

A Novel Externally Applied Neuromuscular Stimulator for the Treatment of Stress Urinary Incontinence in Women—A Pilot Study

Ruth M. Maher, PT, DPT, MPT, BSc*, Brian Caulfield, PhD, MMedSci, BPhysio[†]

Objectives: Neuromuscular electrical stimulation (NMES) is commonly used to treat lower urinary tract dysfunctions. This study evaluated the efficacy of a novel externally applied stimulator in the treatment of stress urinary incontinence (SUI).

Materials and Methods: Nine women were included in this study. Provocative tests included a cough and jumping jack test assessed via pad weight. Ultrasound (US) imaging assessed pelvic floor muscle (PFM) contraction. A bladder filling protocol allowed for delineation of the bladder from the pelvic floor and standardized volume. External electrodes were used during 30 min, at least four times per week treatment protocol at home for eight weeks. Participants were blinded to US and were not instructed regarding pelvic floor contractions.

Results: At week 1, participants could perform PFM contractions verified with US. More importantly, an 87.43% decrease in leakage was noted. At week 8, participants reported a 97.71% decrease in leakage ($p = 0.0001$). Changes noted in Incontinence Impact Questionnaire and Modified Oxford scores were significant ($p = 0.0001$ and $p = 0.0001$).

Conclusions: NMES is frequently used to promote muscle strength and coordination. Studies have shown NMES to be effective in decreasing symptoms associated with SUI; however, few, if any, have used it as a primary treatment modality. The novel device in this study was shown to be effective in improving muscle strength, reducing or ablating the symptoms associated with SUI, and in eliciting PFM contractions. The device is noninvasive and can be used as a home treatment.

Keywords: Bladder control, functional electrical stimulation, functional electrical therapy, muscle contraction, muscle strengthening

Conflict of Interest: An international patent has been applied for by Drs. Maher and Caulfield for the novel device used in this pilot study. Dr. Maher is a consultant for Bio Medical Ltd., Galway, Ireland, who will manufacture the device. She currently provides training services for researchers using the device in other studies and provides assistance with research protocol design. Dr. Caulfield has received grants from Bio-medical Research, Ltd. for his research in neuromuscular electrical stimulation.

INTRODUCTION

Stress urinary incontinence (SUI) is defined by the International Continence Society (ICS) as the complaint of involuntary loss of urine on effort, on physical exertion including sporting activities, or on coughing or sneezing (1,2). The ICS reports prevalence in the range of 25–40% in women worldwide with over half of all incontinent women classified as stress incontinent. More than 30% of women will develop SUI within five years after their first vaginal delivery (3). The financial and effects to social and emotional well-being are costs, which are difficult to quantify. Chong et al. reported that more than \$12 billion are spent annually in the United States, an amount that continues to grow. Almost 70% of the total cost of SUI care comes from routine management including pads, laundry, and dry cleaning, amounting to a significant individual financial burden with the amount spent being directly correlated with severity of symptoms (4). Despite its frequency and impact on quality of life, patients often underreport SUI (5). While some seek surgical intervention, the nonsurgical treatment of SUI is multidimensional with options including simple lifestyle modifications, physical therapy, and pharmacologic therapies.

The goal of physical therapy in the treatment of SUI is to improve pelvic floor muscle (PFM) function by increasing strength, coordination, speed, and endurance (6). Pelvic floor exercises (PFEs) are a first line treatment for SUI, which seek to increase urethral tone and PFM strength and thus prevent urinary leakage. Training the awareness, strength, timing, endurance, voluntary, or reflex coordination of the PFM has a major role in regaining continence (7). Neuromodulation or neuromuscular electrical stimulation (NMES) via transvaginal

Address correspondence to: Ruth M. Maher, PT, DPT, MPT, BSc, Department of Physical Therapy, North Georgia College & State University, 82 College Circle, Dahlonega, GA 30597, USA. Email: rmmaher@northgeorgia.edu

* Department of Physical Therapy, North Georgia College & State University, Dahlonega, GA, USA; and

[†] School of Public Health, Physiotherapy & Population Science, University College Dublin, Belfield, Ireland

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Table 1. Selection Criteria.

Inclusion criteria

- a. Generally healthy (apart from their continence issues)
- b. Female
- c. Body mass index < 30 kg/m²
- d. Age between 20 and 45 years
- e. Good mental health
- f. Written informed consent
- g. Willingness to cooperate
- h. Nonsmoker
- i. Not addicted to alcohol or drugs
- j. Clinical diagnosis of SUI
- k. Successfully completed medical screening questionnaire

Exclusion criteria

- a. Pelvic surgery (including hysterectomy)
- b. On diuretics
- c. Metabolic or hormonal disorder
- d. Back pain
- e. Pregnant/planning to get pregnant
- f. Blood clotting disorder
- g. Metal implants or cardiac pacemakers
- h. Fractures during the past six months
- i. Lower extremity trauma during the past six months or currently experiencing related symptoms or receiving treatment
- j. Epilepsy

SUI, stress urinary incontinence.

Table 2. Participant Characteristics.

	Mean (range)
Age	42.7 years (40–45)
BMI	24.6 kg/m ² (18–28)
Duration of symptoms	9 years (2–15)
Vaginal deliveries	19 years (1–4)
Leaks per day	3.88 (2–7)
IIQ-7 score	56.4 (33.3–76.11)
Modified Oxford Scale score	1.77 (1–5)
Cough test	0.44 g (0–2)
Jump jack ×4	3.5 g (0–10)

Note: Three C sections were reported by two participants: 1 × 2 C sections; 1 × 1 C section.

BMI, body mass index; C section, Cesarean section; IIQ-7, Incontinence Impact Questionnaire.

electrodes is frequently included in a PFE program in an effort to facilitate or enhance an individual's ability to volitionally perform an appropriate PFM contraction. In fact, the literature has shown that inappropriate PFM contractions can exacerbate the symptoms associated with SUI (8). While numerous studies have reported that NMES can be effective in the treatment of SUI, the issues of technique, comfort of treatment, and compliance with treatment are often limiting factors that impact patient outcomes (9–11). The effectiveness of transvaginal NMES is potentially limited by the patient's tolerance to the stimulation intensity, pain, and/or bleeding (10,12,13). Additionally, PFM NMES is usually delivered via a transvaginal electrode. Many women find this mode of delivery uncomfortable and the electrode is difficult to maintain in place in standing.

This has motivated the search to identify an NMES treatment modality that ensures satisfactory recruitment of the PFMs and that is easy to administer and more comfortable for the patient. This resulted in the development of a novel NMES device. This pilot study further evaluates the potential of this novel device as a monotherapy in women with SUI.

MATERIALS AND METHODS

Participant Selection

This prospective pilot study was approved by the ethics committee of the institution and all participants who met the study criteria in Table 1 and provided informed consent were recruited for this study. Nine female participants aged from 40 to 45 years with a diagnosis of SUI were enrolled in this study. The duration of their symptoms spanned 2–15 years. All participants completed a general health history questionnaire, a bladder diary, and the Incontinence Impact Questionnaire (IIQ-7). The pelvic organ prolapse

quantification system was used to screen each participant for the presence of prolapse and pelvic floor musculature strength was assessed as per the Modified Oxford Scale (14). The amount of urine lost while performing four jumping jacks was assessed via pad weight (Table 2). Ultrasound (US) was used for assessment of the PFM contraction. All US images were acquired in the transverse plane with GE Logiq 5 US system (GE Healthcare, Milwaukee, WI, USA) using a curvilinear transducer. An appropriate PFM contraction was deemed to occur if the PFM caused a cranial encroachment of the bladder in the transverse plane. Each participant completed a bladder filling protocol to allow for delineation of the bladder from the pelvic floor fascia and associated PFM. The protocol required emptying the bladder and consuming 500 mL of water one hour prior to testing.

Participants used eight external electrodes with a combined stimulating surface area of 1526 cm² and a current density of 0.03 mA/cm², which were applied to the buttocks, outer hips, and the anterior and posterior proximal thighs for a 30-min treatment protocol at least four times per week at home in standing for eight weeks. Participants were encouraged to alter their neutral standing position during the 30-min bout by changing the pelvic inclination angle slightly and internally/externally rotating the hips. These positional changes affected the current path and participants were able to target the stimulus more anteriorly toward the urethra or more posteriorly toward the rectum. A symmetric biphasic pulse was used. The parameters are outlined in Table 3. Participants were blinded to US and were not instructed regarding pelvic floor contractions.

Statistical Analysis

Data were analyzed for potential effects on outcome including the amount of leakage during provocative tests, number of leaks more than five consecutive days, and quality of life. Descriptive statistics were used to summarize study data. They were reported as percentages or using the arithmetic mean and standard deviation. The Student's *t*-test was used to compare for significant differences in addition to calculation of effect size (Cohen's *d*). An effect size of 0.2 was classified as a small effect, 0.5 as a moderate effect, and 0.8 as a large effect. The *p*-value was set at 0.05. Statistical analyses were performed using PASW Statistics 18 (SPSS, Chicago, IL, USA).

Table 3. Neuromuscular Electrical Stimulation Parameters.

Treatment duration	Frequency	Pulse width	Ramp up/down	On time contraction	Off time rest
30 min	50 Hz	620 μs	0.5 sec	5 sec	0.5 sec

Table 4. Group Mean Scores at Baseline and Following Four and Eight Weeks of Surface NMES Training.

	Baseline values	Four-week follow-up	Eight-week follow-up	Within participants effect size ^{††}	
				Cohen's <i>d</i>	<i>r</i>
IIQ-7 score	56.4 ± 12.5*	32.8 ± 13.1* [†]	15.9 ± 5.3 [†]	4.23	0.91
Leaks in last five days	19.4 ± 8.1 [‡]	1.1 ± 1.7 ^{‡§}	0.4 ± 0.7 [§]	3.31	0.86
Jumping jack test (g)	3.5 ± 2.8 [¶]	0.75 ± 1.0 ^{¶*}	0.3 ± 0.7 [#]	1.82	0.67
Modified Oxford Scale	1.78 ± 1.09**	NA	4.2 ± 0.8**	4.25	0.78

**p* = 0.001.
[†]*p* = 0.0001.
[‡]*p* = 0.0001.
[§]*p* = 0.0001.
[¶]*p* = 0.05.
[#]*p* = 0.004.
^{**}*p* = 0.0001.
^{††}Baseline vs. week 8.
 IIQ-7, Incontinence Impact Questionnaire; NA, not applicable; NMES, neuromuscular electrical stimulation.

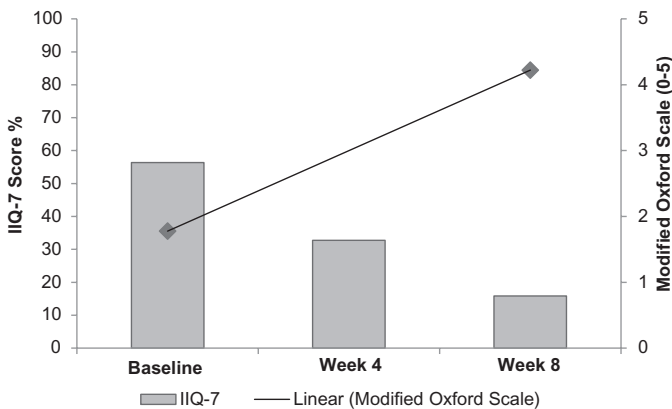


Figure 1. Incontinence Impact Questionnaire (IIQ-7) and Modified Oxford Scale scores from baseline to week 8. Pelvic floor neuromuscular electrical stimulation was administered five days per week for eight weeks.

RESULTS

At week 1, all participants (*N* = 9) could perform appropriate volitional contractions of their PFM in standing but more importantly there was a reported 87.43% decrease in leakage at week 1. At week 8, participants reported a 97.71% decrease in leakage (*p* = 0.0001) and within group effect size was high (*d* = 4.23, *r* = 0.91). IIQ-7 and Modified Oxford scores also changed significantly (*p* = 0.0001) and within group effect size was high and moderate (*d* = 3.31, *r* = 0.86 and *d* = 2.51, *r* = 0.78), respectively (Table 4 and Fig. 1). The results of this pilot study show that externally applied stimulation can provide significant outcomes for those with SUI in a very short period of time. At baseline, US confirmed that no participants could volitionally contract the PFM appropriately in supine or standing. US showed no cranial encroachment of the PFM on the bladder in sitting or standing. Indeed most participants performed a Valsalva maneuver, which was evidenced by caudal displacement of the

bladder in the transverse plane (Fig. 2a,b). Imaging performed throughout the study showed that application of the novel stimulator facilitated an appropriate PFM contraction in standing for all participants, which resulted in cranial encroachment on the bladder by the PFM (Fig. 2c,d). At the cessation of stimulation, participants could volitionally perform an appropriate PFM in standing and reported having a better awareness of the PFM. All stimulation was performed in standing. We believe that this is a more functional position to train the PFM as symptoms associated with SUI are more evident in standing.

DISCUSSION

The evidence supporting the use of NMES in pelvic floor neuromuscular rehabilitation for SUI is equivocal. While some studies have shown a beneficial effect of NMES that is comparable to other conservative interventions, there are other studies that have failed to show a clear benefit (7,10,13). Lack of homogeneity in the study designs and most especially in the equipment used can impact assessment as to the efficacy of NMES in the treatment of SUI. Conventional NMES devices for PFM rehabilitation typically use a vaginal or anal electrode, which is invasive and often causes discomfort and injury and leads to low compliance. Much of this can be attributed to the fact that the size of the vaginal space limits electrode size and ability of the user to reach intensity sufficient to elicit a PFM given the concomitant and relative high current density. Given the location of the PFM, it is difficult for clinicians to assess whether or not NMES elicits a PFM and indeed if the contraction is an appropriate one, i.e., causes a cranial and ventral encroachment of the PFM on the bladder when observed with US in the transverse and sagittal planes. One study reported that only one out of nine participants showed evidence of a PFM contraction during a bout of transvaginal NMES in hook lying, which was evaluated by observation of the perineum (15). Another consideration is the patient position during NMES. If symptoms associated with SUI occur mostly in

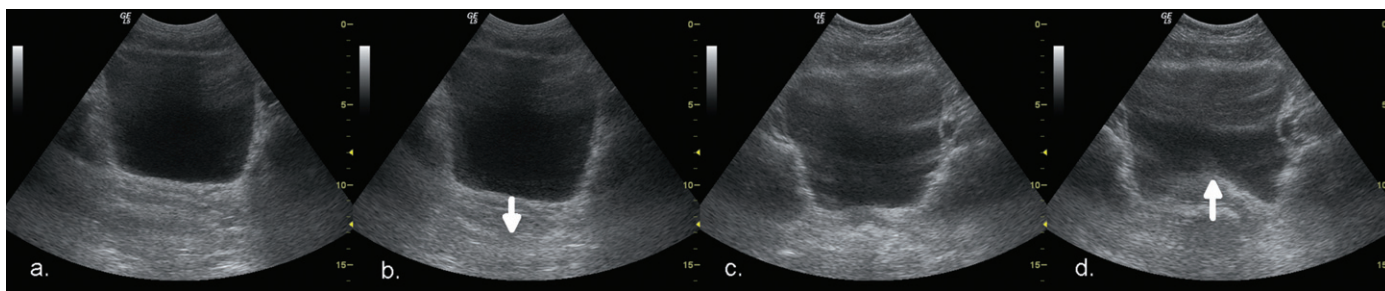


Figure 2. a. Pelvic floor muscle (PFM) at rest followed; b. attempt at voluntary pelvic floor contraction which results in Valsalva and caudal motion (arrow down); c. PFM at rest; and d. PFM contraction elicited by novel stimulator in standing, results in cranial encroachment of PFM on bladder (arrow up).

standing, why is NMES conducted in supine, hook lying, or recumbent sitting? Participant positioning has been shown to have an effect on voluntary PFM recruitment. Sapsford et al. looked at the differences in PFM activity during different types of sitting postures (supported/slumped and unsupported/upright) and found that as more abdominal muscles were recruited to support the body during upright sitting postures, there was a concurrent increase in the amount of PFM activity to possibly accommodate for the increased amount of intra-abdominal pressure created by the trunk musculature (16). This finding was consistent for both continent and incontinent participants. A study by Devreese et al. showed that continent women's superficial muscles almost always contracted before the deep muscles in all positions of supine and standing (17). In the incontinent women, the reverse sequence was observed in three of the six positions (supine, sitting leaning forward, and standing leaning forward). In the other three of the six positions, the activation difference between the superficial vs. deep PFMs was negative. This indicated that the deep PFMs contracted earlier than the superficial PFMs. This implies that incontinent patients with a PFM activation pattern of deep PFMs contracting before superficial PFMs could use the leaning forward position to facilitate the normal contraction in standing. Furthermore, a positional change of more than 10 mm of a vaginal electrode has been shown to affect maximal urethral response to electrical stimulation and differences in nerve supply for the deep vs. superficial PFMs, indicating that a different function for the two PFM layers has been described (18,19). This raises two questions that may explain the equivocal findings regarding the efficacy of conventional NMES for SUI and why the novel device used in this pilot study proved efficacious. Do currently available transvaginal sensors facilitate appropriate timing of PFM firing given the placement of the stimulating area and can the current path change if the patient changes position from supine to standing and activate the deep and superficial layers of the PFM? As few studies, if any, exist to answer these questions, we can only surmise that these factors could play a role as to whether transvaginal NMES does activate the deep and superficial PFM and indeed facilitate a PFM contraction.

CONCLUSIONS

We believe that this is the first study to use US to assess the effect NMES has on PFM in real time. The novel form of PFM NMES used in this pilot study was tolerated well by all participants and was shown to effectively elicit an appropriate PFM contraction in standing. This device also is unique in that the wearer can determine where to focus the current without moving the electrodes, they merely have

to alter the pelvic inclination angle. For example, leaning forward can exquisitely target the anterior pelvic floor including the urethra. Moreover, the results of this pilot in reducing or ablating the symptoms associated with SUI are remarkable. Further study on a larger population with SUI is warranted in addition to a comparative study to assess whether this novel NMES device proves superior to conventional PFM stimulators and other interventions such as PFE.

Authorship Statements

Dr. Maher designed and conducted the data collection and analysis. Dr. Caulfield conducted the data analysis. Dr. Maher prepared the manuscript with input from Dr. Caulfield. All authors approved the final manuscript.

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