

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
<p>Sievert et al. 2010 Germany Case-control Level 3 N=16</p>	<p>Objective: Aim was to investigate potential influences on human nerves and pelvic organs through early implantation of bilateral sacral nerve modulators (SNMs) in complete spinal cord injury (SCI) patients during the acute bladder-areflexia phase</p> <p>Population: 16 males with complete traumatic SCI (>T12, AIS A); 10 in treatment group, 6 controls; mean age 31 (range 19-47)</p> <p>Treatment: Implanted with tined lead electrode/sacral nerve modulator (SNM) at third sacral foramen. Control group prescribed oral antimuscarinics.</p> <p>Outcome Measures: Participants provided bladder, bowel and erectile function diaries and answered questionnaires including laxative use</p>	<ol style="list-style-type: none"> 1. SNM group reported they felt there was sufficient colon movement without oral laxatives. 2. SNM group has improved bowel movement control (incontinence events decreased) 3. All SNM participants reported significantly better quality of life than the controls. The specific SCI questionnaire used was not mentioned and no scores were given. 4. No intra- or post-operative complications were reported for the implant participants.
<p>Lombardi et al. 2011 Italy Retrospective Data Review Level 4 N=75</p>	<p>Objective: To assess the concomitant clinical improvement in incomplete spinal cord injury patients (SCIPs) suffering from neurogenic bowel symptoms (NBSs), neurogenic lower urinary tract symptoms (NLUTSs) and neurogenic erectile dysfunction (NED) using</p>	<ol style="list-style-type: none"> 1. Mean follow-up period from SNM permanent implantation to final visit was 53 months. 2. Patients presenting with NBS improved all parameters by at least 50% compared with baseline for mean (SD) number of occurrences of fecal incontinence (4.33 (1.66) vs 1.25 (1.17)); days with pads

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	<p>sacral neuromodulation (SNM) for NBSs and NLUTSs.</p> <p>Population: 75 males with incomplete SCI who received permanent SNM implantation; Age:18-75yrs; year post injury>6 months; suffering from neurogenic bowel symptoms (NBS), neurogenic lower urinary tract symptoms, and/or neurogenic erectile dysfunction refractory to conservative management</p> <p>Treatment: Sacral neuromodulation implantation (Medtronic, Inc)</p> <p>Stage 1- electrode inserted percutaneously in third sacral foramina.</p> <p>Stage 2- Permanent implantable pulse generator implanted in patient's buttock only if main symptoms improved by at least 50% during phase 1.</p> <p>Follow-ups scheduled at 1, 3, 6 months post implantation, and subsequently every 6 months</p> <p>Outcome Measures: SF-36 health survey questionnaire; number of fecal incontinence episodes per week; number of evacuations per week and</p>	<p>(4.5 (1.51) vs 1.33 (1.16)) and Wexner scores (13.66 (1.50) vs 5.83 (0.98)) per week at baseline vs final visit.</p> <p>3. A significant improvement (20%) in SF-36 scores for all patients compared with baseline.</p> <p>5. 11 adverse reactions were reported (5 individuals required change in stimulation sensation, 2 experienced loss of efficacy, 1 reported pain per leg spasticity, 2 reported pain at implanted pulse generator site, 1 reported adverse change in bowel function.</p>

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	Wexner score (severity of fecal incontinence)	
Holzer et al. 2007 Austria Pre-post Level 4 N=36	<p>Objective: To assess the outcome of SNS in a cohort of patients with incontinence of neurological aetiology.</p> <p>Population: 36 participants with SCI from spinal cord surgery, 11 from spinal cord trauma, 4 from meningomyelocele; 14M 22F; median age 49 (range 10-79) yrs.</p> <p>Treatment: Sacral nerve stimulation in the sacral foramina S2-S4; follow up after 12 and 24 months for those who underwent permanent implantation after initial evaluation (N=29)</p> <p>Outcome Measures: Number of incontinence episodes, maximum resting and squeeze anal canal pressure, American Society of Colorectal Surgeons (ASCRS) Quality of Life questionnaire</p>	<ol style="list-style-type: none"> 1. Median number of incontinence episodes decreased from 7 (range 4-15) to 2 (range 0-5) in 21 days. 2. There were statistically significant improvements in maximum resting and squeeze anal pressure after 12 and 24 months. 4. There was significant improvement in the ASCRS Quality of Life questionnaire for participants who underwent permanent implantation.
Chen & Liao 2015 China Case series Level 4 N=23	<p>Objective: The primary aim was to assess the clinical effects of sacral neuromodulation (SNM) for neurogenic bladder and/or bowel dysfunction with multiple symptoms</p>	<ol style="list-style-type: none"> 1. 75.0% rate of improvement for constipation during testing. 2. After implantation, 12/13 experienced improvement in constipation; 11 of which experienced $\geq 50\%$ improvement.

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	<p>secondary to spinal cord disease or injury.</p> <p>Population: N=23 (17M, 6F) with spinal cord injury or disease underwent SNM testing (7-28 days): Mean (SD) age 37.3 (2.9) Mean (SD) time since onset 15.5 (3.6) years 9 SCI, 9 myelomeningocele 2 complete, 21 incomplete N=13 (10M, 3F) of which underwent permanent SNM implantation: Mean (SD) age 34.1 (3.2) Mean (SD) time since onset 14.4 (4.8) years</p> <p>Treatment: Sacral neuromodulation (SNM)</p> <p>Outcome Measures: Constipation (Wexner score) and bladder measures</p>	<ol style="list-style-type: none"> 3. Loss of effect on constipation in 1 patient at 3 months post implantation. 4. Significant reduction in Wexner score (for those with urinary incontinence; N=9) from baseline to testing phase and from baseline to follow-up (17.5±2.0 months after implantation) stage.
<p>Lombardi et al. 2009 Italy Case-series Level 4 N=23</p>	<p>Objective: Efficacy and safety of sacral neuromodulation (SNM) in incomplete spinal cord-injured patients (SCIPs) affected by chronic neurogenic bowel symptoms (NBSs).</p> <p>Population: 15M 8F; 2 cervical, 9 thoracic, 13 lumbar; mean (SD) age = 36(9) years; 12 participants had constipation (C), 11 had fecal incontinence (FI).</p>	<ol style="list-style-type: none"> 1. Mean time from neurological diagnosis to SNM therapy was 41 months (range 18-96). Mean follow-up time from SNM implantation to final visit was 44.3 months (range 18-96). 2. Both the constipation and fecal incontinence groups experienced significant improvements in the: -Wexner score: <i>C group:</i> pre-SNM=19.91,

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	<p>Treatment: sacral neuromodulation - unilateral implantation in the foramen sacral S3 root</p> <p>Outcome Measures: Wexner questionnaire, SF-36, number of fecal evacuations per week, time per defecation.</p>	<p>post-SNM final visit=6.82 <i>FI group:</i> pre-SNM=13.09, post-SNM final visit=4.91 -had increased evacuations per week: <i>C group:</i> pre-SNM=1.65, post-SNM final visit=4.98 - had decreased number of fecal incontinence per week <i>FI group:</i> pre-SNM=4.55, post-SNM final visit=1.32 - reduced time per defecation: <i>C group:</i> pre-SNM=45.85, post-SNM final visit=11.67 min. - had a decreased number of pads used/day <i>fecal incontinence:</i> pre-SNM=2.36, post-SNM final visit=0.95</p> <p>3. Both groups had a significant improvement in the mental and general health subscales of the SF-36.</p> <p>A total of 1038 months yielded 12 adverse events in 5 patients: 4 related to pain at generator site, 3 to spasticity pain in lower limbs, 1 to excessive tingling in vaginal area, and 4 for battery changes.</p>
<p>Valles et al. 2009 Spain Pre-post Level 4 N=18</p>	<p>Objective: The purposes of this study were to analyze the clinical response of bowel function to the sacral anterior root stimulator and to evaluate physiologic</p>	<p>1. After implantation, fewer patients took laxatives (10 vs. 13) and patients used significantly less methods to evacuate bowel (1.5 vs. 2.1)</p>

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	<p>factors that could determine its efficacy.</p> <p>Population: 9M 9 F; 4 cervical, 13 thoracic, 1 lumbar; AIS: 14 A, 1 B, 3 C; mean age 39 yrs (range 18-63 yrs)</p> <p>Treatment: Sacral anterior root stimulator, follow up from 12-21 months post implantation</p> <p>Outcome Measures: Use of laxatives, number of bowel evacuation methods used, frequency of and time dedicated to bowel movements, prevalence of constipation, Wexner questionnaire</p>	<p>2. The frequency of bowel movements significantly increased (10 vs. 6 participants had bowel movements every day), and time dedicated decreased (11 vs. 9 participants dedicated <30min) but was not significant.</p> <p>4. Prevalence of constipation significantly decreased (7 vs. 11); episodes of fecal incontinence increased (18 vs. 16) and the mean Wexner score decreased (4.6 vs. 5.2) but these results were not significant.</p>
<p>Kachourbos & Creasey 2000 USA Pre-post Level 4 N=16</p>	<p>Objective: To promote health with a neurogenic bladder and bowel using the VOCARE Bladder and Bowel Control System.</p> <p>Population: Adults with SCI (demographics not reported) and a history of bowel complications</p> <p>Treatment: Implantation of sacral roots electrodes (S1-S3) with rhizotomy at the conus medularis. Stimulation was delivered via use of VOCARE Bladder and Bowel Control System (Finetech-Brindley stimulator).</p>	<p>1. Bowel program times were reduced from a mean of 5.4 hours per week pre-operatively to 2.0 hours per week post-operatively.</p> <p>2. Autonomic dysreflexia due to bowel movements was eliminated.</p> <p>3. Users reported a greater sense of independence, increased socialization, greater control over their lives, improved self-image, decreased feelings of depression, improved interpersonal relationships and an overall improvement in quality of life.</p>

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	<p>Outcome Measures: Bowel program times; occurrence of autonomic dysreflexia due to bowel movement; quality of life regarding dependence, socialization, sense of control, and overall quality of life</p>	
<p>Jarrett et al. 2005 USA Pre-post Level 4 N=12</p>	<p>Objective: This study examined the use of sacral nerve stimulation (SNS) to treat faecal incontinence in patients with partial spinal injury.</p> <p>Population: 6 participants with SCI from disc prolapse, 4 from trauma, and 1 from spinal stenosis; 4M 9F; median age 58yrs (range 39-73). Exclusion criteria: paraplegia.</p> <p>Treatment: Temporary sacral nerve stimulation, permanent implant if participants demonstrated positive results, median follow up is 12 months (range 6-24)</p> <p>Outcome Measures: Frequency of incontinence; resting and squeeze anal canal pressure ASCRS QoL questionnaire; SF-36 quality of life questionnaire</p>	<ol style="list-style-type: none"> 1. 12 participants demonstrated positive results and underwent permanent implantation. 2. Mean (SD) frequency of incontinence decreased from 9.33 (7.64) episodes per week at baseline to 2.39 (3.69) at last follow up. 3. ASCRS QoL coping score significantly improved; the SF-36 QoL scores did not change. 3. Neither resting nor squeeze anal canal pressure changed significantly compared to baseline.
<p>Gstaltner et al. 2008 Austria Pre-post</p>	<p>Objective: Treatment of faecal incontinence by permanent sacral nerve stimulation (SNS) in patients</p>	<ol style="list-style-type: none"> 1. Improved fecal continence in all 5 participants (median score of Wexner score)

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Level 4 N=11	<p>suffering from cauda equina syndrome (CES).</p> <p>Population: Cauda equine syndrome with flaccid paresis of the anal sphincter muscle and fecal incontinence</p> <p>Treatment: Participants underwent percutaneous nerve evaluation (PNE); following this analysis, a period of external temporary sacral nerve stimulation was performed in both sides of the S2 or S3, and if the patient showed improvements in outcome measures, a permanent stimulator was implanted (N=5)</p> <p>Outcome Measures: Wexner questionnaire, participants' subjective perceptions of quality of life determined through interview.</p>	<p>decreased from pre-SNS (15 (9-19)) to post-SNS (5(2-9)).</p> <ol style="list-style-type: none"> 2. Reported perianal sensitivity and deliberate retention of feces improved in all 5 participants. 3. Reported improved quality of life in all 5 participants. 4. One complication was reported - one patient had minimal leakage of cerebrospinal fluid following the PNE, after removal of the needle, no further symptoms were reported.
<p>Chia et al. 1996 Singapore Pre-post Level 4 N=8</p>	<p>Objective: This study evaluated the effect of anterior sacral roots stimulator implants on bowel function of patients with spinal cord trauma.</p> <p>Population: Level of injury: 4 C4-C6, 4 T3-T11; 6M: 2F; Age: mean 40, range 20-53yrs. All participants suffered from severe constipation (≤ 2 bowel</p>	<ol style="list-style-type: none"> 1. 6/8 patients had improvement in bowel function: 4/6 were able to evacuate spontaneously after stimulation, 1 described digital evacuation as "easier," 1 used an occasional suppository without the need to digitally evacuate. 5. Six participants with improved bowel routine also showed increased recto-

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	<p>movements/week and/or straining at stool for >25% of the time)</p> <p>Treatment: Anterior sacral roots electrodes (S2,3,4) implanted for electrical stimulation.</p> <p>Outcome Measures: Bowel frequency, laxative use, suppository use, need for digital evacuation, anorectal manometry</p>	<p>anal pressure immediately after stimulation.</p>