Original article

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# Long-term outcome of sacral nerve stimulation for faecal incontinence

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## Abstract

**Aim** Sacral nerve stimulation (SNS) is a minimally invasive treatment for faecal incontinence (FI). We report our experience of patients who have undergone SNS for FI with a minimum of 5 years' follow-up. This is a single centre prospective observational study with the aim to assess the long-term function of SNS.

**Method** All patients implanted with SNS were identified from our prospective database. The date of implantation, first and last clinic follow-up, surgical complications and St Mark's incontinence scores were abstracted and analysed.

**Results** From 1996 to 2014, 381 patients were considered for SNS. Of these, 256 patients met the study inclusion criteria. Median age at implantation was 52 years (range 18–81). The ratio of women to men was 205:51. Indications were urge FI (25%), passive FI (17.9%) and mixed FI (57%). The median of the incontinence score at baseline was 19/24 and this improved to 7/24 at the 6-month follow-up. Of the total cohort, 235 patients received a medium-term follow-up (median 110 months, range 12–270) with a median continence score of 10/24 which was also confirmed at the telephone long-term follow-up on 185 patients (132 months, range 60–276).

**Conclusion** This study demonstrates that SNS is an effective treatment in the long term. SNS results in an improvement of validated scores for approximately 60% of patients; however, there is a significant reduction of efficacy over time due to underlying causes.

**Keywords** sacral nerve stimulation, faecal incontinence, pelvic floor disorders

**What does this paper add to the existing literature?**

This study demonstrated the long-term follow-up of patients who underwent sacral nerve stimulation for faecal incontinence. To the best of our knowledge, these single centre data are the longest-term published results with a median follow-up of 9 years and with the longest follow-up of over 23 years for one individual.

## Introduction

Faecal incontinence (FI) is the involuntary loss of stool [1]. It is a distressing condition which may have a significant negative impact on patient quality of life. Different studies have reported a prevalence of 7%–15% in the community [2–5]. These figures increase to 46% in the elderly population [2,6,7]. Dysfunction of the anal sphincter is believed to be the primary cause for FI. This is often attributed to injury sustained during childbirth. Cerebral vascular accident, spinal trauma, multiple sclerosis, long-standing diabetes, rectal prolapse, loss of rectum from surgery and radiotherapy are other potential causes of FI [8,9].

Treatment of FI starts with conservative measures such as pelvic floor physiotherapy, biofeedback and simple pharmacological measures [10,11]. If these fail, more invasive treatments may be offered. These include neuromodulation, bulking agents, artificial sphincter devices and in selected cases sphincteroplasty [12–14]. The most commonly used and effective form of neuromodulation is sacral nerve stimulation (SNS). It was first reported for urinary dysfunction in 1988 [15] and for FI by Matzel *et al.* [16]. A wide range of published literature supports its use in the short and medium term [17–21]; however, only a few

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reports have investigated its efficacy over a longer term [22–25].

The authors' institution has treated patients with SNS since 1996. The aim of this study was to investigate the long-term functional outcome measures associated with SNS for FI. For the purposes of this study long-term follow-up was defined as implantation of a permanent SNS for > 5 years. The primary outcome measure for this study was long-term function of SNS as assessed by validated FI scores.

## Method

The data of all patients who had undergone permanent SNS since 1996 were recorded in a prospectively collected database. This database was interrogated to identify those who had undergone SNS for FI, which was the inclusion criterion for this study. Patients undergoing SNS for other reasons were excluded from the study. Patients who had undergone permanent SNS implantation with < 5 years of follow-up, or who had incomplete data, were also excluded from the study. The following data were abstracted from the database: date of implantation, date of first and last clinic follow-up, length of follow-up, surgical complications and validated continence scores.

Patients were only considered for SNS when all available conservative treatments for FI had failed. All patients included in this study had a successful trial of peripheral nerve evaluation (PNE) using a unipolar lead (Medtronic, Minneapolis, Minnesota, USA; model 3057) prior to permanent implantation. Patients who had successful PNE were offered permanent SNS implantation (Medtronic; lead models 3889 and/or 3093; implantable pulse generator models Interstim until 2011 and Interstim II since then). Surgical implantation was performed positioning a quadripolar lead in S3 or S4 in a standardized way following national and international guidelines for SNS.

The success of PNE was determined by assessment of prospectively collected patient bowel diaries. A 50% reduction in the number of FI episodes per week or a 50% reduction of validated FI scores after 3–4 weeks of PNE was deemed to be a successful response. While bowel diaries were always used following PNE these results were not uniformly included in our database for the study period and therefore were unavailable for analysis. Functional outcome after both PNE and permanent SNS implantation was evaluated only by the St Mark's FI score [26]. FI scores were recorded at baseline, at the 6-month follow-up and at the last available clinical follow-up (medium-term follow-up). Also, patients received a telephone follow-up at the time of this study (long-term follow-up). Patients who could be contacted to assess long-term follow-up were asked if they perceived they still benefited from SNS and whether they would like further clinical review. St Mark's incontinence score for this group was also collected over the phone [26].

Following permanent SNS implantation, overall long-term success was defined as ≥ 50% reduction of the validated FI scores, as this has remained the standard for primary outcome responder analysis in the most recent major studies. Also, a number of patients with full continence and a number of patients with worsening scores were recorded. Factors associated with SNS outcome measures and the impact of other co-variables (age, gender, type of incontinence) were analysed by univariate logistic regression.

Statistical analyses were performed using GRAPHPAD software (version 2018, Greater San Diego Area, West Coast, Western US). Data were expressed as median and range. The Wilcoxon signed-rank test was used for paired comparison of continuous data. $P$ values < 0.05 were considered statistically significant. All values were expressed as median and range.

## Results

### Demographics

Between January 1996 and December 2014, a total of 381 patients were initially considered for SNS. For the purpose of this study, 46 patients were excluded from the analysis as they received SNS as a treatment for other reasons, such as anal pain, constipation or as part of other research trials. Of the remaining 335 patients, 47 patients failed PNE and a total of 256 patients (205 women, 80%; 51 men, 20%) met the study inclusion criteria (Fig. 1). The median age at the date of SNS permanent implantation was 52 years (range 18–81). In this cohort 64 (25%) patients had urge, 46 (17.9%) had passive and 146 (57%) patients had mixed FI. Twenty-one patients were lost at the medium-term follow-up point. This period was a median of 110 months (12–270). The long-term median follow-up period for all patients included in this study was 132 months (60–276) after permanent SNS implantation; however, long-term follow-up data were available only for 185 (72.2%) patients. Seventy-one patients (27.7%) did not have long-term follow-up: seven had passed away, 11 refused to engage with follow-up and the remaining 53 patients were uncontactable.

### Overall results

Of the total cohort of 256 patients, the median baseline FI score was 19/24 (9–24) while at the 6-month

 

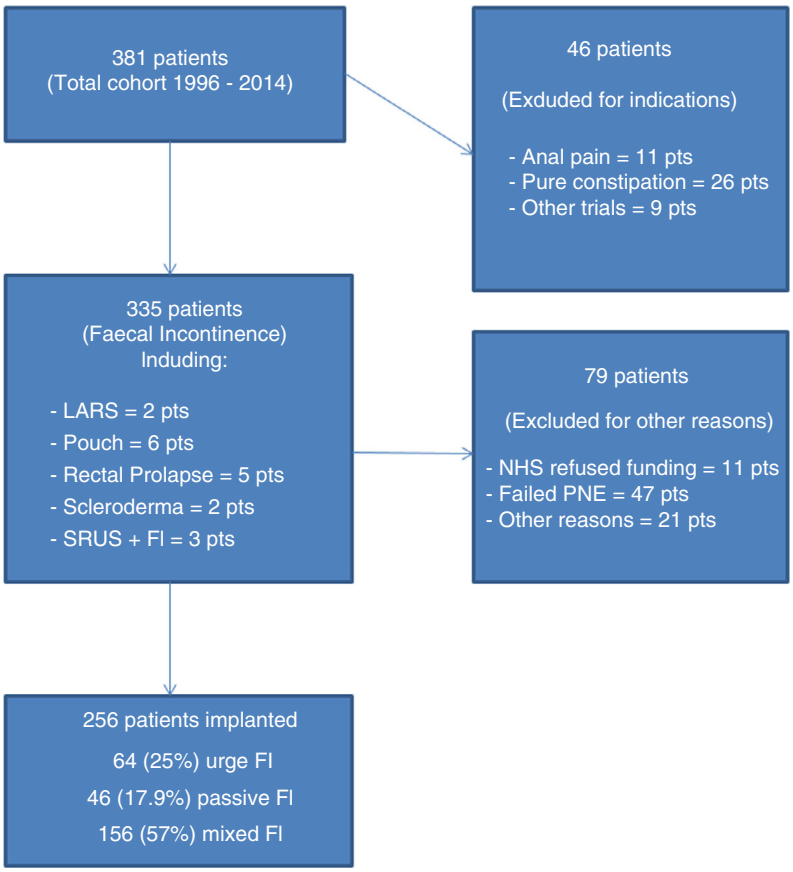


**Figure 1** Total cohort recorded in the database and total number of patients with SNS included in the analysis. LARS, low anterior resection syndrome; SRUS, solitary rectal ulcer syndrome.

treatment point the FI score was 7/24 (0–24), representing a significant reduction from baseline ($P < 0.00001$). At medium-term follow-up (110 months, range 12–270), the St Mark's score for the 235 patients was 10/24 (0–24) ($P < 0.00001$) and at the long-term telephone follow-up (132 months, range 60–276) the St Mark's score was 10/24 (0–21) ($P < 0.00001$), representing again a significant reduction from baseline (Table 1 and Fig. 2). When FI scores at medium-term follow-up (10/24) were compared with long-term follow-up FI scores (10/24) there was no statistically significant difference between these time points (NS; $P = 0.92828$).

### Extent of response

Of the 256 patients, 167 (65.2%) at the 6-month follow-up had a reduction of more than 50% in their St Mark's FI scores. The median FI score for this subgroup compared to baseline was 5/24 (0–14), $P < 0.00001$. Of this group, full continence was achieved in 21 patients (12.5%). Ultimately, of the remaining 89 patients (34.7%) with a reduction of less than 50% in their St Mark's FI scores, the median FI score was 13/24 (7–24), $P < 0.00001$, compared to baseline. Five (5.6%) patients reported no change in continence scores, and three (3.3%) patients reporting an increase in their FI scores.

At medium-term follow-up, the number of patients with a 50% or greater improvement in FI score dropped to 142 (60.4% of the total followed-up cohort, 235 patients), although the median FI score had stabilized at 5/24 (0–15), $P < 0.00001$, compared to the baseline. Of this group, 27 patients (11.4%) reported full continence. Of the remaining 93 (39.5%) patients the median FI score was 13/24 (7–24), $P = 0.00038$, compared to the baseline. The number of patients with no change in continence scores was 4 (1.7%); 17 (7.2%) patients reported an increase in their continence scores.

Of the 185 patients available at long-term follow-up, 115 (62.1%) had a ≥ 50% improvement in FI score with a median St Mark's score of 5/24 (0–11; $P < 0.00001$) compared to baseline. All 115 patients reported over the phone that they had a good and sustained response

 

**Table 1** Overall St Mark's faecal incontinence (FI) scores in the study cohort.

| | Baseline $N = 256$ patients | First follow-up $N = 256$ patients | Medium-term follow-up $N = 235$ patients | Long-term follow-up $N = 185$ patients | $P$ value |
|---|---|---|---|---|---|
| Follow-up | – | 6 months | 110 months (12–270) | 132 months (60–276) | – |
| St Mark's FI score | 19/24 (9–24) | 7/24 (0–24) | 10/24 (0–24) | 10/24 (0–21) | $P < 0.00001$ |

$P$ values represent the difference between baseline and each follow-up point. Values are expressed as median; range is in parentheses.

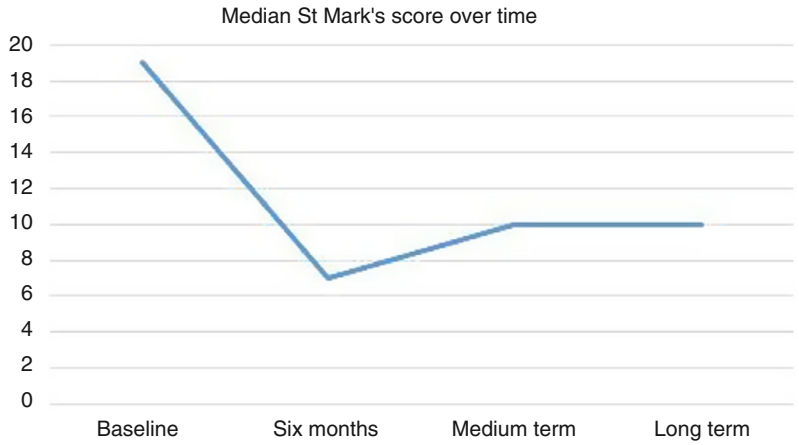


**Figure 2** Median St Mark's FI scores for all patients at baseline, 6-month follow-up, medium-term follow-up and long-term follow-up.

from SNS and would not wish to interrupt the therapy. Of that cohort, 12 (10.4%) patients reported full continence. Of the remaining 70 (37.8%) patients the median FI score was of 13/24 (7–21), $P = 0.002$, compared to the baseline. Of this subgroup, 13 (18.5%) patients reported no change or a deterioration in incontinence score and 12 (17.1%) reported an increase in their continence scores. Thirty-six of the 185 (19.4%) patients interviewed were unwilling to undergo further investigations or clinical assessment for a variety of reasons (age, comorbidities and other priorities). Conversely, 149 (80.5%) patients of the 185 patients were happy to continue their ongoing clinical follow-up. Outcome measures over time are summarized in Table 2.

Passive FI had a significant association at 6 months' time; however, this did not show any impact in the medium and long term. There was no significant association between age, gender and other type of incontinence and the likelihood of successful permanent SNS outcome on regression analyses. Baseline St Mark's score was the only value to have a significant association with the likelihood of successful permanent SNS outcome in the short, medium and long term. Factors associated with functional outcome are reported in Table 3.

### Outcome after treatment failure

Twelve (4.6%) patients of the 256 patient cohort had a poor outcome (lack of efficacy) at the first postoperative follow-up with a median St Mark's FI score of 21/24 (19–24). Deterioration of the scores was noted for nine patients despite multiple stimulation parameter changes. These patients had the SNS device removed. The remaining three patients had lead misplacement or migration which was surgically corrected with a good ultimate outcome and a median St Mark's FI score of 5/24 (5–10).

### Battery changes

Of the 185 patients interviewed at the last follow-up, 121 (65.4%) patients underwent at least one battery change, with 48 (39.6%) of these having two battery changes. Of this total group, there were a further six

 

**Table 2** Extent of response in the 256 patients who underwent 6-month, medium- and long-term follow-up.

| Follow-up | Success | Fully continent | Not successful |
|---|---|---|---|
| 6-month | Patients: 167 (65.2%)<br>FI score: 5/24 (0–14) | Patients: 21 (12.5%) | Patients: 89 (34.7%)<br>FI score: 13/24 (7–24) |
| Medium-term* | Patients: 142 (60.4%)<br>FI score: 5/24 (0–15) | Patients: 27 (11.4%) | Patients: 93 (39.5%)<br>FI score: 13/24 (7–24) |
| Long-term* | Patients: 115 (62.1%)<br>FI score: 5/24 (0–11) | Patients: 12 (10.4%) | Patients: 70 (37.8%)<br>FI score: 13/24 (7–21) |

FI, faecal incontinence.
*Note that 11 patients were lost at the medium-term follow-up and the long-term follow-up was not available for 71 patients. Success was defined as ≥ 50% reduction of the validated FI scores.

**Table 3** Factors associated with SNS outcome measures.

| | | 95% confidence interval | | |
|---|---|---|---|---|
| | Odds ratio | Lower | Upper | *P* value |
| Success at 6 months | | | | |
| Age | 0.9957 | 0.3408 | 1.3672 | 0.6262 |
| Sex (female) | 0.6793 | 0.3443 | 1.3400 | 0.2564 |
| Urge incontinence | 1.7345 | 0.9158 | 3.2853 | 0.0835 |
| Passive incontinence | 0.5052 | 0.2672 | 0.9554 | 0.0368* |
| Mixed incontinence | 1.1038 | 0.6574 | 1.8533 | 0.7090 |
| Baseline score | 1.1255 | 1.0539 | 1.2019 | 0.0003* |
| Success at medium term | | | | |
| Age | 0.9904 | 0.9731 | 1.0079 | 0.2792 |
| Sex (female) | 0.8460 | 0.4291 | 1.6680 | 0.6277 |
| Urge incontinence | 1.2396 | 0.6651 | 2.3104 | 0.4966 |
| Passive incontinence | 0.8903 | 0.4548 | 1.7428 | 0.7351 |
| Mixed incontinence | 0.9590 | 0.5649 | 1.6280 | 0.8768 |
| Baseline score | 1.1672 | 1.0885 | 1.2516 | 0.0000* |
| Success at long term | | | | |
| Age | 0.9828 | 0.9636 | 1.0024 | 0.0824 |
| Sex (female) | 0.7672 | 0.3648 | 0.6136 | 0.4812 |
| Urge incontinence | 0.6375 | 0.3197 | 1.2711 | 0.2026 |
| Passive incontinence | 0.9333 | 0.4496 | 1.9375 | 0.8533 |
| Mixed incontinence | 1.4076 | 0.7754 | 2.5517 | 0.2612 |
| Baseline score | 1.3037 | 1.1891 | 1.4293 | 0.0000* |

SNS, sacral nerve stimulation. Linear logistic regression: values are 95% CI. Incontinence score: St Mark's 24/24.
*$P$ value < 0.05 difference statistically significant.

(5%) patients with postoperative wound infections; four of these six patients healed with a full course of antibiotics, and two had the SNS explanted.

### Complications

Of the total cohort (256 patients), 61 patients had recorded complications (23.8%). Eleven (4.2%) patients had the SNS implant removed for complications rather than treatment failure; 14 (5.4%) had other forms of revisional surgery, 36 (14%) were successfully treated conservatively and 51 (19.9%) patients required a change of their SNS stimulation parameters (Table 4). Wound infection/implant rejection affected 14 (5.4%) patients. Of these, three patients responded to oral antibiotic therapy, while seven required SNS removal. Local chronic pain/numbness, including pain radiating to the leg, was reported by 30 (11.7%) patients; minor postoperative bleeding was recorded in eight (3.1%) patients.

 

## Discussion and conclusions

This study demonstrates that SNS significantly improves FI score for approximately 60% of patients at the medium-term follow-up point. At long-term follow-up, a significant improvement was again recorded for almost 62% of patients. To the best of our knowledge, these data are the longest-term published results of functional outcome measures after SNS for FI. The median follow-up for this study was 11 years (132 months), with one individual being followed up for over 23 years (276 months).

The extended follow-up of this study and its prospective data collection allows an estimation to be made of the long-term efficacy of SNS for FI. However, as with all studies there are several limitations that affect our analyses. Despite the prospective nature of this study there were significant time gaps in the data contained in our database which resulted in a smaller cohort of patients being eligible for inclusion in the study than the total number that were treated at our centre. A lack of recorded bowel diary data for patients who had SNS implanted also meant that change in frequency of incontinent episodes, urgency and quality of life data could not be accurately measured and thus these analyses have been omitted. A further limitation was that only 72% ($n = 185$) of patients were contactable for long-term follow-up. Also, there was lack of other important data recorded in the database, such as previous treatments that patients had received. The final functional outcome measures for those who failed PNE or had their SNS devices removed are unknown as most of the patients have been lost to follow-up.

Other studies have reported SNS outcome measures in the medium to long term [23,24]. In 2015, Altomare *et al.* [25] in a European multicentre SNS outcome group reported results of 228 patients after a median of 84 months of follow-up. They reported that success was maintained in 71% of cases with a range across centres of 65%–80% and full continence achieved in 50% of the cohort [25]. This work followed previously published results again by Altomare *et al.* [24], where continence was reported to improve by at least 50% for 74% of their total cohort at 74 months (60–122) post implant.

In the data presented in this study we did not observe a resumption of full continence in a similar percentage of patients to Altomare *et al.* However, a reduction of incontinence scores and complication rates was similar to Altomare *et al.* and in line with other published studies [25,27,28]. Of note, data from our group published by Hollingshead *et al.* reported that 83% of a small patient cohort were still deriving benefit from SNS, with a significant reduction in FI scores over a 10-year follow-up period (120–138 months) [29]. Nevertheless, the data reported in our study suggest improvements are not sustained in the longer term for more than 60% of patients.

Although our outcome data are less impressive than others reported for shorter follow-up periods [20,21,23], they are still very encouraging results compared to other more invasive techniques (sphincter repair, stoma formation, implantation of artificial bowel sphincter) [30–33]. SNS has clear advantages over the few available techniques for FI including the fact that it can be used for patients with a wide degree of FI causes and with varying degrees of severity. Technical problems are infrequent and there is overwhelming evidence that the complication rate is low. For those patients with loss of efficacy in the longer term, the cause for poor function is often not clear. This could be explained by a deterioration of the patient's condition over time or more simply a loss of response to stimulation. When this occurs it should be kept in mind that many patients who attend clinic in the medium term may require battery replacement. Furthermore, for some patients, efficacy can be restored by adjusting SNS settings such as amplitude, frequency and pulse width of stimulation [34].

In summary, the data presented in this study indicate that SNS is an effective and durable treatment for FI, with decreased FI scores reported by approximately 60% of all patients in the long term. As such it should be considered for patients with FI after conservative measures have failed. The mechanisms of action that mediate SNS function are complex and multifactorial, and

**Table 4** A summary of sacral nerve stimulation (SNS) complications and the overall complication treatments from a total cohort of 256 patients.

| | | | |
|---|---|---|---|
| Total complications | 61 (23.8%) | Overall complications treatment | 61 (23.8%) |
| Failure | 9 (3.5%) | SNS explantation | 11 (4.2%) |
| Infection | 14 (5.4%) | Revisional surgery | 14 (5.4%) |
| Pain/numbness | 30 (11.7%) | Conservative treatment | 36 (14%) |
| Bleeding | 8 (3.1%) | Change of setting | 51 (19.9%) |

 

thus future work will be necessary to determine why not all patients become completely continent, why some initially derive benefit but later report deterioration in function despite SNS optimization and why some patients fail to derive any benefit from PNE or SNS implantation.

In conclusion, this study demonstrates that SNS is an effective treatment for FI in the long term. SNS results in an improvement of validated FI scores for approximately 60% of all patients in the long term; however, there is a slight reduction of efficacy over time due to factors that remain unclear.

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## Conflicts of interest

None.

## Data availability statement

Data available on request due to privacy/ethical restrictions.

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