

Abstract #464 Transcutaneous spinal cord stimulation and pelvic floor rehabilitation: a randomised controlled trial to investigate effect on lower urinary tract function after spinal cord injury

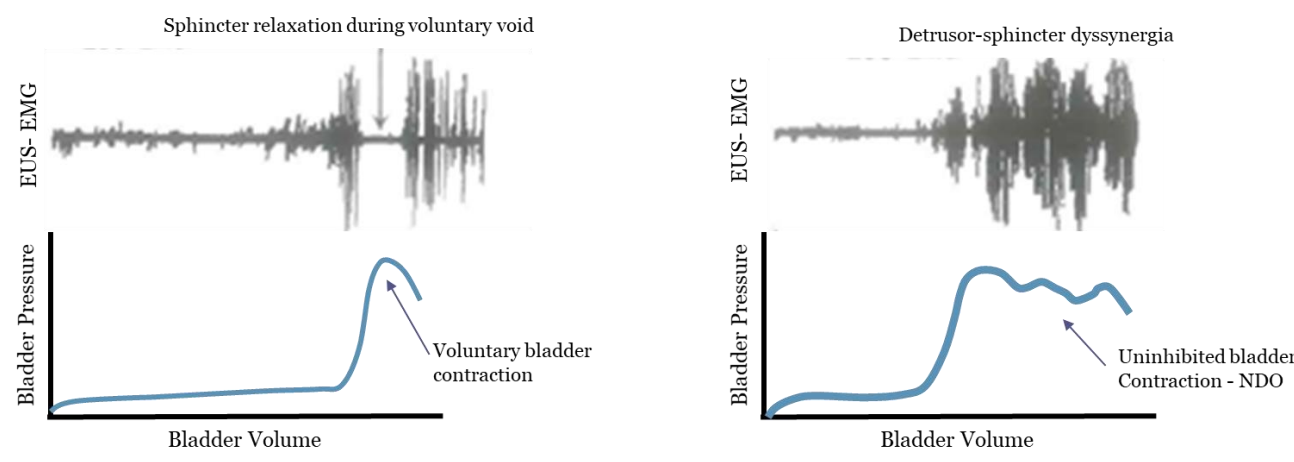
Hannah Houlston, Sarah Knight, Natalia Vasquez and Richard Nobrega

London Spinal Cord Injury Centre, Royal National Orthopaedic Hospital, Stanmore, UK



Hypothesis / aims of study

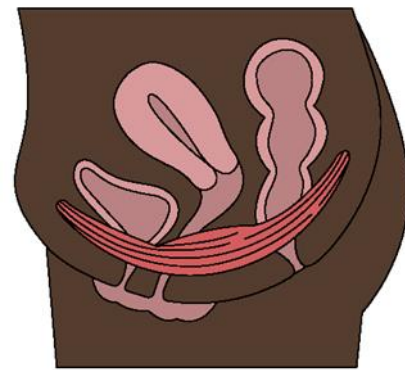
Spinal cord injury (SCI) can result in neurogenic lower urinary tract dysfunction including neurogenic detrusor over-activity (NDO) (1).



Exciting developments in spinal cord stimulation (SCS) have demonstrated potential to improve lower limb motor function when combined with intensive training sessions in people with SCI (2).

There are also indications that SCS can (3):

- Improve bladder capacity
- Reduce NDO, and detrusor sphincter dyssynergia (DSD)
- Improve voiding efficiency



Pelvic floor muscle training (PFMT) can improve voluntary control of NDO and reduce incontinence in people with incomplete SCI (4). SCS has not yet been investigated in conjunction with pelvic floor muscle training (PFMT).

Hypothesis: A combination of transcutaneous SCS (tSCS) with bladder and PFMT can increase bladder capacity and improve voiding efficiency in patients with a supra-sacral SCI.

Study design, materials and methods

The study design was a randomised controlled trial of 8-weeks of PFMT or usual care, plus a single session of transcutaneous SCS (tSCS) combined with cycles of urodynamic bladder filling and emptying. Participants with a supra-sacral SCI, and proven NDO during urodynamics were recruited.



Outcome Measures

- Standard urodynamics - maximum cystometric capacity (MCC) and maximum detrusor pressure (MDP)
- Pelvic floor assessment - Oxford Grading Scale
- Anal Sphincter EMG - 10 x quick pelvic floor contractions (Neurotrac Myoplus Pro)
- Questionnaires: Neurogenic Bladder Symptom Score (NBSS), International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI), Neurogenic Bowel Dysfunction Score (NBDS) and Arizona Sexual Experiences Scale (ASEX)

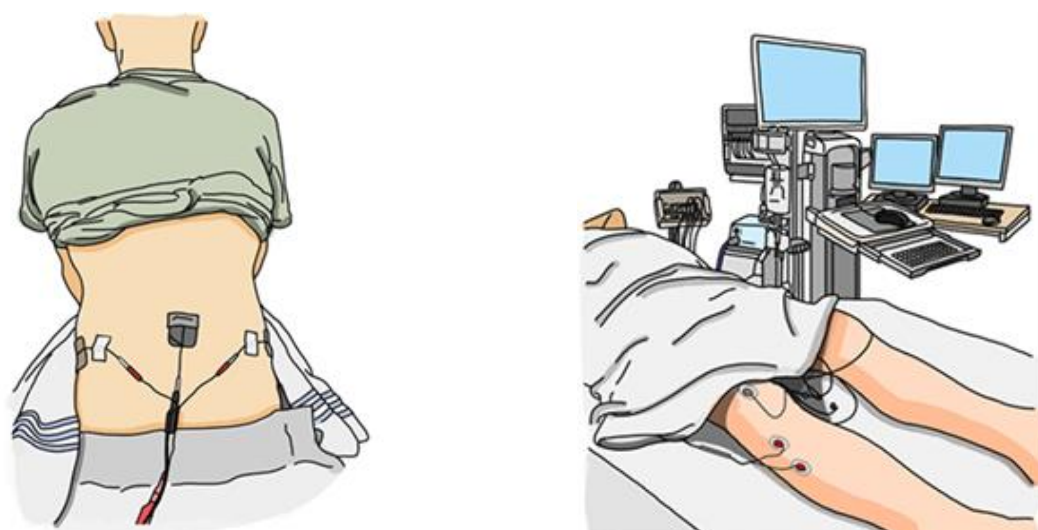
Pelvic Floor Muscle Training Programme

- Individuals randomised to the PFMT group were taught an intensive PFMT programme to complete at home, individually tailored dependent on pelvic floor function.
- Participants completed a supervised session of PFMT at week 2, 4 and 6 of the intervention.
- A PFMT booklet was issued to provide instructions and promote compliance.

Urodynamic cycles with tSCS

Following the 8-week intervention/usual care, all outcome measures were repeated, and a session of urodynamic cycles with tSCS was conducted.

tSCS was delivered through electrodes placed between the T11-12 vertebra and iliac crest.



Following a control urodynamic cycle without stimulation, tSCS (30Hz and 1000µs pulse widths, Digitimer DS7) was applied continuously during urodynamic cycles of bladder filling and emptying, both with and without voluntary pelvic floor exercises (PFE), and then a final control fill.

Primary outcome measures were MCC, MDP, and pelvic floor muscle function – oxford grading scale and EMG net work average (NWA) (uV).

Final Assessments

- Outcome measures were repeated at 6 weeks post-intervention/usual care
- Intervention participants were not obliged to continue with their PFMT between end of intervention and final assessments

Results and interpretation

Participants

Eight participants with SCI were recruited; 5 in the intervention group and 3 in the control group (Table 1). Mean age 55.5 ± 18.3 years old, mean time since injury 18.6 ± 20.7 years.

ID	Sex	Age (years)	Spinal Cord Injury	Cause	Time since injury (years)	Bladder Management	Group allocation
9	Female	62	Spina Bifida	NT	62	Voids	Intervention
10	Male	47	T6-10 incomplete	NT	29	Voids	Control
11	Male	75	T3 AIS D	NT	2	ISC	Intervention
12	Male	59	T5 AIS B	T	2	ISC	Intervention
13	Male	31	C6 AIS C	T	7	ISC	Control
14	Male	46	C4 AIS D	NT	2	ISC	Control
15	Female	39	L2 AIS C	T	19	Voids	Intervention
16	Female	85	T6 incomplete	NT	26	Voids	Intervention

Table 1: Participant demographics. Abbreviations: NT, Non-traumatic; T, Traumatic; ISC, Intermittent Self Catheterisation.

Pelvic Floor Muscle Function

At baseline, majority of intervention participants (n=5) had no detectable pelvic floor muscle contraction on manual palpation via vagina or anus (mean oxford 0 ± 0.4, range:0-1). At end of intervention, isolated pelvic floor motor function was detectable in three participants (mean 2 ± 1.8, range:0-4). At follow up assessment, isolated pelvic floor contraction strength decreased, (mean 1 ± 1.4, range:0-3).

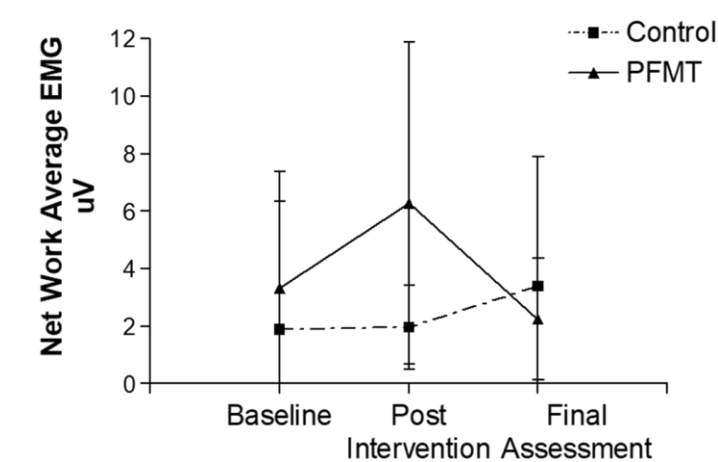


Figure 1: Pelvic floor EMG net work average (uV) at baseline, post-intervention and final assessment

Pelvic floor EMG net work average increased by 3.0 ± 4.5 uV (intervention group), 0.1 ± 3.9 uV (control group), from baseline to post-intervention (Figure 1). At final assessment, majority of participants returned to baseline EMG output. Based on self-report data, majority of participants did not continue with their PFMT or they reduced the intensity of training post-intervention.

Urodynamics

From baseline to post-intervention, mean MCC decreased by 12 ± 81ml and 5 ± 91ml, and MDP decreased by 8 ± 17 cmH₂O and 9 ± 5 cmH₂O, for intervention and control groups, respectively.

Repeated urodynamic cycles with tSCS

- Mean MCC decreased when tSCS was applied, compared to control urodynamics (without tSCS).
- Mean MDP decreased when tSCS was applied, compared to control urodynamics.
- There was minimal change in mean MCC when tSCS was applied with and without PFE.
- Mean MDP decreased when tSCS was applied, which appeared to be further enhanced by tSCS with PFE, reducing by 13.0 ± 31.1 cmH₂O and 19.8 ± 29.6 cmH₂O, respectively (Figure 2).



Figure 2: MCC and MDP during each urodynamic condition, with and without tSCS, for intervention and control group participants.

Questionnaires

There were small changes observed from baseline to post-intervention in both groups. These questionnaires may have limited sensitivity over an 8-week period.

Conclusions

1. There were improvements in pelvic floor motor function for participants who followed the 8-week PFMT intervention
2. There was a reduction in detrusor pressure (MDP)
3. with minimal change in bladder capacity (MCC) across conditions applying tSCS, both with and without PFE, in intervention participants
4. There was a greater reduction in MDP in the intervention group compared to the control group during tSCS urodynamic cycles

We have demonstrated that a combination of tSCS and intensive 8 week PFMT programme may have a positive impact on lower urinary tract function in people with SCI, particularly in relation to detrusor pressure and pelvic floor muscle function.

References

1. Blaivas JG, Sinha HP, Zayed AA, Labib KB. Detrusor-external sphincter dyssynergia. J Urol. 1991;125:542-544.
2. Harkema S, Gerasimenko Y, Hodges J, Burdick J, Angeli C, Chen Y, et al. Effect of epidural stimulation of the lumbosacral spinal cord on voluntary movement, standing, and assisted stepping after motor complete paraplegia: a case study. Lancet. 2011;377(9781):1938-47.
3. Steadman, C.J. and Grill, W.M., 2020. Spinal cord stimulation for the restoration of bladder function after spinal cord injury. Healthcare Technology Letters, 7(3), pp.87-92.
4. Vásquez, N., Knight, S.L., Sussner, J., Gall, A., Ellaway, P.H. and Craggs, M.D., 2015. Pelvic floor muscle training in spinal cord injury and its impact on neurogenic detrusor over-activity and incontinence. Spinal Cord, 53(12), pp.887-889.