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[Clinical Urology: Urological Neurology and Urodynamics]**Transcutaneous Electrical Nerve Stimulation and Temporary S3 Neuromodulation in Idiopathic Detrusor Instability**

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Abstract ^

Purpose: We studied the effects of electrical stimulation on idiopathic detrusor instability.

Materials and Methods: Between January 1993 and December 1994, 30 men and 41 women (mean age plus or minus standard deviation 48 plus/minus 16 years) underwent transcutaneous electrical nerve stimulation (TENS) of the S2-S3 dermatomes, and 13 men and 22 women (mean age 48 plus/minus 12 years) underwent S3 neuromodulation. Subjective assessment was performed using a diary and symptom score of 0 to 14. Objective outcome was analyzed with urodynamic studies.

Results: Mean duration of TENS was 3 plus/minus 1 weeks (range 2 to 4). Although there were no major complications 31 percent of the patients reported local skin irritation. The overall urinary symptom scores improved from 10 plus/minus 2 (range 5 to 14) before the study to 7 plus/minus 3 (range 1 to 14) during stimulation. Urodynamic analysis revealed significant (p less than 0.05) improvements in total bladder capacity and voided volume, and decreases in the number and frequency of unstable contractions.

Mean duration of S3 neuromodulation was 6 plus/minus 1 days (range 4 to 8 days). Four procedures failed due to electrode displacement in 3 cases and procedure intolerance in 1. Hemorrhage from the puncture site occurred in 1 patient. Overall urinary symptom scores were 10 plus/minus 3 (range 5 to 14) before the study and 5 plus/minus 2 (range 2 to 10) during stimulation. Although symptomatic relief was more pronounced with S3 neuromodulation, no statistically significant differences were found regarding urinary symptoms compared to TENS.

Conclusions: In patients with severe detrusor instability refractory to conservative treatments the use of TENS and S3 neuromodulation produced significant changes in urodynamic parameters and presenting symptoms. Our results appear to justify evaluation with neuromodulatory techniques before definitive surgical intervention in these patients.

Key Words: urinary incontinence, electric stimulation therapy, neuroregulators, transcutaneous electric nerve stimulation

Detrusor instability is a common urological problem that is often difficult to treat and may involve up to 10 percent of the population, [1] with an increased prevalence at extremes of life. The International Continence Society defines the unstable detrusor as one shown objectively to contract spontaneously or on provocation during filling while the patient is attempting to inhibit micturition. [2] Idiopathic detrusor instability is diagnosed by exclusion of underlying neurological disease or bladder outflow obstruction.

In the majority of patients the etiology of detrusor instability remains unknown, [3,4] which poses management difficulties. As a result, a variety of different modalities or their combinations have been used to treat patients with detrusor instability. [4] During the years functional electrical stimulation has emerged as an additional option for the treatment of patients with a variety of voiding dysfunctions. [5-7] Different methods and stimulation sites reportedly have been effective in modulating lower urinary tract functions, including intravesical electrical stimulation, [8] anal, [9] vaginal [10] or perineal stimulation, transcutaneous electrical stimulation (TENS) of the suprapubic region [11] and posterior tibial nerve, [12] and electrical stimulation of the sacral nerve roots. [5-7]

TENS has been particularly useful in relieving pain in a variety of diverse conditions, [13] including that associated with interstitial cystitis. Prior reports indicate changes in urodynamic parameters during transcutaneous stimulation, [11,14] suggesting that this therapy was capable of inhibiting detrusor contractions. Such studies provide the rationale for the application of TENS to modulate detrusor function in patients with functional detrusor dysfunction.

The S2-S4 nerve roots bilaterally are concerned primarily with control of the bladder, with the S3 roots mainly innervating the detrusor and levator muscles. [15] Previous studies have shown that stimulation of S3 nerve roots can modulate detrusor activity, [5-7] suggesting a possible basis for an alternative treatment of a variety of voiding dysfunctions. Following initial clinical assessment, patients selected for S3 neuromodulation undergo a period of temporary test stimulation involving insertion of a spinal needle transcutaneously into the S3 sacral foramina using local anesthesia. Once adequate positioning is confirmed with electrostimulation [16] and imaging techniques, the needle is removed leaving the outer sheath in situ. A stimulating wire can then be passed down the sheath deep to the inner table of the bone, maintaining a coupling with the nerve. The outer sheath is removed, and the wire is fixed in place and connected to an external pulse generator. Subjective and objective responses can then be monitored for 3 to 5 days of test stimulation. [17] Patients demonstrating significant symptomatic relief during this period are identified and may be considered for a permanent implantable neuro-prosthesis.

This technique has been used in patients with a variety of functional disorders of the lower urinary tract, including motor, sensory and pelvic pain disorders. Overall, the best outcome (75 percent success rate) was achieved in patients with urge related symptoms and the worst outcome was noted in patients with stress incontinence. [18] The technique also restored voiding in women with chronic urinary retention [6] and pelvic pain. [18] Data were obtained from a wide variety of patients and outcome was mainly based on subjective criteria. Although some improvement in detrusor instability has been reported, [19] experience with S3 neuromodulation in this condition is presently limited. Our prospective study was done to evaluate the clinical and urodynamic outcomes in response to TENS and S3 nerve root stimulation in patients with idiopathic detrusor instability who had poor results with previous treatments.

Materials And Methods

Between January 1993 and December 1994, TENS was performed in 30 men and 41 women 19 to 82 years old (mean age plus or minus standard deviation 48 plus/minus 16), and temporary S3 nerve root stimulation was done in 13 men and 22 women 22 to 77 years old (mean age 48 plus/minus 12 years). Of these patients 9 men and 14 women underwent both procedures. All patients had idiopathic detrusor instability, with mainly increased urinary frequency, urgency, urge incontinence and enuresis. All patients underwent comprehensive evaluation, including patient history and physical examination. Before the study cystoscopy was done with mucosal biopsies and upper tract evaluation when indicated.

Patients were selected for the study on the basis of poor outcome despite extensive trials of conventional treatments, including anticholinergic therapy in 59 patients undergoing TENS and 31 undergoing S3 neuromodulation, simple bladder over distension in 57 and 27, respectively, Helmstein's bladder distension in 6 and 2, respectively, endoscopic bladder transection in 6 and 5, respectively, and subtrigonal injection in 3 and 2, respectively. Before the study all patients were carefully counseled on an individual basis. The nature and objectives of the respective treatments were explained, and instructions were given regarding use of the TENS device and external pulse generator for S3 neuromodulation. All patients were provided with an information sheet regarding the study for consideration at home. Patient admittance to the study was voluntary and informed consent was given. The study was approved by the Newcastle and North Tyneside District Ethics Committee.

TENS

The dual channel TENS stimulator used provided variable control of pulse frequency (2 to 150 Hz.), pulse width (50 to 250 microseconds) and current amplitude, and generated a rectangular biphasic waveform. Stimulation parameters for the study were set at a frequency of 50 Hz. and a pulse width of 200 microseconds. [11] Patients were asked to control the current amplitude to produce a tickling sensation. One channel of the stimulator was used and 2 electrodes were placed bilaterally over the perianal region (S2-S3 dermatomes). Before TENS objective assessments were performed using conventional filling and voiding urodynamic studies (cystometrography) and ambulatory urodynamic studies as previously described. [20] Subjectively, patients were assessed by a standard questionnaire that categorized irritative symptoms from 0 to 14 according to a modified scoring system. [21]

Conventional cystometrography was performed in randomly under 3 conditions: 1) no TENS, 2) TENS over the S2-S3 dermatomes and 3) TENS over the T12 dermatome, which acted as a placebo. Following a 3-week clinical trial with S2-S3 stimulation, ambulatory urodynamic studies were performed with S2-S3 stimulation. Subjective outcome was assessed using symptom scores and a diary card documenting urinary frequency, urge incontinence and use of pads for 1 week before the study and during the 3-week clinical trial. In addition, in 36 patients a further urodynamic study was performed with TENS over the suprapubic region and posterior tibial nerve.

S3 neuromodulation

An electrode was inserted into the S3 sacral foramen using local anesthesia as described previously. [17] Following demonstration of adequate S3 responses, [16] a bipolar cardiac pacing electrode was secured to the puncture site using silk sutures. A length of the electrode was coiled onto itself to minimize accidentally applied traction, and the puncture site and coiled electrode were covered with a sterile semipermeable transparent dressing to allow clinical inspection of the puncture site at all times during the study period. An additional length (approximately 15 cm.) of the electrode was secured to the skin between 2 nonwoven adhesive wound dressings, further minimizing the risks of accidental electrode displacement. Once secured, the stimulating electrode was connected to an external pulse generator, which provided variable control of pulse frequency (25 to 1,550 Hz.), pulse width (50 to 500 microseconds) and current amplitude. A biphasic waveform was used. Stimulation parameters were set at a frequency of 25 Hz. and a pulse width of 200 microseconds. [19] Patients were asked to control the current amplitude to a maximum tolerable level.

Objective assessment was performed with ambulatory urodynamic studies. [20] Standard electromyography equipment was used to obtain recordings from the distal foot and toe muscles, external anal sphincter and urethral sphincter. Surface, concentric needle and catheter mounted ring electrodes were used for the recordings. Urinary frequency, incontinence, use of pads and symptom score were analyzed as described. All objective measurements were performed after a minimum of 3 days of S3 stimulation.

Statistical analysis

Descriptive data were reported as mean values plus or minus standard deviation. Nonparametric analysis was performed with the chi-square test with correction for continuity and the Mann-Whitney U test, with p less than 0.05 considered significant.

Results

TENS

A total of 71 patients underwent a trial of TENS over the S2-S3 dermatomes and evaluable data were available for 59. The study was terminated prematurely in 5 patients who refused participation after a limited period and in 6 with poor compliance. One patient was excluded due to an underlying neuropathy. Although there were no major complications 18 patients (31 percent) reported local skin irritation, which resolved in most cases after replacing the standard carbon-rubber pad stimulating electrodes with hypo-allergic pads and limiting prolonged electrical stimulation. Despite this therapy the severity of skin irritation precluded extension of stimulation beyond the trial period in 1 patient. Mean duration of TENS was 3 plus/minus 1 weeks (range 2 to 4).

The effect of TENS on lower urinary tract symptoms is shown in [Figure 1](#), [Figure 2](#), [Figure 3](#). Daytime frequency improved from 12 plus/minus 7 (range 4 to 40) to 9 plus/minus 5 (range 3 to 30) episodes. Nocturia improved from 3 plus/minus 2 (range 1 to 10) to 2 plus/minus 2 (range 0 to 12) episodes a night. Enuresis, reported by 27 patients before treatment, improved from 3 plus/minus 2 (range 1 to 7) to 1 plus/minus 1 (range 0 to 5) episodes a week. Urgency was categorized into 4 groups from none to severe with urge incontinence [Figure 2](#). Before the study most patients (92 percent) reported experiencing either moderate or severe urgency, often with urge incontinence. During TENS 53 percent of the patients reported only mild to moderate urgency and 14 percent reported significant improvement. Urge incontinence in 45 patients improved from 5 plus/minus 5 (range 1 to 30) to 3 plus/minus 3 (range 0 to 16) episodes a day. Regular use of continence pads, reported by 29 patients before the study, improved from 5 plus/minus 3 (range 1 to 15) to 3 plus/minus 3 (range 0 to 16) every 24 hours [Figure 3](#). Urinary symptom scores were 10 plus/minus 2 (range 5 to 14) before the study and 7 plus/minus 3 (range 1 to 14) during stimulation.

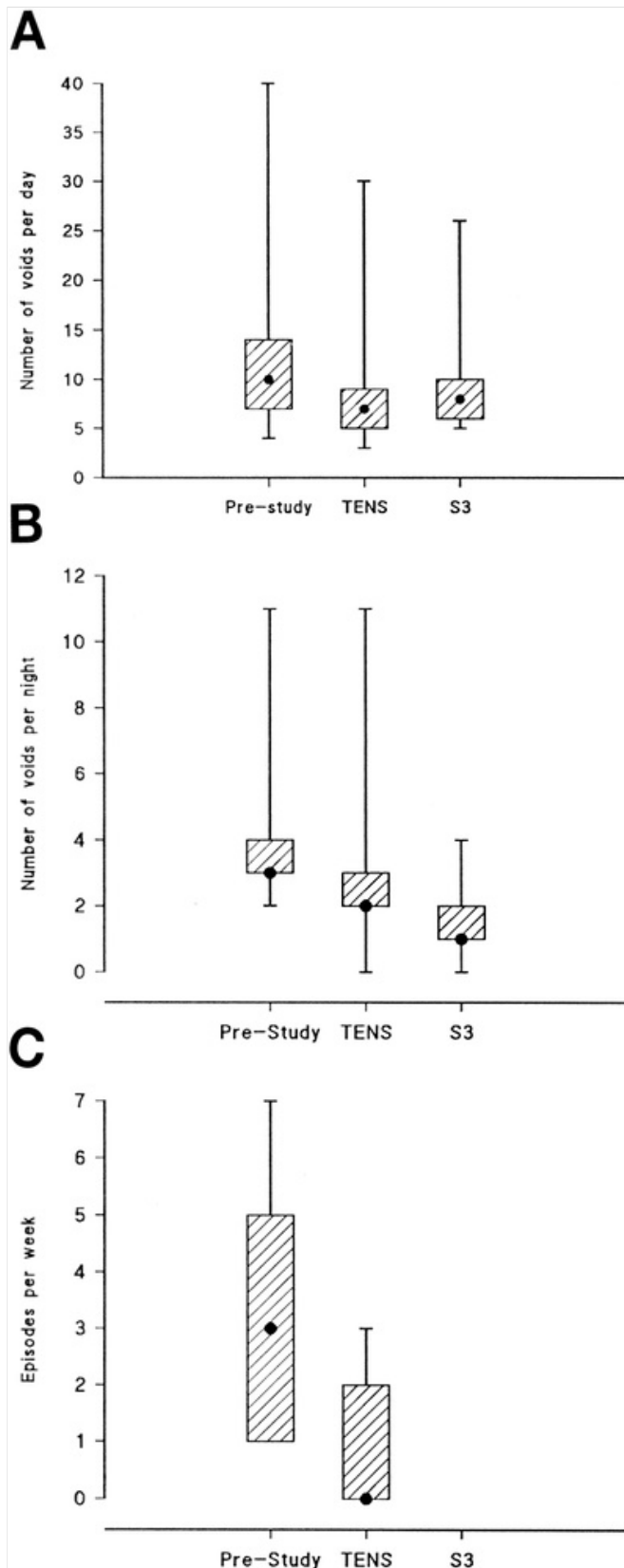


Figure 1. Effects of TENS and S3 neuromodulation on urinary frequency (A), nocturia (B) and enuresis (C). Error bars denote minimum and maximum range. [shaded square], inter-quartile range. [shaded circle], median value.

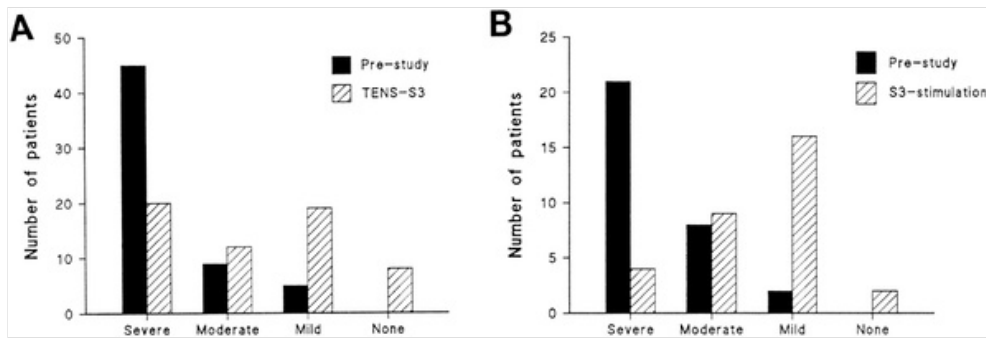


Figure 2. Urinary urgency classified into 4 groups from none to severe with urge incontinence. A, S2-S3 TENS (TENS-S3). B, S3 neuromodulation.

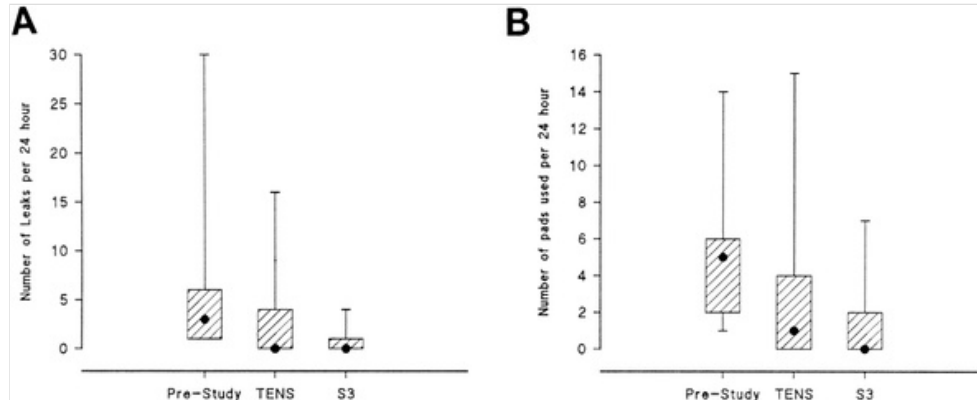


Figure 3. Effects of TENS and S3 neuromodulation on episodes of urinary leakage (A) and use of continence pads (B) per 24 hours. Error bars show minimum and maximum range. [shaded square], inter-quartile range. [shaded circle], median value.

The effects of S2-S3 stimulation during cystometrography compared to no and placebo (T12) stimulation are shown in Table 1. Statistically significant improvements (p less than 0.05) were observed in total bladder capacity, voided volume, and number and frequency of unstable contractions.

Ambulatory urodynamic results obtained before the study and with S2-S3 stimulation are shown in Table 2. Four patients (7 percent) had stable ambulatory urodynamic studies and 7 (12 percent) had stable conventional cystometrographic studies during the stimulation period. The overall outcome of patients with TENS over the S2-S3 dermatomes compared to preoperative values is summarized in Table 3. Significant improvement (p less than 0.05) was observed in enuresis, urge incontinence and use of incontinence pads. There were no differences in success rates based on patient age (younger or older than 40 years) or sex.

Urodynamic Parameter	Mean $\pm$ SD (range)		
	No TENS	S2-S3 TENS	T12 TENS
Increased resting detrusor pressure (cm. water)	10 $\pm$ 9 (0-38)	7 $\pm$ 7 (0-26)	9 $\pm$ 8 (0-35)
Cystometric capacity (ml.)	160 $\pm$ 108 (40-650)	200 $\pm$ 108 (40-550)	163 $\pm$ 100 (90-200)
Total bladder capacity (ml.)	193 $\pm$ 112 (45-650)	248 $\pm$ 135 (60-700)	192 $\pm$ 127 (50-700)
Micturition pressure (cm. water)	48 $\pm$ 23 (14-120)	45 $\pm$ 21 (18-96)	45 $\pm$ 24 (16-124)
Micturition pressure at peak flow (cm. water)	41 $\pm$ 22 (12-120)	39 $\pm$ 20 (14-90)	38 $\pm$ 21 (12-120)
Voided vol. (ml.)	182 $\pm$ 110 (50-580)	220 $\pm$ 126 (50-550)	192 $\pm$ 140 (40-700)
Residual vol. (ml.)	12 $\pm$ 24 (0-100)	13 $\pm$ 25 (0-113)	11 $\pm$ 16 (0-50)
Flow rate (ml./sec.)	13 $\pm$ 7 (3-24)	15 $\pm$ 6 (4-28)	15 $\pm$ 7 (5-33)
Vol. at first unstable contraction (ml.)	99 $\pm$ 103 (5-640)	120 $\pm$ 79 (20-235)	91 $\pm$ 82 (5-370)
No. unstable contractions	4 $\pm$ 3 (1-11)	2 $\pm$ 3 (0-13)	4 $\pm$ 3 (0-11)
Frequency of unstable contractions/hr.	2 $\pm$ 2 (1-8)	1 $\pm$ 1 (0-7)	2 $\pm$ 2 (0-8)
Maximum amplitude of unstable contractions	55 $\pm$ 39 (8-180)	42 $\pm$ 34 (0-112)	47 $\pm$ 33 (8-135)
Vol. of urge incontinence (ml.)	4 $\pm$ 10 (0-50)	1 $\pm$ 2 (0-10)	2 $\pm$ 4 (0-25)

Table 1. The effect of TENS on conventional filling and voiding cystometrography in 59 patients with idiopathic detrusor instability

Urodynamic Parameter	Mean $\pm$ SD (range)		
	No TENS	S2-S3 TENS	p Value*
Duration of study (mins.)	249 $\pm$ 35 (161-330)	244 $\pm$ 29 (120-291)	Not significant
No. voids	5 $\pm$ 2 (2-10)	5 $\pm$ 2 (1-10)	Not significant
Mean voided vol. (ml.)	198 $\pm$ 105 (120-259)	246 $\pm$ 106 (56-490)	<0.05
Mean voiding pressure (cm. water)	65 $\pm$ 29 (27-146)	62 $\pm$ 24 (28-124)	Not significant
Mean residual vol. (ml.)	28 $\pm$ 33 (0-156)	20 $\pm$ 26 (0-163)	Not significant
No. unstable contractions	18 $\pm$ 13 (1-51)	10 $\pm$ 14 (0-67)	<0.05
Frequency of unstable contractions/hr.	4 $\pm$ 3 (1-13)	2 $\pm$ 1 (0-14)	<0.05
Maximum amplitude of unstable contractions (cm. water)	84 $\pm$ 52 (20-180)	57 $\pm$ 52 (0-180)	<0.05
Mean vol. of urge incontinence (ml.)	19 $\pm$ 21 (0-95)	9 $\pm$ 15 (0-50)	<0.05

* Mann-Whitney U test.

Table 2. Effect of TENS over the S2-S3 dermatomes on ambulatory urodynamic studies in 59 patients

Parameter	No. Pts.	No. With Benefit			% Satisfactory Outcome (more than 50% benefit)
		Less Than 50%	50 to 75%	More Than 75%	
TENS					
Urinary frequency	59	43	16	0	37
Enuresis	27	7	9	11	73
Urge incontinence	45	14	7	24	69
Use of pads	29	13	6	10	55
S3 neuromodulation					
Urinary frequency	31	21	8	2	48
Enuresis	14	3	4	7	82
Urge incontinence	21	5	4	12	76
Use of pads	7	6	4	7	65

Table 3. Outcome of TENS and S3 neuromodulation in patients with idiopathic detrusor instability

S3 nerve root stimulation

There was no major morbidity. Of the 35 patients studied 31 successfully completed the trial. Four procedures failed because of electrode displacement within 24 hours of electrode insertion [3] and intolerance to electrical stimulation [1]. Hemorrhage from the puncture site occurred in 1 patient on postoperative day 6, which was treated successfully with removal of the electrode and oral antibiotic therapy (250 mg. amoxicillin 3 times daily and 250 mg. floxacillin 4 times daily) for 5 days. Mean duration of S3 nerve root stimulation was 6 plus/minus 1 days (range 4 to 8). Lower urinary tract symptoms improved in most patients during the temporary period of S3 nerve root stimulation Figure 1, Figure 2, Figure 3. Daytime urinary frequency improved from 13 plus/minus 10 (range 4 to 40) to 9 plus/minus 4 (range 5 to 26) episodes in 24 hours and nocturia improved from 4 plus/minus 2 to 2 plus/minus 1 episodes a night. Enuresis, reported by 14 patients before treatment, improved from 3 plus/minus 2 to no episodes a week during the stimulation period. Before the study most patients (94 percent) reported moderate or severe urgency Figure 2. During stimulation most patients (81 percent) reported only mild to moderate and 2 (7 percent) reported no urgency. Urge incontinence in 21 patients improved from 6 plus/minus 7 (range 1 to 30) to 1 plus/minus 1 (range 0 to 4) episode a day. Regular use of continence pads, reported by 17 patients before the study, improved from 5 plus/minus 4 (range 1 to 14) to 1 plus/minus 2 (range 0 to 7) in 24 hours Figure 3. Urinary symptom scores were 10 plus/minus 3 (range 5 to 14) before and 5 plus/minus 2 (range 2 to 10) during the stimulation period. Ambulatory urodynamic results before the study and with S3 neuromodulation are shown in Table 4. A statistically significant change (p less than 0.05) was observed in voided volume, and number and frequency of unstable contractions. Three patients (10 percent) were urodynamically stable. The overall symptomatic outcome of patients during S3 neuromodulation is summarized in Table 3. Significant improvements were reported in enuresis, urge related urinary leakage and use of pads. No differences were found with respect to patient sex or age (younger or older than 40 years).

Urodynamic Parameter	Mean $\pm$ SD (range)		p Value*
	No Stimulation	S3 Stimulation	
Duration of study (mins.)	248 $\pm$ 35 (182-310)	233 $\pm$ 33 (157-324)	Not significant
No. voids	5 $\pm$ 2 (2-10)	4 $\pm$ 2 (2-10)	Not significant
Mean voided vol. (ml.)	184 $\pm$ 81 (65-412)	277 $\pm$ 107 (104-583)	<0.05
Mean voiding pressure (cm. water)	57 $\pm$ 29 (27-125)	58 $\pm$ 23 (33-114)	Not significant
Mean residual vol. (ml.)	24 $\pm$ 27 (0-101)	28 $\pm$ 35 (0-126)	Not significant
No. unstable contractions	20 $\pm$ 15 (3-51)	9 $\pm$ 11 (0-35)	<0.05
Frequency of unstable contractions/hr.	5 $\pm$ 3 (1-13)	2 $\pm$ 3 (0-8)	<0.05
Maximum amplitude of unstable contractions (cm. water)	75 $\pm$ 49 (25-170)	59 $\pm$ 49 (0-160)	Not significant
Mean vol. of urge incontinence (ml.)	21 $\pm$ 23 (0-95)	15 $\pm$ 26 (0-80)	Not significant

* Mann-Whitney U test.

Table 4. Effect of S3 neuromodulation on ambulatory urodynamic study in 31 patients

Electromyography

Electromyographic evaluation was performed in patients undergoing S3 neuromodulation. Using surface recording electrodes evoked responses were obtained from the small muscles of the foot and great toe on the side of the implanted electrode at a subthreshold current of 2 plus/minus 1 mA., with a maximum tolerated current of 5 plus/minus 1 mA. This procedure confirmed satisfactory positioning of the electrode.

In the first 12 patients external anal sphincter electromyography was performed to assess the effects of electrical stimulation. Anal sphincter electromyography was abnormal in 1 patient (mean duration of potentials 15 plus/minus 6 msec., 44 percent polyphasic activity). In the remaining 11 patients mean duration of potentials was 7 plus/minus 3 msec. and mean amplitude was 559 plus/minus 205 microvolt. [Figure 4](#). Although it was possible to obtain evoked potentials at high current amplitudes, no evoked potentials were obtained from the anal sphincter at subthreshold or threshold stimulation. Therefore, anal sphincter electromyography was not done in the remaining patients.

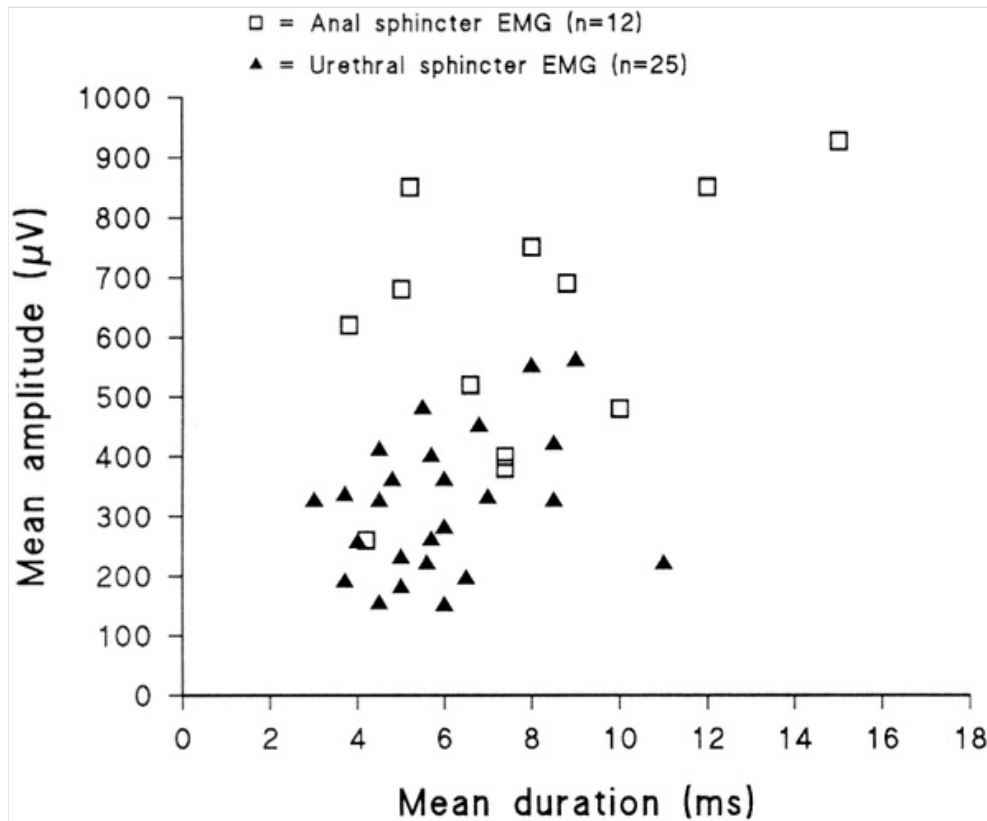


Figure 4. Anal and urethral sphincter electromyography (EMG) in patients undergoing S3 neuromodulation. Each value represents mean of 10 motor unit potentials.

Pelvic floor and external urethral sphincter electromyographic recordings were obtained simultaneously in 25 patients using a catheter mounted ring electrode to record pelvic floor activity and a concentric needle electrode for urethral sphincter activity during S3 neuromodulation. Pelvic floor recordings revealed evidence of progressive increase in the amplitude of electromyographic activity with increment in current amplitude Figure 5. No change was observed in the electromyographic responses obtained from the external urethral sphincter with current increment during S3 stimulation. Mean duration of action potentials was 6 plus/minus 2 msec. and mean amplitude was 319 plus/minus 117 microvolt. Figure 4. We were unable to obtain adequate quality electromyographic recordings in 4 men because of technical difficulty and/or patient intolerance to the procedure.

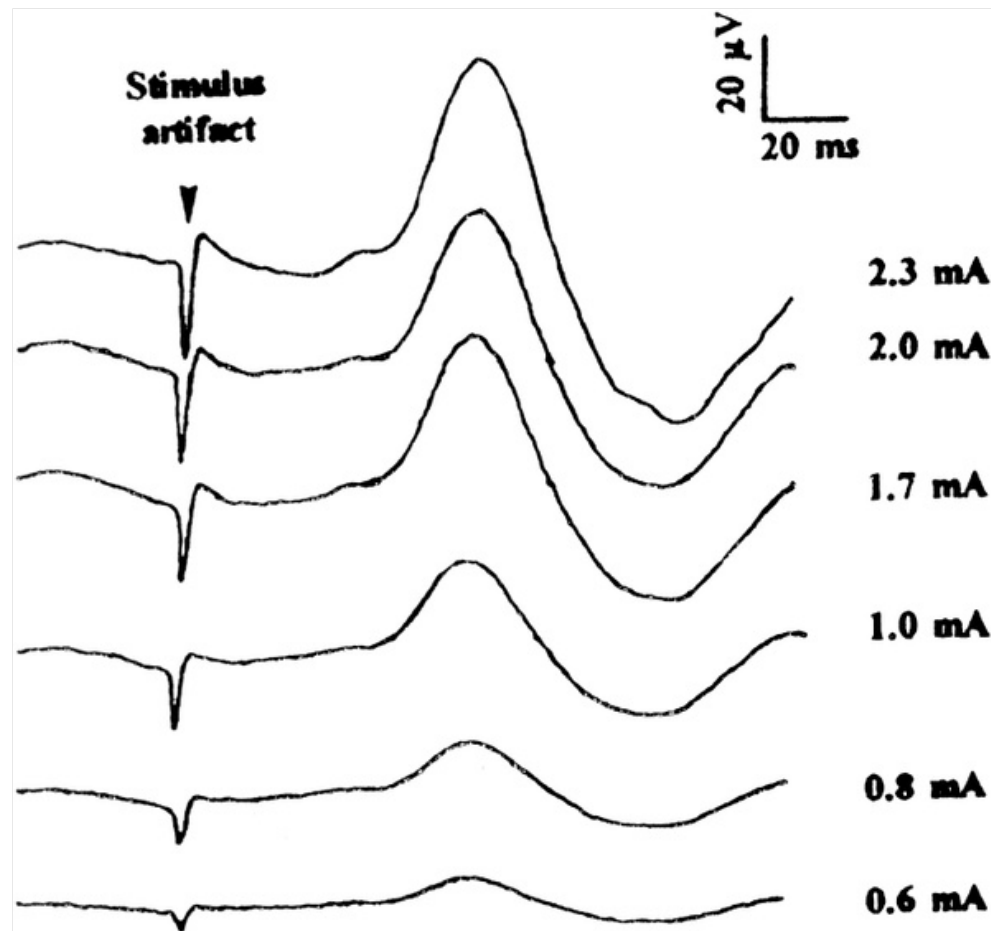


Figure 5. Effect of current increment on pelvic floor electromyographic activity during S3 nerve root stimulation in 1 patients. Recordings were made using catheter mounted ring electrode.

TENS over the suprapubic region and posterior tibial nerve

Previous studies have shown that TENS of the posterior tibial nerve [14] and suprapubic region [11] can modulate detrusor function, particularly in patients with interstitial cystitis. We performed a urodynamic study regarding the effects of TENS at these 2 areas in 17 men and 19 women 19 to 77 years old (mean age 48 plus/minus 16) with idiopathic detrusor instability. Using the aforementioned stimulation parameters, TENS of the posterior tibial nerve and suprapubic region was performed by placing the stimulating electrodes over the appropriate sites as described previously. [11,14] The urodynamic results are summarized in Table 5. No significant differences were observed in any urodynamic parameter during TENS over these 2 regions compared to pre-stimulation parameters. However, in 2 patients TENS of the posterior tibial nerve resulted in an increase in total bladder capacity from 110 and 140 ml. before electrical stimulation to 200 and 210 ml. afterwards, respectively.

Urodynamic Parameter	Mean $\pm$ SD (range)		
	No TENS	TENS Posterior Tibial Nerve	TENS Suprapubic Region
Increased resting detrusor pressure (cm. water)	10 $\pm$ 9 (0-38)	8 $\pm$ 6 (0-24)	9 $\pm$ 7 (0-28)
Cystometric capacity (ml.)	151 $\pm$ 113 (40-650)	138 $\pm$ 74 (50-400)	156 $\pm$ 87 (30-460)
Total bladder capacity (ml.)	185 $\pm$ 112 (65-650)	173 $\pm$ 101 (50-450)	195 $\pm$ 105 (40-512)
Micturition pressure (cm. water)	52 $\pm$ 21 (26-105)	49 $\pm$ 24 (18-114)	45 $\pm$ 24 (16-124)
Micturition pressure at peak flow (cm. water)	43 $\pm$ 20 (16-100)	40 $\pm$ 20 (10-86)	42 $\pm$ 22 (10-98)
Voided vol. (ml.)	171 $\pm$ 109 (50-580)	163 $\pm$ 94 (50-450)	185 $\pm$ 93 (40-450)
Residual vol. (ml.)	14 $\pm$ 21 (0-70)	12 $\pm$ 22 (0-99)	10 $\pm$ 34 (0-202)
Flow rate (ml./sec.)	12 $\pm$ 12 (3-25)	12 $\pm$ 6 (3-27)	13 $\pm$ 5 (4-25)
Vol. at first unstable contraction (ml.)	98 $\pm$ 80 (5-640)	86 $\pm$ 69 (10-350)	92 $\pm$ 73 (5-300)
No. unstable contractions	4 $\pm$ 3 (1-11)	3 $\pm$ 3 (1-12)	4 $\pm$ 3 (1-13)
Frequency of unstable contractions/hr.	2 $\pm$ 2 (1-8)	1 $\pm$ 1 (0-7)	2 $\pm$ 2 (0-8)
Maximum amplitude of unstable contractions	62 $\pm$ 60 (12-180)	54 $\pm$ 39 (10-130)	55 $\pm$ 37 (15-140)
Vol. of urge incontinence (ml.)	5 $\pm$ 12 (0-50)	5 $\pm$ 9 (0-50)	2 $\pm$ 7 (0-30)

Table 5. Effect of TENS of the posterior tibial nerve and suprapubic region on conventional filling and voiding cystometry in 36 patients with idiopathic detrusor instability

Discussion

During the years different forms of electrical stimulation have been useful in patients with a variety of voiding disorder. [5-18] Most studies included a wide variety of patients presenting with frequency, urgency and urinary incontinence. Despite the growing interest in functional electrical stimulation, experience with neuromodulation in patients with proved idiopathic detrusor instability is currently limited. We evaluated the effects of 2 different neuromodulatory techniques in patients with idiopathic detrusor instability.

In our study of TENS patients acted as their own control. further any changes noted with TENS of the S2-S3 dermatomes. During the stimulation period most patients reported some improvement in overall urinary symptoms. Maximum satisfactory benefit (greater than 50 percent improvement) was observed for enuresis (73 percent) and urge incontinence (69 percent), and the least improvement was noted for urinary frequency (37 percent). These changes were reflected in symptom scores. Objectively, we observed changes in urodynamic measurements on cystometrography and ambulatory urodynamic studies Table 1 and Table 2 with TENS over the S2-S3 dermatomes. However, few patients were rendered uroynamically stable during the stimulation period.

The site of TENS clearly is important. We performed a urodynamic study to assess the effects of different sites of stimulation on detrusor function. Previous studies have shown that TENS over the suprapubic region and posterior tibial nerve might modulate detrusor function. [11,14] However, our experience with the suggested sites was discouraging. Suprapubic stimulation did not produce any significant change in the urodynamic parameters and stimulation of the posterior tibial nerve produced urodynamic changes in only 2 patients. The lack of effect of suprapubic TENS and minimal benefits of posterior tibial nerve stimulation on urodynamic recordings compared to S2-S3 dermatome stimulation perhaps illustrate the pathophysiological differences between interstitial cystitis and idiopathic detrusor instability. With respect to stimulation parameters for TENS, as yet there is no consensus regarding optimal stimulation parameters for percutaneous stimulation in patients with detrusor instability. Therefore, we used previously described parameters in patients with interstitial cystitis that have been proved to produce changes in detrusor function. [11] The variable response of the bladder to changes in site of electrical stimulation observed in our study highlights the complex and sensitive nature of neuronal reflexes that influence detrusor function, since apparently slight variations in technique have produced widely differing outcomes. These variations in response of the detrusor to changes in positioning of the stimulating electrode indicate the need for further studies to define optimal positioning of electrodes and stimulation parameters for neuromodulation of the unstable detrusor. Overall, our results favor TENS of the S2-S3 dermatome regions in patients with detrusor instability.

The majority of S3 neuromodulations were performed in a subset of patients who had already undergone a trial of TENS, thus providing an opportunity to compare the relative subjective and objective benefits of the 2 treatment modalities. Although symptomatic relief was more pronounced with S3 neuromodulation, no statistically significant benefits regarding urinary symptoms and urodynamic measurements were found compared to TENS.

There were no major complications after TENS. However, prolonged stimulation resulted in local skin irritation at the site of the carbon-rubber pads in a third of the patients, which was severe enough to preclude continued TENS in only 1. The use of hypo-allergic pads and limiting continuous stimulation to less than 2 hours helped decrease the incidence of local irritation significantly. Complications associated with S3 neuromodulation included electrode migration, hemorrhage and procedure intolerance. Electrode migration was attributed to subcutaneous tunneling of the electrodes, which was used earlier in the study to allow for a more accessible and manageable puncture site. However, we soon realized that excessive tunneling potentially subjects an increased length of the implanted electrode to a tissue sliding effect, thus facilitating migration. The technique was subsequently modified so that the electrodes were anchored at the puncture site without further tunneling. Hemorrhage from the puncture site occurred in 1 patient on postoperative day 6. In the absence of any clinical evidence of infection, it is possible that vascular erosion by the electrode was responsible for the bleeding. Although recovery was complete following removal of the electrode and antibiotic therapy, hemorrhage remains a potential complication of this technique.

To assess the effects of electrical stimulation on pelvic floor and sphincter activity, electromyography was performed in patients undergoing S3 neuromodulation. Using surface recording electrodes, evoked potentials were obtained from the small muscle of the foot and the great toe on the side of the implanted electrode to confirm its continued optimum position. The procedure was noninvasive and completely free of pain, since evoked potentials could be obtained easily at subthreshold levels of stimulation. A measure of individual patient tolerance to electrical stimulation also was provided. Analysis revealed a maximum tolerated current of approximately 5 to 6 mA. and an optimum stimulation parameter of 1 to 3 mA. Earlier in the study external anal sphincter electromyography was obtained in all patients. However, electrically evoked anal sphincter electromyography could be obtained only at supra-threshold stimulation. At this level pelvic floor contractions become clinically apparent and stimulation is uncomfortable for the patients. Accordingly, anal sphincter electromyography was abandoned. Analysis of simultaneous recordings of the pelvic floor and external urethra demonstrated increased electromyographic activity in the pelvic floor (catheter mounted ring electrode) with current increment Figure 5 but there was no evidence of increased electromyographic activity in the external urethral sphincter (concentric needle electrode) at tolerable levels of stimulation. These findings suggest that the beneficial effects of S3 neuromodulation are unlikely to be attributed to increased urethral sphincter tone, and might be due to pelvic floor stimulation and reflex modulation of detrusor activity as suggested previously. [7]

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Conclusions

Our study of patients with severe detrusor instability refractory to conservative treatments revealed that TENS over the S2 to S3 dermatomes and S3 neuromodulation produced significant changes in urodynamic parameters and presenting symptoms. Although the precise mechanism regarding modulation of detrusor activity by electrical stimulation remains unclear, our results suggest an approach that may be beneficial in patients with detrusor instability refractory to conservative treatments. TENS is attractive because of its simplicity, low morbidity and cost-effectiveness, whereas the encouraging response observed with S3 neuro-modulation may justify its careful use as an implantable neuro-prostheses in select patients who respond to temporary stimulation. While these neuromodulatory procedures are time-consuming, the beneficial effects appear to justify their use, particularly before surgery.

REFERENCES

1. Cardoso, L.: Urinary incontinence in women: have we anything new to offer? *Brit. Med. Bull.*, 303: 1453, 1991.

[\[Context Link\]](#)

2. Bates, C. P., Bradley, W. E., Glen, E. S., Melchoir, H., Rowan, D., Sterling, A. M., Sundin, T., Thomas, D., Torrens, M., Turner-Warwick, R., Zinner, N. R. and Hald, T.: Fourth report on the standardisation of terminology of lower urinary tract function. Terminology related to neuromuscular dysfunction of the lower urinary tract. International Continence Society. *Brit. J. Urol.*, 53: 333, 1981.

[\[Context Link\]](#)

3. Bent, A. E.: Etiology and management of detrusor instability and mixed incontinence. *Obst. Gynec. Clin. N. Amer.*, 16: 853, 1989.

[\[Context Link\]](#)

4. Beck, R. P.: Detrusor instability: diagnosis and therapy. *Curr. Opin. Obst. Gynec.*, 2: 591, 1990.

[\[Context Link\]](#)

5. Tanagho, E. A. and Schmidt, R. A.: Electrical stimulation in the clinical management of the neurogenic bladder. *J. Urol.*, 140: 1331, 1988.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

6. Vapnek, J. M. and Schmidt, R. A.: Restoration of voiding in chronic urinary retention using the neuroprosthesis. *World J. Urol.*, 9: 142, 1991.

[\[Context Link\]](#)

7. Elabbady, A. A., Magdy, M., Hassouna, M. M. and Elhilali, M.: Neural stimulation for chronic voiding dysfunctions. *J. Urol.*, 152: 2076, 1994.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

8. Madersbacher, H.: Intravesical electrical stimulation for the rehabilitation of the neuropathic bladder. *Paraplegia*, 28: 349, 1990.

[Bibliographic Links](#) [\[Context Link\]](#)

9. Merrill, D. C.: The treatment of detrusor incontinence by electrical stimulation. *J. Urol.*, 122: 515, 1979.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

10. Schiotz, H. A.: One month maximal electrostimulation for genuine stress incontinence in women. *Neurourol. Urodynam.*, 13: 43, 1994.

[Bibliographic Links](#) [\[Context Link\]](#)

11. Fall, M., Carlsson, C.-A. and Erlandson, B.-E.: Electrical stimulation in interstitial cystitis. *J. Urol.*, 123: 192, 1980.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

12. McGuire, E. J., Shi-Chun, Z., Horwinski, E. R. and Lytton, B.: Treatment of motor and sensory detrusor instability by electrical stimulation. *J. Urol.*, 129: 78, 1983.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

13. Meyler, W. J., de Jongste, M. J. and Rolf, C. A.: Clinical evaluation of pain treatment with electrostimulation: a study on TENS in patients with different pain syndromes. *Clin. J. Pain*, 10: 22, 1994.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

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14. Fall, M. and Lindstrom, S.: Transcutaneous electrical nerve stimulation in classic and nonulcer interstitial cystitis. *Urol. Clin. N. Amer.*, 1: 131, 1994.

[Print Availability](#) [\[Context Link\]](#)

15. Zvara, P., Carrier, S., Kour, N.-W. and Tanagho, E. A.: The detailed neuroanatomy of the human striated urethral sphincter. *Brit. J. Urol.*, 74: 182, 1994.

[Print Availability](#) [Full Text Available Online](#) [Bibliographic Links](#) [\[Context Link\]](#)

16. Schmidt, R. A., Senn, E. and Tanagho, E. A.: Functional evaluation of sacral nerve root integrity. Report of a technique. *Urology*, 35: 388, 1990.

[Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

17. Siegel, S. W.: Management of voiding dysfunction with an implantable neuroprosthesis. *Urol. Clin. N. Amer.*, 19: 163, 1992.

[Print Availability](#) [\[Context Link\]](#)

18. Thon, W. F., Baskin, L. S., Jonas, U., Tanagho, E. A. and Schmidt, R. A.: Neuromodulation of voiding dysfunction and pelvic pain. *World J. Urol.*, 9: 138, 1991.

[\[Context Link\]](#)

19. Koldewijn, E. L., Rosier, P. F. W. M., Meuleman, E. J. H., Koster, A. M., Debruyne, F. M. J. and Van Kerrebroeck, P. E. V.: Predictors of success with neuromodulation in lower urinary tract dysfunction: results of trial stimulation in 100 patients. *J. Urol.*, 152: 2071, 1994.

[Ovid Full Text](#) [Print Availability](#) [Bibliographic Links](#) [\[Context Link\]](#)

20. Robertson, A. S., Davies, J. B., Webb, R. J. and Neal, D. E.: Bladder augmentation and replacement. Urodynamic and clinical review of 25 patients. *Brit. J. Urol.*, 68: 590, 1991.

[Print Availability](#) [Full Text Available Online](#) [Bibliographic Links](#) [\[Context Link\]](#)

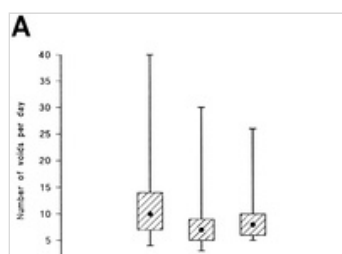
21. Frimodt-Moller, P. C., Jensen, K. M.-E., Iversen, P., Madsen, P. O. and Bruskewitz, R. C.: Analysis of presenting symptoms in prostatic. *J. Urol.*, 132: 272, 1984.

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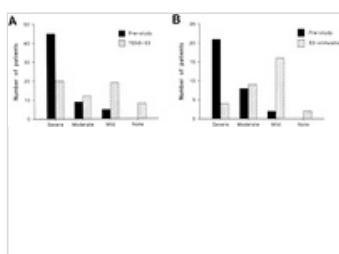
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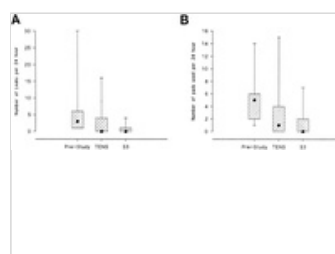
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☐ Figure 1



☐ Figure 2



☐ Figure 3

Procedures Performed	No. Patients	Mean (SD) Age	Mean (SD) Voiding Rate	Mean (SD) Voiding Rate
Pre-DBS	10	68.5 (10.5)	15.0 (10.0)	15.0 (10.0)
DBS	10	68.5 (10.5)	15.0 (10.0)	15.0 (10.0)
S3	10	68.5 (10.5)	15.0 (10.0)	15.0 (10.0)

☐ Table 1

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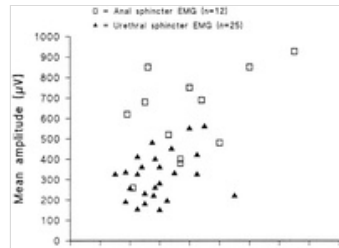
☐ Table 2

Procedures Performed	No. Patients	Mean (SD) Age	Mean (SD) Voiding Rate	Mean (SD) Voiding Rate
Pre-DBS	10	68.5 (10.5)	15.0 (10.0)	15.0 (10.0)
DBS	10	68.5 (10.5)	15.0 (10.0)	15.0 (10.0)
S3	10	68.5 (10.5)	15.0 (10.0)	15.0 (10.0)

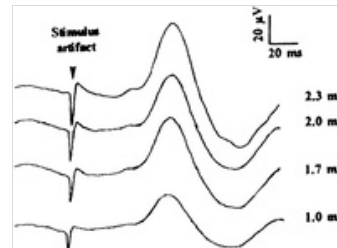
☐ Table 3

Cohort/Study Period	Mean ± SD (range)		p Value ^a
	50–59 (n = 10)	60–69 (n = 10)	
Duration of study (years)	240 ± 10 (100–300)	240 ± 10 (100–300)	Not significant
Age at study entry (years)	55.0 ± 1.0 (50–59)	65.0 ± 1.0 (60–69)	Not significant
Age at study exit (years)	60.0 ± 1.0 (55–64)	67.0 ± 1.0 (60–69)	Not significant
Mean weekly exercise (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly walking (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly cycling (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly swimming (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly other (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly total (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly walking (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly cycling (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly swimming (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly other (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant
Mean weekly total (min/week)	100 ± 10 (0–200)	100 ± 10 (0–200)	Not significant

□ Table 4



□ Figure 4



□ Figure 5

[illegible]

□ Table 5

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