

Table 1: Published Clinical Trials on SNS, by Type of Indication

•	Schmidt 1999	Hassouna 2000	Jonas 2001
Indication	Urge incontinence	Urgency-frequency syndrome	Urinary retention
Type of Study Design	Randomized, non-blinded	(Same as Schmidt 1999)	(Same as Schmidt 1999)
Number of Centers	16	12	13
Consecutive Patients?	No	No	No
Total Eligible Patients, Prior to Test Stimulation	155: 81%F, 19% M	Not Specified	177: 74% F, 26% M (42.9 +/- 12.7 years)
Total Patients Randomized	98: 52 Test, 46 Control	51: 25 Test, 26 Control 90% F, 10% M (39.0 +/- 11.8 years)	68: 37 Test, 31 Control
Characteristics: Test vs. Control Group	No matching performed in this clinical trial	No matching performed in this clinical trial	No matching performed in this clinical trial
Inclusion Criteria	(a) Age greater than 16; (b) Refractory to standard medical therapy; (c) 100 ml bladder capacity with normal upper urinary tract; (d) Good surgical candidate; and (e) Able to complete study documentation and return for follow-up study	(Same as Schmidt 1999)	(Same as Schmidt 1999)
Exclusion Criteria	(a) Neurological conditions (multiple sclerosis, diabetes with peripheral nerve involvement, spinal cord injury, stroke); (b) Stress UI; and (c) Primary pelvic pain	(Same as Schmidt 1999)	(Same as Schmidt 1999, with additional note that bladder outlet obstruction was excluded per discussion with one of study authors)
Drop-Out Rate @	34.6% in test arm	0% in test arm and	21.6% in test arm and

6 Mo.	and 8.7% in control arm	3.8% in control arm	29.0% in control arm
Adjustment for Drop-Outs?	Yes - Via sequential data analysis	Not Applicable	Not Specified
Results @ 6 Mo. for Test Group Compared to Controls: Voiding Diary, Quality-of-Life (QOL) Instrument and Urodynamic Testing	(a) Significant decrease ($p<0.0001$) for incontinent episodes per day, severity rank of incontinence and replacement pads per day; (b) Significantly favorable perceptions on SF-36 Health Survey ($p=0.0008$) and (c) No adverse urodynamic function	(a) Significant ($p<0.0001$) decrease in number of voids per day; (b) Significant ($p=0.01$) increase in volume voided per void; (c) Significantly reduced degree of urgency prior to voiding ($p=0.01$); (d) Significant improvement (at least $p=0.01$) in 7/8 QOL parameters) and (e) No adverse urodynamic function	(a) Significant reduction in catheter volume per catheterization ($p<0.0001$); (b) Significant decrease ($p<0.0001$) in number of catheterizations per day, total catheter volume per day and maximum catheter volume; (c) Significant increase in number of voids per day ($p=0.002$) and total volume voided per day ($p<0.0001$) and (d) No adverse urodynamic function
Duration of Results	Up to 18 months, for single-armed group after crossover occurred at 6 months	At 12 and 24 months, for single-armed group after crossover occurred at 6 months	Up to 18 months, for single-armed group after crossover occurred at 6 months