



Libraries and Learning Services

University of Auckland Research Repository, ResearchSpace

Version

This is the publisher's version. This version is defined in the NISO recommended practice RP-8-2008 <http://www.niso.org/publications/rp/>

Suggested Reference

Benson-Cooper, S., Davenport, E., & Bissett, I. P. (2013). Introduction of sacral neuromodulation for the treatment of faecal incontinence. *New Zealand Medical Journal*, 126(1385), 47-53. Retrieved from <https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2013/vol-126-no-1385/art-benson-cooper>

Copyright

Items in ResearchSpace are protected by copyright, with all rights reserved, unless otherwise indicated. Previously published items are made available in accordance with the copyright policy of the publisher.

For more information, see [General copyright](#), [Publisher copyright](#), [SHERPA/RoMEO](#).

Introduction of sacral neuromodulation for the treatment of faecal incontinence

Sarah Benson-Cooper, Emily Davenport, Ian P Bissett

Abstract

Introduction Faecal incontinence (FI) is a condition that impairs quality of life and ability to function socially. Over the last 15 years a promising new therapy (sacral neuromodulation, SNM) has been introduced which has been associated with marked improvement in many incontinence symptoms.

Aims To assess the early results of SNM in Auckland in terms of improved continence in those undergoing implantation of a permanent stimulator, and determine whether these results are comparable to overseas data.

Methods Patients who met the criteria for SNM; severe faecal incontinence, failure to respond to other measures including biofeedback, dietary modification, and appropriate surgical intervention were offered this treatment.

After an initial bowel diary, patients underwent lead placement connected to an external stimulator and only those who responded had an implanted stimulator placed. Results were assessed by repeated bowel diary, QoL scores and continence scores.

Results Of 29 patients who had initial percutaneous stimulation, 27 showed adequate improvement and went on to permanent implanted stimulator. Of these, results were available on 26. The median number of FI episodes per week preoperatively was 7.25. The median post implantation was one. FI episodes improved following SNM by a mean of 12.21 episodes per week (95% confidence interval 4.91 to 19.51, p value=0.002). For those with longer follow up the initial improvement was sustained. There was a mean follow up time of 10.7 months (range 1 to 30 months).

Conclusion Early results are encouraging, with a significant improvement in faecal incontinence following SNM. The results in Auckland in terms of improvement in symptom severity and quality of life are significant and comparable to other centres. SNM offers a good alternative for patients with end-stage FI.

Faecal incontinence (FI) is a socially stigmatised condition that has a major effect on a patient's quality of life. Many patients are reluctant to seek help until their symptoms are severe or because they fear that there is no available treatment. It affects approximately 13% of the New Zealand (NZ) adult population.¹

The vast majority are treated with conservative management—dietary manipulation, appropriate medication to improve stool consistency, and pelvic floor physiotherapy. Only a few patients require surgical repair of sphincter injuries or prolapse. There remain a small number of patients, refractory to these treatments and incapacitated by faecal incontinence, who are suitable for treatment by sacral neuromodulation (SNM), also known as sacral nerve stimulation. In NZ these patients have previously been

managed by offering a stoma to control the incontinence or by the use of incontinence pads.

SNM is a promising new minimally invasive therapy, which involves implanting a Tined lead (Model 3889 or 3093, Medtronic) into the S3 or S4 foramen and initially connecting this to an external nerve stimulator via a percutaneous lead. It is cost effective and significantly cheaper when compared with stoma formation.²

The present study seeks to determine whether encouraging results achieved overseas with SNM are replicable in a new program set up in New Zealand.

Methods

Patients—Auckland City Hospital offers a tertiary service for the management of patients with severe FI refractory to other measures. SNM is reserved for patients who have failed all other treatments and have at least two episodes of FI per week for a minimum of 12 months.

The decision to perform SNM on each patient was agreed at the Auckland City Hospital monthly pelvic floor multidisciplinary meeting after extensive assessment at the Colorectal Pelvic Floor Clinic. Only four patients had not undergone previous surgery for incontinence. Most patients included had undergone multiple previous procedures—15 patients had sphincter repair, 13 had undergone an anterior delorme's, 7 had anterior mesh rectopexy and 4 patients underwent PTQ injection.

Obstetric trauma was the commonest aetiology, followed by non-obstetric trauma such as perianal injury and sphincterotomy, and then post-radiation and post-anterior resection incontinence. To date, more than 800 patients with faecal incontinence or obstructed defecation have been assessed at this clinic and their results entered on a database.

Data collection—Prior to undergoing SNM patients underwent pelvic floor training from a dedicated pelvic floor physiotherapist, and complete a comprehensive faecal incontinence questionnaire (C-FIQ)³ which includes a faecal incontinence severity index score (FISI),⁴ and a NZ validated incontinence quality of life score.⁵ A two week incontinence diary, trans-anal ultrasonography and anal manometry were also recorded.

The tined four-electrode lead (Model 3889, Medtronic, Minneapolis, MN, USA) and external stimulator (Model 3625, Medtronic) were used to identify patients that were likely to be responders. Lead placement was determined by the best stimulation response in theatre. The technique of lead placement has been previously described in detail by Wöllner.⁶ Outcome was assessed with a screening 2-week incontinence diary, and responders defined as having at least a 50% reduction in the number of FI episodes per week compared with baseline. A permanent implanted stimulator (InterStim Model 3023, Medtronic) was then placed, and incontinence diaries and QoL measures repeated at intervals post operatively to assess results. All patients who had permanent stimulator implanted for treatment for FI at Auckland City Hospital were included in our study.

Statistics—The primary outcome in this study was the difference in the mean number of FI episodes per week after permanent SNM as compared with baseline score. A

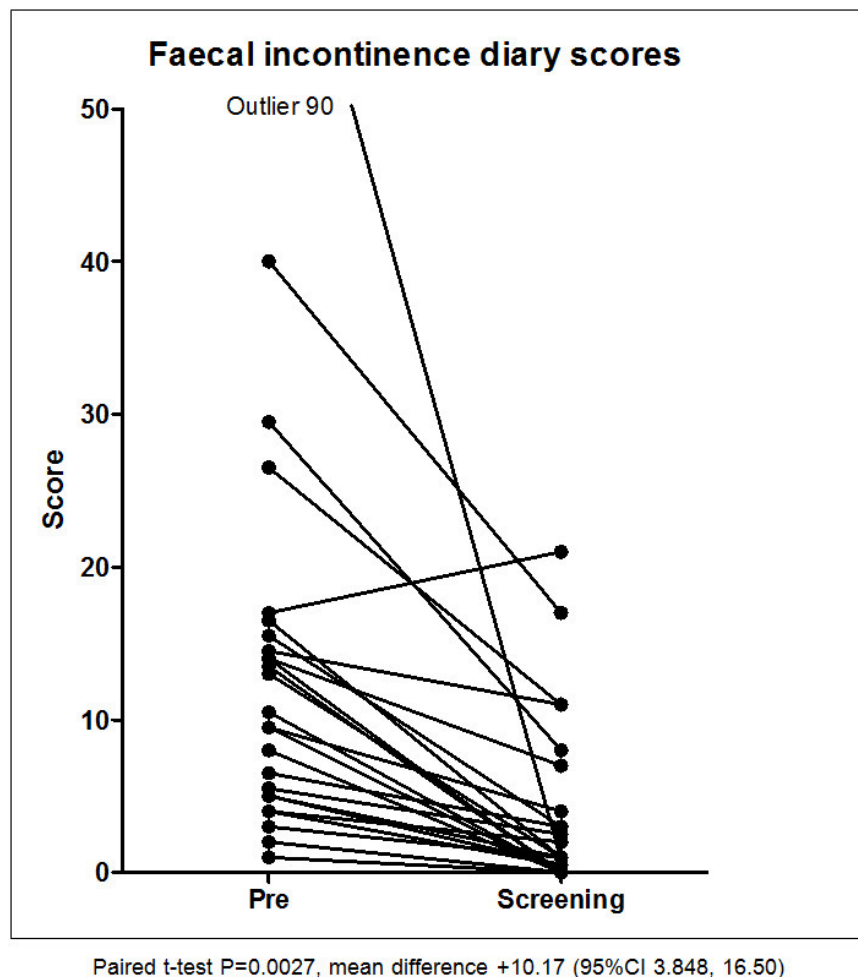
secondary outcome was the difference in total quality of life scores between baseline and post SNM implantation. The paired t test was used to analyse continuous parametric data. $P < 0.05$ was considered statistically significant.

Results

Between 2009 and 2012, 29 patients underwent initial temporary lead placement for faecal incontinence at Auckland City Hospital. Five of these were men and 24 were females, with a median age of 60 years (range 39–84). Eleven of the leads were placed at S3 on the left, 11 at S3 on the right, and 7 at S4 on the left.

Faecal incontinence episodes: baseline vs screening—27 of the 29 showed an adequate improvement and met criteria, determined as 50% reduction in diary-recorded faecal incontinence episodes (with a mean difference of $+10.17$ (95%CI: 3.848–16.50; $p=0.0027$) (Figure 1). Two patients did not meet criteria; one patient had no decrease in FI weekly score, and one patient did not improve by 50% or more.

Figure 1. Baseline versus screening FI diaries

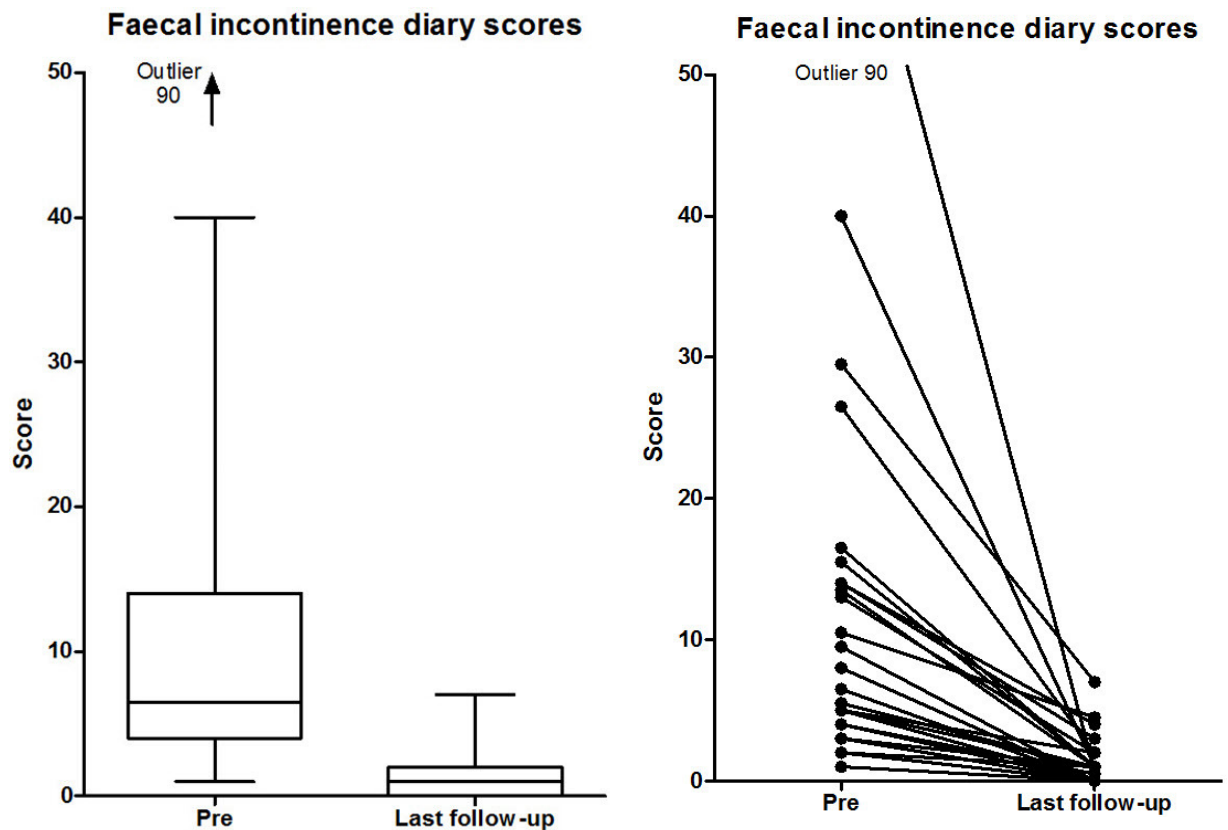


Faecal incontinence episodes: baseline versus last follow up—27 patients went on to have a permanent stimulator implanted. One patient had the permanent stimulator removed following infection after one month and therefore had no post implantation diary completed.

Of the 26 patients with complete data (Figure 2) the median number of incontinence episodes per week at baseline was 7.25 (range 1–90), and post-implantation was 1 (range 0–7). There was a mean difference of -12.2 (95%CI: -4.9–19.5; $p=0.002$). Mean follow up for the 26 patients was 10.7 months (range 1–30 months). For those with longer follow up the initial improvement was sustained.

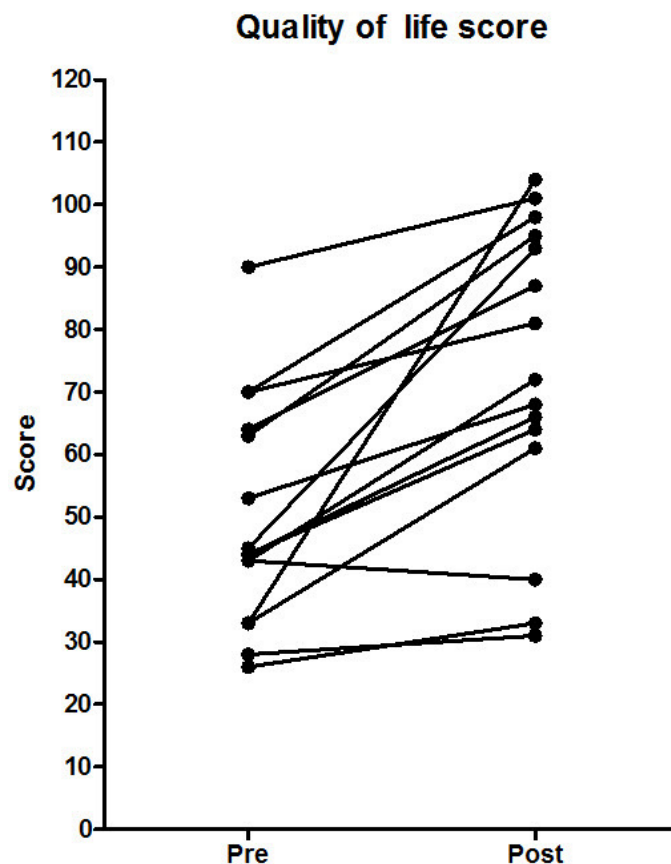
Quality of life—15 patients had both baseline and post-implantation QOL data completed. Scores were a total quality of life score out of 104. Fourteen patients reported improvement in total quality of life score (Figure 3), with a mean difference of +23.0 (95%CI 12.8, 33.2 - $P=0.0003$). One patient reported a decrease in QoL (43/104 to 40/104). This did not correlate with the patients FI diary.

Figure 2. Baseline FI episodes versus last follow up FI episodes



Paired t-test $P=0.0020$, mean difference -12.21 (95%CI: -4.910, -19.51).

Figure 3. Total quality of life score, pre versus post implantation



Paired t-test $P=0.0003$, mean difference $+23.0$ (95%CI 12.76–33.24).

Complications—This procedure was not without complications. There were five patients who developed infections: two of these following temporary lead placement, who then had the lead removed and treatment with intravenous antibiotics. They then went forward for the second stage. Three patients developed infection after permanent stimulator placement, two being successfully treated with intravenous antibiotics alone, and one patient required removal of the permanent stimulator and then declined replacement. Two patients had lead breakage requiring lead replacement. One patient had the stimulator battery fail requiring stimulator replacement. Most patients required a change in programme settings during their follow up.

Discussion

There was a statistically significant improvement in the number of faecal incontinence episodes in patients who underwent permanent stimulator placement for SNM at Auckland City Hospital. In addition to a sustained functional improvement, quality of life was significantly enhanced as measured by total quality of life scores in the 15 patients for whom we had complete data.

A screening trial is an important predictive test for response to SNM; patients who had a good response to the screening trial had an improved and sustained response to the permanent implant.

Unfortunately, as the data was collated retrospectively and post procedure we were unable to obtain complete quality of life data for each patient pre- and post-intervention. However, despite these shortcomings, the data we do have has shown a significant improvement in quality of life scores following SNM. Ideally in future quality of life data would be further analysed in domains (physical, social, emotional, general wellbeing) to provide further information.

So far experience with SNM is short in NZ, with a mean follow-up 10.6 months for this study. Further follow up would be required to assess long-term outcomes and longevity of treatment. We would expect lead fractures or lead failure to become more of a problem in coming years. However, reassuringly, those with longer follow up between one to 3 years have shown no apparent deterioration in FI episodes.

These results are consistent with earlier studies of SNM in FI.^{7,8} In the study by Hetzer et al⁶ 44 patients with severe incontinence were initially assessed with 84% having an improvement in continence on initial, temporary testing and these were then fitted with an implantable stimulator. In these 37 patients there was a significant reduction in faecal incontinence scores, and 34 of them (92%) were deemed to have successfully treated their incontinence.

In a further randomised controlled trial⁸ (involving 60 patients in each arm) patients were randomised to either SNM or best supportive therapy. The SNM patients had significantly fewer incontinence episodes, a better quality of life and almost 50% had perfect continence. Long-term results of SNM in treatment of FI has been reported from Mellgren⁹, and reassuringly results appear durable. We would expect similar durability from our study.

Conclusion

Early results are encouraging, with a significant improvement in FI and improvement in quality of life following SNM. A screening trial is an important predictive test for response to SNM. The results in Auckland, in terms of improvement in symptom severity and quality of life are significant and comparable to other centres.^{7,8} SNM offers a good alternative for patients with end-stage FI.

Competing interests: None known.

Author information: Sarah Benson-Cooper, Registrar, Department of Surgery, Auckland City Hospital, Auckland; Emily Davenport, Fellow, Department of Surgery, Auckland City Hospital, Auckland; Ian P Bissett, Associate Professor, University of Auckland—and Head, Department of Surgery, Auckland City Hospital, Auckland

Acknowledgement: We thank Dr Tom Wang at Auckland City Hospital for his statistical analysis.

Correspondence: Ian P Bissett, Dept of Surgery, Auckland City Hospital, Park Road, Grafton, Auckland 1023, New Zealand. Fax: +64 (09) 3753443; email: i.bissett@auckland.ac.nz

References:

1. Sharma A, Marshall RJ, Macmillan AK, et al. Determining levels of fecal incontinence in the community: a New Zealand cross-sectional study. *Dis Colon Rectum*. 2011;54:1381-7.
2. Hetzer FH, Bieler A, Hahnloser D, et al. Outcome and cost analysis of sacral nerve stimulation for faecal incontinence. *Br J Surg*. 2006;93:1411-7.
3. Macmillan AK, Merrie AE, Marshall RJ, Parry BR. Design and validation of a comprehensive fecal incontinence questionnaire. *Dis Colon Rectum*. 2008;51:1502-22.
4. Rockwood TH, Church JM, Fleshman JW, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence: the fecal incontinence severity index. *Dis Colon Rectum*. 1999;42:1525-32.
5. Rockwood TH, Church JM, Fleshman JW, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum*. 2000;43:9-16.
6. Wöllner J, Hampel C, Kessler TM. Surgery Illustrated – Surgical Atlas Sacral neuromodulation. *BJU Int*. 2012;110:146-59.
7. Hetzer FH, Hahnloser D, Clavien PA, Demartines N. Quality of life and morbidity after permanent sacral nerve stimulation for fecal incontinence. *Arch Surg*. 2007;142:8-13.
8. Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. *Dis Colon Rectum*. 2008;51:494-502.
9. Mellgren A, Wexner SD, Collier JA, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum*. 2011;54:1065-75.