

Sacral neuromodulation for fecal incontinence: Long term outcomes

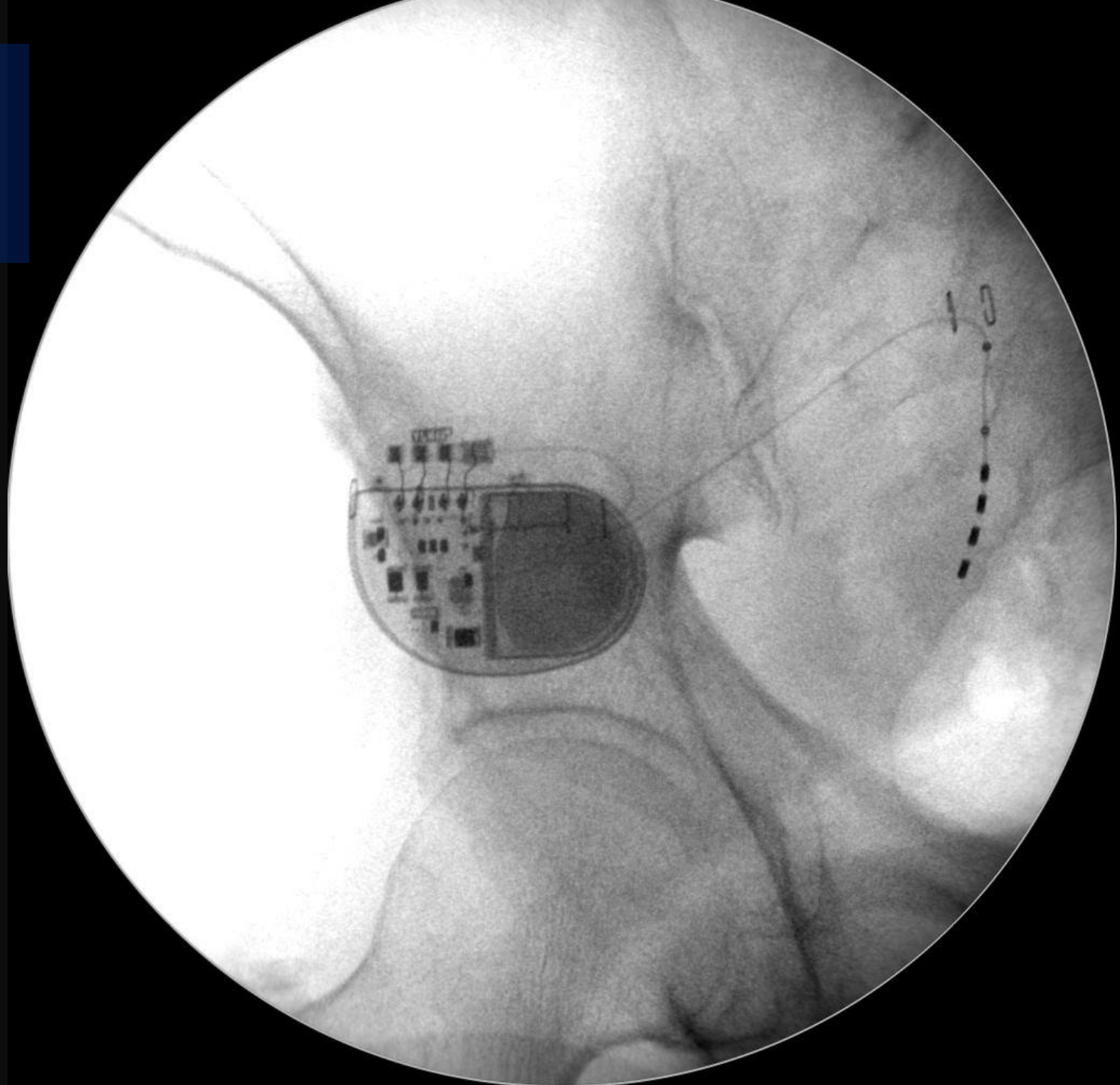
K. E. Matzel

Department of Surgery, University Erlangen, Germany

21. Annual Conference of EGCRS, Cairo 28.08.2019



■ SNM



■ **SNM**

***First implant for FI
June 24, 1994***

***PM-Approval FDA
March 14, 2011***

■ Evidence: Long Term Outcome

- Function

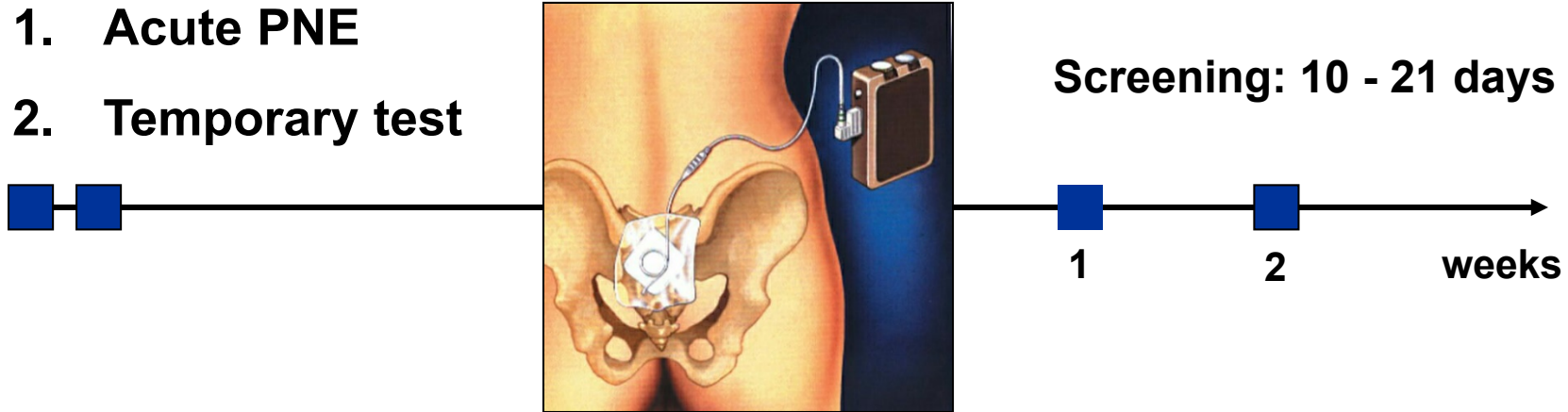
- QoL

■ Challenges with longterm therapy



SNM: Selection

1. Acute PNE
2. Temporary test



<i>Success:</i>	<i>50% Improvement:</i>	<i>Number of IC Days with IC</i>
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<i>Success: 70%- 80%</i>	<i>Improvement</i>	
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SNM: Outcome Measures

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



SNM: Outcome Measures

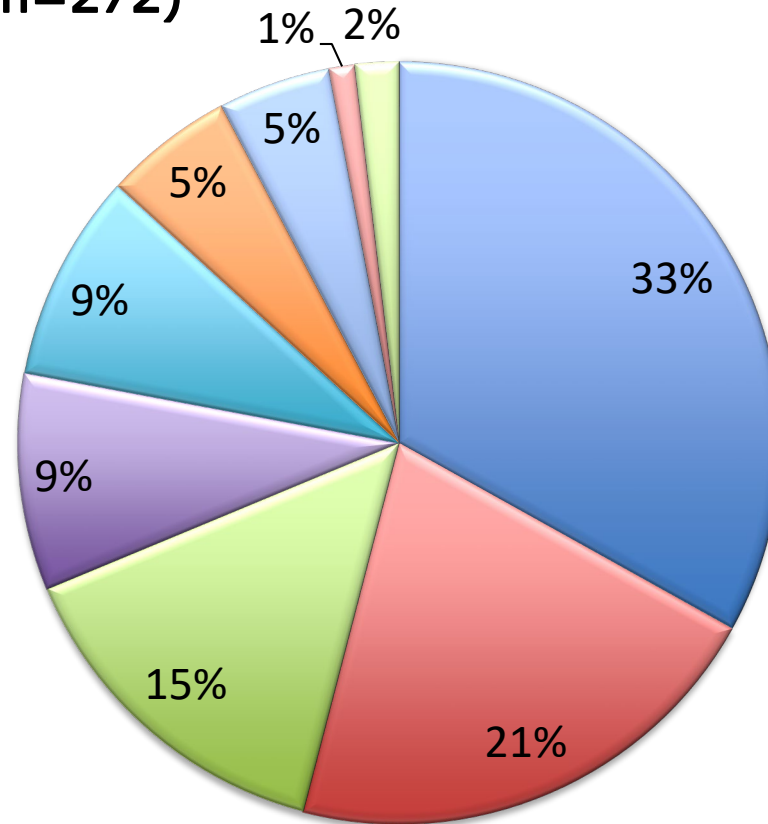
- Frequency of FI (n, days w/ FI)
- FI Score
- Urgency
- QoL

- Classification of success
 - 50% during the test
 - 50% with permanent implant
- PP vs ITT



SNM: Long Term 84 m

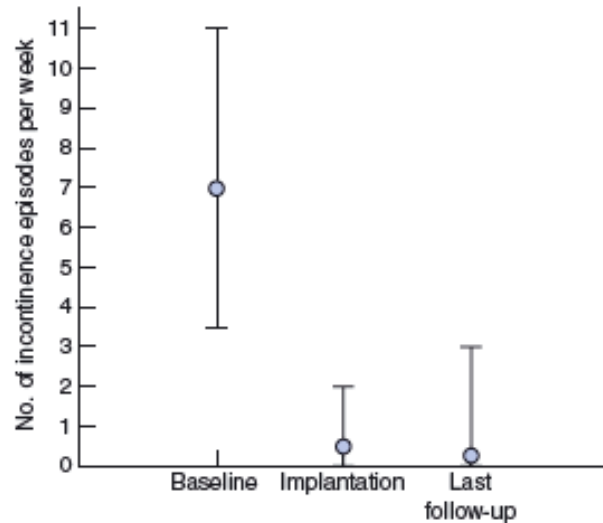
(n=272)



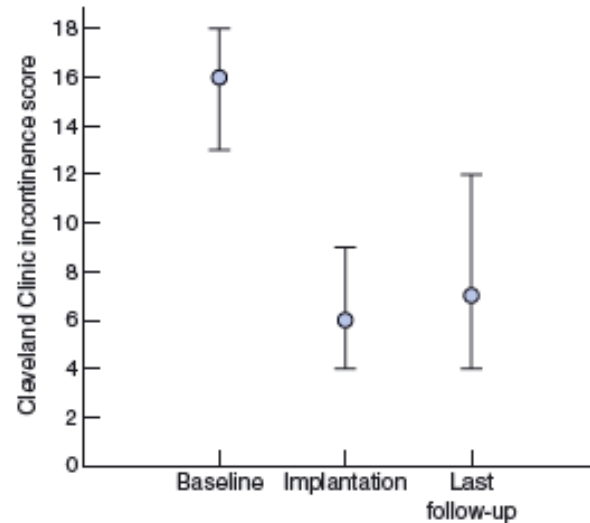
- Idiopathic
- Iatrogenic
- Obstetric
- Neurogenic
- Pelvic operations
- LARS
- Spinal lesions
- Congenital
- others

Altomare et al, Br J Surg. 2015;102:407-15

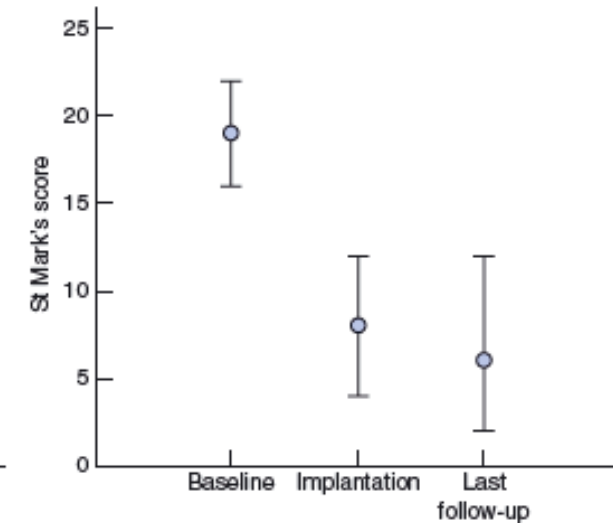
SNM: Long Term 84 m



IC episodes



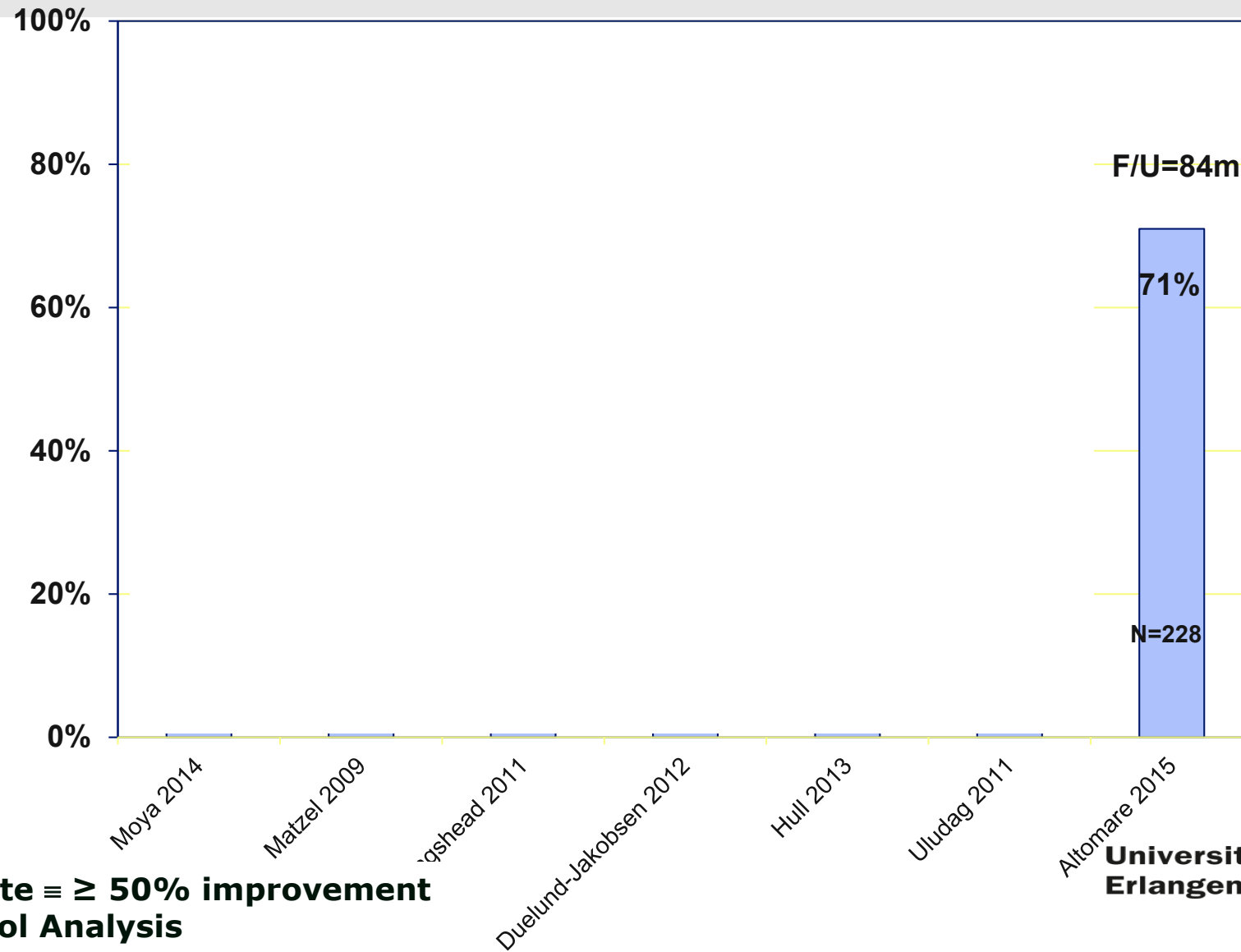
CCIS



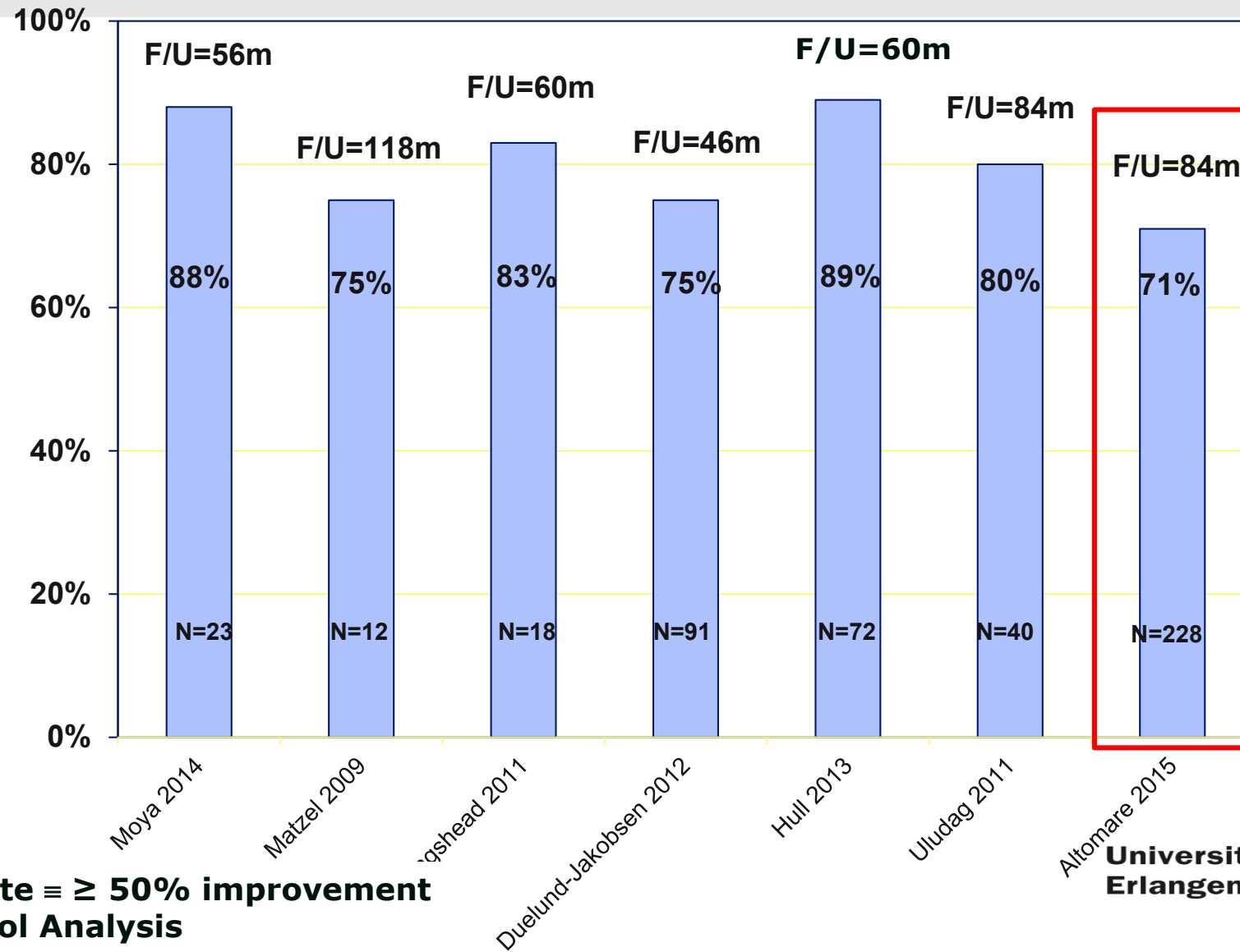
St Mark`s score



Long Term 46-118 m: 50% improvement



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*

Reference	Follow-up (months)*	No. of patients		PP (%)	
		Baseline	Follow-up	≥ 50% improvement	Full continence
Maeda <i>et al.</i> ¹⁵	60	141	101	55.6	n.c.
George <i>et al.</i> ¹⁶	114	23	19	n.a.	52
Moya <i>et al.</i> ¹⁷	56	52	50	96	n.c.
Matzel <i>et al.</i> ¹⁸	118	12	9	78	44
Lim <i>et al.</i> ¹⁹	51	53	41	n.c.	n.c.
Hollingshead <i>et al.</i> ²⁰	60†	86	18	21	n.a.
Vallet <i>et al.</i> ²¹	44‡	32	23	72	4
Duelund-Jakobsen <i>et al.</i> ²²			91		
Altomare <i>et al.</i> ³¹			52		
Hull <i>et al.</i> ³²			77		
Uludağ <i>et al.</i> ²³			36		
Present study	84	407	228	71.3	50.0
Summary median (range)	85 (44–118)	55 (12–407)	36.5 (9–228)	78 (21–96)	36 (4–52)

**84
months**

**>50%:71%
100%:50%**

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**85 (44–118)
months**

**>50%:78%
100%:36%**

SNM: Long Term Results: FI episodes short vs. medium vs. long

Reference	Median follow-up (months)	Permanent implants			Faecal incontinence episodes			<i>P</i>
		No. at baseline	No. at follow-up	% at follow-up	No. at. baseline*	No. at follow-up*	Difference	
Summary*								
Short term	12 (1–12)		27 (8–106)	88 (39–100)	8 (1–16)	1 (0–5)	–7 (–1 to –13)	
Medium term	24 (15–36)		16 (5–86)	64 (12–100)	8 (1–26)	1 (0–4)	–7 (–1 to –25)	
Long term	51 (44–118)		13 (2–147)	70 (6–100)	8 (1–12)	1 (0–2)	–7 (–1 to –12)	

short (12m): 8 (1-16) → 1 (0-5)
medium (24m): 8 (1-26) → 1 (0-4)
long (51m): 8 (1-12) → 1 (0-2)

Thin et al, BJS. 100, 1430-47, 2013



SNM: Results: CCIS

short vs. medium vs. long

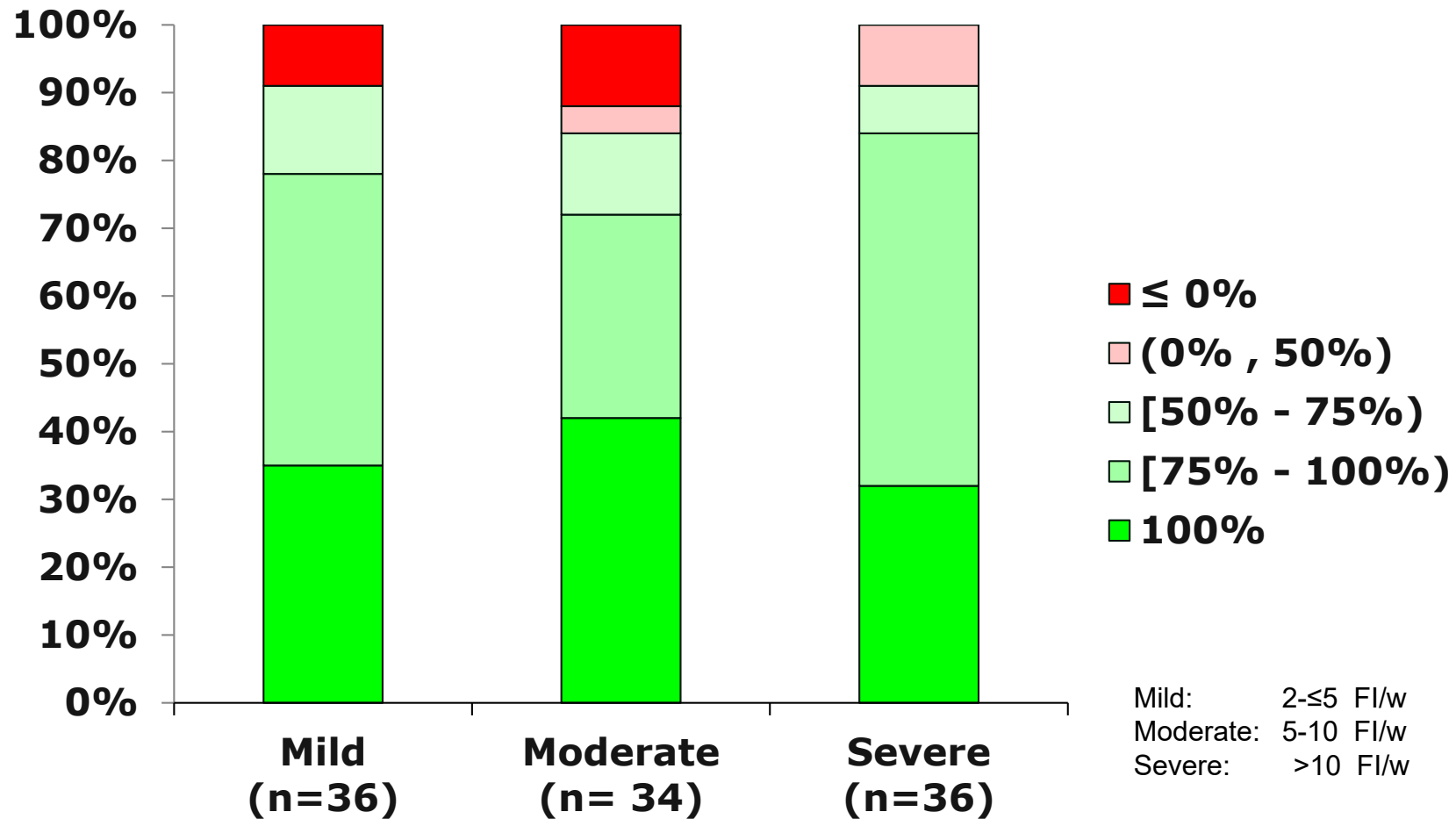
Reference	Median follow-up (months)	Permanent implants			Baseline score*	Follow-up score*	Score difference	P
		No. at baseline	No. at follow-up	% at follow-up				
Summary*								
Short term	6 (1-12)	29 (11-130)	100 (85-100)	15 (12-16)	6 (1-10)	-9 (-3 to -15)		
Medium term	24 (13-36)	41 (10-126)	100 (27-100)	15 (14-18)	8 (3-12)	-7 (-3 to -14)		
Long term	50 (37-118)	23 (9-87)	75 (8-100)	15 (12-20)	7 (5-10)	-8 (-4 to -13)		

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

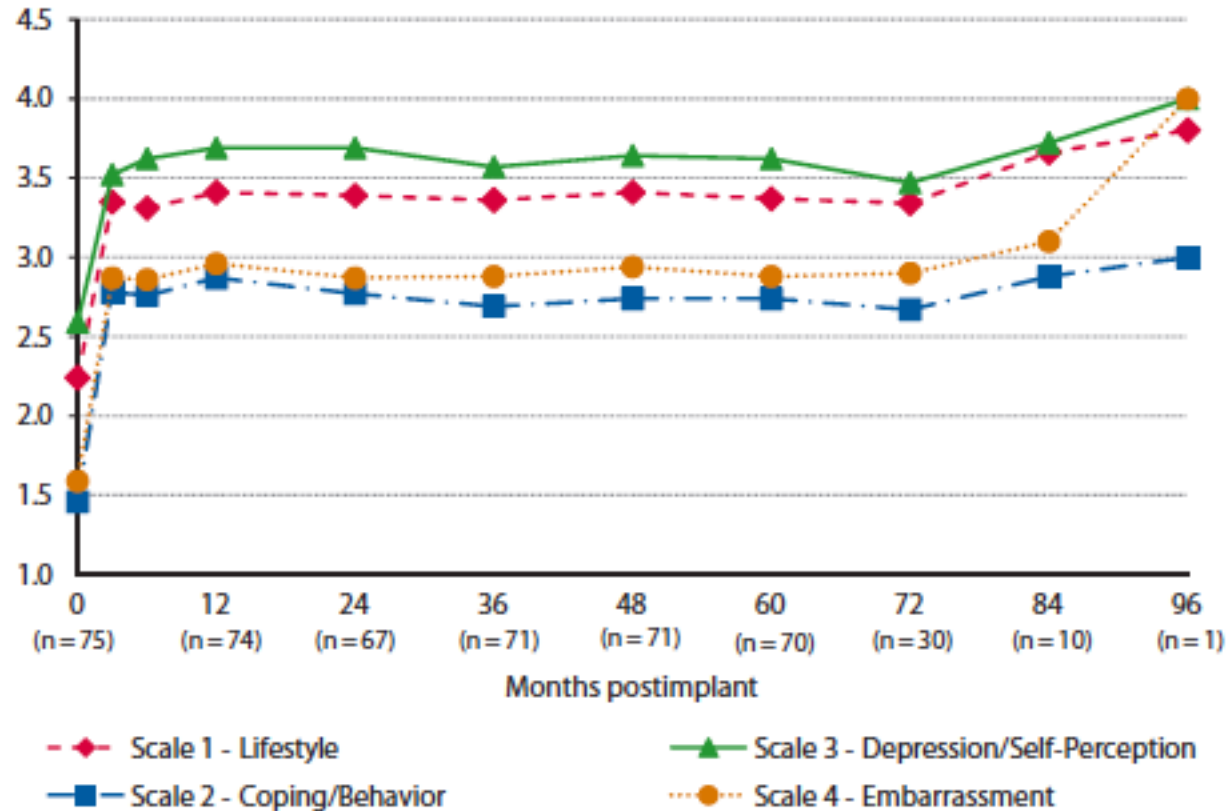


SNM IC: Efficacy after 5y



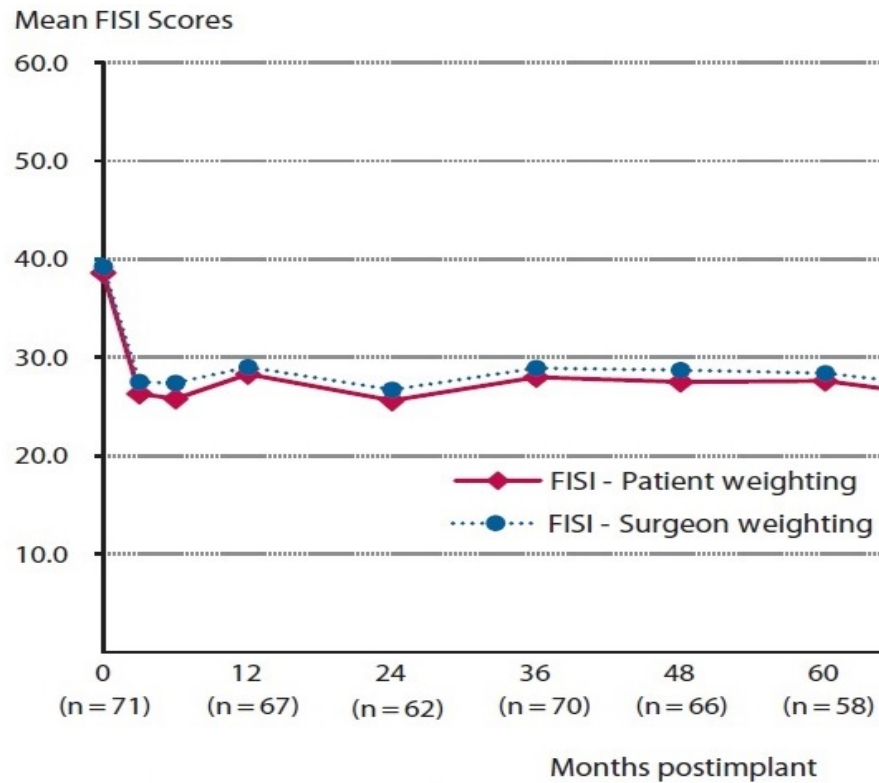
SNM North American Multicenter Trial: 5 y

Mean FIQL Score

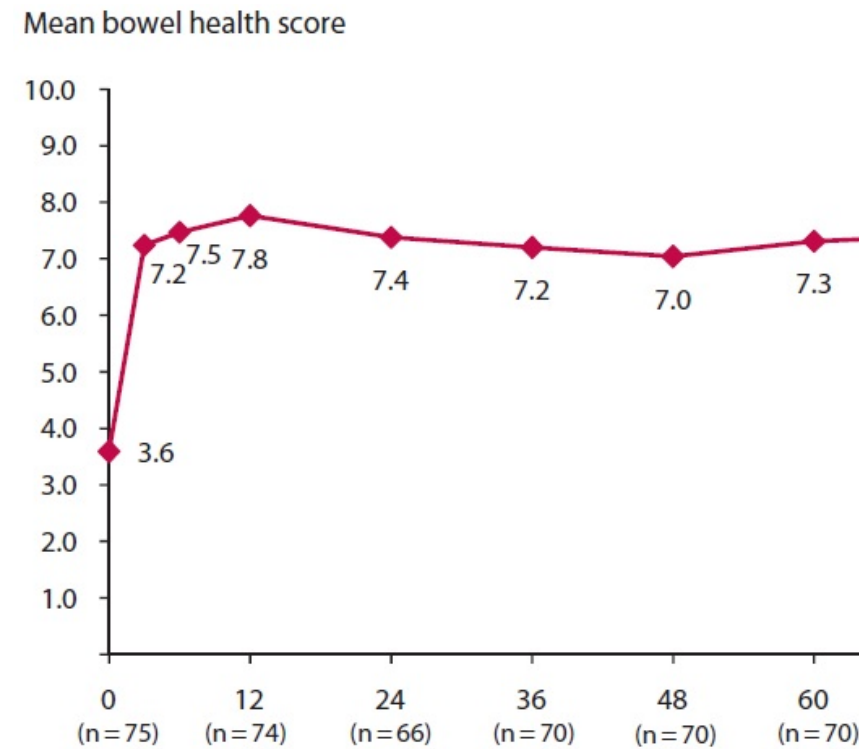


SNM QoL

Mean FISI Score

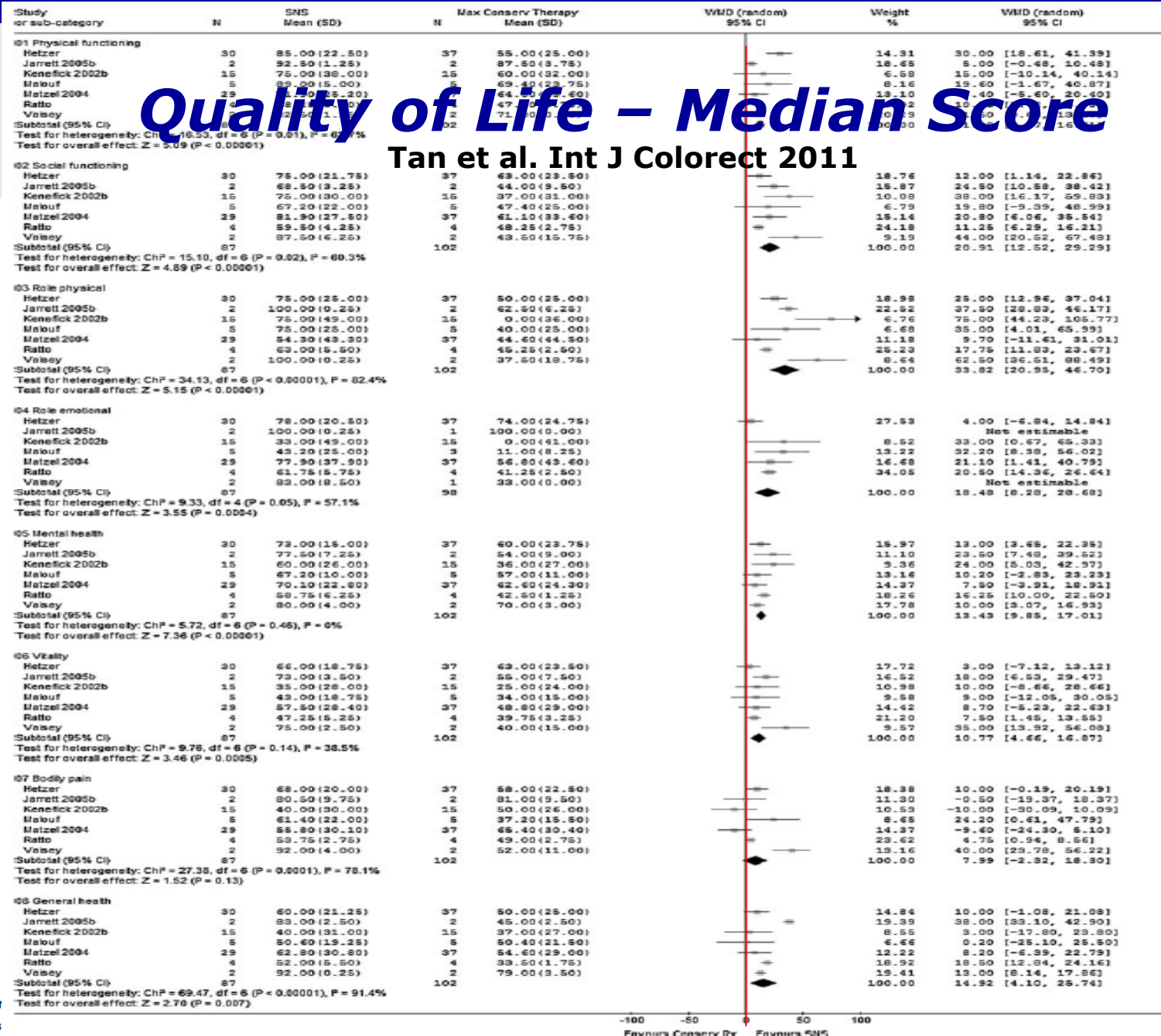


Mean Bowel Health Score

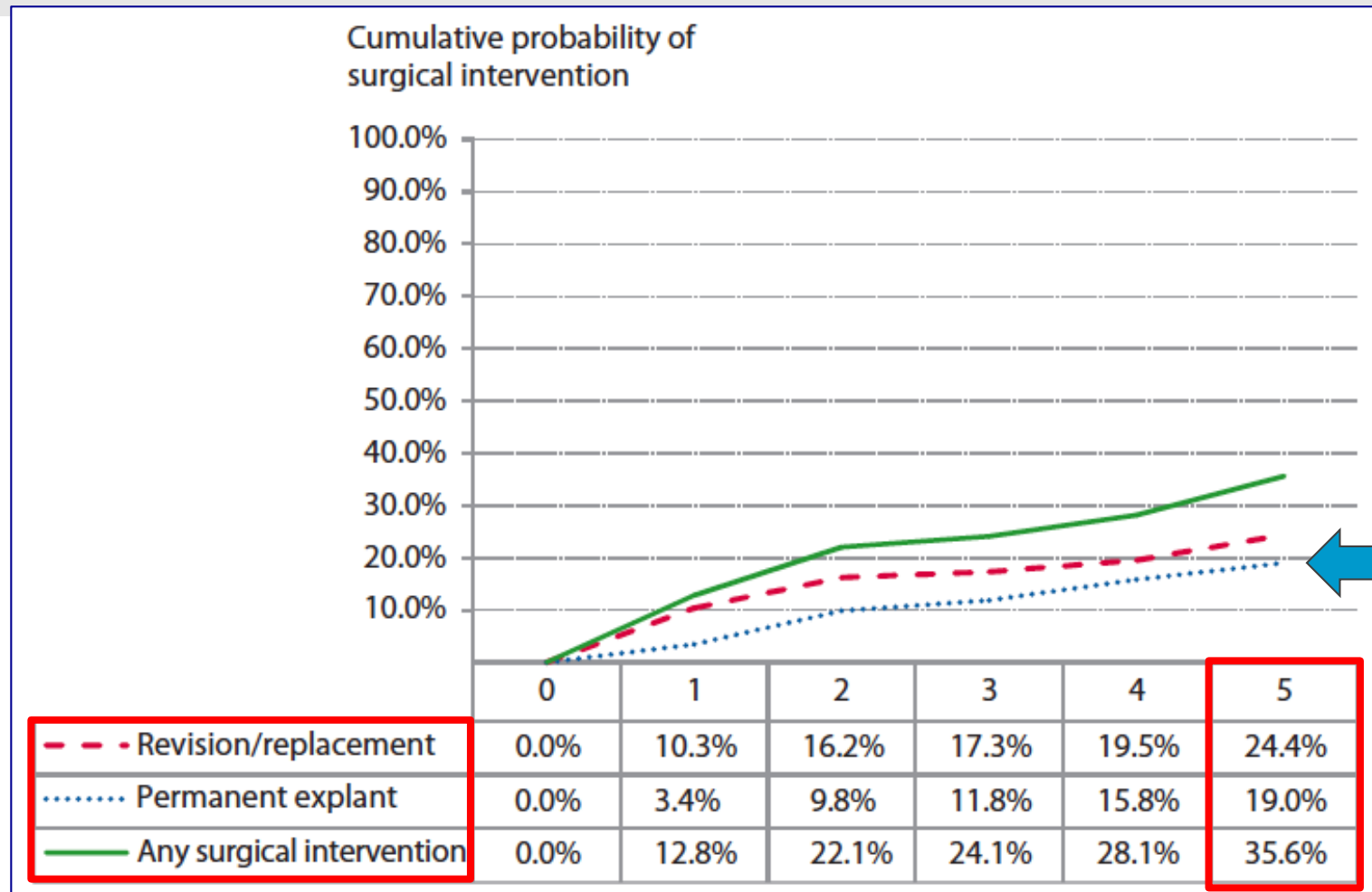


Quality of Life – Median Score

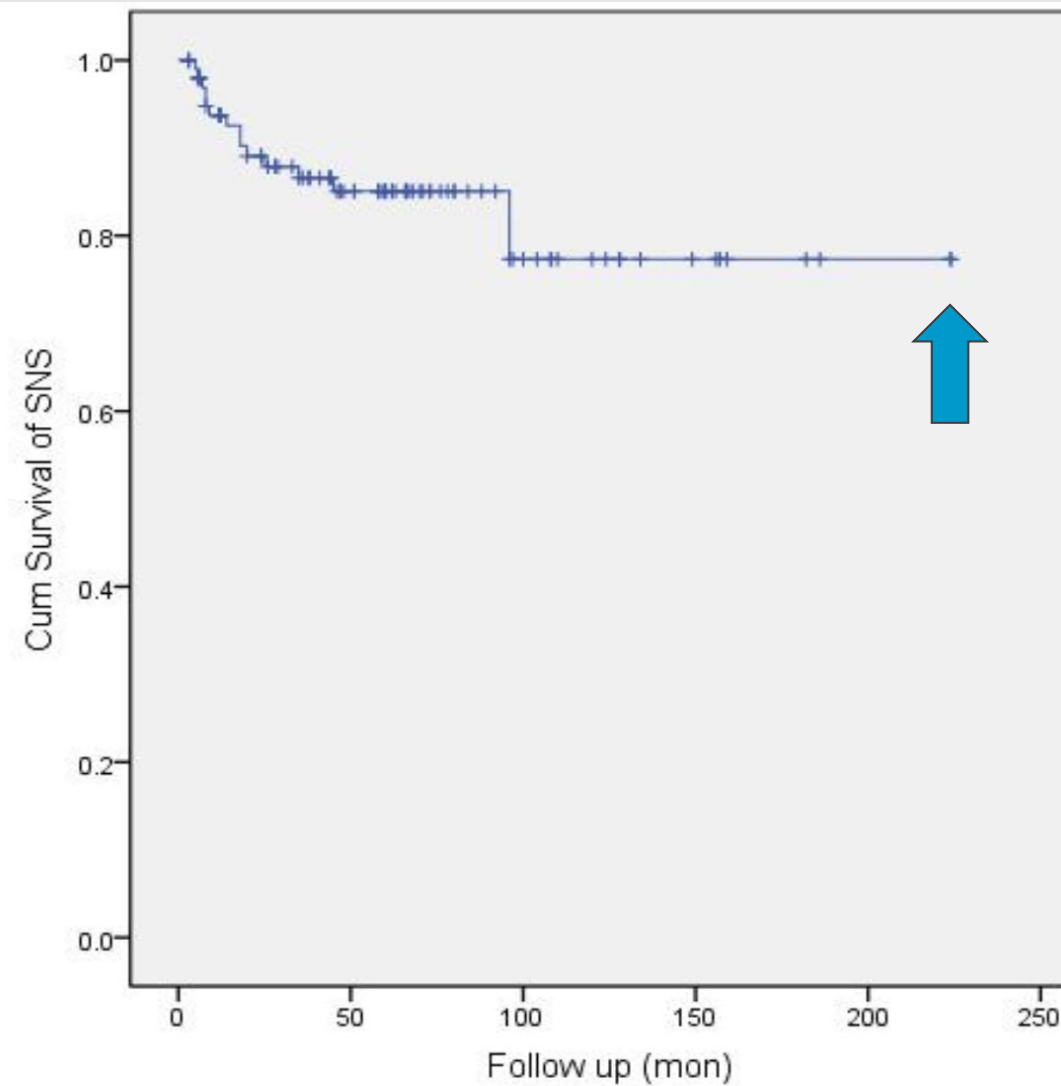
Tan et al. Int J Colorect 2011



SNM: Device Retention Rate 5 y: 81%



SNM:18 y: Device Retention Rate: 78%

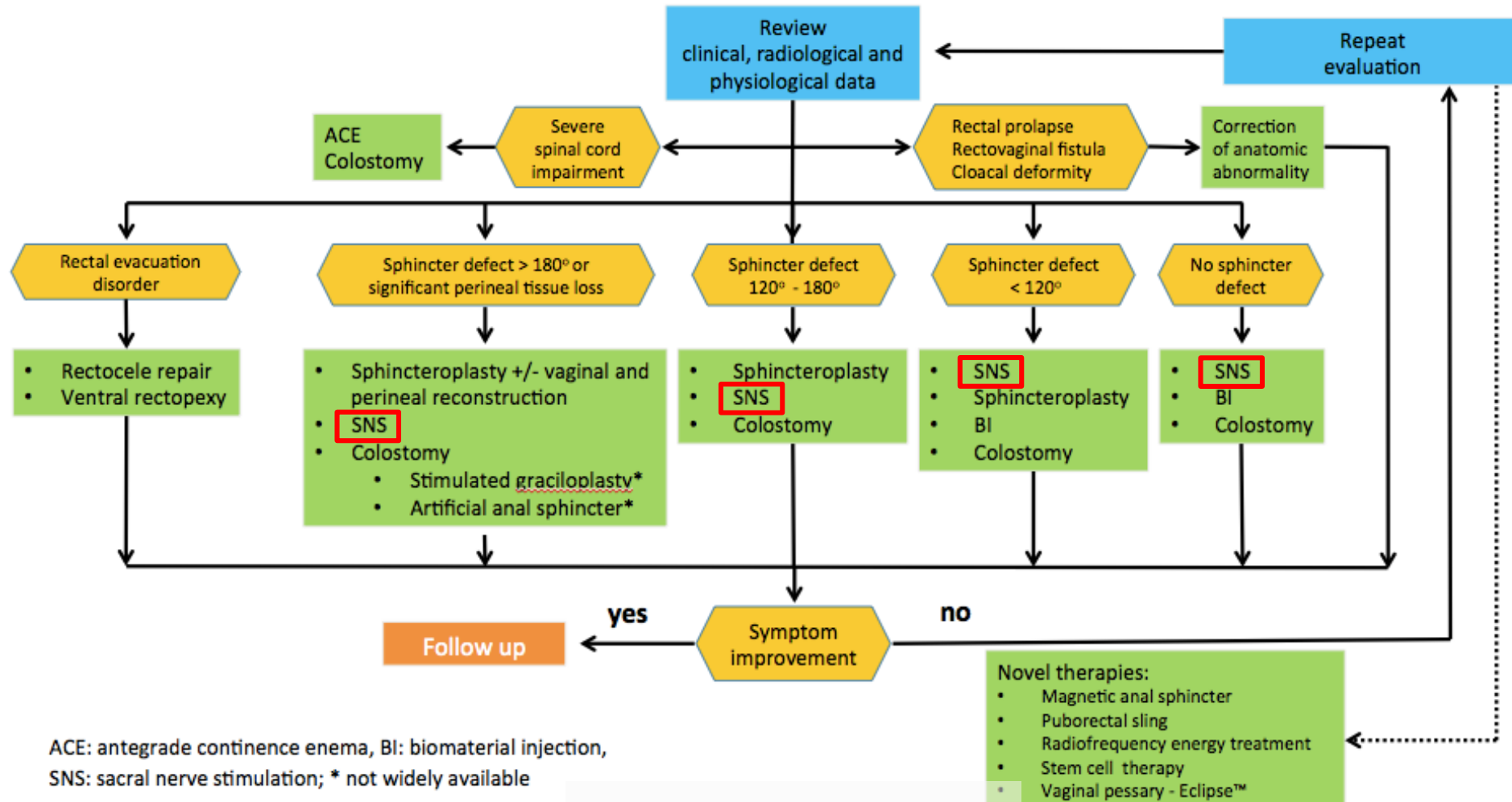


SNM for Fecal Incontinence

- **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



Challenges SNM Longterm

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



Battery Longevity

	Battery life (years)	Publication year
Medtronic estimate ⁽¹⁾	Ø4.4 yr	2012
Author's opinion ⁽²⁾	5-7 yr	2018
Author's opinion ⁽³⁾	5-7 yr	2017
Real-life data ⁽⁴⁾	≈ 6 yr (5-7)* _γ	2019
Real-life data ⁽⁵⁾	≥ 5 yr* _γ	2016
Real-life data ⁽⁶⁾	5.3 yr (<2V)* _γ	2016
Real-life data ⁽⁷⁾	6.3 yr* _γ	2014

* explicitly referred to Interstim II; _γ median values

[1] cited in Cameron AP et al. *Neurourol Urodyn.* 2013;32:238-41; [2] Tahseen S. *Int Urogynecol J.* 2018;29:1081-1091; [3] Fontaine CL et al. *Urol Ann* 9:249-252; [4] Widmann B et al. *J Neurogastroenterol Motil.* 2019;25:159-170; [5] Duchalais et al. *Int J Colorectal Dis.* 2016;31:439-44; [6] Siegel S et al. *Female Pelvic Med Reconstr Surg.* 2018;24(4):267-271; [17] Cui Zhe <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**

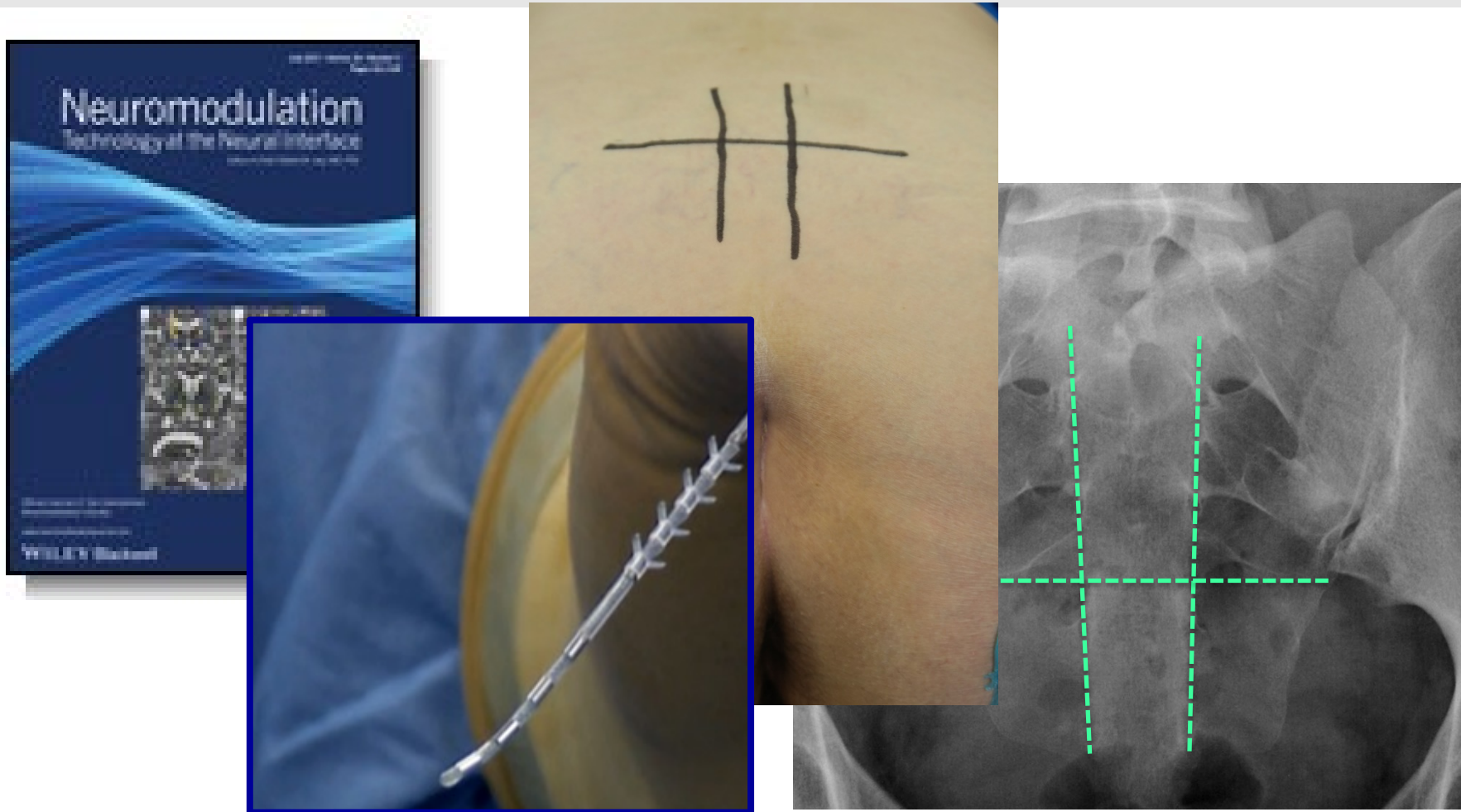


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- **median battery life:**
 - **Amplitude $\leq 2V$ (n=15): 64 months**
 - **Amplitude $> 2V$ (n=12): 38 months**
- **optimized lead placement**
- **programming using extended duration cycling (e.g. 10 min ON; 10 min OFF)**



Standardised Electrode Placement Technique



Current Mean Amplitudes Historical Data vs. Standardised Technique

2011

- Traditional implantation technique
- **≈2.1V @12months**

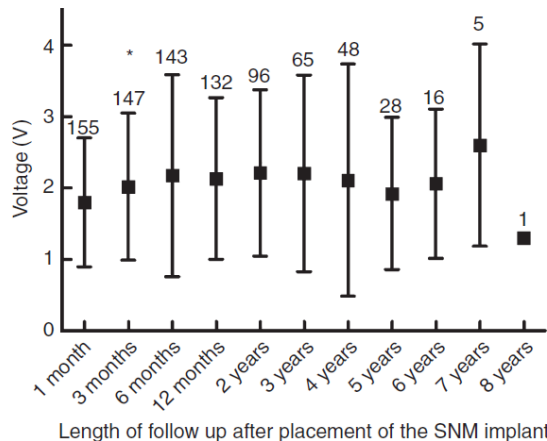


Figure 1 Mean voltage of the sacral nerve modulation (SNM)

Govaert B et al *Colorectal Dis.* 2011;13:78-81

2018

- Optimized lead placement with 3889 tined lead and curved stylet
- **1.0V @12month**

Duelund-Jakobsen J et al. *Colorectal Dis.* 2018; 20:O152-O157.

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)



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**

Variable	Group A (N=32)	Group B (N=7)
PRO (0-10)	7.6 ± 1.6	5.5 ± 0.9
ΔCCF-FI	-0.63	+1.86
ΔFIQL	+0.27	-0.46

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

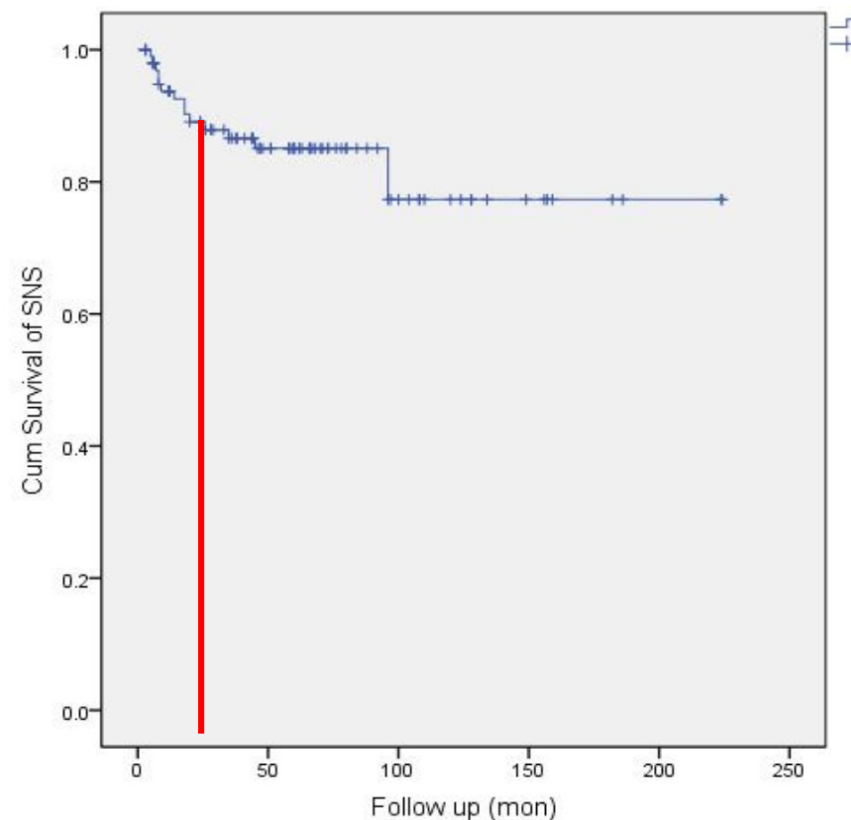
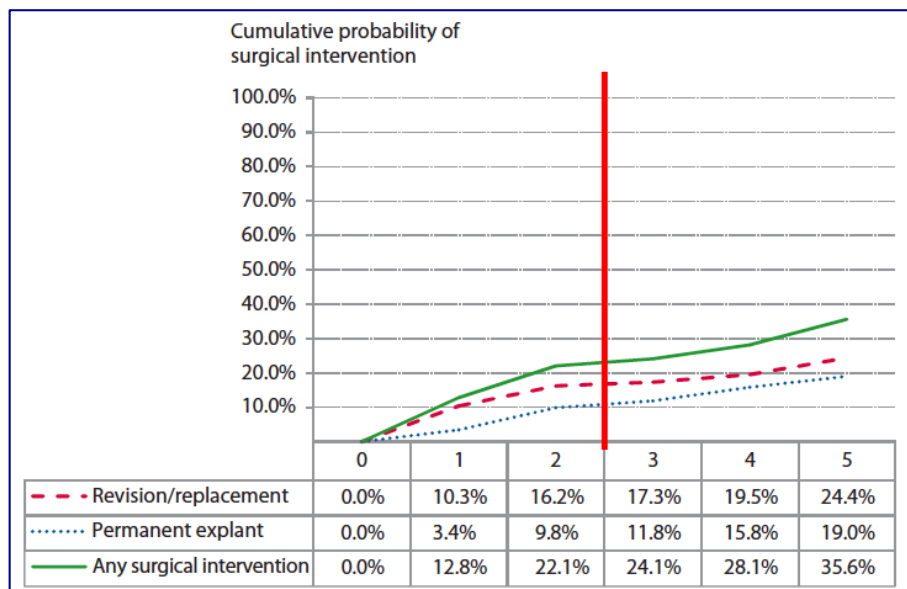
- **Loss of efficacy typically occurs *within the first 2 years of the treatment*** [1]
- **The mean time to definitive failure was *13.6 months (range 3–42.4)*** [2]

[1] Maeda Y et al, Br J Surg. 2011;98:140-147

[2] Melenhorst J, et al. Colorectal Dis. 2007;9:725-30



Loss of Effectiveness



Hull et al. Dis Colon Rectum 56, 234-45, 2013

Reasons for Loss of Effectiveness

- **Technical failure**

- High ($>4000\ \Omega$) or low impedance ($<50\ \Omega$), lead migration

- **Fibrosis around the lead**



Reasons for Loss of Effectiveness

- **Technical failure**
 - High ($>4000\ \Omega$) or low impedance ($<50\ \Omega$), lead migration
- **Fibrosis around the lead**
- **New or progressive metabolic or neurologic issues**
- **“Accommodation” by the nervous system (steady increase of the amplitude)**



Reasons for Loss of Effectiveness

- **Technical failure**
 - High ($>4000\ \Omega$) or low impedance ($<50\ \Omega$), lead migration
- **Fibrosis around the lead**
- **New or progressive metabolic or neurologic issues**
- **“Accommodation” by the nervous system (steady increase of the amplitude)**
- **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

- ∅ 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 ?

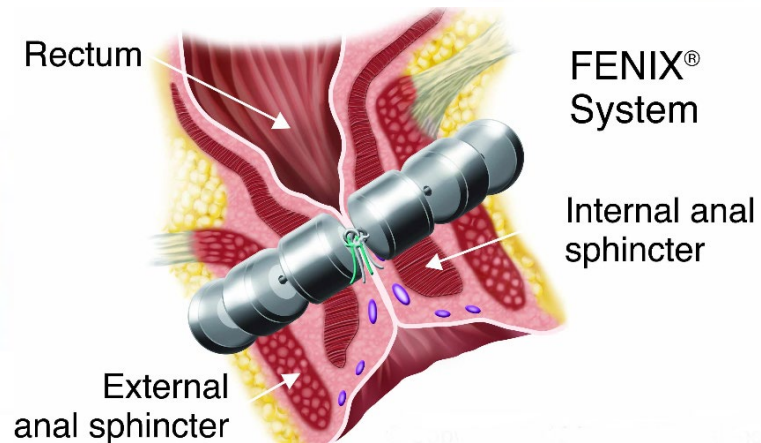
- **Reprogramming**
- **Adjuvant therapies**
 - Medication, transanal irrigation
 - Bulking agents / gatekeeper
- **Revision surgery**
 - Fresh nerve roots
- **Surgical alternatives**
- **Stoma**



Failure of SNM: Surgical Alternatives



***No more
available***

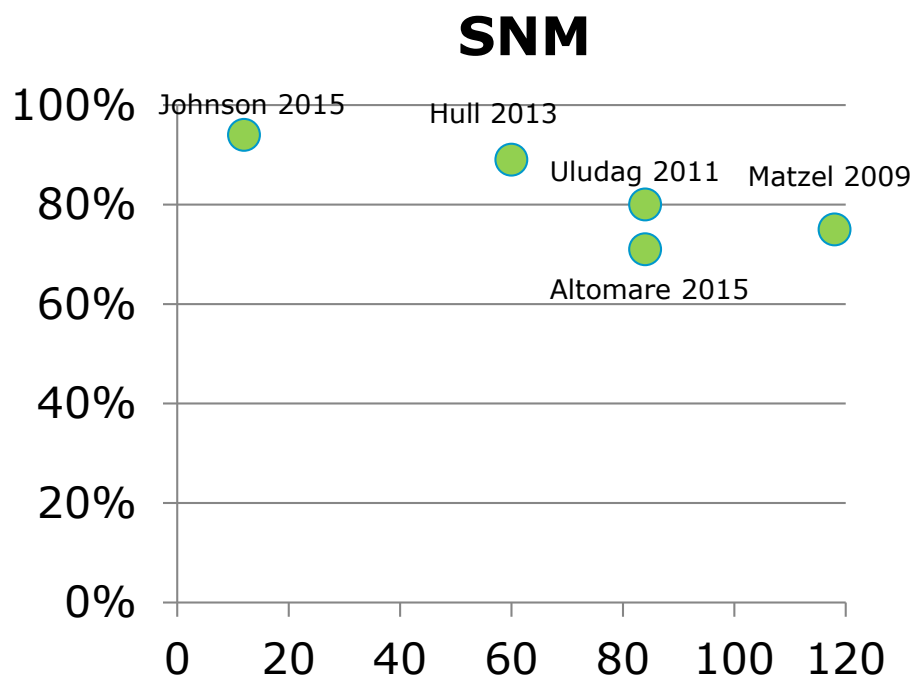


Failure of SNM: Surgical Alternatives

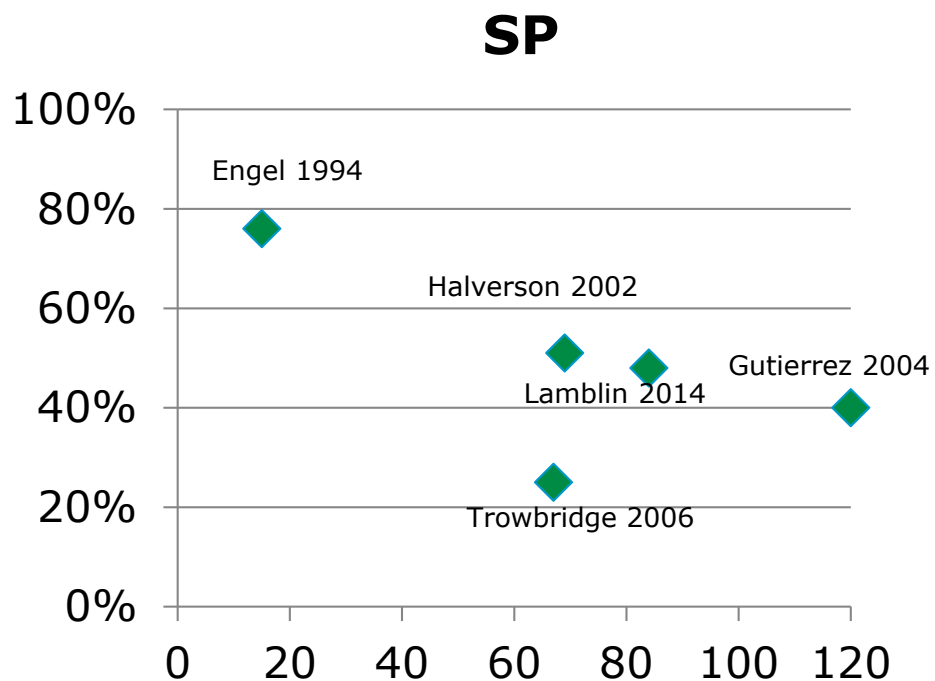
- **Sphincteroplasty**
- **Sphincter augmentation**
 - Gatekeeper
 - Bioinjectables
- **Sphincter replacement**
 - AMI Band
- **Stoma**
 - Colostoma



Long-term : SNM and Sphincteroplasty

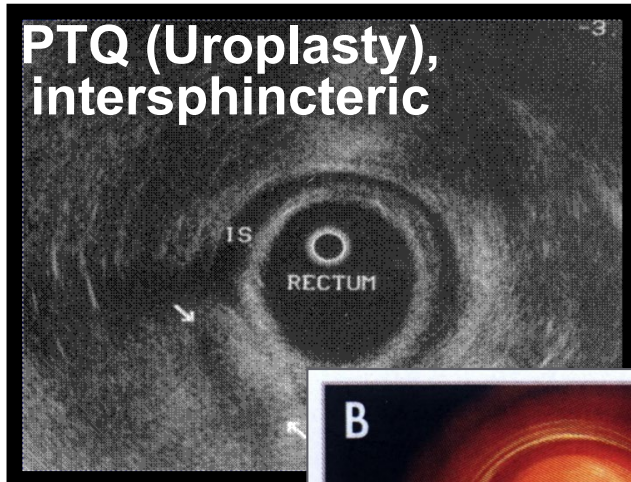


* defined as $\geq 50\%$ improvement of symptoms
per protocol analysis

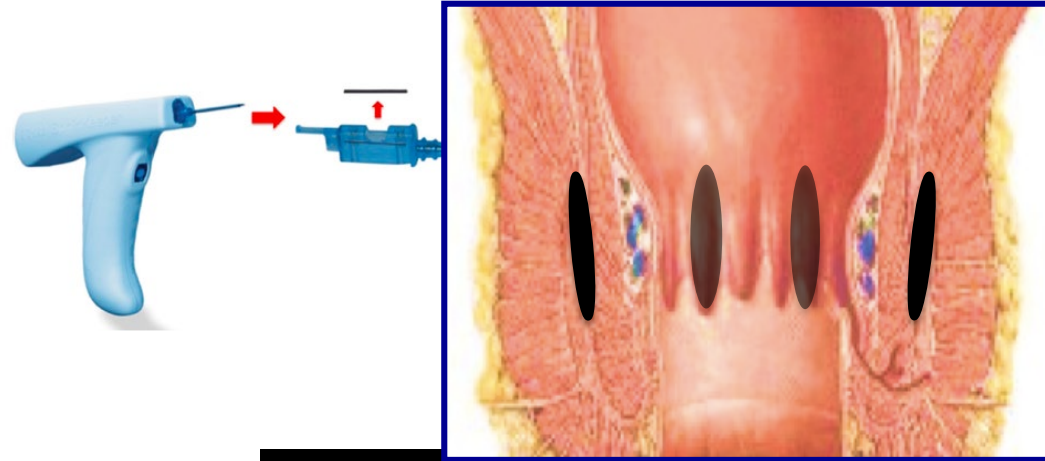


per protocol analysis
Success parameters may vary

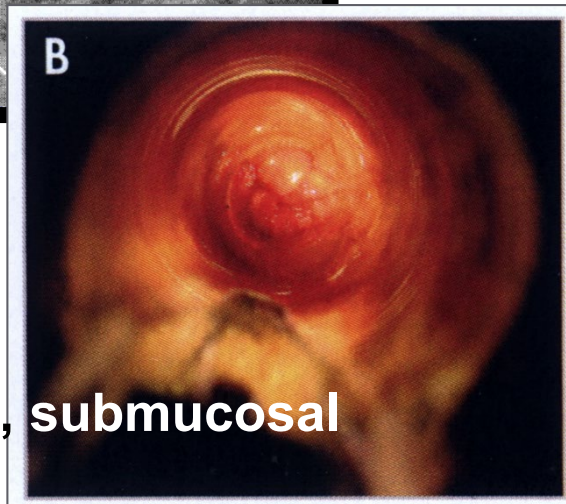
Injectables / Bulking Agents



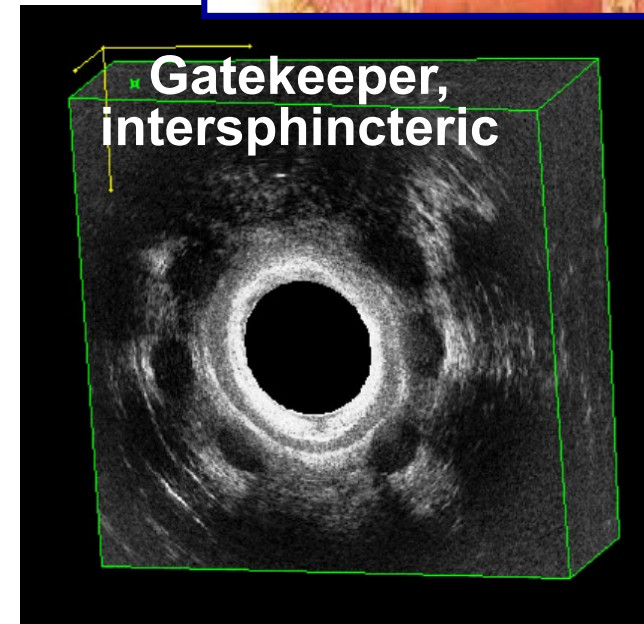
*Tjandra et al
DCR, 47, 2004*



NashDx, submucosal



Graf et al ASCRS 2006



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Failure of SNM: Surgical Alternatives

- **Sphincteroplasty**
- **Sphincter augmentation**
 - Gatekeeper
 - Bioinjectables
- **Sphincter replacement**
 - AMI Band
- **Stoma**
 - Colostoma



SNM Longterm Outcome: Summary

- **First line: conservative treatment**
- **Longterm: Sustained clinical benefit:
Incontinence, QoL**
- **Reproducible results**
- **Central role in current treatment
algorithms „Surgical treatment for FI“**
- **Maintenance needed**



Thank you

