Sacral neuromodulation for fecal incontinence: Long term outcomes

K. E. Matzel
Department of Surgery, University Erlangen, Germany

21. Annual Conference of EGCRS, Cairo 28.08.2019
First implant for FI
June 24, 1994

PM-Approval FDA
March 14, 2011
Evidence: Long Term Outcome

- Function
- QoL

Challenges with longterm therapy
1. Acute PNE
2. Temporary test

Success: 50% Improvement: Number of IC Days with IC

Success: 70%-80% Improvement
SNM: Outcome Measures

- Frequency of FI (n, days w/ FI)
- FI Score
- Urgency
- QoL
**SNM: Outcome Measures**

- Frequency of FI (n, days w/ FI)
- FI Score
- Urgency
- QoL

- Classification of success
  - 50% during the test
  - 50% with permanent implant
- PP vs ITT
SNM: Long Term 84 m

(n=272)

- Idiopathic: 33%
- Iatrogenic: 15%
- Obstetric: 9%
- Neurogenic: 9%
- Pelvic operations: 9%
- LARS: 5%
- Spinal lesions: 5%
- Congenital: 2%
- Others: 2%

IC episodes  CCIS  St Mark's score

SNM: Long Term 84 m

Long Term 46-118 m: 50% improvement

Success rate $\geq 50\%$ improvement

Per Protocol Analysis

Universitätsklinikum Erlangen
Success rate $\geq 50\%$ improvement

Per Protocol Analysis

Long Term 46-118 m: 50% improvement
Long-term outcomes of sacral nerve stimulation for faecal incontinence

D. F. Altomare¹, S. Giuratrabocchetta¹, C. H. Knowles², A. Muñoz Duyos³, J. Robert-Yap⁴ and K. E. Matzel⁵ on behalf of the European SNS Outcome Study Group

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<td>Summary median (range)</td>
<td>85 (44–118)</td>
<td>55 (12–407)</td>
<td>36.5 (9–228)</td>
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<td>36 (4–52)</td>
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>50%: 71%

100%: 50%

84 months
Long-term outcomes of sacral nerve stimulation for faecal incontinence

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85 (44–118) months

>50%: 78%

100%: 36%
**SNM: Long Term Results: FI episodes**

**short vs. medium vs. long**

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<tr>
<th>Reference</th>
<th>Median follow-up (months)</th>
<th>No. at baseline</th>
<th>No. at follow-up</th>
<th>% at follow-up</th>
<th>No. at baseline*</th>
<th>No. at follow-up*</th>
<th>Difference</th>
<th>P</th>
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<tr>
<td><strong>Summary</strong></td>
<td></td>
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<tr>
<td>Short term</td>
<td>12 (1–12)</td>
<td>27 (6–106)</td>
<td>88 (39–100)</td>
<td>8 (1–16)</td>
<td>1 (0–5)</td>
<td>−7 (−1 to −13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium term</td>
<td>24 (15–36)</td>
<td>16 (5–66)</td>
<td>64 (12–100)</td>
<td>8 (1–26)</td>
<td>1 (0–4)</td>
<td>−7 (−1 to −25)</td>
<td></td>
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<tr>
<td>Long term</td>
<td>51 (44–118)</td>
<td>13 (2–147)</td>
<td>70 (6–100)</td>
<td>8 (1–12)</td>
<td>1 (0–2)</td>
<td>−7 (−1 to −12)</td>
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short (12m): $8 (1-16) \rightarrow 1 (0-5)$

medium (24m): $8 (1-26) \rightarrow 1 (0-4)$

long (51m): $8 (1-12) \rightarrow 1 (0-2)$

Thin et al, BJS. 100, 1430-47, 2013
**SNM: Results: CCIS**

**short vs. medium vs. long**

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<th>Permanent implants</th>
<th>Reference</th>
<th>Median follow-up (months)</th>
<th>No. at baseline</th>
<th>% at follow-up</th>
<th>Baseline score*</th>
<th>Follow-up score*</th>
<th>Score difference</th>
<th>P</th>
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<td><strong>Short term</strong></td>
<td></td>
<td>6 (1-12)</td>
<td>29 (11-130)</td>
<td>100 (65-100)</td>
<td>15 (12-16)</td>
<td>6 (1-10)</td>
<td>-9 (-3 to -15)</td>
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<td><strong>Medium term</strong></td>
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<td>24 (13-36)</td>
<td>41 (10-126)</td>
<td>100 (27-100)</td>
<td>15 (14-18)</td>
<td>8 (3-12)</td>
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<td><strong>Long term</strong></td>
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<td>50 (37-118)</td>
<td>23 (9-87)</td>
<td>75 (8-100)</td>
<td>15 (12-20)</td>
<td>7 (5-10)</td>
<td>-8 (-4 to -13)</td>
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short (6m): 15 (12-16) ➔ 6 (1-10)  
medium (24m): 15 (14-18) ➔ 8 (3-12)  
long (50m): 15 (12-20) ➔ 7 (5-10)  

*Thin et al, BJS. 100, 1430-47, 2013*
**SNM IC: Efficacy after 5y**

Mellgren A et al, Dis Col Rectum, 56 (5), 43, 2013

- **Mild** (n=36):
  - ≤ 0%
  - [0% - 50%)
  - [50% - 75%)
  - [75% - 100%)
  - 100%

- **Moderate** (n=34):
  - ≤ 0%
  - (50%, 75%)
  - [50% - 75%)
  - [75% - 100%)
  - 100%

- **Severe** (n=36):
  - ≤ 0%
  - (0%, 50%)
  - [50% - 75%)
  - [75% - 100%)
  - 100%

**Thresholds:**
- Mild: 2-5 Fl/w
- Moderate: 5-10 Fl/w
- Severe: >10 Fl/w
Mean FIQL Score

*SNM North American Multicenter Trial: 5 y*

Mean FISI Score

Mean Bowel Health Score

Mean FISI Scores

Mean bowel health score

### Quality of Life – Median Score

Tan et al. Int J Colorect 2011

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>SIRS</th>
<th>Mean (SD)</th>
<th>Max Cryotherapy</th>
<th>VAS (median) 90% CI</th>
<th>Weight</th>
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SNM: Device Retention Rate 5 y: 81%
SNM:18 y: Device Retention Rate: 78%
SNM for Fecal Incontinence

- Efficacy: mostly immediately, IC & QoL improved (LE3)
- Incontinence scores & incontinence episodes/week are significantly decreased (LE2)
- SNS can be primary treatment for patients with sphincter defects (LE3)
- RCTs: QoL (SF-12, ASCRS, FIQL, EQ-4D) improved (LE2)
- The mechanism of action is most likely multifactorial and dependent on the underlying condition (LE4)
- Cost Benefit (LE3)
Surgery for FI Algorithm

Review clinical, radiological and physiological data

Rectal prolapse
- Rectovaginal fistula
- Cloacal deformity

Correction of anatomic abnormality

Repeat evaluation

ACE Colostomy

Severe spinal cord impairment

Rectal evacuation disorder

Sphincter defect > 180° or significant perineal tissue loss

ACE
- Rectocele repair
- Ventral rectopexy
- Sphincteroplasty +/- vaginal and perineal reconstruction
- Colostomy
  - Stimulated graciloplasty
  - Artificial anal sphincter

Sphincter defect 120° - 180°

Sphincteroplasty
- SNS
- Colostomy

Sphincter defect < 120°

Sphincteroplasty
- SNS
- Colostomy
- BL
- Colostomy

No sphincter defect

Follow up

Symptom improvement

yes

SNS
- BI
- Colostomy

no

SNS

Novel therapies:
- Magnetic anal sphincter
- Pubopectral sling
- Radiofrequency energy treatment
- Stem cell therapy
- Vaginal pessary: Eclipse

ACE: antegrade continence enema, BL: biomaterial injection, SNS: sacral nerve stimulation; * not widely available
Challenges SNM Longterm

- Battery longevity: replacement
- Function after replacement for battery depletion
- Loss of efficacy
## Battery Longevity

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<th>Source</th>
<th>Battery life (years)</th>
<th>Publication year</th>
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<tr>
<td>Medtronic estimate (1)</td>
<td>Ø4.4 yr</td>
<td>2012</td>
</tr>
<tr>
<td>Author’s opinion (2)</td>
<td>5-7 yr</td>
<td>2018</td>
</tr>
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<td>2017</td>
</tr>
<tr>
<td>Real-life data (4)</td>
<td>≈ 6 yr (5-7)*γ</td>
<td>2019</td>
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<td>Real-life data (5)</td>
<td>≥ 5 yr*γ</td>
<td>2016</td>
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<td>Real-life data (6)</td>
<td>5.3 yr (&lt;2V)*γ</td>
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<td>Real-life data (7)</td>
<td>6.3 yr*γ</td>
<td>2014</td>
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* explicitly referred to Interstim II; γ median values

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https://pdfs.semanticscholar.org/ef17/aa6b02290ced3ac8599de48b6205e735b0df.pdf
How to Improve Battery Life?

- N: 27: battery exchange without lead revision at the time of battery depletion

- Median battery life:
  - Amplitude $\leq$ 2V (n=15): 64 months
  - Amplitude $>$ 2V (n=12): 38 months

How to Improve Battery Life?

- **N: 27**: battery exchange without lead revision at the time of battery depletion

- **median battery life:**
  - Amplitude $\leq 2V$ (n=15): 64 months
  - Amplitude $> 2V$ (n=12): 38 months

- optimized lead placement

- programming using extended duration cycling (e.g. 10 min ON; 10 min OFF)

Standardised Electrode Placement Technique

Current Mean Amplitudes
Historical Data vs. Standardized Technique

2011
- Traditional implantation technique
- $\approx 2.1V@12\text{months}$

2018
- Optimized lead placement
  with 3889 tined lead and curved stylet
- $1.0V@12\text{month}$

Long-term Outcome after IPG exchange

- N: 143: N: 39: Replacement: (F: N=37)
- Med. follow-up before replacement: 115 months
- Med. follow-up after replacement: 29 months

- 82% (32/39): satisfaction similar as before IPG replacement
- 18% (7/39): reduced satisfaction, similar as before IPG replacement

Satisfied patients were younger (65 years vs. 76 years)

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<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (N=32)</th>
<th>Group B (N=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRO (0-10)</td>
<td>7.6 ± 1.6</td>
<td>5.5 ± 0.9</td>
</tr>
<tr>
<td>ΔCCF-FI</td>
<td>-0.63</td>
<td>+1.86</td>
</tr>
<tr>
<td>ΔFIQL</td>
<td>+0.27</td>
<td>-0.46</td>
</tr>
</tbody>
</table>

PRO: patient-reported outcome (0-10 with 10 reflecting the best clinical outcome/satisfaction); CCF-FI: Cleveland Clinic Fecal Incontinence Score; FIQL: Fecal Incontinence Quality of Life score
Loss of Effectiveness

- Loss of efficacy typically occurs within the first 2 years of the treatment [1]
- The mean time to definitive failure was 13.6 months (range 3–42.4) [2]

Loss of Effectiveness

Reasons for Loss of Effectiveness

- Technical failure
  - High (>4000 Ω) or low impedance (<50Ω), lead migration
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- **Insufficient test duration and waning placebo effect**

- **No clear-cut definition of treatment success, symptoms fluctuate over time, changing patient expectation** (change with increased confidence and activity)

Prevention for Loss of Effectiveness

- Commonly used cut-off for chronic implant and considered successful treatment: 50%
- If cut-off for the improvement of incontinence episodes required to avoid lack of efficacy over time: > 90% during test stimulation
- A highly selective patient population leads to better success rates, but will exclude many patients who may have a clinical benefit

Predictors for Poorer Efficacy

- Ø age, gender, duration of symptoms, main causes of FI, type of FI (i.e. active or passive), baseline symptom scores or medications taken.
- Only loose stools and a history of diarrhea
- Presence of an internal rectal prolapse (III, IV)
- Treatment success rates tended to be less favorable in men compared with women (1 y vs 5 ys: 89% and 44% vs 92% and 64%)
  - etiological profile of refractory FI in men was different from that in women, including predominantly anal surgery and LARS
Failed SNM: What to do?

- Reprogramming
- Adjuvant therapies
  - Medication, transanal irrigation
  - Bulking agents / gatekeeper
- Revision surgery
  - Fresh nerve roots
- Surgical alternatives
- Stoma
Failure of SNM: Surgical Alternatives

No more available
Failure of SNM: Surgical Alternatives

- Sphincteroplasty
- Sphincter augmentation
  - Gatekeeper
  - Bioinjectables
- Sphincter replacement
  - AMI Band
- Stoma
  - Colostoma
Long-term: SNM and Sphincteroplasty

- SNM: * defined as ≥ 50% improvement of symptoms per protocol analysis
- SP: Success parameters may vary

Graphs showing success rates for SNM and SP, with different studies referenced:


5th International Consultation on Incontinence, Paris February, 2012.
Failure of SNM: Surgical Alternatives

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SNM Longterm Outcome: Summary

- First line: conservative treatment
- Longterm: Sustained clinical benefit: Incontinence, QoL
- Reproducable results
- Central role in current treatment algorithms „Surgical treatment for FI“
- Maintainence needed
Thank you