Sacral Neuromodulation

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History of Sacral Nerve Stimulation

Electrical Stimulation for urinary dysfunction

1982:
First SNS implant in urological patient by Drs Tanagho and Schmidt

Department of Urology,
UCSF, California
History of Sacral Nerve Stimulation

- **1982** – Department of Urology, University of California at San Francisco initiated clinical program.
- **1985-92** – Multi-center trial conducted by Urosystems, Inc.
- **1997** - InterStim FDA approval for treatment of urgency urinary incontinence in the US.
- **1994** - Anal electric stimulation was first described for treatment of fecal incontinence.
- **April, 1999** - FDA approval of the InterStim System for treatment of symptoms of urgency-frequency and urinary retention.
- **2010** - FDA approval for FI

Today over 100,000 implants performed worldwide

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SNS

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InterStim Therapy for Urinary and Bowel Control is a therapeutic approach for patients with overactive bladder, urinary retention, fecal incontinence, constipation and double incontinence.

InterStim Therapy uses sacral neuromodulation to modulate the neural reflexes that influence the bladder, urethral and anal sphincters and pelvic floor.
Effects Of SNS

- Resolution of pelvic floor muscle tension/pain.
- Decrease in vestibulitis / vulvodynia.
- Decrease in urethral and bladder pain/burning.
- Decrease in perineal pain.
- Normalization of bowel function.
Benefits of InterStim Therapy

- Marked Reduction or elimination of incontinence
- Improvement in Quality of Life
- Safe, reversible & compatible with alternative treatments
- Minimally invasive procedure
- Use of test stimulation as an accurate and low-cost predictor of clinical success
- Improved economic management of patients
Sacral Neuromodulation

**Maim indications**
- Fecal Incontinence
- Urinary Incontinence (OEB)
- Perineal Pain

**Minor indications**
- Constipation
- Hindgut disfunction
- Urinary retention
**CONTRAINDICATIONS**

- **Contraindications** include an inadequate clinical response to a therapeutic trial and limited cognitive function which interferes with the operation of the neurostimulatory device.

- Patients who anticipate the need for future magnetic resonance imaging (MRI)s are also not ideal candidates.
SNS

- > 100’000 patients have been implanted with InterStim for:
  - OAB
  - Urinary Retention
  - Fecal Incontinence
  - Constipation
  - Double incontinence
- Endorsed by International Consultation on Incontinence (ICI):
  - Grade A for treating women with OAB
  - Grade B for treating fecal incontinence with no sphincter defect
- 6-11% adverse events (from the Swiss National Registry)
  usually transient and treatable effectively.
- Efficacy sustained over long time for OAB, Urinary Retention and Fecal Incontinence
Patients are embarrassed to talk to physicians about voiding problems.

Many physicians typically do not ask patients about voiding problems.

Quality of life issues:

- Anxiety, depression, infections, nocturia, odors, embarrassment, diet restrictions, discomfort / pain, limitations of social activities and employment opportunities, and cost of protective garments.
Prevalence
Faecal Incontinence

Fecal incontinence prevalence
Up to 7% of general population

Severe Faecal Incontinence (Wexner >15) :
1.4% population >40 years

(Perry et al. Gut 2002)
Conservative Treatment

Dietary and lifestyle advice

Maximal medical therapy

Behavioural (Biofeedback) therapy

(Only if all of these fail- consider invasive/surgical intervention)
Bioplastique Implant
Treatment Options (Surgical)

Before planning these.....

-------- Sacral Nerve Stimulation

Sphincter surgery

Dynamic graciloplasty

Artificial bowel sphincter

Stoma
Overactive bladder (OAB)

Symptoms*:
- Urgency
- Frequency and nocturia
- Urge urinary incontinence (UUI)

Prevalence increases in the elderly:
- More common than diabetes
- Similar to asthma

Majority are females (80%)

Fantl JA et al. AHCPR Publication No. 96-0682
Treatment Options for Overactive Bladder

- Behavior modification
- Medications
  - Antimuscarinics
  - Anticholinergics
  - Botox
- Surgical Procedures
Treatment algorithm OAB

Initial Screening

Voiding Diary

Urodynamic Workup

Behavioral Techniques

Medications

Continue as Appropriate

SNS Test Stimulation

Implant Permanent System

Test Using Staged Implant Procedure

Consider Other Surgical Intervention

Adapted from Abrams P et al. BJU Int 2003;91:355-359

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Sacral Nerve Stimulation Therapeutic Sequence

Assessment and Selection

Percutaneous Nerve Evaluation (PNE)
2-3 Week Test Stimulation

Permanent Implantation
Test stimulation
Test Stimulation (PNE)

General / Local Anesthesia

Day case / Out patient procedure

(Single dose prophylactic antibiotics)
Tined Leads Models
Anchoring with Tines
Patient Assessment

History of:

- Voiding dysfunction or fecal disturbances.

Physical exam

- Rule out outlet obstruction
- Intravesical or intra-rectal Pathology

Urodynamic studies/Endoscopy

Manometry

PNML—greater than 2.4 millisecond

Dynamic/Defecating proctogram

Endo anal US

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Patient Indications for Sacral Nerve Stimulation (SNS)

- Overactive Bladder
  - Urge/ frequency
  - Urge Incontinence

- Urinary Retention in the absence of outlet Obstruction

- Chronic Pelvic Pain
Patient Indications for Sacral Nerve Stimulation (SNS)

- Fecal incontinence (1/week)
- Soiling
- Constipation (no organic cause, refractory to medications)
- Anal and rectal pain

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Exclusion Criteria

- Congenital anorectal malformations
- Present full thickness rectal prolapse
- Chronic bowel diseases (e.g. IBD)
- Chronic diarrhoea (unmanageable by diet or drugs)
- Stoma *in situ*
- Bleeding complications
- Pregnancy
- Anatomical limitations preventing placement
- Skin / tissue disease that would significantly increase the risk of infection.
<table>
<thead>
<tr>
<th>Study</th>
<th>Test</th>
<th>Improvement</th>
<th>Implanted</th>
<th>Functioning (&gt;50%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rosen 2001</td>
<td>20</td>
<td>80%</td>
<td>16</td>
<td>12 (75%)</td>
</tr>
<tr>
<td>Matzel 2004</td>
<td>37</td>
<td>92%</td>
<td>34</td>
<td>30 (88%)</td>
</tr>
<tr>
<td>Jarrett 2004</td>
<td>59</td>
<td>78%</td>
<td>46</td>
<td>44 (96%)</td>
</tr>
<tr>
<td>Rasmussen 2004</td>
<td>45</td>
<td>82%</td>
<td>37</td>
<td>32 (86%)</td>
</tr>
<tr>
<td>Uludag 2004</td>
<td>75</td>
<td>83%</td>
<td>50</td>
<td>48 (96%)</td>
</tr>
<tr>
<td>Hetzer 2006</td>
<td>36</td>
<td>92%</td>
<td>33</td>
<td>31 (94%)</td>
</tr>
<tr>
<td>Faucheron 2006</td>
<td>40</td>
<td>75%</td>
<td>29</td>
<td>24 (83%)</td>
</tr>
<tr>
<td>Baeten 2007</td>
<td>134</td>
<td>74%</td>
<td>100</td>
<td>79 (79%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>446</td>
<td>82%</td>
<td><strong>345 (77%)</strong></td>
<td><strong>300 (87%)</strong></td>
</tr>
</tbody>
</table>
InterStim is effective in FI patients who failed conservative treatments
Rosen, Gastroenterology 2001
St Marks results over a 10 year period
Hollingshead, Colorectal Dis. 2010

Improvements In FI

Baseline
Lastest FU

Incontinence / week  Cleveland clinic cont. score  St Marks cont. score
International results

Long-term Efficacy and Safety of Sacral Nerve Stimulation for Fecal Incontinence 2011

Anders Mellgren, M.D., Ph.D.1 • Steven D. Wexner, M.D.2 • John A. Coller, M.D.3
Ghislain Devroede, M.D.4 • Darin R. Lerew, Ph.D.5 • Robert D. Madoff, M.D.1
Tracy Hull, M.D.6 and for the SNS Study Group
1 Division of Colon and Rectal Surgery, University of Minnesota, Minneapolis, Minnesota
2 Department of Colorectal Surgery, Cleveland Clinic Florida, Weston, Florida
3 Department of Colon and Rectal Surgery, Lahey Clinic, Burlington, Massachusetts
4 Department of Surgery, Centre Hospitalier Universitaire de Sherbrooke, Fleurimont, Canada
5 Medtronic, Inc., Minneapolis, Minnesota
6 Department of Colorectal Surgery, Cleveland Clinic Foundation, Cleveland, Ohio

Wolfson Pelvic floor clinic 2011
International results

One hundred thirty-three patients underwent test stimulation with a 90% success rate, of whom 120 (110 females) with a mean age of 60.5 years and a mean duration of fecal incontinence of 7 years received chronic implantation. Mean length of follow-up was 3.1 (range, 0.2–6.1) years, with 83 patients completing all or part of the 3-year follow-up assessment. At 3 years follow-up, 86% of patients (\( P \leq 0.0001 \)) reported 50% reduction in the number of incontinent episodes per week compared with baseline and the number of incontinent episodes per week decreased from a mean of 9.4 at baseline to 1.7. Perfect continence was achieved in 40% of subjects.
After SNS implant

**FIGURE 1.** Frequency of incontinent episodes or days per week. All paired tests comparing follow-up to baseline had a $P$ value of less than .0001.
FIQOL with SNM

![Graph showing mean FIQOL scores](image)

**FIGURE 5.** Fecal incontinence quality of life (FIQOL) assessment score. All paired tests comparing follow-up with baseline had a $P$ value of less than .0001.
After SNS implant

**FIGURE 2.** Improvement categories in weekly incontinent episodes. All exact-binomial tests comparing the success rate (proportion of subjects with ≥50% reduction in weekly incontinent episodes) at follow-up against a null value of 50% had a P value of less than .0001.

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After SNS implant

FIGURE 9. Use of protective pads.
SNS IMPLANTS IN WE

Uro vs. Gastro (by INSS sold)

<table>
<thead>
<tr>
<th>Year</th>
<th>Uro (sold)</th>
<th>Gastro (sold)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY06</td>
<td>819</td>
<td>1,159</td>
</tr>
<tr>
<td>FY07</td>
<td>1,037</td>
<td>1,447</td>
</tr>
<tr>
<td>FY08</td>
<td>1,422</td>
<td>1,565</td>
</tr>
<tr>
<td>FY09</td>
<td>1,772</td>
<td>1,901</td>
</tr>
<tr>
<td>FY10</td>
<td>2,142</td>
<td>2,244</td>
</tr>
</tbody>
</table>

Wolfson Pelvic floor clinic 2011
SNS IMPLANTS IN WE

Uro vs. Gastro (by INSs sold)

- FY06: Uro 1,159, Gastro 819
- FY07: Uro 1,447, Gastro 1,037
- FY08: Uro 1,565, Gastro 1,422
- FY09: Uro 1,901, Gastro 1,772
- FY10: Uro 2,244, Gastro 2,142

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InterStim Therapy for FI is effective in the long term

Michelsen, Colon Rectum. 2010 Apr;53(4):414-21
Sacral Nerve Stimulation for Fecal Incontinence
Results of a 120 Patient Prospective Multicenter Study
Wexner et al Annals of Surgery – March 2010

- FDA approved protocol
- 133 – test stimulation: 90% success rate (120)
- Mean follow up 28 months (2.2-69.5)

Results:
- At 12 month 83% achieved therapeutic success
- 41% achieved 100% continence

- At 24 month 85% therapeutic success
- Incontinence episodes reduced from 9.4 to 1.9 per week at 12 months and to 2.9 at 2 years
85% of patients with FI are successful at 2 years
InterStim improves significant QoL for FI
Hetzer et al, Arch Surg. 2007

Before InterStim (N = 37)  After 6 months InterStim (N = 30)

Worse

Best

Lifestyle  Coping and behaviour  Depression and self-perception  Embarrassment

Physical functioning  Social function  Mental health  Vitality

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Sacral Nerve Stimulation is more Effective than Optimal Medical Therapy for Severe Fecal Incontinence: A Randomized, Controlled Study


Chung Hung Yeh, M.D. Carolyn Murray-Green

Department of Colorectal Surgery, Epworth Hospital, University of Melbourne, Melbourne, Australia

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Patients (aged 39–86 years) with severe fecal incontinence were randomized to have sacral nerve stimulation (SNS group; n=60) or best supportive therapy (control; n=60), which consisted of pelvic floor exercises, bulking agent, and dietary manipulation. Full assessment included endoanal ultrasound, anorectal physiology, two-week bowel diary, and fecal incontinence quality of life index. The follow-up duration was 12 months.
InterStim vs. Optimal Medical FI Therapy
Tjandra, Dis Colon Rectum. 2008 May;51(5):494-502

Number of Incontinence Episodes per Week

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>3 months post implant</th>
<th>12 months post implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNS group</td>
<td>9.2</td>
<td>8.1</td>
<td>9.4</td>
</tr>
<tr>
<td>Control group</td>
<td>9.5</td>
<td>2.9</td>
<td>3.1</td>
</tr>
</tbody>
</table>

Not significant

p = 0.0149
p = 0.0031
International results

Treatment of slow-transit constipation with sacral nerve modulation

G. Naldini*, J. Martellucci†, L. Moraldi*, R. Balestri* and M. Rossi*

*General Surgery IV, Hospital of Pisa, Pisa, Italy, †General Surgery I, University of Siena, Siena, Italy 2010
Fifteen patients with STC were treated from March 2003 to May 2006. Nine (60%) underwent permanent implantation. After SNM, the mean improvement of Wexner Constipation Score (CCS) and QoL was 10 and 6.2 respectively. There were no complications.

The mean follow-up period was 42 months.

Conclusion Sacral nerve modulation seems to be a useful treatment for constipated patients.
Sacral nerve stimulation induces pan-colonic propagating pressure waves and increases defecation frequency in patients with slow-transit constipation

P. G. Dinning*, S. E. Fuentealba†, M. L. Kennedy‡, D. Z. Lubowski§* and I. J. Cook†*

*Department of Medicine, University of New South Wales, Sydney. †Departments of Gastroenterology and ‡Colorectal Surgery, St George Hospital, Kogarah, NSW, Australia

![Graph showing bowel movements and laxative use](image)

Baseline | InterStim sub-chronic testing phase
---|---
Bowel movements: 0.8 vs. 7.4, P = 0.0003
Laxative use: 4.7 vs. 1.5, P = 0.05
International results

Sacral neuromodulation for the management of severe constipation: development of a constipation treatment protocol

Abhiram Sharma & Ben Liu & Philip Waudby & Graeme S. Duthie 2011
International results

**Results** Temporary neuromodulation wires were implanted in 21 patients (20 female). Significant bowel diary improvement was seen in 12 (57%) patients ($p<0.01$). Improvements in bowel diaries have been maintained over a median follow-up period of 38 months (18–62 months).

**Conclusion** Sacral neuromodulation can provide long-term symptom relief in selected patients with severe constipation. Sacral neuromodulation should be incorporated into the treatment algorithm for chronic constipation.
Mowatt and Jarrett reported a review on SNS in incontinence (36) and constipation (2 pts.) in three studies.

The constipated pts had bowel movements increased from 2 to 5 per week and bloating reduced from 79% to 33%, but they concluded that the time of temporary stimulation does not always assess the benefit. (Neurourol Urodyn. 2008, 27(3):155-61)
Summary of evidence:

Eighty four (84) studies including 3,386 patients have been peer reviewed and published; 10% (8/84) are Level 1 (randomised controlled trials [RCTs]), and 90% are Level 4 (case series). Clinical success has been reported in 45% to 100% of patients over mean follow-up periods of 6 to 117 months (over 9 years).
Summary of evidence:

- **Fecal incontinence**
  Within a total of 26 studies, 2 graded Level 1 and 24 graded Level 4, **1,008 patients** underwent SNM, with followed-up for up to 138 months.
  **81%** of patients had been successfully treated.

- **Constipation**
  Two Level 4 studies (case series) followed **15 constipated patients** for 6 and 38 months.
  **75%** of 4 patients with severe constipation reported complete cure.
Romans et al. studied the effect of SNS on rectal function and evaluated the rectal function as a predictive factor of clinical response to SNS. (18 pts.) They stated that SNS does not significantly modify rectal function, and increased rectal capacity may be a predictive factor of poor response. (Neurogastroenterol Motil. 2008, 20(10):1127-31)
Any correlation To Anorectal Physiology ??

<table>
<thead>
<tr>
<th></th>
<th>Before SNS</th>
<th>After SNS</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FS (ml)</td>
<td>43 (16-230)</td>
<td>62 (4-186)</td>
<td>0.1</td>
</tr>
<tr>
<td>DTD (ml)</td>
<td>70 (30-443)</td>
<td>98 (30-327)</td>
<td>0.011</td>
</tr>
<tr>
<td>MTV (ml)</td>
<td>130 (68-667)</td>
<td>166 (74-578)</td>
<td>0.031</td>
</tr>
<tr>
<td>ARP (cm H₂O)</td>
<td>31 (0-109)</td>
<td>38 (0-111)</td>
<td>0.045</td>
</tr>
<tr>
<td>MSP (cm H₂O)</td>
<td>51 (0-127)</td>
<td>54 (0-118)</td>
<td>0.44</td>
</tr>
</tbody>
</table>

FS = first sensation; DTD = desire to defecate; MTV = maximal tolerable volume; ARP = anal resting pressure; MSP = maximum squeeze pressure; SNS = sacral nerve stimulation.

Data are medians with ranges in parentheses.
"Of all the developments in colorectal surgery in this decade, this is one of the most exciting," said Joe J. Tjandra, MD, from the Epworth Hospital Colorectal Center in Melbourne, Australia, "It dramatically improves patients' lives."

"The nice thing about sacral neuromodulation is that it affects muscle as well as sensation and reflexes, which are all important in continence,"

"We found it to be effective in about 75% of patients with severe fecal incontinence largely independent of the etiology."
Thank you
מחירים אינטרסטים לסל

زيוד השтелת למעט מ"מ 3,480$ + $3,000 (₪3,480 + מ"מ)

찌וד השтелה הבובה 15,602$ + $13,450 (₪15,602 + מ"מ)

סה"כ 19,082$ + $16,450 (₪19,082 + מ"מ)

אורכ ח"י ניוורוסטים מור כ- 5 שנים
הערכה קוסטרבייט. מיתוך ديיוותים בספרות אורת ח"י
הנוירוסטים מור בין 5 ל-9 שנים - ממוצע 7.3 שנים

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