

Outcome and cost analysis of sacral nerve stimulation for faecal incontinence

F. H. Hetzer, A. Bieler, D. Hahnloser, F. Löhlein, P.-A. Clavien and N. Demartines

Division of Visceral and Transplantation Surgery, University Hospital of Zurich, Ramistrasse 100, CH 8091 Zurich, Switzerland

Correspondence to: Dr F. H. Hetzer (e-mail: franc.hetzer@bluewin.ch)

Background: Sacral nerve stimulation (SNS) may be successful in treating incapacitating faecal incontinence. The technique is expensive, and no cost analysis is currently available. The aim of this study was to assess clinical outcome and analyse cost-effectiveness.

Methods: Thirty-six consecutive patients underwent a two-stage SNS procedure. Outcome parameters and real costs were assessed prospectively.

Results: SNS was tested successfully in 33 of 36 patients, and 31 patients were stimulated permanently. In the first stage, eight of 36 patients reported minor complications (pain, infection or electrode dislocation), resulting in a cost of €4053 (range €2838–7273) per patient. For the second stage (permanent stimulation), eight of 33 patients had an infection, pain or loss of effectiveness, resulting in a cost of €11 292 (range €7406–20 274) per patient. Estimated costs for further follow-up were €997 per year. The 5-year cumulative cost for SNS was €22 150 per patient, compared with €33 996 for colostomy, €31 590 for dynamic graciloplasty and €3234 for conservative treatment.

Conclusion: SNS is a highly cost-effective treatment for faecal incontinence. Options for further reduction of SNS costs include strict patient selection, treatment in an outpatient setting and using cheaper devices.

Paper accepted 14 September 2006

Published online 4 October 2006 in Wiley InterScience (www.bjs.co.uk). DOI: 10.1002/bjs.5491

Introduction

Sacral nerve stimulation (SNS) was first used in patients with urinary urge incontinence in 1989¹. Evidence of success in the first three patients treated with SNS for faecal incontinence was only published in 1995². The effectiveness of SNS was subsequently proven in two randomized trials^{3,4}, and many other studies have demonstrated excellent results with success rates ranging between 70 and 85 per cent^{5–7}. The success of SNS is measured by analysis of patient continence diaries, but medium-term follow-up is available in only a few studies. These studies have suggested a significant improvement in quality of life in patients treated with SNS^{7–9}.

New medical treatments or technical approaches for faecal incontinence must not only prove that the technique is both safe and effective but also demonstrate cost-effectiveness to gain wide acceptance by healthcare payers¹⁰. The stimulation electrodes and pulse generator used in SNS are expensive, and therefore cost analysis is both warranted and important. At present, there are

no published data on the economic impact of SNS. The aim of this study was to assess clinical outcome and costs associated with SNS prospectively and to compare these with alternative medical or surgical treatments for patients with faecal incontinence.

Patients and methods

Patient demographics

Between January 2003 and September 2005, 44 consecutive patients were evaluated for SNS. Patients were included who had more than one episode of faecal incontinence per week with either solid or liquid stool for at least a year and failed medical therapy, including antidiarrhoeal medication and biofeedback treatment. Exclusion criteria were congenital rectal malformation, external rectal prolapse, inflammatory bowel disease, chronic diarrhoea and pregnancy. Thirty-six patients fulfilled these criteria. The aetiologies of faecal incontinence were anal sphincter defect in 16 patients (after obstetric or perianal surgery),

Table 1 Aetiology of faecal incontinence

	No. of patients	Permanent implantation
Anal sphincter defect	16	14
Idiopathic	9	7
Pelvic surgery	6	5
Neurogenic	5	5
Total	36	31

idiopathic in nine, pelvic surgery (low anterior resection, rectal prolapse surgery and total proctocolectomy for familial adenomatous polyposis) in six and neurogenic (spinal cord trauma, multiple sclerosis, residual Guillain-Barré polyneuritis) in five (*Table 1*).

Two-stage procedure of sacral nerve stimulation

After informed consent, SNS was performed in two stages. The first stage was percutaneous nerve evaluation, followed by implantation of a permanent lead (tined lead electrode; Medtronic, Minneapolis, Minnesota, USA) for the screening phase in all patients¹¹. A permanent electrode was introduced only when a pelvic floor response was observed with stimulation of less than 4 V, as perineural fibrosis may be induced by higher voltages (stage I). During the 2–3-week screening phase, the effect of SNS on continence was documented by patients in a diary. If the screening phase showed more than 50 per cent reduction in symptoms as measured by the incontinence diary or the Cleveland Clinic Continence Score¹², the implantable pulse generator (IPG) (InterStim®; Medtronic) was permanently implanted (stage II). The stimulation starting parameters were identical for all patients: pulse width 210 µs, frequency 15 Hz and an adaptable amplitude that ranged between 0.5 and 3.5 V.

Cost analysis

The SNS cost analysis was performed on an intention-to-treat basis that included the direct costs for unsuccessful as well as successful procedures. After an unsuccessful screening period, patients underwent a new test phase, a neosphincter procedure (dynamic graciloplasty) or a colostomy. The other option was to remove the electrode and return to conservative management of faecal incontinence (pads, diapers and enema). The costs for further treatments after failed SNS were not included in the analysis.

The analysis was performed from a hospital perspective; therefore only direct medical costs were assessed. These included hospital stay (hospital stay less than 12 h,

€128; more than 12 h, €640 per 24 h), outpatient visits, medications, operations and complication costs.

The operation costs included professional and facility fees (€529 for stage I; €810 for stage II). Material costs included tined lead (€1841), IPG (unilateral €6191; bilateral (InterStim Twin®; Medtronic) €11 126) and patient programmer (€512). The costs of anaesthesia were €349 for stage I and €584 for stage II. The costs for complications included material, operation costs, medication and hospital stay. The longevity of the neurostimulator battery is limited and depends on the amplitude used; for the purpose of this analysis, based on experience with dynamic graciloplasty, a median battery lifetime of 7 years was used.

The ideal course

The treatment pathway for an 'ideal' SNS patient was used for comparison (*Table 2*). This patient was treated in an outpatient setting using local anaesthesia and without complications. 'Extra' costs for hospital stay for both stages, percutaneous nerve evaluation and IPG implantation, included costs for patients who stayed in hospital for longer than 12 h, usually overnight. Overnight stay at either stage was offered to patients for medical reasons, such as prolonged recovery after general anaesthesia. Complication costs for both stages included all of the above costs associated with complications such as material, surgery and additional costs for hospital stay.

Comparison with other therapeutic options

Costs of SNS were compared with real costs of anterior sphincteroplasty performed in the authors' department in

Table 2 Costs for stage I (percutaneous nerve evaluation and test electrode implantation) and stage II (implantation of pulse generator) of sacral nerve stimulation

	Ideal patient cost (€)	Study patient cost (€)
Stage I		
Material (including device)	2360	2761
Operation	478	504
Extra costs for hospital stay	0	293
Complications	0	495
Total	2838	4053
Stage II		
Material (including device)	7536	9061
Operation	800	849
Extra costs for hospital stay	0	254
Complications	0	1128
Total	8336	11 292

the same period as well as costs of conservative treatment, colostomy and dynamic graciloplasty. Conservative treatment of faecal incontinence usually has no direct hospital costs, so costs outside the hospital, such as diapers, enemas, pads and medications, were included. These costs, as well as those of colostomy and dynamic graciloplasty, were based on data from a previous study on the cost-effectiveness of dynamic graciloplasty, in which Adang *et al.*¹³ calculated all direct costs of the neosphincter procedure in 1998. For comparison, their results were transformed with an online inflation-calculating tool (www.westegg.com/inflation/) from 1998 to 2005. Costs are expressed in euros by their median values and range.

Results

Stage I

Stage I was performed 41 times in 36 patients (29 women) with a median age of 61 (range 15–88) years (*Fig. 1*). In five patients, stage I had to be repeated because of loss of effectiveness (two), electrode dislocation (two) or prolapsed rectum (one). The latter patient had an internal rectum prolapse diagnosed during screening. Six months after successful stapled transanal rectal resection, but with persisting faecal incontinence, a second screening was performed. The costs for these five patients were included in the costs of complications. Nineteen of 36 of the initial first stages were performed under local anaesthesia and 23 of 36 patients needed less than 12 h in hospital. The median hospital stay for the first stage was 18 (range 12–48) h and that for a second test, including complications, was 26 (range 12–48) h. In addition, a median of 1.6 outpatient visits was necessary during the screening phase (range 1–5 days).

No severe complications were observed. Minor complications after the first stage occurred in eight patients. *Fig. 1* gives an overview of the complications and *Table 3* of their costs. In three patients, the test electrode had to be removed after unsuccessful screening (effectiveness less than 50 per cent); of these, one patient later underwent an anal sphincter repair and two preferred conservative treatment. In one patient, the electrode was defective and needed to be replaced. Three patients had an infection at the extension of the electrode; the extensions were removed and the patients treated with oral antibiotics. The electrode dislocated in three patients, two repeated the first stage and one needed a new electrode at the time of IPG implantation. One patient developed pain and the electrode was replaced. For three patients, the screening phase was unsuccessful (symptom improvement less than 50 per cent) and the electrodes were removed.

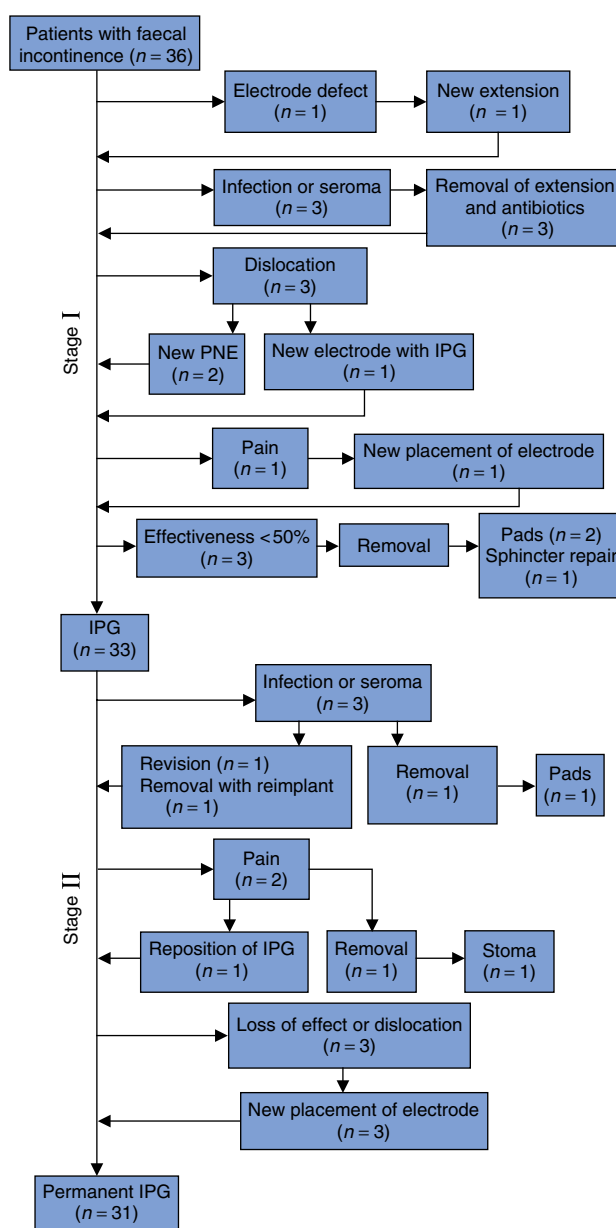


Fig. 1 Overview of treatment success and complications of sacral nerve stimulation in 36 patients with faecal incontinence. IPG, implantable pulse generator; PNE, percutaneous nerve evaluation (with implantation of an electrode)

Stage II: implantation of pulse generator

Screening was successful in 33 patients (26 women) and an IPG was implanted (*Fig. 1*). In 23 of 33 patients, these implantations were performed in an outpatient setting (less than 12 h). For the remaining 12 IPG implantations (including two reimplantations), the median hospital stay

Table 3 Costs for complications of percutaneous nerve evaluation and test electrode implantation (stage I) and implantation of the IPG (stage II)

	Cost (€)
Stage I	
Electrode dislocation (<i>n</i> = 3)	8317
Electrode removal (<i>n</i> = 2)	1219
Electrode removal and replacement (at IPG implantation) because of infection (<i>n</i> = 1)	2772
Electrode defect and replacement (at IPG implantation) (<i>n</i> = 1)	2772
Electrode repositioning because of pain (<i>n</i> = 1)	2772
Total	17 852
Cost per study patient (<i>n</i> = 36)	495
Stage II	
Electrode removal (<i>n</i> = 2)	1930
Reimplantation because of electrode dislocation (<i>n</i> = 3)	25 142
New stimulator because of electrode infection (<i>n</i> = 1)	9205
Revision (<i>n</i> = 2); seroma (<i>n</i> = 1); pain at IPG insertion site (<i>n</i> = 1)	4331
Total	40 608
Cost per study patient (<i>n</i> = 36)*	1128

*The number of patients was taken as 36 in order to perform an intention-to-treat calculation. IPG, implantable pulse generator.

was 1.4 (range 1–2) days. Nineteen of the first IPG implantations and one of the second were performed under local anaesthesia. A stimulator for two electrodes (InterStim Twin®) was implanted in four patients for whom unilateral stimulation was insufficient. This led to higher costs for these patients, because a Twin® stimulator is more expensive.

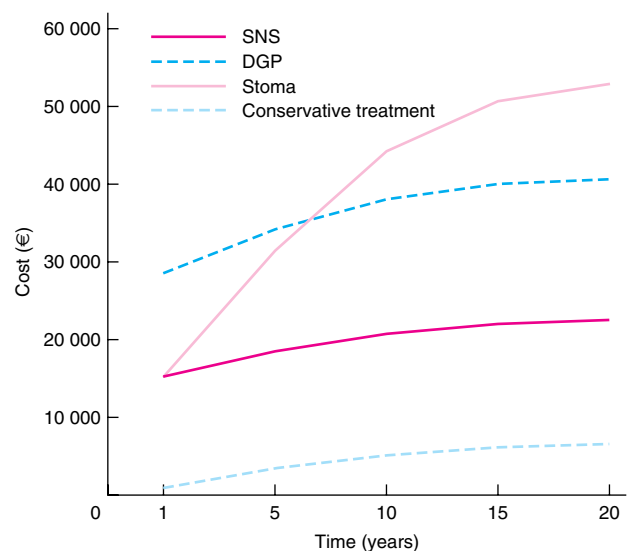
Postoperative complications after permanent implantation occurred in eight of 33 patients. Two patients developed a wound infection and the system (IPG and electrode) had to be removed; one of these was successfully reimplanted and the other patient used pads. One patient developed a seroma and needed a simple surgical revision without device removal. The fourth developed pain at the stimulator location site, and a reposition was performed successfully. The fifth developed increasing pain in the perineum and along the leg, and the system was removed. One patient had an accident that dislocated the electrode, which was successfully reimplanted. Electrode dislocation occurred in two other patients, who had a loss of effect to less than 50 per cent and needed new electrode placement.

During the first stage, a significant reduction of incontinence symptoms was found most frequently in patients with a neurogenic disorder (five of five) or an

Table 4 Cost comparison of sacral nerve stimulation for faecal incontinence with other treatment options for the first year and subsequent years

	First year costs (€)	Annual costs (€)
Sacral nerve stimulation	15 345	997
Sphincter repair	5327	0
Dynamic graciloplasty*	28 317	1659
Stoma*	14 609	5339
Conservative treatment*	779	779

*From Adang *et al.*¹³.

**Fig. 2** Estimated long-term costs per patient for each treatment: sacral nerve stimulation (SNS), dynamic graciloplasty (DGP)*, stoma* and conservative treatment* after 1, 5, 10, 15 and 20 years. Costs are in euros and discounted to present values at a 5 per cent rate (*from Adang *et al.*¹³)

anal sphincter defect (14 of 16), resulting in the highest implantation rate in these groups (Table 1).

Overall, of 36 patients tested, SNS was successful in 33 and remained effective in 31.

Costs

The median costs for an ideal course of SNS were €2838 for stage I and €8337 for stage II. The real costs for the study patients (including inefficient treatment, complications and follow-up costs) were €4053 (range €2838–7273) for stage I and €11 292 (range €8205–20 274) for stage II. Material was responsible for 68 per cent of the costs of stage I and 82 per cent of those for stage II. Therefore the overall cost in this study was €15 345 (range €11 974–28 346)

per patient compared with €11 974 for an ideal course (Table 2). This was taken as the cost for one successful SNS procedure for the first year; the subsequent annual cost, for battery replacement every 7 years and annual outpatient consultations, was calculated as €997. Table 4 and Fig. 2 show a comparison of the projected costs for four treatment options over 20 years.

In the same period, 13 patients with a median age of 58 (range 37–78) years underwent anterior sphincter repair. All operations were performed under general anaesthesia, median hospital stay was 6 (range 4–15) days and the median number of follow-up visits was 3 (range 1–15). One patient developed a perineal wound infection that required surgical intervention. Overall median costs for a patient undergoing an anterior anal sphincter repair were €5327 (range €4294–13 040).

Discussion

This prospective single-centre cost analysis of SNS in 36 consecutive patients was based on actual costs including treatment failure, complications and follow-up. SNS expenses were €15 345 per patient for the first year and €997 annually thereafter. Costs can be kept low by the omission of general anaesthesia and performing SNS in an outpatient setting. Compared with other surgical treatment options, such as dynamic graciloplasty (€28 317 in the first year and €1659 for subsequent years) or stoma formation (€14 609 and €5339)¹³, SNS is more cost-effective in the short term, although long-term results are still pending. However, the initial high success rate in this series (31 of 36 patients) is promising. Only conservative treatment (€779 per year) and anterior anal sphincter repair (€5327) were less expensive. However, with conservative treatment quality of life is significantly reduced¹³, and a symptomatic recurrence rate of up to 50 per cent in the long term is described after anal sphincter repair¹⁴. The comparison with the anal sphincter repair group is limited in that some of the patients in the SNS group would not have been suitable for an anal sphincter repair.

Initially, SNS was recommended for patients with idiopathic faecal incontinence⁷. Other indications were included only later¹⁵. In the present series, the highest success rates were observed in patients with neurogenic aetiology (five of five) and small anal sphincter defects (14 of 16), mainly after a history of complicated vaginal delivery. These women frequently wait a long time before seeking advice, and childbirth may have taken place many years before the appearance of incontinence symptoms¹⁶. The incontinence is often of complex aetiology, caused by a combination of structural defect of the anal sphincter,

rectal hypersensitivity and sphincter weakness by ageing and pudendal nerve dysfunction^{16,17}. SNS can increase anal sphincter pressures, as shown by Rosen *et al.*¹⁸, but it is most likely that an improvement in rectal sensibility in response to electrical stimulation increases continence and may explain the good results in this patient group. Before SNS was available, these patients may have undergone overlapping anal sphincter repair with modest long-term improvement¹⁴. It is now the authors' strategy to offer SNS testing to incontinent patients with small sphincter defects (less than 90° in circumference measured by endoanal ultrasonography) before anal sphincter repair.

Some centres perform SNS in a two-stage procedure under general anaesthesia^{5,18,19}. This may simplify the procedure for the surgeon, but it increases costs. In addition, the authors' experience shows that test electrode placement is more precise in patients who are awake, as they can report sensitive responses during the procedure. Besides visualization of the pelvic floor contraction, patients under local anaesthesia can tell the surgeons during the operation whether the response is symmetrical and if there are any disturbing sensations in the legs¹¹. Conversion to general anaesthesia was rare in this series (three of 41 electrode implantations). A limiting factor for the use of local anaesthesia was the presence of small sacral foramina, which make the introduction of the foramen needle or the electrode painful. The possibility of sacral root blockade does not permit the injection of local anaesthesia in the foramen itself.

Although the tined lead electrode (€1528) is more expensive than the conventional screening electrode (€127), the authors have shown that the success rate of the screening phase is significantly improved by using the tined lead¹¹. Two factors may explain this. First, the tined lead electrode is designed for both screening and permanent stimulation; therefore, a change of electrode is no longer necessary at the time of IPG implantation and failures after permanent implantation are avoided. Second, the quadripole tined lead allows the localization (pole) of the stimulation to be moved during the screening test in order to correct slight dislocations that may occur in the first days after introducing the electrode. This programming avoids false-negative screening tests and increases the success rate of the first stage.

Individual costs for the first stage were increased by using a tined lead electrode, but overall costs were reduced owing to the significantly higher screening success rate: from 30 to 90 per cent in the experience of the present authors¹¹ and others^{20,21}, compared with 26 and 71 per cent with a conventional test electrode^{22,23}. The use of both local anaesthesia and a tined lead electrode for screening allowed

an outpatient setting for the SNS procedure, thus reducing costs, whereas a neosphincter procedure, for example, is associated with a hospital stay of at least 5–7 days.

Not only can SNS be performed with low operation and patient care costs, but complications are less frequent and less severe, and therefore less expensive. Minor complications, such as an infection during the screening period, often occur at the site of the extension cable, but with early diagnosis and sufficiently long tunnelling, the extension can be removed under local anaesthesia without having to remove the electrode. In the present study, three infections were noted during the first stage, but the tined lead was retained in all three patients. With the exception of two wound infections after the second stage that required the removal of the electrode and IPG, no severe or life-threatening complications were observed. Most of the infections reported elsewhere occurred where a tined lead was not used^{5,18,19} and the incidence was similar to that in the present study if a permanent electrode was used for screening. This contrasts with the high complication and reoperation rates of up to 50 per cent for a complex reconstruction procedure, such as dynamic graciloplasty^{24,25} and artificial sphincter implantation²⁶. Some complications following SNS in the present study were associated with lack of experience with the technique, although the surgeons had started in 2001 and tested more than 20 patients before the beginning of the study. This minimally invasive technique has now nearly replaced neosphincter procedures, such as dynamic graciloplasty⁵. In addition, the first stage of SNS identifies patients who are unlikely to benefit, and these are not implanted, with reduced costs for unsuccessful treatment. For these reasons, a randomized study comparing the cost-effectiveness of SNS with dynamic graciloplasty would be almost impossible to perform.

References

- 1 Tanagho EA, Schmidt RA, Orvis BR. Neural stimulation for control of voiding dysfunction: a preliminary report in 22 patients with serious neuropathic voiding disorders. *J Urol* 1989; **142**: 340–345.
- 2 Matzel KE, Stadelmaier U, Hohenfellner M, Gall FP. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 1995; **346**: 1124–1127.
- 3 Vaizey CJ, Kamm MA, Roy AJ, Nicholls RJ. Double-blind crossover study of sacral nerve stimulation for faecal incontinence. *Dis Colon Rectum* 2000; **43**: 298–302.
- 4 Leroi AM, Parc Y, Lehur PA, Mion F, Barth X, Rullier E *et al.* Efficacy of sacral nerve stimulation for faecal incontinence: results of a multicenter double-blind crossover study. *Ann Surg* 2005; **242**: 662–669.
- 5 Uludağ Ö, Koch SM, van Gemert WG, Dejong CH, Baeten CG. Sacral neuromodulation in patients with fecal incontinence: a single-center study. *Dis Colon Rectum* 2004; **47**: 1350–1357.
- 6 Matzel KE, Kamm MA, Stosser M, Baeten CG, Christiansen J, Madoff R *et al.* Sacral spinal nerve stimulation for faecal incontinence: multicentre study. *Lancet* 2004; **363**: 1270–1276.
- 7 Kenefick NJ, Christiansen J. A review of sacral nerve stimulation for the treatment of faecal incontinence. *Colorectal Dis* 2004; **6**: 75–80.
- 8 Tjandra JJ, Lim JF, Matzel K. Sacral nerve stimulation: an emerging treatment for faecal incontinence. *ANZ J Surg* 2004; **74**: 1098–1106.
- 9 Hetzer FH, Hahnloser D, Clavien PA, Demartines N. Quality of life and morbidity after permanent sacral nerve stimulation for fecal incontinence. *Arch Surg* 2006; in press.
- 10 Malouf AJ, Chambers MG, Kamm MA. Clinical and economic evaluation of surgical treatments for faecal incontinence. *Br J Surg* 2001; **88**: 1029–1036.
- 11 Hetzer FH, Hahnloser D, Knoblauch Y, Löhlein F, Demartines N. New screening technique for sacral nerve stimulation in local anaesthesia. *Tech Coloproctol* 2005; **9**: 25–28.
- 12 Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum* 1993; **36**: 77–97.
- 13 Adang EM, Engel GL, Rutten FF, Geerdes BP, Baeten CG. Cost-effectiveness of dynamic graciloplasty in patients with fecal incontinence. *Dis Colon Rectum* 1998; **41**: 725–733, discussion 733–734.
- 14 Malouf AJ, Norton CS, Engel AF, Nicholls RJ, Kamm MA. Long-term results of overlapping anterior anal-sphincter repair for obstetric trauma. *Lancet* 2000; **355**: 260–265.
- 15 Jarrett ME, Mowatt G, Glazener CM, Fraser C, Nicholls RJ, Grant AM *et al.* Systematic review of sacral nerve stimulation for faecal incontinence and constipation. *Br J Surg* 2004; **91**: 1559–1569.
- 16 Lunniss PJ, Gladman MA, Hetzer FH, Williams NS, Scott SM. Risk factors in acquired faecal incontinence. *J R Soc Med* 2004; **97**: 111–116.
- 17 Jameson JS, Chia YW, Kamm MA, Speakman CT, Chye YH, Henry MM. Effect of age, sex and parity on anorectal function. *Br J Surg* 1994; **81**: 1689–1692.
- 18 Rosen HR, Urbarz C, Holzer B, Novi G, Schiessel R. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology* 2001; **121**: 536–541.
- 19 Rasmussen OO, Buntzen S, Sorensen M, Laurberg S, Christiansen J. Sacral nerve stimulation in fecal incontinence. *Dis Colon Rectum* 2004; **47**: 1158–1162, discussion 1162–1163.
- 20 Scheepens WA, Van Koeveeringe GA, De Bie RA, Weil EH, Van Kerrebroeck PE. Long-term efficacy and safety results of the two-stage implantation technique in sacral neuromodulation. *BJU Int* 2002; **90**: 840–845.
- 21 Spinelli M, Giardiello G, Arduini A, van den Hombergh U. New percutaneous technique of sacral nerve stimulation has

- high initial success rate: preliminary results. *Eur Urol* 2003; **43**: 70–74.
- 22 Ganio E, Luc AR, Clerico G, Trompetto M. Sacral nerve stimulation for treatment of fecal incontinence: a novel approach for intractable fecal incontinence. *Dis Colon Rectum* 2001; **44**: 619–629, discussion 629–631.
- 23 Uludağ Ö, Darby M, Dejong CH, Schouten WR, Baeten CG. Sacral neuromodulation is effective in the treatment of fecal incontinence with intact sphincter muscles; a prospective study. *Ned Tijdschr Geneesk* 2002; **146**: 989–993.
- 24 Chapman AE, Geerdes B, Hewett P, Young J, Evers T, Kiroff G *et al.* Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg* 2002; **89**: 138–153.
- 25 Geerdes BP, Heineman E, Konsten J, Soeters PB, Baeten CG. Dynamic graciloplasty. Complications and management. *Dis Colon Rectum* 1996; **39**: 912–917.
- 26 Mundy L, Merlin TL, Maddern GJ, Hiller JE. Systematic review of safety and effectiveness of an artificial bowel sphincter for faecal incontinence. *Br J Surg* 2004; **91**: 665–672.