

**Improvement in Over Active Bladder Symptoms in Patients
Using Functional Electrical Stimulation of the Common
Peroneal Nerve for Walking.**

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Abstract

Objective: Functional Electrical Stimulation is used to improve walking speed and reduce falls in people with upper motor neurone foot drop. Following anecdotal observations of changes in bladder symptoms, an observational study was performed to explore this association further.

Design: 47 consecutive patients attending for set up with Functional Electrical Stimulation during a six month period were asked to complete a questionnaire assessing bladder symptoms (ICIQ-OAB) at baseline and 3 months during routine appointments.

Subjects: 35 (75%) had multiple sclerosis, the other 12 subjects had a total of 9 diagnoses including 3 with stroke. Other conditions included cerebral palsy, motor neurone disease, hereditary spastic paraparesis, meningioma and spinocerebellar ataxias.

Results: Improvement in over active bladder symptoms was not significant in the whole cohort however was in patients with multiple sclerosis ($n=35$; mean change in ICIQ-OAB score 1.0, $p=0.043$). Specifically, significant improvements were seen in urgency and urge incontinence in multiple sclerosis patients. There was a significant negative correlation of moderate strength within the multiple sclerosis cohort between baseline walking speed and subsequent change in ICIQ-OAB score (correlation coefficient of $r=-0.40$, $p=0.046$). Thus greater changes in bladder symptoms were seen with lower baseline walking speeds.

Conclusion: The results of this exploratory study suggest that Functional Electrical Stimulation use does improve over active bladder symptoms in people with multiple

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3 sclerosis. Further exploration is needed to study this association and explore
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5 whether the mechanism is similar to that of Percutaneous Tibial Nerve Stimulation, a
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7 recognised treatment for the over active bladder.
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For Peer Review

Introduction

Functional Electrical Stimulation is a recognised management strategy for people with foot drop secondary to an upper motor neurone disorder, approved as effective by the UK National Institute for Health and Clinical Excellence (NICE).¹ Surface skin electrodes are placed over the Common Peroneal Nerve and/or the tibialis anterior muscle activating the dorsiflexors and evertors, thus improving the ability to clear the foot during swing phase of gait; improving stability and reducing falls.²

Percutaneous Tibial Nerve Stimulation has been shown to be a safe, clinically and cost-effective treatment (also NICE approved) for the management of drug refractory overactive bladder symptoms in people with neurological disorders.³⁻⁶ It involves inserting a stimulating needle 3 fingerbreadths above the medial malleolus close to the Tibial Nerve and placing a surface electrode on the same leg near the arch of the foot. Most treatment schedules consist of 12 outpatient sessions lasting 30 minutes each (adjustable pulse intensity 0–10mA, fixed pulse width of 200 microseconds, frequency 20Hz).^{3,4} The mechanism by which Percutaneous Tibial Nerve Stimulation works to improve bladder dysfunction remains uncertain. It is likely that stimulation of a somatic peripheral nerve results in alteration of signaling centrally in the spinal cord interneurons and peripherally at sympathetic and parasympathetic postganglionic nerve terminals and synapses involved in the voiding reflex, thereby resulting in an alteration of bladder functions.^{7,8}

In our experience some patients report improvement in lower urinary tract symptoms after the commencement of Functional Electrical Stimulation to aid walking. The Tibial and Common Peroneal nerves are the terminal branches of the sciatic nerve, both are derived from L4-S3 sharing a common innervation, we therefore

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3 hypothesise that Functional Electrical Stimulation may have effects on lower urinary
4 tract functions similar to Percutaneous Tibial Nerve Stimulation treatment. We
5 therefore studied our clinic population for any possible relationship between the use
6 of Functional Electrical Stimulation and changes in bladder symptoms, to inform the
7 design of a future study.
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18 **Methods**

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20 Consecutive patients attending for set up with Functional Electrical Stimulation using
21 the Odstock Dropped Foot Stimulator (ODFS®) Pace device (single channelled, foot
22 switch triggered: maximum amplitude 100mA, 350µs pulse, 40Hz) during a six month
23 period were asked to complete a questionnaire on their urinary functions at baseline
24 and 3 months during their routine physiotherapy appointments. The ICIQ-OAB
25 questionnaire provides a brief and robust measure to assess the impact of
26 overactive bladder symptoms. It is scored from 0-16 with greater values indicating
27 increased symptom severity of urinary frequency, urgency, nocturia and urinary
28 incontinence.^{9,10}
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41 No further details were collected regarding bladder management and this continued
42 as normal practice. The service evaluation was reviewed and registered with the
43 Clinical Governance Department.
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51 **Statistical Analysis**

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53 Data was analysed using SPSS; the Wilcoxon Signed-Rank Test was used to
54 compare ICIQ-OAB scores at baseline and 3 months and Spearman's Rank
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3 Correlation Coefficient to assess the relationship between baseline walking speed
4 and ICIQ-OAB scores with change in ICIQ-OAB scores.
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10 **Results**

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14 Of the 47 subjects proceeding to Functional Electrical Stimulation set up within the 6
15 month period 35 (75%) had a diagnosis of multiple sclerosis, the other 12 subjects
16 had a total of 9 diagnoses including 3 with stroke. Other conditions included cerebral
17 palsy, motor neurone disease, hereditary spastic paraparesis, meningioma and
18 spinocerebellar ataxias.
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25 There was a significant improvement of the ICIQ-OAB score (a reduction in score
26 indicates an improvement in bladder symptoms) in the multiple sclerosis population
27 over the 3 month period ($p=0.043$). When urinary symptoms were separately
28 analysed, significant improvements were seen in urgency and urge incontinence
29 (Table 1).
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37 There was a significant negative correlation of moderate strength in multiple
38 sclerosis patients between baseline walking speed and the subsequent change in
39 ICIQ-OAB score (correlation coefficient of $r=-0.40$, $p=0.046$). Thus greater
40 improvements in bladder symptoms were seen with lower baseline walking speeds
41 (Figure 1).
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49 With respect to bladder impairment, a significant negative correlation of moderate
50 strength was shown between baseline ICIQ-OAB score and change in score; thus
51 patients with worse bladder symptoms at baseline had smaller improvement in ICIQ-
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3 OAB scores (Whole group $r=-0.466$, $p=0.001$, multiple sclerosis group $r=-0.442$,
4 $p=0.008$) (Figure 2).
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10 **Discussion**

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14 The results of this study demonstrate a statistically significant improvement in
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16 overactive bladder symptoms after 3 months of functional electrical stimulation use
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18 to improve walking in multiple sclerosis patients. The one unit reduction (17%)
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20 observed reflects a recognised clinically important difference.¹¹
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24 When individual symptoms of bladder dysfunction were considered, the main areas
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26 demonstrating improvement were urinary urgency and urge incontinence. The
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28 impact of bladder dysfunction may of course be influenced by improvements in
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30 mobility and speed of accessing toileting facilities particularly with regard to
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32 incontinence. However it is unlikely that participants would report changes in urgency
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34 simply as a result of an orthotic effect on their walking. It would however be
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36 invaluable to correlate these findings with objective evidence of improvements in
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38 urinary dysfunction through urodynamic studies.
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42 Despite significant changes in the sub-scores of the ICIQ-OAB assessing urinary
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44 urgency and urge incontinence, the change in overall score was not significant when
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46 all patients were considered together. We postulate that this may reflect the
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48 differences in the neurological insult; multiple sclerosis has a heavy burden of spinal
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50 cord pathology whereas the other group was predominantly comprised of cerebral
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52 origin disorders. This association is perhaps borne out further by the significant
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54 correlation within the multiple sclerosis cohort between baseline walking speed and
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3 the subsequent change in ICIQ-OAB score, demonstrating that perhaps those
4 patients with a higher spinal cord disease burden (slower walking speeds) had
5 greater improvement in overactive bladder symptoms. Studies of Percutaneous
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the subsequent change in ICIQ-OAB score, demonstrating that perhaps those patients with a higher spinal cord disease burden (slower walking speeds) had greater improvement in overactive bladder symptoms. Studies of Percutaneous Tibial Nerve Stimulation have also demonstrated particular efficacy in patients with multiple sclerosis and for all aspects of their urinary symptoms,^{12,13}

Analysis revealed a significant negative moderate correlation between baseline ICIQ-OAB score and change in score, demonstrating that people with less severe bladder symptoms at baseline were more likely to show improvements following Functional Electrical Stimulation use. This warrants further investigation with urodynamic studies but is an interesting observation as it suggests individuals with mild urinary symptoms may be able to avoid drug treatments and be managed solely through neuromodulation.

The mode of delivery of Percutaneous Tibial Nerve Stimulation and Functional Electrical Stimulation clearly differ. Percutaneous Tibial Nerve Stimulation is usually delivered as a course of weekly 30 minute treatment sessions over 12 weeks giving a total dosage of 6 hours in 3 months, whereas Functional Electrical Stimulation may deliver this much in a single day albeit of a reduced intensity. This study did not collect information on dosage (step count) or intensity (amplitude), two important aspects to consider in future study designs.

This is an observational study and has limitations, a further study designed to specifically evaluate efficacy with pathophysiological correlates including urodynamics is warranted. We do not propose that Functional Electrical Stimulation be used to treat urinary symptoms but it does however for the first time indicate that its use may improve bladder dysfunction and could have implications for

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3 commencing or continuing bladder treatments in users of Functional Electrical
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5 Stimulation.
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10 **Clinical Message**

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13 • Functional Electrical Stimulation to aid walking may improve neurogenic
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15 bladder symptoms particularly in patients with multiple sclerosis
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23
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Table 1**Subject demographic and ICIQ-OAB Scores**

	All n=47		Multiple Sclerosis n=35		Other n=12	
Age (years); mean (range)	51 (32-70)		52 (37-70)		49 (32-66)	
	Baseline	3 months	Baseline	3 months	Baseline	3 months
ICIQ-OAB Mean (SD)	6.00 (3.28)	5.60 (2.92)	6.00 (5.00)	5.00 (5.00)*	3.42 (1.73)	4.08 (2.39)
Question 3 Frequency Median (IQR)	1(2)	1(2)	1(2)	1(2)	0(0)	0(1.75)
Question 4 Nocturia Median (IQR)	1(1)	1(1)	2(1)	1(1)	1(0)	1(1)
Question 5 Urgency Median (IQR)	2(2)	2(2)*	2(1)	2(2)*	1(1)	1(1)
Question 6 Urge Urinary Incontinence Median (IQR)	1(1)	1(1)*	2(2)	1(1)	1(1.75)	1(1)

*Significant change $p < 0.05$

MS multiple sclerosis; SD standard deviation; IQR= Interquartile range;

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7 Figure 1. Scatterplot of baseline walking speed and change in ICIQ-OAB score in
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13 Figure 2. Scatterplot of baseline ICIQ-OAB score and change in ICIQ-OAB score in
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Figure 1

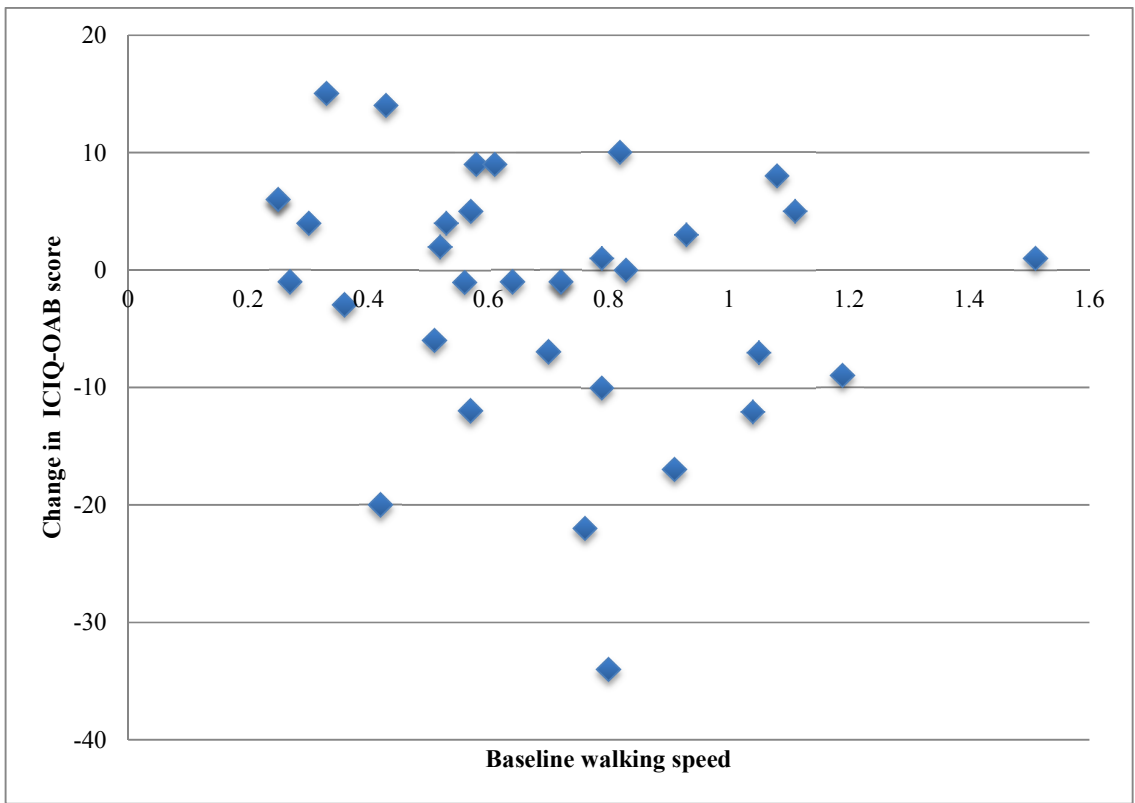


Figure 2

