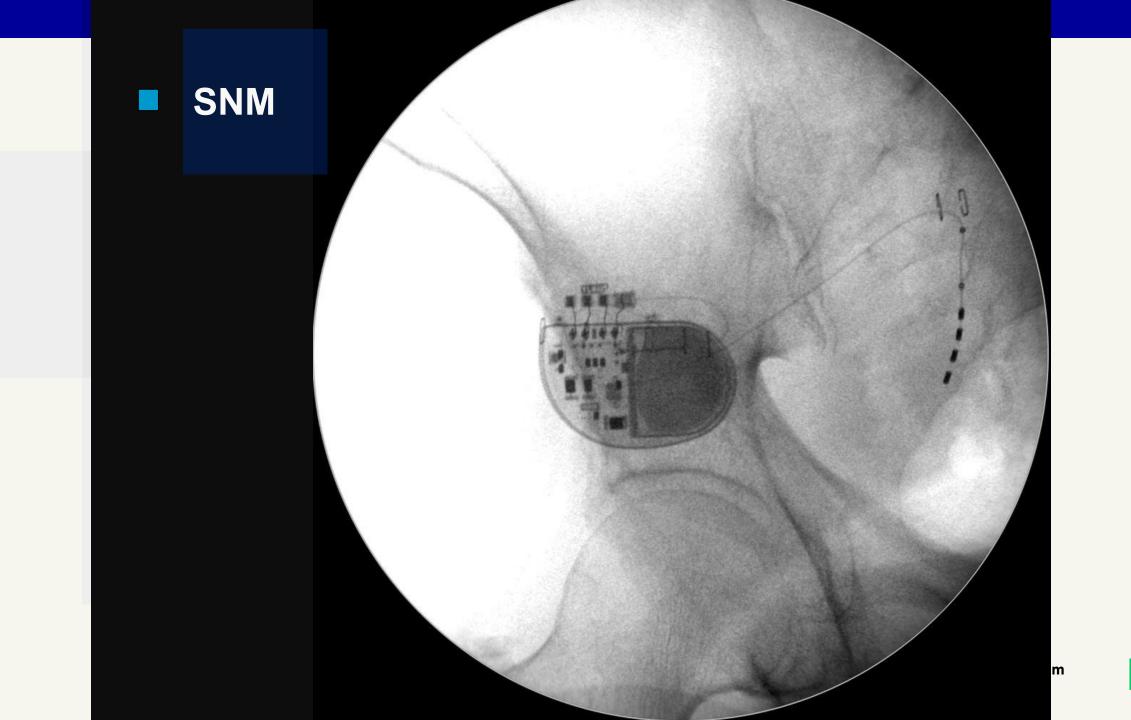
Sacral neuromodulation for fecal incontinence: Long term outcomes

#### 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

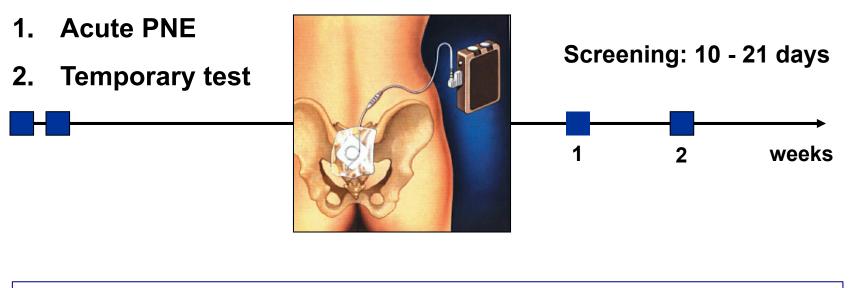
# Evidence: Long Term Outcome

- Function
- QoL

# Challenges with longterm therapy



# **SNM: Selection**



Success:50% Improvement:Number of ICDays with IC

Success: 70%-80% Improvement



# **SNM: Outcome Measures**

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

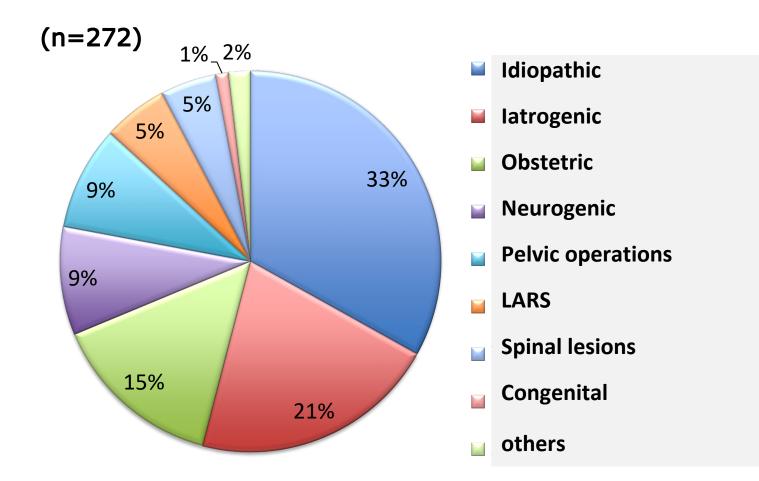


# **SNM: Outcome Measures**

- 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



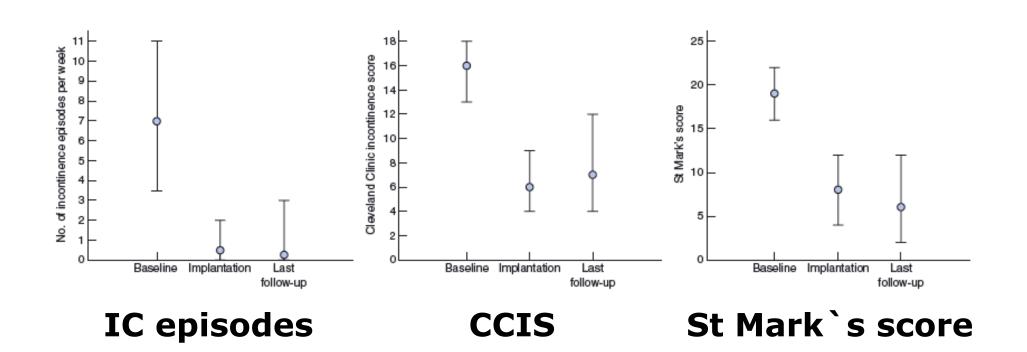
# SNM: Long Term 84 m





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

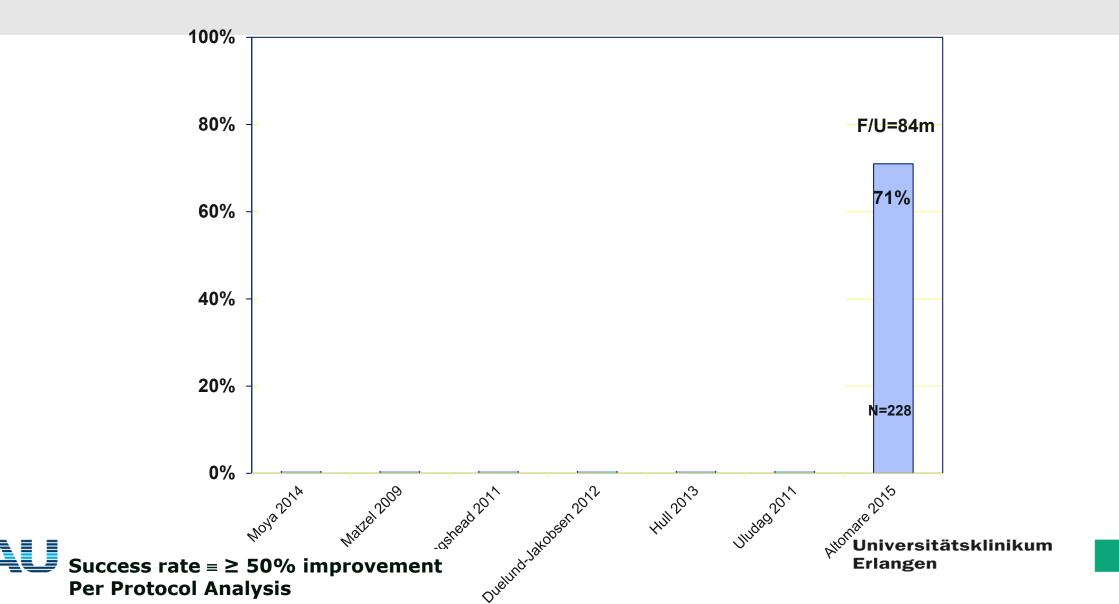
SNM: Long Term 84 m



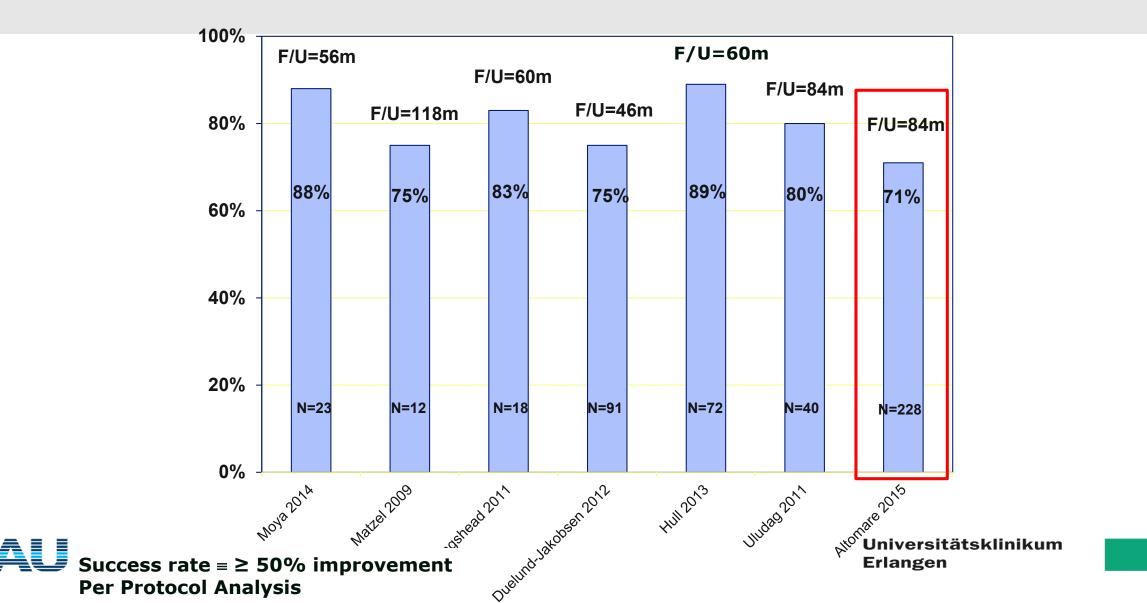


Altomare et al, Br J Surg. 2015;102:407-15

## Long Term 46-118 m: 50% improvement



## Long Term 46-118 m: 50% improvement



#### **Original article**

# Long-term outcomes of sacral nerve stimulation for faecal incontinence

D. F. Altomare<sup>1</sup>, S. Giuratrabocchetta<sup>1</sup>, C. H. Knowles<sup>2</sup>, A. Muñoz Duyos<sup>3</sup>, J. Robert-Yap<sup>4</sup> and K. E. Matzel<sup>5</sup> on behalf of the European SNS Outcome Study Group\*

|                                 |                        | No. of      | patients     | PP (                 | %)              |
|---------------------------------|------------------------|-------------|--------------|----------------------|-----------------|
| Reference                       | Follow-up<br>(months)* | Baseline    | Follow-up    | ≥ 50%<br>improvement | Full continence |
| Maeda et al. <sup>15</sup>      | 60                     | 141         | 101          | 55.6                 | ñ.c.            |
| George et al. <sup>16</sup>     | 114                    | 23          | 19           | n.a.                 | 52              |
| Moya et al. <sup>17</sup>       | 56                     | 52          | 50           | 96                   | n.c.            |
| Matzel et al. <sup>18</sup>     | 118                    | 12          | 9            | 78                   | 44              |
| Lim <i>et al.</i> <sup>19</sup> | 51                     | 53          | 41           | n.c.                 | n.c.            |
| Hollingshead et al.20           | 60†                    | 86          | 18           | 21                   | n.a.            |
| Vallet et al.21                 | 44‡                    | 32          | 23           | 72                   | 4               |
| Duelund-Jakobsen et a           | 84                     |             | 91           | >50%:                | 710/            |
| Altomare et al. <sup>31</sup>   |                        |             | 52           |                      |                 |
| Hull et al. <sup>32</sup>       | mont                   | hs          | 77           | 100%                 | :50%            |
| Uludağ et al. <sup>23</sup>     | 0-                     | 00          | 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)       |



BJS 2015, 102, 407-15

#### Original article

# Long-term outcomes of sacral nerve stimulation for faecal incontinence

D. F. Altomare<sup>1</sup>, S. Giuratrabocchetta<sup>1</sup>, C. H. Knowles<sup>2</sup>, A. Muñoz Duyos<sup>3</sup>, J. Robert-Yap<sup>4</sup> and K. E. Matzel<sup>5</sup> on behalf of the European SNS Outcome Study Group\*

|                                    |                        | No. of      | patients     | PP (                 | %)              |
|------------------------------------|------------------------|-------------|--------------|----------------------|-----------------|
| Reference                          | Follow-up<br>(months)* | Baseline    | Follow-up    | ≥ 50%<br>improvement | Full continence |
| Maeda et al. <sup>15</sup>         | 60                     | 141         | 101          | 55.6                 | n.c.            |
| George et al. <sup>16</sup>        | 114                    | 23          | 19           | n.a.                 | 52              |
| Moya et al. <sup>17</sup>          | 56                     | 52          | 50           | 96                   | n.c.            |
| Matzel <i>et al.</i> <sup>18</sup> | 118                    | 12          | 9            | 78                   | 44              |
| Lim et al. <sup>19</sup>           | 51                     | 53          | 41           | n.c.                 | n.c.            |
| Hollingshead et al.20              | 60†                    | 86          | 18           | 21                   | n.a.            |
| Vallet et al.21                    | 44‡                    | 32          | 23           | 72                   | 4               |
| Duelund-Jakobsen et a              | 85 (44-                | 118)        | 91           | >50%                 | 780/            |
| Altomare et al. <sup>31</sup>      |                        |             | 52           |                      |                 |
| Hull et al. <sup>32</sup>          | mont                   | hs          | 77           | 100%                 | :36%            |
| Uludağ et al. <sup>23</sup>        | U-1                    | 50          | 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)       |

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BJS 2015, 102, 407-15

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

|  |  | Permanent implants |                                       |  | Faecal incontinence episodes     |                               |  |   |  |
|--|--|--------------------|---------------------------------------|--|----------------------------------|-------------------------------|--|---|--|
| Reference  | Median<br>follow-up (months)           | No. at<br>baseline | No. at<br>follow-up                   | % at<br>follow-up                        | No. at.<br>baseline*             | No. at<br>follow-up*          | Difference                             | Р |  |
| Summary*<br>Short term<br>Medium term<br>Long term | 12 (1–12)<br>24 (15–36)<br>51 (44–118) |                    | 27 (8–106)<br>16 (5–86)<br>13 (2–147) | 88 (39–100)<br>64 (12–100)<br>70 (6–100) | 8 (1–16)<br>8 (1–26)<br>8 (1–12) | 1 (0–5)<br>1 (0–4)<br>1 (0–2) | 7 (1 to13)<br>7 (1 to25)<br>7 (1 to12) |   |  |
|  | short (1                               | 2m):               |                                       | 8 (1-1                                   | 5) 🔿                             | 1 (0-                         | 5)                                     |   |  |
|  | medium                                 | <b>(24</b> m       | ):                                    | 8 (1-2                                   | 5) 🔿                             | 1 (0-                         | 4)                                     |   |  |
|  | long (51                               | <b>m):</b>         |                                       | 8 (1-12                                  | 2) 🔿                             | 1 (0-                         | 2)                                     |   |  |



## SNM: Results: CCIS

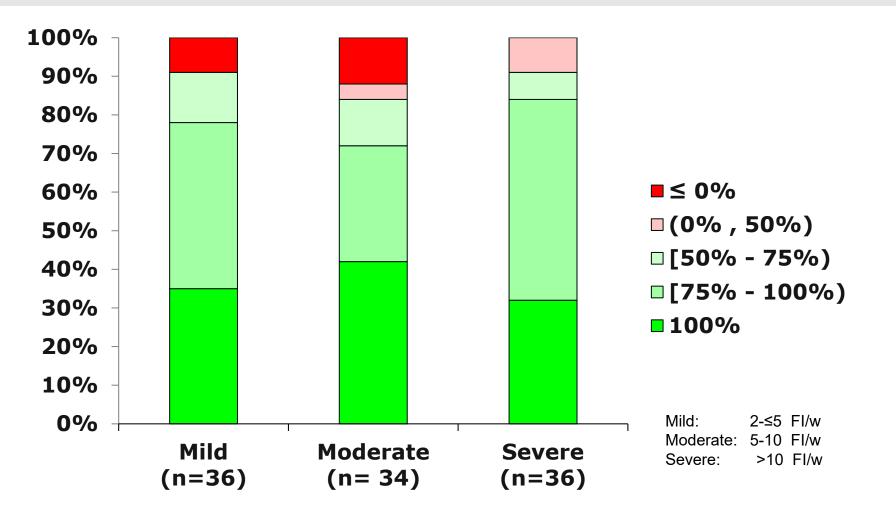
# short vs. medium vs. long

|                           |                              |                    | Permanent imp                           | plants                       |                          |                      |                                  |  |
|---------------------------|------------------------------|--------------------|---|------------------------------|--------------------------|----------------------|----------------------------------|--|
| Reference                 | Median<br>follow-up (months) | No. at<br>baseline | No. at<br>follow-up                     | % at<br>follow-up            | Baseline<br>score*       | Follow-up<br>score*  | Score<br>difference              |  |
| Summary*                  |                              |                    | ~ | 100.005.100                  |                          |                      |                                  |  |
| Short term<br>Medium term | 6 (1-12)<br>24 (13-36)       |                    | 29 (11–130)<br>41 (10–126)              | 100 (65–100)<br>100 (27–100) | 15 (12–16)<br>15 (14–18) | 6 (1–10)<br>8 (3–12) | -9 (-3 to -15)<br>-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)                   |  |
|                           |                              | •                  |   |                              |                          | C ( 4                | 10)                              |  |

| short (6m):   | 15 (12-16) 🔿 6 (1-10) |
|---------------|-----------------------|
| medium (24m): | 15 (14-18) 눡 8 (3-12) |
| long (50m):   | 15 (12-20) 💛 7 (5-10) |



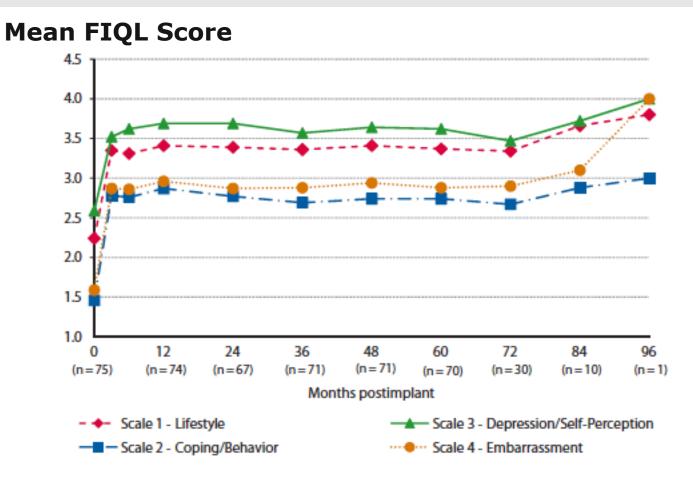
# SNM IC: Efficacy after 5y





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

# SNM North American Multicenter Trial: 5 y



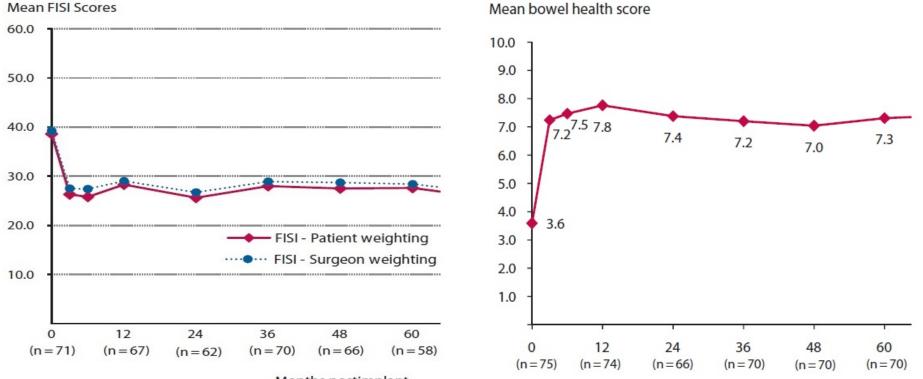


Hull et al, Dis Col Rectum, 56, 234-45, 2013



#### Mean FISI Score

#### Mean Bowel Health Score



Months postimplant



Hull T et al. Dis Colon Rectum. 2013;56:234-245 Mellgren A et al. Dis Colon Rectum. 2011;54:1065-1075

| Study<br>or sub-category   | N                                 | SNS<br>Mean (SD)             | N Na: | Conserv Therapy<br>Mean (SD) | WWD (random)<br>95% Cl | Weight         | WHD (random)<br>95% Cl   |
|--|-----------------------------------|------------------------------|-------|------------------------------|------------------------|----------------|--|
| 01 Physical functioning  |                                   |                              |       |                              |                        |                |  |
| Hetzer   | 30                                | 85.00(22.50)                 | 37    | 55.00(25.00)                 |                        | 14.31          | 30.00 [18.61, 41.39]   |
| Jamett 2005b<br>Kenefick 2002b   | 15                                | 92.50(1.25)                  | 2     | 87.50(3.75)                  | -                      | 18.65          | 5.00 [-0.48, 10.48]  |
| Referics 20020   | 15                                | 89 00(5 00)                  | 15    | 69 40(23 25)                 | - Media                | 6.55           | 15.00 [-10.14, 40.14]<br>19.60 [-1.67, 40.87]                      |
| Hatzel 2004  | 29                                | 1 0 25.201                   |       | 64. 0 ( 8. 60)               |                        | 18.10          | .40 [-5.60, 20.40]   |
| Ratto  |                                   |                              |       | 47.0.7.0                     |                        | 1002           |  |
| Valsey   |                                   |                              | 2     | 71 00 0.                     |                        | 0 19           |  |
| Subtotal (95% CI)  | B                                 |                              | 02    |                              |                        | 1 00 00        | 1 . 16 .   |
| Test for heterogeneity: Ch = 16.1  | 53, df = 6 ()                     | P = 0.01), P = 67 /%         |       |                              |                        |                |  |
| Test for overall effect: Z = 5.09 (8   | P < 0.00001                       | 0                            | _     | . <b></b> .                  |                        |                |  |
|  |                                   |                              | Tan o | tal Int                      | J Colorect 2011        |                |  |
| 02 Social functioning  |                                   |                              |       | L all IIIL                   |                        |                |  |
| Hetzer   | 30                                | 75.00(21.75)                 | 37    | 63.00(23.50)                 |                        | 18.76          | 12.00 [1.14, 22.86]  |
| Jarrett 2005b  | 2                                 | 68.50(3.25)                  | 2     | 44.00(9.50)                  |                        | 15.87          | 24.50 [10.58, 38.42]   |
| Kenefick 2002b   | 1.5                               | 75.00(30.00)                 | 15    | 37.00(31.00)                 |                        | 10.08          | 38.00 [16.17, 59.83]   |
| Malouf   | 5                                 | 67.20(22.00)                 | 5     | 47.40(25.00)                 |                        | 6.79           | 19.80 [-9.39, 48.99]   |
| Matzel 2004  | 29                                | 81.90(27.50)                 | 37    | 61.10(33.60)                 |                        | 15.14          | 20.80 [6.06, 35.54]  |
| Ratio  | 4                                 | 59.50(4.25)                  | 4     | 48.25(2.75)                  | -                      | 24.18          | 11.25 [6.29, 16.21]  |
| Vaisey   | 2                                 | 87.50(6.25)                  | 2     | 43.50(15.75)                 |                        | 9.19           | 44.00 [20.52, 67.48]   |
| Subtotal (95% CI)  | 87                                |                              | 102   |                              | •                      | 100.00         | 20.91 [12.52, 29.29]   |
| Test for heterogeneity: ChP = 15.<br>Test for overall effect: Z = 4.89 (8                      | 10, df = 6 ()<br>P < 0.00001      | P = 0.02), P = 60.3%         |       |                              |                        |                |  |
| 3 Role physical  |                                   |                              |       |                              |                        |                |  |
| Hetzer<br>Jamett 2005b   | -30                               | 75.00(25.00)                 | 37    | 50.00(25.00)                 |                        | 18.98          | 25.00 [12.96, 37.04]   |
| Jamen 20055<br>Kenefick 2002b  | 2                                 | 100.00(0.25) 75.00(49.00)    | 2     | 62.50(6.25)                  |                        | 22.52          | 37.50 [28.83, 46.17] 75.00 [44.23, 105.77]                         |
| Kenefick 2002b   | 15                                | 75.00(49.00)                 | 15    | 60.00(36.00)                 |                        | + 6.76<br>6.68 | 75.00 [44.23, 105.77] 35.00 [4.01, 65.99]                          |
| Malout<br>Matzel 2004  | 29                                | 75.00(25.00)<br>54.30(43.30) | 37    | 40.00(25.00)                 |                        | 6.68           | 35.00 [4.01, 65.99]<br>9.70 [-11.61, 31.01]                        |
| Ratto  | 29                                | 54.30(43.30)<br>63.00(5.50)  | 37    | 44.60(44.50) 45.25(2.50)     |                        | 11.18          |  |
| Vaisev   | 2                                 | 100.00(0.25)                 | 2     | 37.50(18.75)                 |                        | 8.64           | 17.75 [11.03, 23.67]<br>62.50 [36.51, 88.49]                       |
| Valsey<br>Jubiotal (95% Cib  | 87                                | 100.00(0.28)                 | 102   | 37.80(18.75)                 |                        | 100.00         | 33.82 [20.95, 46.70]   |
| Fest for heterogeneity: ChP = 34.1   |                                   | P = 0.000015 E = 03 404      |       |                              | -                      | 100.00         | 33.82 [20.95, 46.70]   |
| rest for overall effect: Z = 5.15 ()   | P < 0.00001                       | )                            |       |                              |                        |                |  |
| 4 Role emotional   |                                   |                              |       |                              |                        |                |  |
| Hetzer   | 30                                | 78.00(20.50)                 | 37    | 74.00(24.75)                 |                        | 27.53          | 4.00 [-6.84, 14.84]  |
| Jamett 2005b   | 2                                 | 100.00(0.25)                 | 1     | 100.00(0.00)                 |                        |                | Not estimable  |
| Kenefick 2002b   | 15                                | 33.00(49.00)                 | 15    | 0.00(41.00)                  |                        | 8.52           | 33.00 10.67, 65.331  |
| Halouf   | 5                                 | 43.20(25.00)                 | 3     | 11.00(8.25)                  |                        | 13.22          | 32.20 [8.38, 56.02]  |
| Hatzel 2004  | 29                                | 77.90(37.90)                 | 37    | 56.00(43.60)                 |                        | 16.68          | 21.10 [1.41, 40.79]  |
| Ratio  | 4                                 | 61.75(5.75)                  | 4     | 41.25(2.50)                  | -                      | 34.05          | 20.50 [14.36, 26.64]   |
| Valsey   | 2                                 | 83.00(8.50)                  | 1     | 33.00(0.00)                  |                        |                | Not estimable  |
| Subtotal (95% CI)<br>Test for heterogeneity: ChP = 9.3<br>Test for overall effect: Z = 3.55 () | 87<br>3, df = 4 (P<br>P = 0.0004) | = 0.05), P = 57.1%           | 58    |                              | -                      | 100.00         | 18.48 [8.28, 28.68]  |
| 05 Mental beath  |                                   |                              |       |                              |                        |                |  |
| Hetzer   | 30                                | 73.00(15.00)                 | 37    | 60.00(23.75)                 |                        | 15.97          | 13.00 [3.65, 22.35]  |
| Jamett 2005b   | 2                                 | 27.50(7.25)                  | 2     | 54.00(9.00)                  |                        | 11.10          | 23.50 [7.48, 39.52]  |
| Kenefick 2002b   | 15                                | 60.00(26.00)                 | 15    | 36.00(27.00)                 |                        | 3.36           | 24.00 [5.03, 42.97]  |
| Halouf   | 5                                 | 67.20(10.00)                 | 5     | 57.00(11.00)                 |                        | 13.16          | 10.20 [-2.83, 23.23]   |
| Hatzel 2004  | 29                                | 70.10(22.00)                 | 37    | 62.60(24.30)                 |                        | 14.37          | 7.50 [-3.91, 10.91]  |
| Ratto  | 4                                 | 58,75(6,25)                  | 4     | 42.50(1.25)                  | -                      | 18.26          | 16.25 [10.00, 22.50]   |
| Valacy   | 2                                 | 80.00(4.00)                  | 2     | 70.00(3.00)                  | -#-                    | 17.78          | 10.00 [3.07, 16.93]  |
| Subtotal (95% Ci)  | 87                                |                              | 102   |                              | •                      | 1.00.00        | 13.43 [9.85, 17.01]  |
| Test for heterogeneity: ChP = 5.7<br>Test for overall effect: Z = 7.36 (i                      | 2, df = 6 (P<br>P < 0.00001       | = 0.46), F = 0%              |       |                              |                        |                |  |
| 16 Vitality  |                                   |                              |       |                              |                        |                |  |
| Hetzer   | 30                                | 66.00(18.75)                 | 37    | 63.00(23.50)                 | -                      | 17.72          | 3.00 [-7.12, 13.12]  |
| Jamett 2005b   | 2                                 | 73.00(3.50)                  | 2     | 55.00(7.50)                  |                        | 16.52          | 18.00 [6.53, 29.47]  |
| Kenefick 2002b   | 15                                | 35.00(28.00)                 | 15    | 25.00(24.00)                 |                        | 10.98          | 10.00 [-8.66, 28.66]   |
| Halouf   | 5                                 | 43.00(18.75)                 | 5     | 34.00(15.00)                 |                        | 9.58           | 9.00 [-12.05, 30.05]   |
| Matzel 2004  | 29                                | 57.50(28.40)                 | 37    | 48.80(29.00)                 |                        | 14.42          | 8.70 [-5.23, 22.63]  |
| Ratto  | 4                                 | 47.25(5.25)                  | 4     | 39.75(3.25)                  | -                      | 21.20          | 7.50 [1.45, 13.55]   |
| Valsey   | 2                                 | 75.00(2.50)                  | 2     | 40.00(15.00)                 |                        | 9.57           | 35.00 [13.92, 56.08]   |
| Subtotal (95% CI)  | 87                                |                              | 102   |                              | •                      | 100.00         | 35.00 [13.92, 56.08]<br>10.77 [4.66, 16.07]                        |
| Test for heterogeneity: ChP = 9.76<br>Test for overall effect Z = 3.46 (i                      | 6, df = 6 (P                      | = 0.14), P = 38.5%           |       |                              | -                      |                |  |
| 07 Bodily pain   |                                   |                              |       |                              |                        |                |  |
| Hetzer   | 30                                | 68.00(20.00)                 | 37    | 58.00(22.50)                 |                        | 18.38          | 10.00 [-0.19, 20.19]   |
| Jamett 2005b   | 2                                 | 80.50(9.75)                  | 2     | 81.00(9.50)                  |                        | 11.30          | -0.50 [-19.37, 18.37]  |
| Kenefick 2002b   | 15                                | 40.00(30.00)                 | 15    | 50.00(26.00)                 |                        | 10.53          | -10.00 [-30.09, 10.09]   |
| Halouf   | 5                                 | 61.40(22.00)                 | 5     | 37.20(15.50)                 |                        | 8.65           | 24.20 [0.61, 47.79]  |
| Matzel 2004  | 29                                | 55.80(30.10)                 | 37    | 65.40(30.40)                 |                        | 14.37          | -9.60 [-24.30, 5.10]   |
| Ratto  | 4                                 | 53.75(2.75)                  | 4     | 49.00(2.75)                  | -                      | 23.62          | 4.75 [0.94, 8.56]  |
| Valsey   | 2                                 | 92.00(4.00)                  | 2     | 52.00(11.00)                 |                        | 13.16          | 40.00 [23.78, 56.22]   |
| subtotal (95% CI)  | 87                                |                              | 102   |                              | •                      | 100.00         | 7.99 [-2.32, 18.30]  |
| est for heterogeneity: ChP = 27.1<br>est for overall effect Z = 1.52 (i                        | 38, df = 6 ()                     | P = 0.0001), P = 78.1%       |       |                              | -                      |                |  |
| 8 General heath  |                                   |                              |       |                              |                        |                |  |
| Hetzer   | 30                                | 60.00(21.25)                 | 37    | 50.00(25.00)                 |                        | 14.84          | 10 00 1-1 08 21 001  |
| Jamett 2005b   | 30                                | 83.00(2.50)                  | 37    | 45.00(25.00)                 |                        | 19.39          | 10.00 [-1.08, 21.08]   |
| Jamett 20055<br>Kenefick 2002b   | 15                                | 83.00(2.50)                  | 15    | 45.00(2.50)                  | -                      | 19.39          | 38.00 [33.10, 42.90]   |
|  | 15                                | 40.00(31.00) 50.60(19.25)    | 15    | 37.00(27.00) 50.40(21.50)    |                        | 6.66           | 3.00 [-17.80, 23.80]<br>0.20 [-25.10, 25.50]                       |
|  | 29                                | 62,80(30,80)                 | 37    | 54.60(29.00)                 |                        | 12.22          | 8.20 [-6.39, 22.79]  |
| Malouf   |                                   |                              |       | 33.50(1.75)                  | -                      | 18.92          | 10 50 112 04 24 151  |
| Malouf<br>Matzel 2004  |                                   |                              |       |                              |                        |                |  |
| Malouf<br>Matzel 2004<br>Ratto   | 4                                 | 52.00(5.50)                  | 4     |                              | -                      |                | 10 00 10 14 17 051   |
| Malouf<br>Matzel 2004<br>Ratto<br>Voisey   | 2                                 | 52.00(5.50)<br>92.00(0.25)   | 2     | 79.00(3.50)                  | +                      | 19.41          | 13.00 [8.14, 17.86]  |
| Malouf<br>Matzel 2004<br>Ratto   | 2 87                              | 92.00(0.25)                  | 102   |                              | ÷                      |                | 18.50 [12.84, 24.16]<br>13.00 [8.14, 17.86]<br>14.92 [4.10, 25.74] |

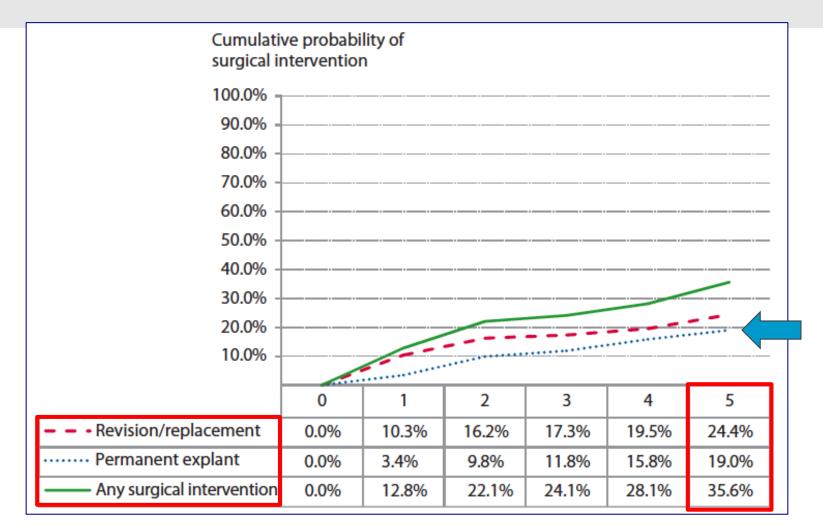
tätsklinikum

n



<sup>-100 -50 0 50 100</sup> Feynura Censery By Feynura SNS

# SNM: Device Retention Rate 5 y: 81%

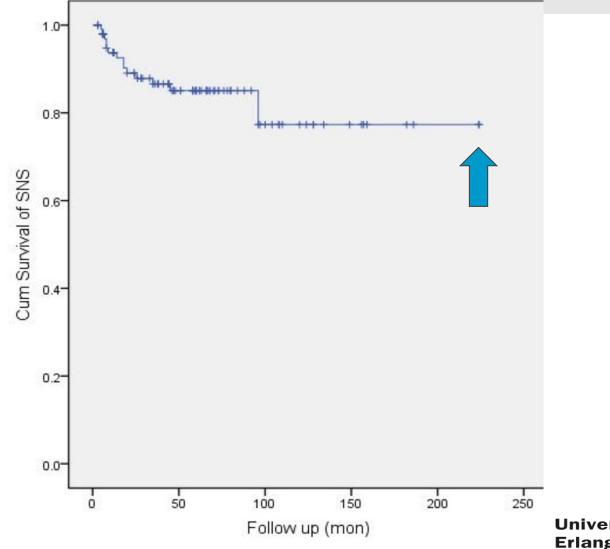




Universitätsklinikum Erlangen

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

# SNM:18 y: Device Retention Rate: 78%





# **SNM for Fecal Incontinence**

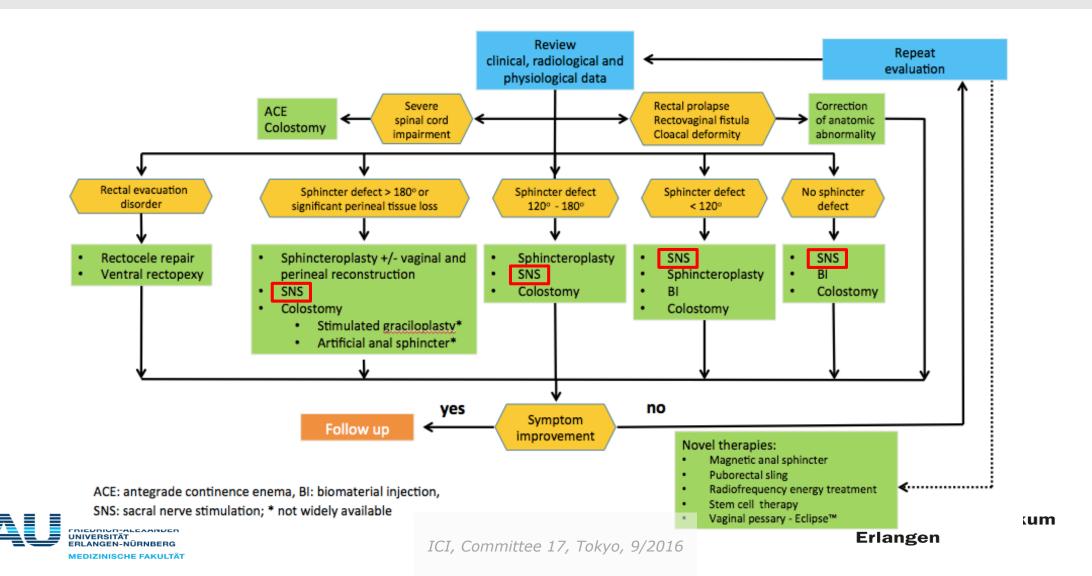
Efficacy: mostly immediately, IC & Qol improved (LE3)

- 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





# Battery longevity: replacement

# Function after replacement for battery depletion

Loss of efficacy



# **Battery Longevity**

|                        | Battery life<br>(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)*≆             | 2019             |
| Real-life data (5)     | ≥ 5 yr* <sup>γ</sup>       | 2016             |
| Real-life data (6)     | 5.3 yr (<2V)* <sub>Ÿ</sub> | 2016             |
| Real-life data (7)     | 6.3 yr* <sup></sup>        | 2014             |

\* explicitly referred to Interstim II; <sup>v</sup> 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

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# How to Improve Battery Life?

- N: 27: battery exchange without lead revision at the time of battery depletion
- median battery life:
  - Amplitude ≤ 2V (n=15): 64 months
  - Amplitude > 2V (n=12): 38 months

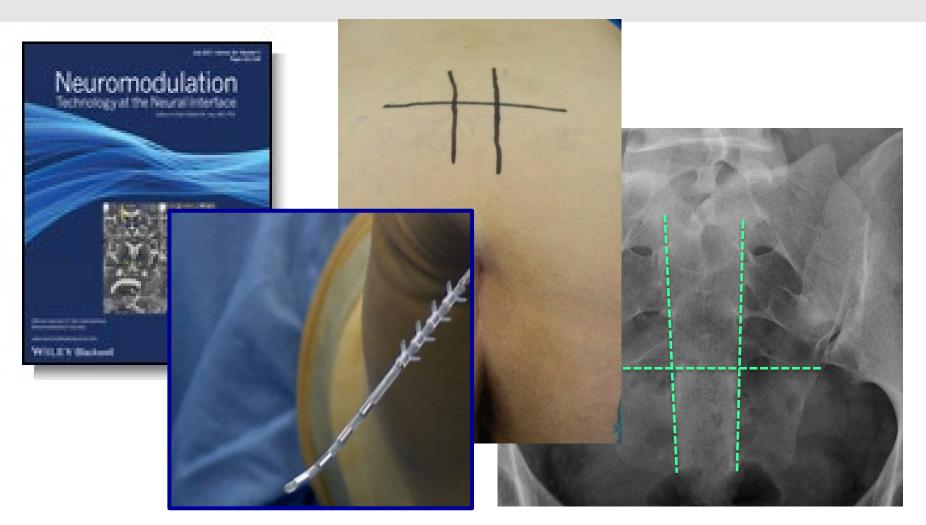


# How to Improve Battery Life?

- N: 27: battery exchange without lead revision at the time of battery depletion
- median battery life:
  - Amplitude ≤ 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





Matzel KE, et al Neuromodulation. 2017;20:816-824

# *Current Mean Amplitudes Historical Data vs. Standarisied Technique*

# 2011

- Traditional implantation technique
- ≈2.1V @12months

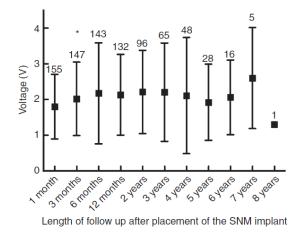


Figure I Mean voltage of the sacral nerve modulation (SNM)

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; 20:0152-0157.

# 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
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| Variable       | Group A<br>(N=32) | Group B<br>(N=7) |
|----------------|-------------------|------------------|
| PRO (0-10)     | 7.6 ± 1.6         | 5.5 ± 0.9        |
| <b>∆CCF-FI</b> | -0.63             | +1.86            |
| ∆FIQL          | +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



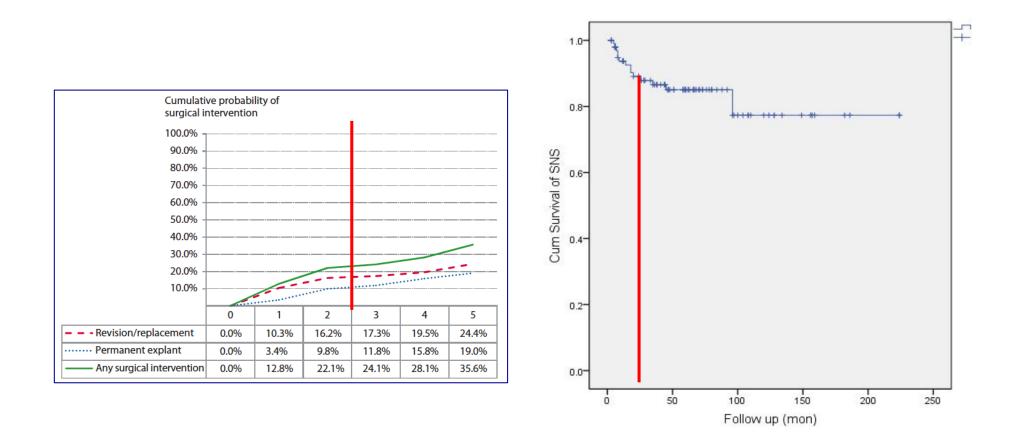


- Loss of efficacy typically occurs within the first
   2 years of the treatment [1]
- The mean time to definitive failure was 13.6 months (range 3–42.4) [2]



[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



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EDIZINISCHE FAKULTÄT

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- New or progressive metabolic or neurologic issues
- "Accommodation" by the nervous system (steady increase of the amplitude)

Pettit. Int Urogynecol J 2010, 21 (Suppl 2):S491–S496; Siegel S, et al. Female Pelvic Med Reconstr Surg. 2018;24:267-271; Maeda Y et al. Br J Surg. 2011;98:140-147; Maeda Y et al. FRIEDRICH-ALEXAN Ann Surg. 2014;259:1126-31

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- 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)

Pettit. Int Urogynecol J 2010, 21 (Suppl 2):S491–S496; Siegel S, et al. Female Pelvic Med Reconstr Surg. 2018;24:267-271; Maeda Y et al. Br J Surg. 2011;98:140-147; Maeda Y et al. FRIEDRICH-ALEXAN Ann Surg. 2014;259:1126-31 UNIVERSITÄT ERLANGEN-NÜRNBERG

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# **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



Gallas et al. Colorectal Dis. 2011 13:689–696 Prapasrivorakul S et al. Int J Colorectal Dis. 2015 30:229-34 Brochard Cet al. Neuromodulation. 2019;22:745-750.

# Failed SNM: What to do ?

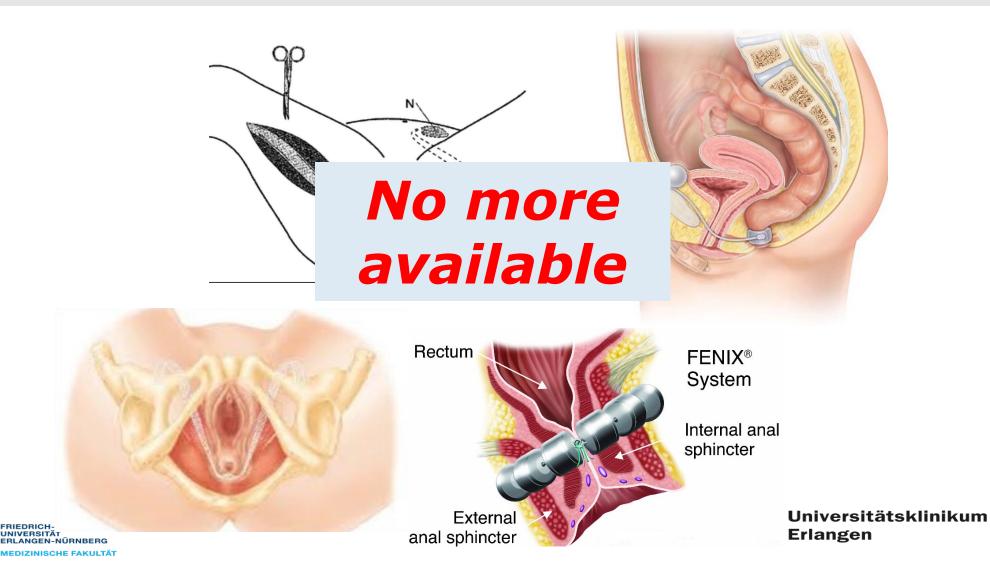
# Reprogramming

# Adjuvant therapies

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



## Failure of SNM: Surgical Alternatives



# Failure of SNM: Surgical Alternatives

# Sphincteroplasty

# Sphincter augmentation

- Gatekeeper
- Bioinjectables

# Sphincter replacement

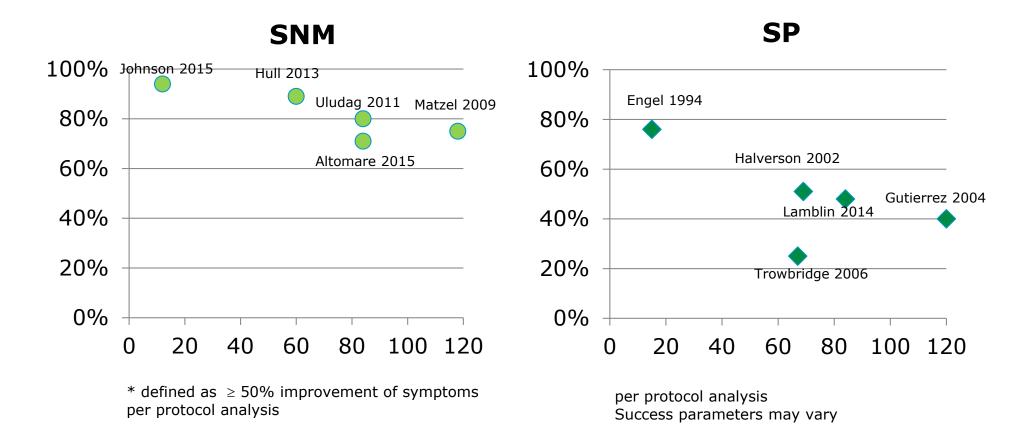
AMI Band

### Stoma

Colostoma



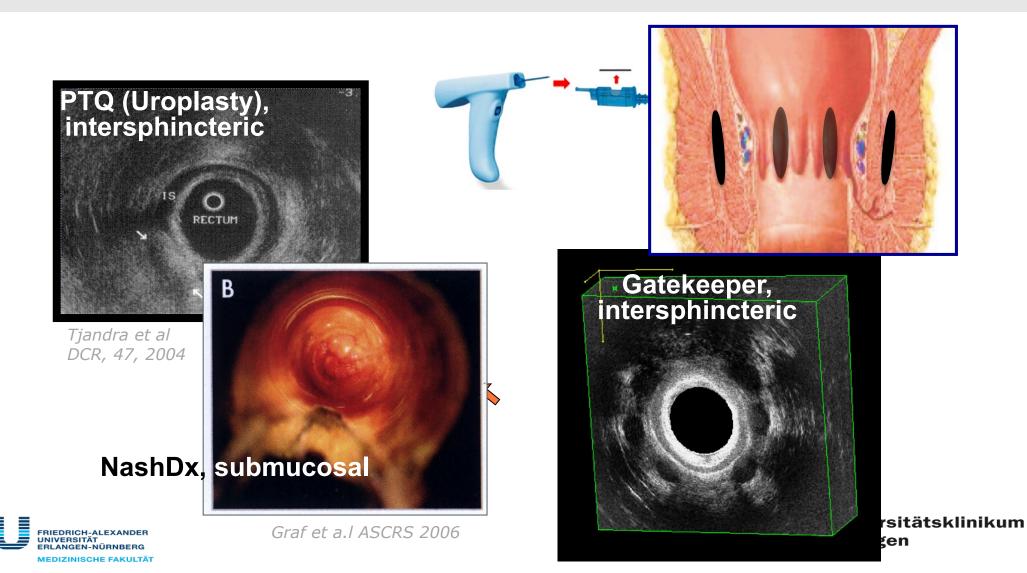
# Long-term : SNM and Sphincteroplasty





5th International Consultation on Incontinence, Paris February, 2012.

# Injectables / Bulking Agents



# 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
- Reproducable results
- Central role in current treatement algorithms "Surgical treatment for FI"
- Maintainence needed



# Thank you

