline had a *p* value of less than 0.001



**Fig. 3** Ability to delay evacuation

**Fig. 2** Endosonography findings versus Wexner score. All paired tests comparing follow-up to baseline had a *p* value of less than 0.001. There was no difference in the improvement achieved between endosonography findings (*p* > 0.05)

All patients noticed improvement in their ability to delay evacuation, which was statistically significant (*p* < 0.05). These results are presented in Fig. 3.

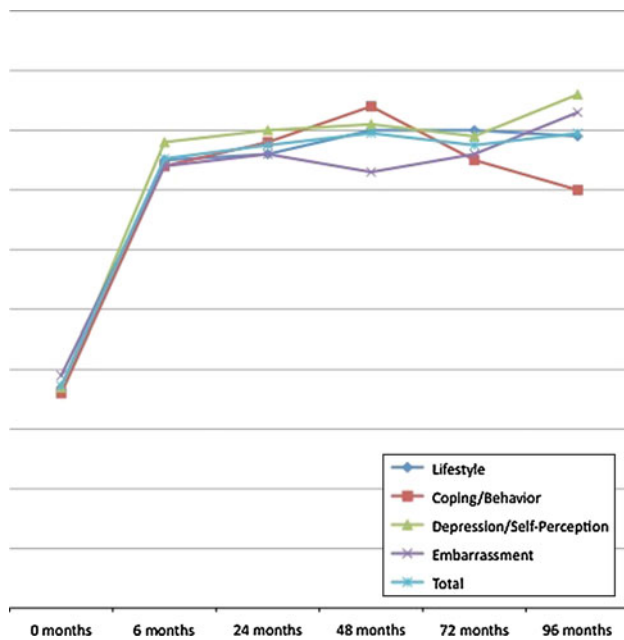
Effect on quality of life

Sacral nerve stimulation had a positive impact on quality of life, as demonstrated by significant improvements in all 4

parts of the FIQLS. The improvement in all these scales remained consistent throughout all the years of follow-up (Fig. 4).

Manometry

There was a nonsignificant trend for an increase in the median anal MRP from 49.67 (±16.4 SD) mmHg at baseline to 49.86 (±14.9 SD) mmHg after 6 months of treatment with SNS (*p* = 0.707) and in the MSP pressure from 73.79 (±31.6 SD) mmHg at baseline to 76.12 (±24.7



**Fig. 4** FIQLS during follow-up. All paired tests comparing follow-up to baseline had a  $p$  value of less than 0.001

SD) mmHg after 6 months of treatment with SNS ( $p = 0.220$ ).

#### Voltage variations

Continuous stimulation parameters were set at a pulse width of 210  $\mu$ s, frequency of 16 Hz and the lowest sensible amplitude possible. Except for minor changes in the amplitude and polarity, the parameters did not change during the permanent stimulation. The median stimulation amplitude at definitive SNS implantation and the 6-month follow-up were 0.624 V (SEM: 0.2291) and 0.632 V (SEM: 0.2281), respectively. There was a nonsignificant trend for an increase in the median voltage during follow-up ( $p = 0.893$ ).

#### Effect on urinary incontinence

Urinary incontinence was present in 18 patients, and 13 of these patients noticed an improvement in their urinary symptoms. However, urodynamic studies were not performed, and the urinary symptoms were not documented by urinary voiding diaries. The subjective improvement in the urinary symptoms remained unchanged during the follow-up period.

#### Adverse events

There were no surgical complications during the PNE test. Of the 50 patients with implants, 2 (4 %) experienced

implant site infection, which required device explantation, antibiotic treatment, and new implantation 2 months after the device was removed. Three patients (6 %) experienced implant site pain and episodes of extremity pain and paresthesias that were refractory to medical management and also required device explantation. After a fall, 1 patient (2 %) experienced a sudden worsening of the functional results because the electrode was broken without displacement; a new electrode was successfully implanted under local anaesthesia. In another case (2 %), after vaginal delivery, the patient had a sudden worsening of the functional results of the SNS because the electrode was broken with displacement; a new electrode was successfully implanted under local anaesthesia. There was no cessation of the clinical response during the follow-up, and no complications were found. Finally, we explanted another device when a patient planned to have an MRI, and at the time of data cut-off for this manuscript, the device has not been still re-implanted.

At the time of the data cut-off, 3 neurostimulators (6 %) lost their charge and had to be replaced, without complications. In these 3 patients, the charge losses occurred 62, 83 and 100 months after the first implantation.

## Discussion

Once medical management options have been exhausted, surgery is the only treatment alternative for patients with FI. The surgical options include post-anal repair, anterior sphincteroplasty, muscle transposition (dynamic graciloplasty, gluteal muscle transposition) and artificial sphincter implantation. Unfortunately, the results of these operations are rarely good, with many adverse events and a long-term success rate of less than 50 % [17–23].

In 1981 at the University of California, SNS was used for the first time to treat patients for urge urinary incontinence [24]. In some patients, who had associated FI, the symptoms of anal incontinence improved. However, SNS was not used to treat FI until 1995, when this procedure was first tested by Matzel [25] in 3 patients. Different studies [13, 26–34] have reported good results with minimal adverse events and good success rates of 70–90 %.

To our knowledge, the present study is one of the longest clinical, manometric and quality of life follow-ups in a single centre. In our study, we report a permanent implant of the pulse generator of 96 %, which is a very high percentage compared with other studies [13, 33]. We believe that this high percentage is due to the careful selection of patients. As the exact mechanism of SNS is not clear, the type of patient who will benefit most cannot be predicted, and a PNE test is essential to identify those patients who are suitable for permanent implantation.

**Table 4** Results of sacral nerve stimulation in faecal incontinence

	<i>N</i>	Device implant	Success rate (%)	Follow-up
Matzel [26]	37	34	92	9.8 years
Altomare [32]	60	52	87	74 months
George [41]	25	23	92	114 months
Hetzer [33]	36	31	86	5 years
Damon [42]	119	102	91	48 months
Present study	52	50	96	57 months

Compared with baseline, the Wexner score decreased significantly after definitive implantation, from 15 (preoperative) to 4 (6-month follow-up). Conaghan et al. [35] and Kenefick et al. [36] suggested that some patients with anal sphincter defects and FI do benefit significantly after the SNS. In a prospective study designed to assess the effectiveness of SNS in 21 patients with external anal sphincter defects, Chan et al. [37] concluded that SNS is a successful treatment for FI. In our study, which included 13 patients (25 %) with anal sphincter defects (6 internal sphincter injuries and 7 external sphincter injuries), there were no significant differences between the sphincter defect and intact sphincter groups based on the Wexner score and FIQLS results of all patients during follow-up. In addition, we found that SNS appears to be equally effective independent of the aetiology, manometric results and endosonography findings.

Similar to the Wexner score, the quality of life score was significantly different in the patients with permanent implantation. SNS had a positive impact on quality of life, as shown by the significant improvements in all 4 parts of the FIQLS, and those results were maintained throughout the follow-up.

The effect of SNS on anal sphincter pressure is not clear. Some studies report an increase in the MRP and MSP [25, 38, 39], and others report an increase in only one of these values or no increase at all [30, 40]. In our study, anorectal manometry was performed before the surgery and 6 months after the permanent implantation, with no significant trend for an increase in the median anal MRP and MSP. The stimulation settings and method of measurement are not standardised between different groups, and the results are often not comparable.

The long-term efficacy of SNS is very good (Table 4). Matzel et al. [26] reported a persistent efficacy as judged by the Wexner score, FIQLS and number of incontinent episodes per week, after a mean period of 9.8 years (range 7–14 years). Our results are similar, with a mean period of 56 months (range 12–121 months). Altomare et al. [32], with a mean follow-up period of 74 ± 14 months (range

60–122 months), noted a similar persistent efficacy. Other studies with shorter follow-up times [13, 27, 30, 31, 33, 34] reported similar results. However, Gourcerol et al. [34] reported an unexplained early failure rate in approximately one-third of the FI patients treated with permanent SNS. None of the patients included in the present study experienced this early failure.

This study demonstrated that SNS is associated with a minimal number of adverse events. However, the most common adverse events were implant site pain, without response to medical treatment, that required device explantation, with a rate of 6 %. Another reported adverse event was implant site infection (4 %). During PNE, the most commonly reported event was lead displacement, with an overall complication rate of 6.4 %. The most common reported complication after device implantation was pain around the implanted stimulator site (13 %), which in most cases required only medical treatment. Infection, with an estimated incidence of 4 %, is the second most common adverse event. Small numbers of other complications, like skin erosion, haematoma, cellulitis and local allergic reaction, have been reported [43]. Regardless, the occurrence of adverse events was lower than that seen in other surgical procedures for FI.

## Conclusions

Sacral nerve stimulation is a safe and effective treatment for patients with FI. It improves patients' quality of life, and the results are maintained over time. SNS reduces the need for more invasive procedures such as dynamic graciloplasty and an artificial anal sphincter [44]. We found that SNS appears to be equally effective independent of the aetiology, manometric results and endosonography findings. Further neurophysiological research is necessary to understand the mechanism of SNS and predict the type of patient who will benefit from this treatment.

**Conflict of interest** None.

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