

Clinical Evaluation Report

TensCare Itouch Sure

Update and application to Sure Pro

Update of Clinical Evaluation

This report was originally published on 10/10/2011 to consider the clinical evidence for the Risk/Benefit of the itouch Sure

A revision was published on 2/9/15 to review publications since that date and consider the application of the Clinical Evaluation to Elise and Viva

This update

- A) Reviews the applicability of the previous clinical Evaluations to the Sure Pro and considers the evidence for the additional programmes:
- B) Pelvic Floor Workout
- C) Transcutaneous Tibial Nerve Stimulation for Urge Incontinence.
- D) Chronic Pelvic Pain Relief

A: Application of Sure Clinical Evaluation to Sure Pro



Sure



Sure Pro

1) Indications for Use

Indications for use for both products are the same:-

To provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence.

The international identification code for this type of product is:

GMDNS [36784] Stimulator, electrical, neuromuscular, incontinence

2) Electrical output

	Sure	Sure Pro
Channels	1	2
Max output mA	99	99
Intensity steps mA	0.5	1
Control mode	Constant current 160-470 Ohm Constant voltage 470-2000 Ohm	Constant current 160-470 Ohm Constant voltage 470-1500 Ohm
OC cutout above	2.5 k Ohm	2.5 k Ohm
Power Supply	2x AA Alkaline	Rechargeable Lithium 3.2V
Buttons	7	5
UsageLog	✓	✓
Keypad lock	Manual	Automatic
Stress 1	50 Hz/ 300µs W/R=5/10	50 Hz/ 300µs W/R=5/10
Urge	10 Hz/200 µs W/R=5/10	10 Hz/200 µs W/R=5/10
Mixed	20 Hz/250 µs W/R=5/10	10/50Hz, 200/300 µs
Urge 2	×	10 Hz/200 W/R=Continuous
Tone / Stress 2	35Hz/250 W/R=3/6	35Hz/250 W/R=3/6
SENS	×	3/10/20/30/40Hz, 250/200 us
PFWA	×	3-45Hz 250us W=4s
PFWB	×	W=6s
ENDURANCE	×	20Hz 250 us W/R=5/10
PAIN	×	4Hz 200us Continuous
TIBN	×	10hz 200uS Continuous
	×	
Manual settings	×	✓

Sure Pro CUSTOM PROGRAMME SETTING RANGE:

Hz : 4-90 in steps of 1

µS : 50 - 350 in steps of 5

Ramp 1-10s in steps of 0.5

Work : 0.5 - 30 in steps of 0.5

Rest : 0.5 - 60 in steps of 0.5

Timer 5-60 mins in steps of 5

The electrical output of the **Sure Pro** in programmes Stress, Urge and Tone is identical with that of the Sure.

The manual settings of the **Sure Pro** are within the range reported in the RCTs reviewed in the Sure Clinical Evaluation, or within the range reported in TENS RCTs (Ref 53).

Review of the clinical evidence shows that no additional adverse effects have been reported within this range.

Despite the lack of objective supporting evidence, it is common practice for Women's Health Physiotherapists in the UK to adjust stimulation settings to suit the patient's condition – adjusting work/rest ratio during the course of treatment as muscle strength and endurance increases. Most pelvic floor stimulators marketed for professional use include manual settings.

The Risk of providing manual settings is that using inappropriate settings could reduce the effectiveness of the treatment.

Lack of effective treatment may affect quality of life, but not adversely affect general health (the majority of incontinent patients receive no treatment). Any lack of effect should be detected by referring to the patient's bladder diary.

The **Sure Pro** User Manual contains an additional warning for manual programmes:

"Muscle stimulation has many variables, and we recommend that you take professional advice before using these programmes".

Impact on safety and performance

Differences in electrical output do not affect the Risk/Benefit calculation

3) Materials

Sure and Sure Pro use the same vaginal electrode, and have similar case construction.

Impact on safety and performance

Differences in materials do not affect the Risk/Benefit calculation

Conclusion

Differences in materials do not affect the Risk/Benefit calculation

4) Design

Sure Pro

Sure Pro has a more complicated control panel with a dedicated ON/OFF button and a total of 12 buttons instead of 6.

Sure power supply is 2 x AA batteries. Sure Pro power supply is a rechargeable lithium battery which must be removed to recharge.

The Sure Pro design is very similar to the Sports TENS 2. Tenscare have sold this product for home use for 3 years. Post marketing surveillance has confirmed that Usability is acceptable for this market.

Conclusion

Differences in design do not affect the Risk/Benefit calculation

5) Clinical Use

Both products are designed for both home use and a clinical setting.

The Sure Pro is more complex, with two output channels and additional manual settings and preset programmes. It is therefore better adapted for clinical use.

B: Pelvic Floor Workout Programmes

The Pelvic Floor Workout programmes use settings within the range of those referred to in published clinical trials for Urge and Stress incontinence.

The difference is that these programmes combine many settings in a series of treatment phases intended to give a balance of muscle training for both strength and endurance, and to relieve Urge.

The original idea was based on unpublished clinical observations by Jeanette Haslam that sudden large changes in stimulation frequency could aggravate symptoms of urge incontinence. She reasoned that small, progressive changes could achieve the same therapeutic effect without risking aggravating the Urge.

There is only one published reference to Pelvic Floor Workout:

Mary Dolman

EMS for urinary incontinence: Levator 100

BJ Community Nursing 2000 vol5 no 5 217-220

However, since the year 2000 Pelvic Floor Workout Programmes have been included in most continence stimulators manufactured in the UK, in particular the Neen Pericalm and Verity Pelvitone.

No adverse reactions to these products have been published, and they are still on the market in Europe, USA and Australia.

Pericalm PFW

PELVIC FLOOR WORK OUT AND LACK OF SENSITIVITY (34 MIN) PFW	6 Sequential phases: Phase 1: 2Hz for 4 min, Phase 2: 10Hz for 10 min, Phase 3: 15Hz for 5 min, Phase 4: 20Hz for 5 min, Phase 5: 30Hz for 5 min, Phase 6: 10Hz for 5 min All phases are 5 seconds work, 5 seconds rest at 220 μ S, 0.8 seconds ramp.
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Neurotrac Pelvitone PFW

Programme: P09	Pelvic Floor Work Out	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	4	15	8	8	10
Mode		W/R	W/R	W/R	W/R	W/R
Frequency work	Hz	20	10	20	30	10
Pulse duration	µS	250	250	250	200	250
Ramp up time	secs	0.8	0.8	0.8	0.6	0.8
Ramp down time	secs	0	0	0	0	0
Work time	secs	5	5	5	5	5
Rest time	secs	5	5	5	6	7
Alternating						
Synchronous		*	*	*	*	*
Overall time	45 min					

C: Transcutaneous Tibial Nerve Stimulation for Urge Incontinence.

Search terms: continence, urge, overactive bladder, transcutaneous tibial nerve stimulation

Excluded: Percutaneous - An alternative invasive therapy.

Results: search results were divided into three patient groups:

- Adults
- Children
- Faecal incontinence

Only adult urinary incontinence is mentioned in the Sure Pro user manual.

A systematic review by Slovak⁴⁰ in 2015 found that:

“There is promising evidence for the efficacy of a transcutaneous stimulation approach, but adequate standardisation of stimulation criteria and outcome measures will be necessary”

A table of the main features of the papers discovered is shown below as Table C1.

No papers reported any significant adverse effects.

Five papers were published after the Slovak review:

REF	22	Liu
	24	Manríquez
	25	Mariotti
	27	Ojha
	31	Perissinotto

All five were had study design or patient numbers that constitutes only weak evidence. However all reported positive results and no adverse effects.

Search results for Children and Faecal incontinence are outside the scope of this Clinical Evaluation, but are included for completeness as Table C2 and Table C3.

Conclusion

There is currently only weak evidence for the clinical benefits of TPTNS. However the technology is well established, with earliest reports dating from 1996.

Known Adverse Effects are rare and minor. Adding TPTNS to the SurePro does not significantly affect the Risk/Benefit calculation.

Table C1: Adult urinary incontinence

Ref	Author	Title	Pub date	Type	Patients	Treatment	Outcome
2	AMARENCO	URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER	2003	Prospective	44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. 29 women and 15 men	“Contact electrodes were placed with electrode gel on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode. The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 Hz. The intensity level was then chosen as the intensity immediately under the threshold determining motor contraction. In addition, no pain was to be noted during the stimulation procedure, which necessarily had to be comfortable for the patient. at 10 Hz. 200 milliseconds in continuous mode.”	Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 96.4 ml. and it was 232.1 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 129.5 ml. and it was 277.4 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume (p 0.0001) and significant improvement in maximum cystometric capacity (p 0.0001). The test was considered positive in 22 of the 44 patients. Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.
3	Ammi	Transcutaneous posterior tibial nerve stimulation-evaluation of a therapeutic option in the management of anticholinergic	2014	Prospective observational	43 consecutive	daily stimulation at home	TPTNS is well tolerated and is effective in one half of the patients studied after they failed anticholinergic treatment. TPTNS could become a second therapeutic option

		refractory overactive bladder					before surgical treatment in the management strategy of OAB.
5	Booth	A feasibility study of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in elderly adults in residential care	2013		30>65yrs	Two self-adhesive surface electrodes were positioned according to the protocol used by Amarenco et al⁷ and Shreiner et al,¹⁵ with the negative electrode 2 cm behind the medial malleolus and the positive electrode 10 cm proximal to it. Correct positioning was determined by noting a halux reaction (plantar flexion of great toe or fanning of all toes) or the participant's description of tingling, pulsing, or movement in the great toe. 10 Hz 200 ms continuous mode. intensity (range 0e50 mA) was determined according to the comfort level of the participant.	Conclusion: TPTNS is safe and acceptable with evidence of potential benefit for bladder and bowel dysfunction in older male and female residents of care homes. Data support the feasibility of a substantive trial of TPTNS in this population.
6	Bower	A URODYNAMIC STUDY OF SURFACE NEUROMODULATION VERSUS SHAM IN DETRUSOR INSTABILITY AND SENSORY URGENCY	1998	CT	A consecutive series of women with proved detrusor instability or sensory urgency were randomized to 3 surface neuromodulation groups.	Electrical current was delivered to the suprapubic region and third sacral foramina via a TENS unit with sham neuromodulation control.	Sham transcutaneous electrical nerve stimulation did not alter the outcome measures. However, neuromodulation delivered across the suprapubic and sacral skin effected a reduction in mean maximum height of detrusor contraction. A current which inhibits motor activity was not superior to that which inhibits sensory perception in reducing detrusor pressure. Response in sensory urgency was poor.
7	Bristow	TENS: a treatment option for bladder dysfunction	1996	Review	To ascertain the mode of action and benefits of transcutaneous electrical nerve stimulation (TENS) in detrusor overactivity, stress incontinence and		The mode of action of TENS and optimal stimulation parameters in bladder dysfunction remain unclear. Lack of strict selection criteria and deficient reporting of

					interstitial cystitis, an English-language literature search using Medline (1984-1995) was undertaken with detrusor instability, incontinence, interstitial cystitis, neuromodulation, transcutaneous electrical nerve stimulation and urodynamics as keywords and the material so identified was reviewed.	subjective and objective outcomes precluded full assessment of therapeutic efficacy. A beneficial effect was evident in some studies of detrusor overactivity and interstitial cystitis. A trial of TENS in detrusor overactivity and interstitial cystitis refractory to conventional therapy would seem justified. Continued experimental research and further clinical studies will lead to refinement of the treatment modality
10	de Seze	Transcutaneous posterior tibial nerve stimulation for treatment of the overactive bladder syndrome in multiple sclerosis:	2011	multicenter prospective study.	70 MS patients	Clinical improvement of OAB was shown in 82.6% and 83.3% of the patients on D30 and D90, respectively, with significant improvement of primary and secondary outcomes compared to baseline. The initial acute cystometric response to TPTNS was positive in 51.2% of the patients (increase of >30% of cystometric capacity and/or reflex volume), without correlation with TPTNS clinical efficiency. The procedure was well tolerated. Chronic TPTNS appears to be effective in the management of severe OAB in MS, without compromising bladder emptying or inducing side effect. Treatment may be effective even in the absence of an acute cystometric effect. Additional works are required to demonstrate long-term efficacy of TPTNS.
11	Fjorback	Electrical stimulation of sacral dermatomes in multiple sclerosis patients with neurogenic detrusor overactivity.	2007	Prospective controlled trial Comparison of no stim to DPN or sacral stim	A total of 14 MS patients (8 M, 6 F) with low bladder capacity (<300 ml) and a recent urodynamic study showing detrusor	The control filling showed detrusor overactivity in 12 of the 14 patients. In 10 of the 12 patients one or more detrusor contractions could be suppressed with DPN stimulation. Electrical stimulation of the sacral dermatomes failed to suppress detrusor contractions in all patients.

					overactivity incontinence		CONCLUSIONS: Although therapeutic effects may be present from stimulation of the sacral dermatomes, we were unable to demonstrate any acute effects during urodynamics. For this reason stimulation of the sacral dermatomes is not an option in a system that relies on the acute suppression of a detrusor contraction
12	Guo	TENS in the treatment of patients with poststroke urinary incontinence	2014	controlled	61 post stroke	Treatment frequency of 30 minutes once a day for 60 days. The positive electrode was placed on the second lumbar spinous process, and the negative electrodes were inside the middle and lower third of the junction between the posterior superior iliac spine and ischia node	The daily micturition, nocturia, urgent urination, and urge UI in the treatment group significantly improved compared to the control group ($P<0.05$). The patients in the treatment group were superior in the self-care ability of daily living and also had an advantage over the indexes on maximum cystometry volume, flow rate, and the pressure of detrusor in the end of the filling phase. CONCLUSION: TENS improved incontinence symptoms, enhanced the quality of life, and decreased adverse effects; hence, it is recommended in treating poststroke UI.
13	Hu	Current density distribution under surface electrode on posterior tibial nerve electrical stimulation.	2005	Theoretical model	ES on the posterior tibial nerve is commonly used in the measurement of somatosensory evoked potential (SEP). To improve the efficiency of stimulation, the potential field and current density distributions under the surface electrodes were simulated with a three layer theoretical model. The mirror method was used to analyze the potential field of point charge. Integration of the field and the stimulus area provide the potential field for one surface electric pole. Potential field distribution of the bipolar electrodes was calculated by superimposition of two unipolar fields. Finally, the current density distribution was calculated by Laplace equation. An analytical solution of the potential field was obtained; thereafter the numerical solution of the current		From the model and simulation, the potential and current density distributions were not found to be evenly distributed under transcutaneous stimulation electrode and the maximum current density is located under the poles. The result suggests that bipolar stimulator should be applied axially along the stimulated nerve course

					density distribution was calculated. The potential field and current density distribution were simulated by 2-D plot.	
15	Hasan	Transcutaneous electrical nerve stimulation and temporary S3 neuromodulation in idiopathic detrusor instability.	1996	PURPOSE: We studied the effects of electrical stimulation on idiopathic detrusor instability	30 men and 41 women (mean age plus or minus standard deviation 48 +/- 16 years) underwent TENS of the S2-S3 dermatomes, and 13 men and 22 women (mean age 48 +/- 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. Mean duration of TENS was 3 +/- 1 weeks (range 2 to 4). Although there were no major complications 31% of the patients reported local skin irritation.	The overall urinary symptom scores improved from 10 +/- 2 (range 5 to 14) before the study to 7 +/- 3 (range 1 to 14) during stimulation. Urodynamic analysis revealed significant (p < 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 +/- 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 +/- 3 (range 5 to 14) before the study and 5 +/- 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.
22	Liu	Effects of TENS at Two Frequencies on Urinary Incontinence in Poststroke Patients	2015	RCT	Eighty-one patients with poststroke urinary incontinence were recruited and randomized into the TENS currents were biphasic square waves with pulse durations of 150 µsecs and pulse frequencies of 20 Hz or 75 Hz and were applied	The patients treated with 20 Hz had superior Overactive Bladder Symptom Scores, Barthel Index totals, urodynamic values, and voiding diary parameters (P < 0.05). In the 75-Hz group, values were

					following three groups with a 1:1 ratio: a 20-Hz TENS group, a 75-Hz TENS group, and a no-treatment control group (n = 27 per group).	for 30 mins once per day for 90 days. The positive electrodes were placed in the region of the second sacral level on opposite sides of the vertebral column; the negative electrodes were placed on the inside of the middle and lower third of the junction between the posterior superior iliac spine and the ischial node. OAB Symptom Scores, Barthel Index, urodynamic values, and voiding diary parameters were assessed before and after 90 days.	statistically improved compared with the no-treatment group ($P < 0.05$), but the results were significantly inferior to those of the 20-Hz group ($P < 0.05$). CONCLUSIONS: Twenty-hertz TENS improved incontinence symptoms and promoted activities of daily living better than 75-Hz TENS. These results will aid future research regarding TENS parameters.
24	Manríquez	Transcutaneous posterior tibial nerve stimulation versus extended release oxybutynin in overactive bladder patients.	2015	prospective randomized trial	Seventy female patients were randomized to receive either 10mg E.R.O. daily or T.C. PTNS,	TENS 20Hz, 200cycles/s, and normal stimulation setting for two 30-min sessions, each week for a 12-week period. Pre-treatment and after the 12-week intervention, each patient completed a 3-day voiding diary and a self-report quality of life questionnaire (OAB-q). Statistical analysis was performed using Stata V12.1.	Sixty-four patients completed the treatment protocol. There were no significant differences between study groups in terms of age, body mass index, past hormone replacement therapy, smoking habits, menopause status, and parity. Prior to treatment, there were also no significant differences in the analysis of the 3-day voiding diary or in the OAB-q questionnaire results. Following the 12-week study, there was a statistically significant reduction in frequency of urination, urgency episodes, and urge incontinent episodes compared to pre-treatment values. However, there were no significant differences in these values between intervention groups after 12-weeks of therapy. There was a similar

							improvement in OAB-q scores in both treatment groups following therapy, and the T.C. PTNS group showed a statistically significant improvement over the E.R.O. in domain 2 of the OAB-q questionnaire. The other two domains showed similar improvement in both study groups. CONCLUSION: T.C. PTNS and E.R.O. demonstrated similar improvements in subjects with OAB in a 12-week study.
25	Mariotti	Recovery of Urinary Continence After Radical Prostatectomy Using Early vs Late Pelvic Floor Electrical Stimulation and Biofeedback-associated Treatment	2015	Prospective.		Total of 120 patients who underwent RP were prospectively included in the study. In group 1 (60 cases), we included patients who presented a urinary leakage weight ≥50 g for 24 hours, 14 days after catheter removal. In group 2 (60 cases), we included patients who continued to present a urinary leakage weight ≥50 g for 24 hours, 12 months after surgery. In both groups, patients were prospectively submitted to the same program of BF+FES.	Mean leakage weight became significantly lower (P <.002) in group 1 than in group 2 starting from visit 1 (2 weeks) through visit 7 (24 weeks). However, a significant difference (P <.05) between the 2 groups in terms of percentage of continent patients was achieved only at 2 weeks (group 1 = 20%; group 2 = 0%) and 4 weeks (group 1 = 66.7%; group 2 = 46.7%). The objective continence rate 6 months after the beginning of treatment was 96.7% in group 1 and 91.7% in group 2. Conclusion In our experience, the treatment with BF and FES has a significant positive effect on the recovery of urinary continence independently to the time in which it is used (early vs delayed). This protocol might represent a noninvasive method for all patients undergoing RP, also in a 12-month interval from surgery.
27	Ojha	Neuromodulation by surface electrical stimulation of peripheral nerves for reduction of detrusor overactivity in	2015	Pilot study	Ten persons with observable F-wave from tibial nerve were included in the PTN group. Five	Stimulation was given at 20 Hz, 10-40 mA for 20 minutes/session/day for 14 consecutive days. Interventions Surface	Outcome measures Qualitative analysis using voiding diary data and quantitative analysis using CMG data comparing pre- and post-intervention. Results P value obtained from voiding chart

		patients with spinal cord injury.			persons who had F-wave absent but preserved bulbocavernosus reflex were included in the DPN group. Detrusor overactivity was recorded using CMG on days 1 and 15	stimulation of peripheral nerves for reduction of detrusor overactivity.	was 0.021 for PTN and 0.062 for DPN. P value obtained from CMG data was not significant in both groups. In one subject, treatment was extended to 4 weeks and further improvement in voiding diary was seen. Conclusions In this pilot study of 15 patients, voiding chart data showed statistically significant improvement following PTN stimulation and trend of improvement following DPN stimulation. However, the CMG data were not statistically significant in this sample population. Further studies with larger, appropriately powered sample size would be helpful to demonstrate the associations of symptoms with CMG data.
28	Ohannessian	Transcutaneous tibial nerve stimulation in the overactive bladder syndrome in patients with Parkinson's syndromes.	2013	prospective monocentric study	Six female patients with PD or MSA suffering from overactive bladder syndrome for a six-week study period.	Daily sessions of 20 minutes of TNS were provided. The primary outcome measurement was the Patient Global Impression of Improvement (PGI-I scale). The secondary outcomes measurements were symptom and quality of life scores, bladder diary and urodynamics. The outcomes after 6 weeks of TNS were compared to baseline.	TNS was considered as an effective treatment by five patients out of six (83%) who ask to pursue the treatment and were still doing it 6 months after the end of the study. A trend improvement was observed in only two of the secondary evaluation criteria the V8 median score 21/40 to 14/40 (P=0.2) and the maximum cystometric capacity increased from 211 mL ± 106 to 260 mL ± 226 (P=0.6) after SNT. CONCLUSION: Although urodynamics and symptoms scores did not show significant difference, an efficacy of TNS on overactive bladder in PD and MSA is possible. Additional placebo controlled works enrolling more patients are required to ensure these preliminary results.
29	Okada	Transcutaneous electrical stimulation of thigh muscles in the treatment of detrusor overactivity,	1998	Prospective	Nineteen patients with detrusor overactivity, comprising 14 with	Electrical stimulation was applied alternately to the quadriceps and hamstring muscles of one or both legs	All 19 patients tolerated the therapy well and none reported any adverse effects. The mean maximum cystometric capacity increased significantly (P < 0.05) after

					detrusor hyperreflexia (DH) and five with idiopathic detrusor instability (IDI), were studied.	through surface electrodes for 20 min. The treatment was given once a day for 14 days and then the patients were evaluated urodynamically.	treatment. In 11 of the 19 patients, the maximum cystometric capacity was increased by > 50% of the pretreatment value; this occurred in eight of 14 of those with DH and in three of five of those with IDI. In six of the 11 who responded in this way, there was a clinical improvement in their urinary incontinence and frequency for several weeks to 3 months after the period of therapy. A second 14-day treatment was also effective in all four patients who underwent a repeat trial. CONCLUSION: This method of transcutaneous electrical stimulation can inhibit DH as well as IDI with no adverse effects. The suppressive effect on detrusor overactivity may persist for several months and repeat trials appear to be effective. Thus, we believe that this new stimulation technique should be tried as an alternative to other types of electrical stimulation and augmentation cystoplasty.
31	Perissinotto	Transcutaneous tibial nerve stimulation in the treatment of lower urinary tract symptoms and its impact on health	2015	RCT	Eight patients received TTNS treatment and 5 subjects allocated to group II were managed with sham surface electrodes that delivered no electrical stimulation.	Assessments were performed before and after the treatment; they included a 3-day bladder diary, Overactive Bladder Questionnaire (OAB-V8), and the International Consultation on Incontinence Quality of Life Questionnaire Short Form (ICIQ-SF), and urodynamic evaluation.	Following 5 weeks of treatment, patients allocated to TTNS demonstrated statistically significant reductions in the number of urgency episodes ($P = .004$) and reductions in nocturia episodes ($P < .01$). Participants allocated to active treatment also showed better results after treatment in the OAB-V8 and ICIQ-SF scores ($P < .01$, respectively). Urodynamic testing revealed that patients in the active treatment group showed improvements in intravesical volume at strong desire to void ($P < .05$) and volume at urgency ($P < .01$) when compared to subjects in the sham treatment group. CONCLUSION: These findings suggest that TTNS is effective in the treatment of LUTS in patients with

						PD, reducing urgency and nocturia episodes and improving urodynamic parameters as well as symptom scores measured by the OAB-V8 and health-related quality-of-life scores measured by the ICIQ-SF.
33	Rai	Cochrane-anticholinergics vs active therapies for OAB	2012	Review		Main results Twenty three trials were included with a total of 3685 participants, one was a cross-over trial and the other 22 were parallel group trials. The duration of follow up varied from two to 52 weeks. The trials were generally small and of poor methodological quality. During treatment, symptomatic improvement was more common amongst those participants on anticholinergic drugs compared with bladder training in seven small trials (73/174, 42% versus 98/172, 57% not improved: risk ratio 0.74, 95% confidence interval 0.61 to 0.91). Augmentation of bladder training with anticholinergics was also associated with more improvements than bladder training alone in three small trials (23/85, 27% versus 37/79, 47% not improved: risk ratio 0.57, 95% confidence interval 0.38 to 0.88). However, it was less clear whether an anticholinergic combined with bladder training was better than the anticholinergic alone, in three trials (for example 74/296, 25% versus 95/306, 31% not improved: risk ratio 0.80, 95% confidence interval 0.62 to 1.04). The other information on whether combining behavioural modification strategies with an anticholinergic was better than the anticholinergic alone was scanty and inconclusive. Similarly, it was unclear whether these complex strategies alone were better than anticholinergics alone. In this review, seven small trials comparing an anticholinergic to various types of electrical stimulation modalities such as Intravaginal Electrical Stimulation (IES), transcutaneous electrical nerve stimulation (TENS), the Stoller Afferent Nerve Stimulation System (SANS) neuromodulation and percutaneous posterior tibial nerve stimulation (PTNS) were identified. Subjective improvement rates tended to favour the electrical stimulation group in three small trials (54% not improved with the anticholinergic versus 28/86, 33% with electrical stimulation: risk ratio 0.64, 95% confidence interval 1.15 to 2.34). However, this was statistically significant only for one type of stimulation, percutaneous posterior tibial nerve stimulation (risk ratio 2.21, 95% confidence interval 1.13 to 4.33), and was not supported by significant

						differences in improvement, urinary frequency, urgency, nocturia, incontinence episodes or quality of life. The most commonly reported adverse effect among anticholinergics was dry mouth, although this did not necessarily result in withdrawal from treatment. For all comparisons there were too few data to compare symptoms or side effects after treatment had ended. However, it is unlikely that the effects of anticholinergics persist after stopping treatment. Authors' conclusions The use of anticholinergic drugs in the management of overactive bladder syndrome is well established when compared to placebo treatment. During initial treatment of overactive bladder syndrome there was more symptomatic improvement when (a) anticholinergics were compared with bladder training alone, and (b) anticholinergics combined with bladder training were compared with bladder training alone. Limited evidence from small trials might suggest electrical stimulation is a better option in patients who are refractory to anticholinergic therapy, but more evidence comparing individual types of electrostimulation to the most effective types of anticholinergics is required to establish this. These results should be viewed with caution in view of the different classes and varying doses of individual anticholinergics used in this review. Anticholinergics had well recognised side effects, such as dry mouth.
35	Schreiner	Randomized trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women.	2010	RCT	51 elderly women (>60 years) with UUI. All were treated with 12 weeks of bladder retraining and pelvic floor muscle exercises	25 were randomly selected to receive TTNS in addition to the standard therapy. The cases were evaluated at the baseline and after the end of therapy by 3-day bladder diary, quality of life questionnaires (QoL), and subjective response. RESULTS: Of the patients, 68.0% in TTNS group reported cure or improvement vs. 34.6% in the control group (P = 0.017). TTNS showed significant improvement in most areas of QoL and in UUI parameters when compared with the control group. CONCLUSION: TTNS is efficacious to treat UUI in older women.
36	Skeil	Transcutaneous electrical nerve stimulation in the treatment of neurological patients with urinary symptoms	2001	Prospective	In all, 44 patients (13 men and 33 women, mean age 50.8 years) were recruited.	The placing of electrode pads on the sacral dermatomes 2.5 cm either side of and 2.5 cm above the natal cleft was The commonest disease was multiple sclerosis and the commonest impairments para/tetraplegia or hemiplegia. There was no change in the neurological status of the 34 patients completing the study. Irritative

					Patients with urinary symptoms from any kind of neurological disease were prospectively recruited. Before attending the first assessment patients were asked to complete a week's diary recording the frequency of micturition, incontinence episodes, and frequency of pad and clothes changing. At the first assessment the patients completed the Frimodt-Moller urinary symptom questionnaire, and quality-of-life scales	demonstrated, and the patient instructed to use TENS for 90 min twice a day. The current strength applied was set to that which the patient could tolerate, at a square-wave of 20 Hz and 200-micros duration. Six weeks later the patients were further assessed, where the diary exercise, questionnaires and urodynamics were repeated.	voiding symptoms were significantly decreased (0.68-0.61, $P = 0.003$) and diaries also showed significant improvements in the 24 h frequency of micturition ($P = 0.01$), incontinence episodes ($P = 0.04$) and clothes changes ($P = 0.02$). Urodynamics showed detrusor hyper-reflexia in most patients. The only significant changes after TENS were an increased postvoid residual volume (from a mean of 134 mL to 160 mL, $P = 0.03$) and an increase in the volume leaked during the urodynamic study with TENS on (from a mean of 4.7 mL to 12 mL, $P = 0.003$). There were no significant changes in the quality-of-life scores. Of the 34 patients completing the study, half still reported a benefit from TENS at 1 year, although some patients found it took 3-4 weeks to work. CONCLUSION: TENS applied to the sacral dermatomes of neurological patients with urinary symptoms had a minimal effect on urodynamic data but significantly improved irritative urinary symptoms, 24-h urinary frequency, incontinence and clothes changing. The lack of effect on quality-of-life measures probably reflects the lack of sensitivity in the tools used in this group of patients. We therefore recommend using TENS in this often problematical group of patients.
37	McGuire	Treatment of motor and sensory detrusor instability by electrical stimulation	1983		15 patients with a variety of neural lesions.	A new application of electrical stimulation to inhibit detrusor activity has been used	The results were astonishingly good and the device was well tolerated. In patients treated successfully for detrusor instability an absence of urgency occurred as a by-product of electrical stimulation. Therefore, stimulation was used to treat uncomfortable bladder urgency without

							detrusor instability and was successful in the majority of patients.
38	Radziszewski	Transcutaneous electrical stimulation of urinary bladder in patients with spinal cord injuries	2009		The effect of urinary bladder stimulation was assessed in 22 patients (4 females, 18 males) with spinal injuries (19 with injuries to the lumbo-sacral spine and 3 with cervical spine injuries)	The treatment consisted of 30 procedures of transcutaneous electrical stimulation of the urinary bladder. A pulsed sinusoid current was used with a pulse duration of 200 ms, break duration of 1,000 ms, intensity of 15-20 mA, frequency of 50 Hz, and duration of stimulation of 15 min. A urodynamic study was carried out in each patient at baseline and on completion of the electrical stimulation therapy (immediately and after 2 months).	Electrical stimulation of the neurogenic urinary bladder produced increases in the cystometric bladder capacity and reduction in the amount of residual urine (72% of patients), with reduction of intravesical pressure at peak urine flow (59% of the patients). The dynamic aspects of micturition also improved with increased peak voiding velocity in 77.3% of the patients. More than half of the patients (57%) still had elevated intravesical pressures during micturition that posed a risk to the function of the upper urinary tract despite significant decreases following the stimulation therapy. Micturition, which was absent at baseline, was restored in three patients. No local complications were observed. CONCLUSIONS: Transcutaneous electrical stimulation of the urinary bladder in patients with neurogenic bladder dysfunction improves lower urinary tract function. Urodynamic studies executed 2 months after finishing TES show persistent results.
39	Slovak	The assessment of a novel electrical stimulation waveform recently introduced for the treatment of overactive bladder	2013				
40	Slovak	Non-invasive transcutaneous electrical stimulation in the treatment of overactive bladder	2015	Review article			There is promising evidence for the efficacy of a transcutaneous stimulation approach, but adequate standardisation of stimulation criteria and outcome measures will be necessary

41	Soomro	A crossover randomized trial of transcutaneous electrical nerve stimulation and oxybutynin in patients with detrusor instability	2001		A total of 13 male and 30 female patients were studied. Patients with frequency, urgency, urge incontinence and proved detrusor instability were studied with urodynamics, quality of life instruments, and frequency and volume charts.	Patients were randomized to transcutaneous electrical nerve stimulation or oxybutynin. After 6 weeks of treatment, they were reassessed and after a washout of 2 weeks, they were started on the second arm of treatment and reassessed 6 weeks later.	Functional capacity had increased and number of voids daily had decreased significantly compared with before treatment in both arms ($p < 0.005$). There were significant improvements in symptom specific quality of life measures but no changes were found on the global Short Form 36 (SF-36) quality of life questionnaire. The volume to first desire to void and first unstable contraction had increased significantly with oxybutynin but not with transcutaneous electrical nerve stimulation. Of 23 patients 7 were stabilized with treatment, including 2 with oxybutynin only, 2 with either nerve stimulation or oxybutynin and the remaining 3 with only nerve stimulation. Total bladder capacity did not change significantly with either treatment but patients noticed side effects more commonly with oxybutynin. CONCLUSIONS: Both treatments clearly improved subjective parameters. However, only oxybutynin showed significant improvements in objective urodynamic parameters. Transcutaneous electrical nerve stimulation can be used in patients who cannot take oxybutynin. Further studies are needed to show the long-term efficacy and cost analyses of nerve stimulation.
42	Svihra	Neuromodulative treatment of overactive bladder—noninvasive tibial nerve stimulation	2002		The study included 28 females of average age 54 year (range 45 to 63). Mean IPSS was 17 (range 12 to 21), mean index of quality of life IQOL	All patients suffered from overactive bladder (OAB) without bladder outlet obstruction. OAB was examined by the Behavioral urge score BUS (0.0—the best and 1.0—the worst	Group I with stimulation did achieve statistically significant changes following the treatment: decrease of mean IPSS from 17 +/- 3 points to 6 +/- 4 points after the treatment, increase in mean IQOL from 36 +/- 10 to 68 +/- 20 and decrease of mean BUS from 0.65 +/- 0.12 to 0.43 +/- 0.16.

					was 30 (range 12 to 78) and mean BUS score was 0.68 (range 0.50 to 0.86).	score), the International prostate symptom score IPSS (0--the best and 35--the worst score) and the Incontinence quality of life questionnaire IQOL (0.0--the worst and 1.0--the best index). The patients were divided into 3 groups: Group I--patients with electrode attached behind the medial ankle of the left lower extremity. The intensity of stimulation corresponded to 70% of the maximum amplitude of response from musculus abductor hallucis. Frequency of stimulation was 1 Hz and duration of the square impulse was 0.1 ms. Surface stimulation lasted 30 minutes and was repeated once a week. Group II--patients were treated by oral oxybutynin 5 mg t.i.d. Group III--patients without treatment. The BUS, IPSS, and IQOL were repeated after the treatment.	Group II had similar statistically significant differences after the treatment of OAB. Group III noted no changes in the complaints. CONCLUSION: Noninvasive stimulation had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated. (Fig. 1, Tab. 1, Ref. 18.).
43	Takahashi	Effect of sacral surface therapeutic electrical stimulation on the lower urinary tract in urinary disturbance	2001				

44	Tellenbach	Transcutaneous electrical nerve stimulation: an effective treatment for refractory non-neurogenic overactive bladder syndrome?,	2013	Prospective investigation	A consecutive series of 42 patients treated with TENS for refractory OAB. Mean age of the 42 patients (25 women, 17 men) was 48 years (range, 18-76).	Effects were evaluated using bladder diary for at least 48 h and satisfaction assessment at baseline, after 12 weeks of TENS treatment, and at the last known follow-up. Adverse events related to TENS were also assessed.	TENS was successful following 12 weeks of treatment in 21 (50 %) patients, and the positive effect was sustained during a mean follow-up of 21 months (range, 6-83 months) in 18 patients. Following 12 weeks of TENS treatment, mean number of voids per 24 h decreased significantly from 15 to 11 ($p < 0.001$) and mean voided volume increased significantly from 160 to 230 mL ($p < 0.001$). In addition, TENS completely restored continence in 7 (39 %) of the 18 incontinent patients. Before TENS, all 42 patients were dissatisfied or very dissatisfied; following 12 weeks of TENS treatment, 21 (50 %) patients felt satisfied or very satisfied ($p < 0.001$). No adverse events related to TENS were noted. CONCLUSIONS: TENS seems to be an effective and safe treatment for refractory OAB warranting randomized, placebo-controlled trials.
48	Vodusek	Detrusor inhibition induced by stimulation of pudendal nerve afferents	1986				A critical analysis of therapeutic vesicoinhibitory electrical stimulation is presented based on a study of ten patients with suprasacral spinal cord lesions and detrusor hyperreflexia. The detrusor contraction was either completely abolished, or the threshold of the contraction significantly increased, with electrical stimulation delivered to the dorsal nerves of penis (or clitoris) via surface electrodes. A current strength of 0.09 to 3.5 times the bulbocavernosus reflex threshold was used.
49	Walsh	Non-invasive antidromic neurostimulation: a simple effective method for improving bladder storage	2001				

50	Walsh	Transcutaneous sacral neurostimulation for irritative voiding dysfunction	1999		32 patients with refractory irritative voiding dysfunction (31 female and 1 male; mean age 47 years) were recruited to the study.	Ambulatory transcutaneous electrical neurostimulation was applied bilaterally to the third sacral dermatomes for 1 week. Symptoms of frequency, nocturia, urgency, and bladder pain were scored by each patient throughout and up to 6 months following treatment.	The mean daytime frequency was reduced from 11.3 to 7.96 ($p = 0.01$). Nocturia episodes were reduced from a mean of 2.6 to 1.8 ($p = 0.01$). Urgency and bladder pain mean symptom scores were reduced from 5.97 to 4.89 and from 1.48 to 0.64, respectively. After stopping therapy, symptoms returned to pretreatment levels within 2 weeks in 40% of the patients and within 6 months in 100%. Three patients who continued with neurostimulation remained satisfied with this treatment modality at 6 months. CONCLUSIONS: Transcutaneous third sacral nerve stimulation may be an effective and noninvasive ambulatory technique for the treatment of patients with refractory irritative voiding dysfunction. Following an initial response, patients may successfully apply this treatment themselves to ensure long-term relief.
51	Yokozuka	Effects and indications of sacral surface therapeutic electrical stimulation in refractory urinary incontinence	2004		Seven neurogenic bladder, five unstable bladder and six nocturia cases were investigated. Twelve were outpatients and six were residents.	Surface electrodes were placed at the posterior sacral foramina of S2 and S4. Stimulation conditions were duration 0.3 ms, frequency 20 Hz and maximum intensity. The stimulation was continued for 15 min twice daily for over one month.	Subjective findings showed incontinence frequency significantly decreased from 2.3 $\pm$ 1.4 times/day before therapy to 1.3 $\pm$ 2.0 times/day after therapy ($p < 0.01$); 55.5% of patients were improved or greatly improved. Objective findings showed that maximum vesical capacity (MVC) significantly increased from 208.2 $\pm$ 94.5 ml before therapy to 282.1 $\pm$ 66.8 ml ($p < 0.001$). Uninhibited contraction significantly decreased from 40.4 $\pm$ 31.4 cmH₂O before therapy to 25.7 $\pm$ 23.9 cmH₂O ($p < 0.01$); 44% of patients were improved or greatly improved. This therapy was effective in particular for cases whose MVC was small before applying SS-TES. CONCLUSION:

							SS-TES was effective in some patients with refractory urinary incontinence.
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Table C2: Children

1	Alcantara	TENS for the treatment of urinary urgency or urge-incontinence in children and adolescents- a Phase II clinical trial.	2015	Phase II clinical trial	25, 5-14 yrs.	Twenty TENS sessions were conducted, twice weekly, using a Quark® Dualpex 961 apparatus. The variables analyzed were daily micturition, dynamics ultrasonography of the lower urinary tract pre- and post-treatment and responses to a questionnaire on urinary leakage applied during each session.	RESULTS: The mean age of the 25 children participating in the study was 7.80 ± 2.22 years, most were female (92%) and had urge-incontinence (92%). The difference in urinary leakage pre- and post-treatment was statistically significant ($p = 0.04$); a decline in the symptom of urinary leakage was reported by all caregivers in children who completed the 20th session; the ultrasound parameters, although not statistically significant, showed a reduction in the percentage of children with detrusor contractions (from 62.5% to 43.5%); and a more adequate pre-micturition bladder volume of 4.2% post-treatment compared with 19.0% prior to treatment. DISCUSSION: The electro-stimulation carried out during the twice weekly sessions appeared to be effective and urinary incontinence declined in half of the patients from the 12th session onwards. However, there is a need for a study involving a larger number of patients to confirm the results obtained
4	Barroso	Posterior tibial nerve stimulation vs	2013	Prospective	22 consecutive children		We found that parasacral transcutaneous electrical nerve stimulation is more effective in

		parasacral transcutaneous neuromodulation for overactive bladder in children					resolving overactive bladder symptoms, which matches parental perception. However, there were no statistically significant differences in the evaluation by dysfunctional voiding symptom score, or in complete resolution of urgency or diurnal incontinence
9	De Oliveira	Parasacral TENS in children with primary monosymptomatic enuresis a prospective randomized clinical trial	2013	Prospective Randomized 29 girls 16 boys		Neural stimulation was performed with the electrodes placed in the sacral region (S2/S3). Sessions always followed the same pattern, with duration of 20 minutes, frequency of 10 Hz, a generated pulse of 700 μ s and intensity determined by the sensitivity threshold of the child	RESULTS: Rate of wet nights was 77% in controls and 78.3% in the experimental group at onset of treatment ($p = 0.82$), and 49.5% and 31.2%, respectively, at the end of treatment ($p = 0.02$). Analyzing the average rate of improvement, there was a significantly greater increase in dry nights in the group undergoing neural stimulation (61.8%) compared to controls (37.3%, $p = 0.0038$). At the end of treatment percent improvement in children undergoing electrical stimulation had no relation to gender ($p = 0.391$) or age ($p = 0.911$). Conclusion Treatment of primary monosymptomatic enuresis with 10 sessions of parasacral transcutaneous electrical neural stimulation plus behavioral therapy proved to be effective. However, no patient had complete resolution of symptoms.
14	Hagstroem	TENS for refractory daytime urinary urge incontinence	2009		27 children 5-14 with daytime Urge	4 weeks of 2 hours daily TENS. S3.	The active group had a significantly greater decrease in daily incontinence episodes compared to the sham treated group ($p < 0.01$). Transcutaneous electrical nerve stimulation did not alter maximal and average voided volumes. Conclusion Sacral transcutaneous electrical nerve stimulation seems superior to placebo for refractory daytime incontinence in children with overactive bladder. This effect does not seem to be a consequence of improved bladder reservoir function.

19	Kajbafzadeh	Transcutaneous interferential electrical stimulation for the management of non - neuropathic underactive bladder in children- a randomised clinical trial.,	2015	RCT	In all, 36 children with UAB without neuropathic disease [15 boys, 21 girls; mean (sd) age 8.9 (2.6) years] were enrolled and then randomly allocated to two equal treatment groups comprising IFES and control groups.	The control group underwent only standard urotherapy comprising diet, hydration, scheduled voiding, toilet training, and pelvic floor and abdominal muscles relaxation. Children in the IFES group likewise underwent standard urotherapy and also received IFES. Children in both groups underwent a 15-session treatment programme twice a week. A complete voiding and bowel habit diary was completed by parents before, after treatment, and 1 year later. Bladder ultrasound and uroflowmetry/electromyography were performed before, at the end of treatment course, and at the 1-year follow-up.	The mean (sd) number of voiding episodes before treatment was 2.6 (1) and 2.7 (0.76) times/day in the IFES and control groups, respectively, which significantly increased after IFES therapy in IFES group, compared with only standard urotherapy in the control group [6.3 (1.4) vs 4.7 (1.3) times/day, $P < 0.002$]. The mean (sd) bladder capacity before treatment was 424 (123) and 463 (121) mL in the control and IFES groups, respectively, which decreased significantly at 1 year after treatment in the IFES group compared with the controls, at 227 (86) vs 344 (127) mL ($P < 0.01$). Maximum urine flow increased and voiding time decreased significantly in the IFES group compared with controls at the end of treatment sessions and 1 year later ($P < 0.05$). All the children had abnormal flow curves at the beginning of the study. The flow curve became normal in 14/18 (77%) of the children in the IFES group and six of 18 (33%) in the control group by the end of follow-up ($P < 0.007$). At the end of the treatment course, night-time wetting was improved in all children who had this symptom before the treatment in the IFES group ($P < 0.01$). CONCLUSION: Combining IFES and urotherapy is a safe and effective therapy in the management of children with UAB.
20	Lecompte	Evaluation of transcutaneous electrical posterior tibial nerve stimulation for the treatment of	2015		Eight children: 4 with anorectal malformations, 3 with neurological causes (1 medullary	treated with PTNS. Six children had associated urinary leaks.	After six months, five patients had no more fecal leakage, two patients were improved and one did not respond. Five out of the 6 patients with urinary leaks were continent at 6 months.

		fecal and urinary leaks in children- preliminary results.			lipoma, 1 Arnold Chiari malformation, 1 sacrococcygeal teratoma) and 1 with Hirschsprung's disease presenting with serious anal incontinence, despite extensive bowel management during at least 2 years,	Jorge-Wexner score for defecation and Schurch score for urine were used before treatment and after the second and sixth months of stimulation.	CONCLUSION: PTNS is a noninvasive technique and painless modality which seems to be effective for the treatment of fecal and urinary leaks in children even with congenital digestive pathologies or neurological malformations. These results will be confirmed in a prospective study.
23	Lordelo	Transcutaneous electrical nerve stimulation in children with overactive bladder: a randomized clinical trial	2010	RCT	We prospectively randomized 25 girls and 12 boys with an average age of 7.6 years (range 4 to 12) into the test (active treatment) or sham (superficial scapular electrical stimulation) group	A total of 20 sessions, 20 minutes each (10 Hz) were performed 3 times weekly. The criteria used to evaluate the rate of success were 1) self-reported cure, or significant, mild or no improvement; 2) visual analogue scale (level of success 0 to 10); 3) percent improvement; 4) modified Toronto score; and 5) maximum voided volume, average voided volume and number of voids daily based on bladder diary entries. After completion of the 20 sessions controls who were not cured underwent active treatment.	A total of 21 patients in the test group and 16 in the sham group underwent treatment. Among the active treatment group 61.9% of parents reported cure. In the sham group no parent reported cure ($p < 0.001$). Regarding visual analogue scale a score of 10 was indicated by 13 parents in the test group, while 1 parent in the sham group indicated a score of 9 ($p = 0.002$). Additionally 100% improvement was reported by 12 parents in the test group and no parent in the sham group. Toronto score improved significantly in the test group ($p < 0.001$) and sham group ($p = 0.008$). However, the score was reduced more significantly in the test group compared to the sham group ($p = 0.011$). In the test group average and maximum voided volumes showed a statistically significant increase and the number of voids daily decreased. After superficial scapular electrical stimulation 13 of the 16 patients who underwent parasacral transcutaneous electrical nerve stimulation were cured. CONCLUSIONS: This is the first known randomized clinical trial to demonstrate that parasacral transcutaneous

							electrical nerve stimulation is effective in the treatment of children with overactive bladder.
26	Moeller	TENS Increases Rectal Activity in Children	2015	Double blind, placebo controlled	20 children with OAB (mean age 8.6 ± 1.8 years; 7 girls), 48-hour urodynamic monitoring including rectal manometry was performed. After 24-hours of baseline investigation without stimulation the children were randomised to either active TENS (n = 10) or placebo (n = 10).	Surface electrodes were placed over the sacral bone. The exterior of active and placebo stimulators was identical. Starting in the morning, the children received either continuous TENS stimulation or placebo until bedtime. Rectal contractions were defined as pressure runs exceeding 5 cm H₂O and lasting ≥ 3 minutes.	At baseline there was no significant difference in proportion of time with rectal contractions in the 2 groups (TENS group median 31% [range 12%-66%] vs placebo group median 31% [range 10%-66%]; P=0.75); however, on the day of stimulation there was more time with rectal contractions in the group receiving TENS (median 51% [range 25%-78%]) compared with placebo (median 32% [range 4%-68%]; P=0.02). Also, there was an increase in time with rectal contractions in the TENS group (P=0.007) but not in the placebo group (P=0.39). The night after the TENS was disabled, rectal activity in both groups returned to baseline level. CONCLUSIONS: TENS acutely increases time with rectal contractions in children undergoing urodynamic investigation. The effect disappears when the stimulator is turned off.
30	Patidar	Transcutaneous posterior tibial nerve stimulation in pediatric overactive bladder- A preliminary report.	2015	single-blinded, prospective, sham controlled randomized trial	40 children with non-neurogenic OAB refractory to behavioural and anticholinergic therapy were randomized either to test group or sham group.	Neuromodulation was performed using two self-adhesive electrodes cephalad to medial malleolus. In test group the stimulation intensity 0 to 10 mA, pulse width of 200 μs frequency of 20 Hz. In sham group patch electrodes were applied to simulate the test group but no stimulation was given.	On assessment of subjective improvement of OAB symptoms, 66.66% patients reported cure and 23.81% patients reported significant improvement of symptoms in test group whereas in sham group only 6.25% patients reported significant improvement. In test group 71.42% patients reported complete improvement in incontinence whereas in sham group only 12.5% patient reported complete improvement. The AVV, MVV and NV improved significantly in test group (p <0.001) as compared to sham group (Table). DISCUSSION:

					In both groups, weekly session of 30 min was given for a period of 12 weeks. The OAB symptoms, severity of incontinence, number of voids daily (NV), average voided volume (AVV) and maximum voided volume (MVV) were evaluated before and after treatment.	The present study is unique as none of the earlier studies in children were sham controlled. It is also first PTNS study in which patch electrodes were used; therefore it is completely noninvasive. This technique provides better patient acceptability and compliance. This study proved that, there is a definite effect of PTNS as compared to placebo because when patients from sham group were treated actively, they responded well. The present study has few limitations as it has relatively short follow-up period of 12 weeks. Relapse of OAB symptoms and maintenance schedule of PTNS need to be assessed further. CONCLUSION: Transcutaneous PTNS is superior to placebo in treatment of non-neurogenic overactive bladder in children. In view of its effectiveness and acceptability we believe that transcutaneous PTNS should be part of pediatric urology armamentarium for treatment of OAB.
32	Quintiliano	Parasacral TENS vs oxybutynin for the treatment of overactive bladder in children	2015		Nine boys and 19 girls with a mean $\pm$ SD age of 6.4 ± 2.18 years were randomly divided into group 1- parasacral transcutaneous electrical stimulation with placebo drug and group 2- oxybutynin with sham scapular electrical therapy.	Success was assessed by 1) the rate of complete symptom resolution, 2) a visual analog scale of 0 to 10, 3) the dysfunctional voiding score system, 4) voiding diary records, 5) Rome III criteria and 6) side effect frequency in each group. A total of 13 and 15 patients were randomized to groups 1 and 2, respectively. Symptoms completely resolved in 6 patients in group 1 (46%) and 3 in group 2 (20%) ($p = 0.204$). A statistically significant improvement was found in the 2 groups in the dysfunctional voiding score system and voiding diary records. However, no statistically significant difference was found between the groups in the visual analog scale score, voiding frequency, and maximum and mean voided volume ($p = 0.295, 0.098, 0.538$ and 0.650, respectively). Constipation improved in 100% of group 1 patients but in only 55% in group 2 ($p = 0.031$ vs 0.073). Group 1 showed no side effects while dry

						mouth, hyperthermia and hyperemia developed in 58%, 25% and 50% of group 2 patients ($p = 0.002$, 0.096 and 0.005, respectively). Treatment was discontinued by 13.3% of patients in group 2. CONCLUSIONS: Parasacral transcutaneous electrical stimulation was as effective as oxybutynin to treat overactive bladder in children. However, transcutaneous parasacral electrical stimulation was more effective against constipation and showed no detectable side effects. Oxybutynin was more effective for decreasing voiding frequency.
34	Sillén	Effects of (TENS) on overactive bladder symptoms in children a randomized controlled trial.	2014		Sixty-two children with symptoms of OAB and incontinence were included.	The children were randomized either to standard urotherapy treatment alone or a combination of standard urotherapy and TENS. The effect variables were taken from a voiding-drinking diary: number of voiding, number of incontinence episodes, and maximum voided volume. Both treatment groups had good treatment results, with no significant difference between the groups. In the standard treatment group 13/28 (46%) were completely dry and 11/28 (40%) had a decrease in incontinence episodes, compared to 16/24 (67%) and 3/24 (13%), respectively, in the standard+TENS group ($p=0.303$). The number of voiding decreased in two-thirds of the patients in both groups. However, maximal voided volume only increased in the standard treatment group. Subjectively 72% and 80% considered themselves significantly improved or free of symptoms. Previous treatment was registered in 15/55 (27%). All efficacy variables decreased in those with previous treatment, but with no difference between the standard and standard+TENS treatment groups. The only difference noted was when comparing the children without previous treatment in the groups: a significantly higher proportion were completely dry in the TENS group (12/18 [71%] versus 10/22 [48%], $p=0.05$).

							CONCLUSION: Our results showed no significant difference overall in treatment response to OAB symptoms between urotherapy only and urotherapy+TENS, whereas a tendency to difference was found in children without previous treatment. Thus with good urotherapy support, TENS only seems to have marginal additional effects on OAB symptoms.
46	Tugtepe	The effectiveness of transcutaneous electrical neural stimulation therapy in patients with urinary incontinence resistant to initial medical treatment or biofeedback	2015		>5 years. 27 patients.	TENS was performed on S3 dermatome, every day for 3 months. Each session lasted 20 min 10 Hz 350 μ s. Intensity was determined by the child's sensitivity threshold	After 3 months of TENS; a statistically significant decrease was observed in the number of patients with frequency, urge incontinence, urinary tract infections and constipation. There was a decrease in the number of patients with fractionated voiding, although this change was not statistically significant. Similarly, for uroflow-EMG parameters; bladder capacity, Qmax, Qave and flow time increased while voiding time and PVR decreased. Changes seen in bladder capacity, Qmax and PVR were statically significant, while other changes were not. Patients' response rates after 3 months of TENS were; complete response in 70.4%, partial response in 22.2% and no response in 7.4%

Table C3 Faecal incontinence

8	Cohen-Zubary	Home electrical stimulation for women with fecal incontinence:	2015	preliminary randomized controlled trial	36 women		Results Only females who received home electrical stimulation (HES) reported a significant improvement in Vaizey incontinence score ($p = 0.001$), anxiety ($p = 0.046$), and in frequency of leaked solid stool ($p = 0.013$). A significant improvement in pelvic floor muscle strength was achieved by both groups. HES was much cheaper compared to the cost of standardized biofeedback training (SBT) Conclusions Home electrical stimulation may offer an alternative to standardized biofeedback training as it is effective and generally well-tolerated therapy for females with fecal incontinence.
16	Horrocks	Systematic review of tibial nerve stimulation to treat faecal incontinence.	2014	Systematic review		Two forms of tibial nerve stimulation are used to treat faecal incontinence (FI): percutaneous (PTNS) and transcutaneous (TTNS) tibial nerve stimulation. This article critically appraises the literature on both procedures. METHODS: A systematic review was performed adhering to the PRISMA framework. A comprehensive literature search was conducted, with	Twelve articles met eligibility criteria; six related to PTNS, five to TTNS, and one to both procedures. These included ten case series and two randomized clinical trials (RCTs). Case series were evaluated using the National Institute for Health and Care Excellence quality assessment for case series, scoring 3-6 of 8. RCTs were evaluated using the Jadad score, scoring 4 of a possible 5 marks, and the Cochrane Collaboration bias assessment tool. From one RCT and case series reports, the success rate of TTNS was 0-45 per cent. In an RCT of TTNS versus sham, no patient had a reduction in weekly FI episodes of 50 per cent or more, whereas in an RCT of PTNS versus TTNS versus sham, 82 per cent of patients undergoing PTNS, 45 per cent of those having TTNS, and 13 per cent of patients in the sham group had treatment success.

						systematic methodological quality assessment and data extraction. Summary measures for individual outcome variables are reported.	CONCLUSION: PTNS and TTNS result in significant improvements in some outcome measures; however, TTNS was not superior to sham stimulation in a large, adequately powered, RCT.
18	Jimenez	Efficacy and quality of life after transcutaneous posterior tibial neuromodulation for faecal incontinence.	2015	A prospective non-randomized cohort study	All patients with faecal incontinence who met the inclusion criteria were included Twenty-seven patients of median age 67 (interquartile range 60-69) years and a male to female ratio of 1/6 were included.	treated as outpatients during a 3-month period by unilateral neuromodulation of the posterior tibial nerve. The patients were followed 3-monthly for 1 year. Severity scales, a bowel diary and quality of life scales were evaluated prospectively before and after treatment. Faecal incontinence was for solid stools in 48.1% of patients with urgency in 55.6%. About one-third (34.6%) had a sphincter defect on ultrasound and reduction of anal canal pressure in 85.2%.	RESULTS: There was a significant improvement in episodes of incontinence on the Wexner score and visual analogue scale assessment and a decrease in the number of episodes of incontinence per unit time. The Fecal Incontinence Quality of Life score was improved at the end of the follow-up. No adverse effects were observed. The cost of the treatment was €135 per patient. CONCLUSION: Transcutaneous posterior tibial nerve neuromodulation provides good treatment for faecal incontinence in terms of efficacy and quality of life.
21	Leroi	Transcutaneous electrical tibial nerve stimulation in the treatment of fecal incontinence: a randomized trial	2012	randomized, double-blind, sham-controlled trial	144 patients aged 30-82 years from nine centers were randomly assigned to receive either active or sham	The primary end point was the response to treatment based on the number of incontinence and urgency episodes. Secondary end points	No statistically significant difference was seen between active and sham TENS in terms of an improvement in the median number of FI/urgency episodes per week. Thirty-four patients (47%) who received the active TENS treatment exhibited a >30% decrease in the FI

					stimulations for 3 months	were severity scores, quality of life scores, delay to postpone defecation, patient self-assessment of treatment efficacy, physician assessment of TENS efficacy, anorectal manometry, and adverse events.	severity score compared with 19 patients (27%) who received the sham treatment (odds ratio 2.4, 95% confidence interval 1.1-5.1, P=0.02). No differences in delay to postpone defecation, patient self-assessment of treatment efficacy, or anorectal manometry were seen between the two groups. The evaluating physicians rated the active stimulations as more effective than the sham stimulations (P=0.01). One minor therapy-related adverse event was observed (1.5%) (see Supplementary Consort 1b). CONCLUSIONS: We failed to demonstrate any benefit of TENS on our primary end-point
45	Thomas	Bilateral transcutaneous posterior tibial nerve stimulation for the treatment of fecal incontinence.	2013	single-group pilot prospective study.	Twenty patients with fecal incontinence were recruited consecutively. Conservative therapy had failed to improve the fecal incontinence in all 20 patients.	All patients received 30 minutes of daily bilateral stimulation for 6 weeks. The bilateral stimulation was administered by each patient at home. No further stimulation was given after 6 weeks, and the patients were followed up until their symptoms returned to the prestimulation state (baseline).	Seventeen patients completed 6 weeks of treatment. Two patients achieved complete continence. Ten (59%) achieved a $\geq 50\%$ reduction in frequency of incontinent episodes. Overall, there was a significant reduction in median (interquartile range) frequency of incontinent episodes per week of 6 (8.25) to 2 (7.25) ($p = 0.03$). There was a significant improvement in the ability to defer defecation from 3 (4) to 5 (8) minutes ($p = 0.03$). There was no change in the St Mark's incontinence score. One domain of the Rockwood fecal incontinence quality-of-life score and of the Medical Outcomes Study Short Form 36 score improved significantly. LIMITATIONS: This study was limited by its small size and its lack of blinding and control. CONCLUSIONS: Bilateral transcutaneous posterior tibial nerve stimulation appears to be a cheap and effective treatment for fecal incontinence. It can easily be used by the patient at home

47	Vitton	Transcutaneous electrical posterior tibial nerve stimulation for faecal incontinence-effects on symptoms and quality of life.	2010		Twenty-four patients suffering from faecal incontinence treated 20 min per day by applying transcutaneous electrical posterior tibial nerve stimulation for 3 months. A clinical evaluation was performed at the end of treatment, with Wexner's score and analogical scales for symptoms. After 3 months, if the treatment was successful, patients were proposed to continue on the treatment. Predictive factors such as age, symptom duration, proctologic history, obstetrical history, ano-rectal manometric data and quality-of-life score were also analysed.	RESULTS: At 3 months, 13 patients (54%) reported a significant symptomatic improvement with a significant modification in the Wexner's score (14 vs 12, $p < 0.025$). At a median follow-up of 15 months, there were still 11 patients whose condition was improved. CONCLUSION: This study shows encouraging mid-term results, and even if further randomized studies are necessary, transcutaneous electrical posterior tibial nerve stimulation may be a new and easy-to-use therapeutic option to treat faecal incontinence
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D: Chronic Pelvic Pain Relief

Search terms: chronic pelvic pain electrical stimulation

Results:

Reference 1 refers only to References 2,3,5 & 6

Reference 4 is withdrawn

Reference 5 relates to penile electrodes, which are outside of the scope of this evaluation

References 2 & 3 used 8Hz stimulation compared with 4Hz in the Sure Pro

No adverse effects related to TENS were reported.

Conclusion:

There is weak evidence that low frequency intravaginal TENS help alleviate chronic pelvic pain in women.

There is no evidence of increased Risk with this application

Risk/Benefit calculation remains acceptable

Table C3 Chronic Pelvic Pain

1	Vincent	Therapies Targeting the Nervous System for Chronic Pelvic Pain Relief	2015	RCOG Scientific impact paper	Transcutaneous electrical nerve stimulation (TENS) is a familiar form of analgesia used during labour. The exact mechanism by which it exerts an analgesic effect is not known. It had long been assumed to work via the ‘gate-control’ theory, whereby activity in large diameter Aβ fibres inhibits activity in smaller fibres (Aδ and C: those transmitting pain) from the same segments. However, electrical stimulation of small fibres alone can also produce segmental and extrasegmental inhibition leading to analgesia.¹⁴ Furthermore, the use of low-frequency electrical stimulation increases the release of endogenous opioids, thereby further reducing pain in both acute and chronic situations.²⁸ It has been shown to be effective in reducing pain in men with CPPS/prostatitis^{29,30} but has not been evaluated in women with CPP specifically. In view of the location of pain in women with CPP, intravaginal electrical stimulation (IVES) has been proposed as an alternative strategy. Preliminary data suggested that IVES is associated with a significant reduction in pain and dyspareunia, with the reduction in pain being maintained at 7 months’ follow-up.³¹ More recently, IVES for CPP was assessed in a placebo- (sham stimulation) controlled randomised trial.³² This confirmed that active stimulation was superior to sham, with a significant reduction in pain intensity at the end of the 5-week course of treatment. However, there was no long term follow-up in this study. Cites articles 2,3,5,6 below		
2	de Oliveira Bernardes	intravaginal electrical stimulation for the treatment of chronic pelvic pain	2005		Between May 2002 and February 2004, 24 women with CPP with no apparent cause were evaluated.	They underwent 10 sessions of intravaginal electrical stimulation. A program for measuring chronic diffuse pain, with a frequency of 8 Hz, variation in intensity and frequency, pulse length of 1 msec, and adjustment to the bearable intensity of each individual patient	Intravaginal electrical stimulation was effective in alleviating pain in women with CPP, as evaluated at the end of treatment and 2 weeks, 4 weeks and 7 months after completion of treatment (p<0.05). There were significantly fewer complaints of dyspareunia following treatment (p = 0.0005). CONCLUSION: Intravaginal electrical stimulation is effective in the alleviation of pain in women with CPP.

						(in milliamps) was utilized. Treatment consisted of 30-minute applications, 2 or 3 times per week	
3	de Oliveira Bernardes	Use of intravaginal electrical stimulation for the treatment of chronic pelvic pain	2010	randomized, double-blind, crossover clinical trial	26 women were randomly allocated to active (group I, n = 15) or placebo (group II, n = 11) IVES.	All women underwent 10 30-minute, twice-weekly sessions. The groups were then crossed over for a further 10 sessions. Pain was evaluated using a visual analog scale (VAS) before and after each series. Frequency of 8Hz, variation in intensity and frequency, pulse length of 1msec, and adjustment to the bearable intensity of each individual patient (in milliamps) was utilized.	At the end of the first series, 5 of 11 women who initiated with the placebo had a VAS pain score > 3 (p = 0.0253); however, when they crossed over to active IVES, only 1 had a VAS pain score > 3 at the end of the series (p = 0.0143). In the 15 women who initiated with active IVES, 2 had a score > 3 at the end of the series (p = 0.0005); however, when they crossed over to the placebo, 3 had a VAS pain score > 3 at the end of treatment (p = 0.0833). After the 2 sessions, 54.6% who initiated with placebo and 80% who initiated with active IVES had a VAS pain score < 3. CONCLUSION: Intravaginal electrical stimulation was more effective than a placebo in alleviating pain in women with CPP
5	Schneider	Refractory chronic pelvic pain syndrome in men: can transcutaneous electrical nerve stimulation help?	2013	Prospective	A consecutive series of 60 men treated with TENS for refractory CPPS was evaluated prospectively at an academic tertiary referral centre.	TENS was performed at home with an Elpha 4 Conti (Danmeter A/S; Odense, Denmark) stimulation device applying PEN2 circular penile electrodes (Sugar	The mean (95% confidence interval, CI; range) age of the 60 men was 46.9 (43.5-50.3; 21-82) years. TENS was successful after 12 weeks of treatment in 29 (48%) patients and a positive effect was sustained during a mean (95%, CI; range) follow-up of 43.6 (33.2-56; 6-88) months in 21 patients. After 12 weeks of TENS treatment, mean (95% CI) pain visual analogue scale

						International, Chevillon-sur-Huillard, France) (Fig. 1). Bipolar stimulation of 80 Hz and 150 ms at the sensory threshold level was used for 30 min, twice a day. The effects of treatment were evaluated by a pain diary and by the quality of life item of the National Institutes of Health Chronic Prostatitis Symptom Index at baseline, after 12 weeks of TENS treatment, and at last known follow-up. Adverse events related to TENS were also assessed.	decreased significantly (P < 0.001) from 6.6 (6.3-6.9) to 3.9 (3.2-4.6). Patients' quality of life changed significantly after TENS treatment (P < 0.001). Before TENS, all 60 patients felt mostly dissatisfied (n = 17; 28%), unhappy (n = 28; 47%) or terrible (n = 15; 25%). After 12 weeks of TENS treatment, 29 (48%) patients felt mostly satisfied (n = 5), pleased (n = 18) or delighted (n = 6). No adverse events related to TENS were noted. CONCLUSION: TENS may be an effective and safe treatment for refractory CPPS in men, warranting randomized, placebo-controlled trials.
6	Sikiru	Transcutaneous Electrical Nerve Stimulation (TENS) in the Symptomatic Management of Chronic Prostatitis/Chronic Pelvic Pain Syndrome:	2008	A Placebo-Control Randomized Trial Design: A pretest, posttest randomized double blind design was	Twenty-four patients diagnosed with chronic prostatitis-category IIIA and IIIB.	Pre treatment pain level was assessed using the NIH-CP (pain domain) index. The TENS group received TENS treatment, 5 times per week for a period of 4 weeks (mean treatment frequency, intensity, pulse width and	All subjects were placed on antibiotics throughout the treatment period. Outcome measures: Post-treatment pain level was also assessed using NIH-CP pain index. Result: Findings of the study revealed significant effect of TENS on chronic prostatitis pain at p < 0.05.

				used in data collection.		duration of 60Hz, 100µS, 25mA and 20 minutes respectively). The Analgesic group received no TENS treatment but continued analgesics; the Control group received no TENS and Analgesic but placebo.	Conclusion: TENS is an effective means of non-invasive symptomatic management of chronic prostatitis pain.
7	Rees Prostatitis Expert Reference Group (PERG)	Diagnosis and treatment of chronic bacterial prostatitis and chronic prostatitis/chronic pelvic pain syndrome: a consensus guideline	2015			The following specialist physiotherapy treatment options may be considered: pelvic floor re-education; local pelvic floor relaxation; biofeedback; general relaxation; deep relaxation/mindfulness; trigger point release; myofascial release; stretches; exercise for pain management; TENS; acupuncture for trigger point release and pain management; bladder retraining.	
8	Tirlapur	Nerve stimulation for chronic pelvic pain and bladder pain syndrome:	2013	systematic review		Chronic pelvic pain (CPP) and bladder pain syndrome (BPS) can have a negative impact on quality of life. Neuromodulation has been suggested as a possible treatment for refractory pain. To assess the effectiveness of tibial and sacral nerve stimulation in the treatment of BPS and CPP. We searched until July 2012: the Cochrane Library, EMBASE (1980–2012), Medline (1950–2012), Web of knowledge (1900–2012), LILACS (1982–2012) and SIGLE (1990–2012) with no language restrictions. We manually searched through bibliographies and conference proceedings of the International Continence Society. Randomized and prospective quasi-randomized controlled studies vs. sham nerve stimulation treatment or usual care of patients with CPP and BPS who underwent sacral or tibial nerve stimulation were included. Any studies involving transcutaneous stimulation were excluded. The outcome was a cure or improvement in symptoms. Three studies with 169 patients treated with tibial nerve stimulation were included; two for CPP and one for BPS. There were improvements in pain, urinary and quality of life scores. There were no	

						reported data for sacral nerve stimulation. There is scanty literature reporting variable success of posterior tibial nerve stimulation in improving pain, urinary symptoms and quality of life in CPP and BPS. In view of the dearth of quality literature, a large multi-centered clinical trial investigating the effectiveness of electrical nerve stimulation to treat BPS and CPP along with the cost-analysis of this treatment is recommended
9	Udoji	New directions in the treatment of pelvic pain	2013	Review		Transcutaneous electrical stimulation is associated with a moderate degree of success in this population [5]. Intravaginal electrical stimulation is a more invasive type of transcutaneous electrical stimulation. Its efficacy was tested with a randomized, double-blind crossover trial of 26 women with CPP. The authors assessed pain severity at the end of 20 weeks of twice-weekly 30-min therapy sessions, reporting that it was associated with greater pain relief than placebo [3].

3: Conclusions

- 1 Review of new clinical evidence confirms that there is no substantive change to the Elise/Viva Clinical Evaluation Update of September 2015
- 2 The Clinical Evaluations of the itouch Sure and Elise are applicable to the Sure Pro
- 3 The Pelvic Floor Workout programmes use settings similar to those referred to in published clinical trials for Urge and Stress incontinence and are similar to those commercially widely available for 16 years. They introduce no change to the risk/benefit calculation.
- 4 There is weak evidence for the efficacy of TPTNS, and no reported TENS-related adverse effects. Addition of TPTNS introduces no change to the Risk/Benefit calculation
- 5 There is weak evidence for the efficacy of low frequency TENS for the relief of chronic pelvic pain. Addition of TENS for pain relief introduces no change to the Risk/Benefit calculation

6 Conclusion

The risks identified in the risk management documentation were addressed by reference to existing standards.
The updated review of clinical data has revealed no additional risks.

The review of Clinical Data has revealed no information to suggest that the Sure Pro presents any additional risk, or any less performance than those products already on the market.

The comparison between itouch Sure and Sure Pro technical characteristics has revealed no information to suggest that they present any additional risk, or any less performance than the itouch Sure.

The additional features of the Sure Pro make no significant difference to the Risk/Benefit calculation

The minor undesirable side effects reported in clinical trials constitute an acceptable risk when weighed against the performances intended.



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References for Tibial Nerve Stimulation

1. Alcantara AC, Mello MJ, Costa e Silva EJ, Silva BB, Ribeiro Neto JP. TENS for the treatment of urinary urgency or urge-incontinence in children and adolescents- a Phase II clinical trial., *J Bras Nefrol*. 2015 Jul-Sep; 37 (3):422-6. doi: 10.5935/0101-2800.20150065.
2. G. Amarenco, S. Sheikh Ismael, A. Even-Schneider, P. Raibaut, S. Demaille-Wlodyka, B. Parratte and J. Kerdraon, Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder, *J Urol*. 2003 Jun;169(6):2210-5.
3. Ammi M, Chautard D, Brassart E, Culty T, Azzouzi AR, Bigot P., Transcutaneous posterior tibial nerve stimulation- evaluation of a therapeutic option in the management of anticholinergic refractory overactive bladder. *Int Urogynecol J*. 2014 Aug;25(8):1065-9. doi: 10.1007/s00192-014-2359-0. Epub 2014 Mar 6
4. Barroso U Jr, Viterbo W, Bittencourt J, Farias T, Lordêlo P. Posterior tibial nerve stimulation vs parasacral transcutaneous neuromodulation for overactive bladder in children., *J Urol*. 2013 Aug;190(2):673-7. doi: 10.1016/j.juro.2013.02.034. Epub 2013 Feb 16.
5. J. Booth, S. Hagen, D. McClurg, C. Norton, C. Macinnes, B. Collins, *et al.*, A feasibility study of transcutaneous posterior tibial nerve stimulation for bladder and bowel dysfunction in elderly adults in residential care, *J Am Med Dir Assoc*, 14 (2013), pp. 270–274
6. W.F. Bower, K.H. Moore, R.D. Adams, R. Shepherd, A urodynamic study of surface neuromodulation versus sham in detrusor instability and sensory urgency, *J Urol*, 160 (6 Pt 1) (1998), pp. 2133–2136
7. S.E. Bristow, S.T. Hasan, D.E. Neal, TENS: a treatment option for bladder dysfunction, *Int Urogynecol J Pelvic Floor Dysfunct*, 7 (1996), pp. 185–190
8. N Cohen-Zubary , R Gingold-Belfer , I Lambort, N Wasserberg, H Krissi, S Levy, Y Niv, R Dickman, Home electrical stimulation for women with fecal incontinence: a preliminary randomized controlled trial, *International Journal of Colorectal Disease* April 2015, Volume 30, Issue 4, pp 521-528
9. de Oliveira LF, de Oliveira DM, da Silva de Paula LI, de Figueiredo AA, de Bessa J Jr, de Sá CA, Bastos Netto JM. , Parasacral TENS in children with primary monosymptomatic enuresis a prospective randomized clinical trial., *J Urol*. 2013 Oct;190(4):1359-63. doi: 10.1016/j.juro.2013.03.108. Epub 2013 Mar 29.
10. M. de Seze, P. Raibaut, P. Gallien, A. Even-Schneider, P. Denys, V. Bonniaud, *et al.*, Transcutaneous posterior tibial nerve stimulation for treatment of the overactive bladder syndrome in multiple sclerosis: results of a multicentre prospective study, *Neurourol Urodyn*, 30 (2011), pp. 306–311
11. M.V. Fjorback, F.S. Van Rey, N.J. Rijkhoff, M. Nohr, T. Petersen, J.P. Heesakkers, Electrical stimulation of sacral dermatomes in multiple sclerosis patients with neurogenic detrusor overactivity, *Neurourol Urodyn*, 26 (2007), pp. 525–530
12. Guo ZF, Liu Y, Hu GH, Liu H, Xu YF., TENS in the treatment of patients with poststroke urinary incontinence, *Clin Interv Aging*. 2014 May 23;9:851-6. doi: 10.2147/CIA.S61084. eCollection 2014.
13. Hu Y, Xie XB, Pang LY, Li XH, Luk KD., Current density distribution under surface electrode on posterior tibial nerve electrical stimulation, *Conf Proc IEEE Eng Med Biol Soc*. 2005;4:3650-2.
14. S. Hagstroem, B. Mahler, B. Madsen, J.C. Djurhuus, S. Rittig, Transcutaneous electrical nerve stimulation for refractory daytime urinary urge incontinence, *J Urol*, 182 (4 Suppl.) (2009), pp. 2072–2078
15. S.T. Hasan, W.A. Robson, A.K. Pridie, D.E. Neal, Transcutaneous electrical nerve stimulation and temporary S₃ neuromodulation in idiopathic detrusor instability, *J Urol*, 155 (1996), pp. 2005–2011
16. Horrocks EJ, Thin N, Thaha MA, Taylor SJ, Norton C, Knowles CH. Systematic review of tibial nerve stimulation to treat faecal incontinence. *Br J Surg*. 2014 Apr;101(5):457-68

17. Iqbal F, Collins B, Thomas GP, Askari A, Tan E, Nicholls RJ, Vaizey CJ. Bilateral transcutaneous tibial nerve stimulation for chronic constipation. *Colorectal Dis.* 2015 Aug 31
18. Jiménez-Toscano M, Vega D, Fernandez-Cebrián JM, Valle Martín B, Jiménez-Almonacid P, Rueda Orgaz JA. Efficacy and quality of life after transcutaneous posterior tibial neuromodulation for faecal incontinence. *Colorectal Dis.* 2015 Aug;17(8):718-23
19. Kajbafzadeh AM, Sharifi-Rad L, Ladi-Seyedian SS, Mozafarpour S. Transcutaneous interferential electrical stimulation for the management of non -neuropathic underactive bladder in children- a randomised clinical trial., *BJU Int.* 2015 Jun 18. doi: 10.1111/bju.13207.
20. Lecompte JF, Hery G, Guys JM, Louis-Borrione C Evaluation of transcutaneous electrical posterior tibial nerve stimulation for the treatment of fecal and urinary leaks in children- preliminary results. *J Pediatr Surg.* 2015 Apr;50(4):630-3. doi: 10.1016/j.jpedsurg.2014.05.033. Epub 2014 Jul 4.
21. A.M. Leroi, L. Siproudhis, I. Etienney, H. Damon, F. Zerbib, G. Amarenco, *et al.*, Transcutaneous electrical tibial nerve stimulation in the treatment of fecal incontinence: a randomized trial (CONSORT 1a), *Am J Gastroenterol*, 107 (2012), pp. 1888–189
22. Liu Y, Xu G, Luo M, Teng HF. Effects of TENS at Two Frequencies on Urinary Incontinence in Poststroke Patients- A Randomized Controlled Trial. *Am J Phys Med Rehabil.* 2015 Aug 7.
23. P. Lordelo, A. Teles, M.L. Veiga, L.C. Correia, U. Barroso Jr., Transcutaneous electrical nerve stimulation in children with overactive bladder: a randomized clinical trial, *J Urol*, 184 (2010), pp. 683–689
24. Manríquez V, Guzmán R, Naser M, Aguilera A, Narvaez S, Castro A, Swift S, Digesu GA. Transcutaneous posterior tibial nerve stimulation versus extended release oxybutynin in overactive bladder patients. A prospective randomized trial. *Eur J Obstet Gynecol Reprod Biol.* 2015 Oct 20;196:6-10.
25. G Mariotti, S Salciccia, M Innocenzi, A Gentilucci, A Fasulo, V Gentile, A Sciarra, Recovery of Urinary Continence After Radical Prostatectomy Using Early vs Late Pelvic Floor Electrical Stimulation and Biofeedback-associated Treatment, *Urology* Volume 86, Issue 1, July 2015, Pages 115–121
26. Moeller Joensson I, Hagstroem S, Siggaard C, Bower W, Djurhuus JC, Krogh K., TENS Increases Rectal Activity in Children *J Pediatr Gastroenterol Nutr.* 2015 Jul;61(1):80-4.
27. Ojha R, George J, Chandy BR, Tharion G, Devasahayam SR., Neuromodulation by surface electrical stimulation of peripheral nerves for reduction of detrusor overactivity in patients with spinal cord injury. *J Spinal Cord Med.* 2015 Mar;38(2):207-
28. Ohannessian A, Kaboré FA, Agostini A, Lenne Aurier K, Witjas T, Azulay JP, Karsenty G., Transcutaneous tibial nerve stimulation in the overactive bladder syndrome in patients with Parkinson's syndromes, *Prog Urol.* 2013 Sep;23(11):936-9.
29. N. Okada, Y. Igawa, A. Ogawa, O. Nishizawa, Transcutaneous electrical stimulation of thigh muscles in the treatment of detrusor overactivity, *Br J Urol*, 81 (1998), pp. 560–564
30. Patidar N, Mittal V1, Kumar M, Sureka SK, Arora S, Ansari MS., Transcutaneous posterior tibial nerve stimulation in pediatric overactive bladder- A preliminary report. *J Pediatr Urol.* 2015 Dec;11(6):351.e1-6
31. Perissinotto MC, D'Ancona CA, Lucio A, Campos RM, Abreu A., Transcutaneous tibial nerve stimulation in the treatment of lower urinary tract symptoms and its impact on health, *J Wound Ostomy Continence Nurs.* 2015 Jan-Feb;42(1):94-9.
32. Quintiliano F, Veiga ML, Moraes M, Cunha C, de Oliveira LF, Lordelo P, Bastos Netto JM, Barroso Júnior U., Parasacral TENS vs oxybutynin for the treatment of overactive bladder in children, *J Urol.* 2015 May;193(5 Suppl):1749-53.
33. Rai_et_al-2012-Cochrane-anticholinergics vs active therapies for OAB
34. Sillén U, Arwidsson C, Doroszkiewicz M, Antonsson H, Jansson I, Ståhlkint M, Abrahamsson K, Sjöström S., Effects of (TENS) on overactive bladder symptoms in children a randomized controlled trial. *J Pediatr Urol.* 2014 Dec;10(6):1100-5

35. Schreiner L, dos Santos TG, Knorst MR, da Silva Filho IG., Randomized trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women. *Int Urogynecol J*. 2010 Sep;21(9):1065-70. doi: 10.1007/s00192-010-1165-6. Epub 2010 May 11
36. D. Skeil, A.C. Thorpe, Transcutaneous electrical nerve stimulation in the treatment of neurological patients with urinary symptoms, *BJU Int*, 88 (2001), pp. 899–908
37. E.J. McGuire, S.C. Zhang, E.R. Horwinski, B. Lytton, Treatment of motor and sensory detrusor instability by electrical stimulation, *J Urol*, 129 (1983), pp. 78–79
38. K. Radziszewski, H. Zielinski, P. Radziszewski, R. Swiecicki, Transcutaneous electrical stimulation of urinary bladder in patients with spinal cord injuries, *Int Urol Nephrol*, 41 (2009), pp. 497–503
39. M. Slovak, A.T. Barker, C.R. Chapple, The assessment of a novel electrical stimulation waveform recently introduced for the treatment of overactive bladder, *Physiol Meas*, 34 (2013), pp. 479–486
40. M Slovak, CR Chapple, AT Barker , Non-invasive transcutaneous electrical stimulation in the treatment of overactive bladder, *Asian Journal of Urology* (2015) 2, 92e101
41. N.A. Soomro, M.H. Khadra, W. Robson, D.E. Neal, A crossover randomized trial of transcutaneous electrical nerve stimulation and oxybutynin in patients with detrusor instability, *J Urol*, 166 (2001), pp. 146–149
42. J. Svihra, E. Kurca, J. Luptak, J. Kliment, Neuromodulative treatment of overactive bladder–noninvasive tibial nerve stimulation, *Bratisl Lek Listy*, 103 (2002), pp. 480–483
43. K.N.T. Takahashi, S. Tanaka, Effect of sacral surface therapeutic electrical stimulation on the lower urinary tract in urinary disturbance, *Sogo Rehabiriteshon*, 29 (2001), pp. 851–858
44. M. Tellenbach, M. Schneider, L. Mordasini, G.N. Thalmann, T.M. Kessler, Transcutaneous electrical nerve stimulation: an effective treatment for refractory non-neurogenic overactive bladder syndrome?, *World J Urol*, 31 (2013), pp. 1205–1210
45. Thomas GP1, Dudding TC, Nicholls RJ, Vaizey CJ., Bilateral transcutaneous posterior tibial nerve stimulation for the treatment of fecal incontinence., *Dis Colon Rectum*. 2013 Sep;56(9):1075-9. doi: 10.1097/DCR.0b013e31829bf940.
46. H. Tugtepe , D.T. Thomas , R. Ergun , A. Kalyoncu , A. Kaynak , C. Kastarli ,T.E. Dagli The effectiveness of transcutaneous electrical neural stimulation therapy in patients with urinary incontinence resistant to initial medical treatment or biofeedback , *Journal of Pediatric Urology* Volume 11, Issue 3, June 2015, Pages 137.e1–137.
47. Vitton V, Damon H, Roman S, Mion F. Transcutaneous electrical posterior tibial nerve stimulation for faecal incontinence- effects on symptoms and quality of life. *Int J Colorectal Dis*. 2010 Aug;25(8):1017-20. doi: 10.1007/s00384-010-0962-1. Epub 2010 Jun 4
48. D.B. Vodusek, J.K. Light, J.M. Libby, Detrusor inhibition induced by stimulation of pudendal nerve afferents, *Neurourol Urodyn*, 5 (1986), pp. 381–389
49. I.K. Walsh, T. Thompson, W.G. Loughridge, S.R. Johnston, P.F. Keane, A.R. Stone, Non-invasive antidromic neurostimulation: a simple effective method for improving bladder storage, *Neurourol Urodyn*, 20 (2001), pp. 73–84
50. I.K. Walsh, R.S. Johnston, P.F. Kean, Transcutaneous sacral neurostimulation for irritative voiding dysfunction, *Eur Urol*, 35 (1999), pp. 192–196
51. J.S. Wheeler Jr., C.J. Robinson, D.J. Culkin, J.M. Bolan, The effect of thigh muscle reconditioning by electrical stimulation on urodynamic activity in SCI patients, *J Am Paraplegia Soc*, 9 (1–2) (1986), pp. 16–23
52. M. Yokozuka, T. Namima, H. Nakagawa, M. Ichie, Y. Handa, Effects and indications of sacral surface therapeutic electrical stimulation in refractory urinary incontinence, *Clin Rehabil*, 18 (2004), pp. 899–907
53. Bennett M et al (2011) Methodological quality in randomised controlled trials of transcutaneous electric nerve stimulation for pain: low fidelity may explain negative findings. *Pain*; 152: 6, 1226-1232.

References for Chronic Pelvic Pain

Pelvic Pain 4Hz

Search: chronic pelvic pain electrical stimulation

1. Therapies Targeting the Nervous System for Chronic Pelvic Pain Relief. RCOG Scientific Impact Paper No. 46 January 2015
2. de Oliveira Bernardes N, Bahamondes L. Intravaginal electrical stimulation for the treatment of chronic pelvic pain. *J Reprod Med* 2005;50:267–72.
3. de Oliveira Bernardes N, Marques A, Ganunny C, Bahamondes L. Use of intravaginal electrical stimulation for the treatment of chronic pelvic pain: a randomized, double-blind, crossover clinical trial. *J Reprod Med* 2010;55:19–24.
4. Nnoaham KE, Kumbang J. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. *Cochrane Database Syst Rev* 2008;(3):CD003222. WITHDRAWN – TO BE REPLACE WITH NEW REVIEWS ON NEUROPATHIC PAIN AND FIBROMYALGIA
5. Schneider MP, Tellenbach M, Mordasini L, Thalmann GN, Kessler TM. Refractory chronic pelvic pain syndrome in men: can transcutaneous electrical nerve stimulation help? *BJU Int* 2013;112:E159–63.
6. Sikiru L, Shmaila H, Muhammed SA. Transcutaneous electrical nerve stimulation (TENS) in the symptomatic management of chronic prostatitis/chronic pelvic pain syndrome: a placebo-control randomized trial. *Int Braz J Urol* 2008;34:708–14.
7. Jon Rees, Mark Abrahams*, Andrew Doble† and Alison Cooper‡ for the Prostatitis Expert Reference Group (PERG). Diagnosis and treatment of chronic bacterial prostatitis and chronic prostatitis/chronic pelvic pain syndrome: a consensus guideline. *BJU Int* 2015; 116: 509–525
8. Tirlapur SA, Vlismas A, Ball E, Khan KS. Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review. *Acta Obstet Gynecol Scand* 2013; 92: 881–887
9. Mercy A Udoji and Timothy J Ness*, New directions in the treatment of pelvic pain, *Pain Manag.* 2013 September; 3(5): 387–394. doi:10.2217/pmt.13.40.