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A NOVEL EXTERNALLY APPLIED NEUROMUSCULAR STIMULATOR FOR THE TREATMENT OF STRESS URINARY INCONTINENCE– A PILOT STUDY

Hypothesis / aims of study

The purpose of this study was to evaluate the efficacy of a novel externally applied neuromuscular stimulator in the treatment of those with stress urinary incontinence (SUI).

Study design, materials and methods

This pilot study evaluated the efficacy of a novel externally applied neuromuscular stimulator in nine female participants aged from 40 to 45 years with a diagnosis of stress urinary incontinence (SUI). The duration of their symptoms spanned 2 – 15 years. All subjects completed a general health history questionnaire, a bladder diary and a quality of life questionnaire (IIQ-7). Each subject had a digital examination of their pelvic floor musculature (PFM) which was scored as per the Modified Oxford Scale. The amount of urine lost during a cough test and 4 jumping jacks was assessed via pad weight. Ultrasound imaging was used for assessment of PFM contraction, and to establish bladder volume. Each subject completed a bladder filling protocol to allow for delineation of the bladder from the pelvic floor fascia and associated PFM. Subjects used external electrodes and followed a 30 minute treatment protocol at least 4 times per week at home in standing for eight weeks. Subjects were blinded to sonography and were not instructed regarding pelvic floor contractions.

Table 1. Subjects' characteristics at baseline

Variables	N = 9
Mean Age (range)	42.7 (40 - 45)
Mean BMI (range)	24.6 (18 - 28)
Duration of Symptoms (range)	9 (2 - 15)
No of vaginal deliveries (range)	19 (1 – 4)
Nos. of C-Sections	3
Mean leaks per day (range)	3.88 (2 – 7)
Mean IIQ 7 Score (range)	56.4 (33.3 – 76.11)
Mean Oxford Scale Score (range)	1.77 (1 - 3)
Mean Cough test/grms (range)	0.44 (0 - 2)
Mean Jump jack x 4/grms (range)	3.5 (0 - 10)

Results

At week one all subjects (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 one. At week eight subjects reported a 97.71% decrease in leakage (P= 0.00009). IIQ-7 and Modified Oxford scores also changed significantly (P = 0.0000009 and P=0.0001).

Table 1.
Group mean scores at baseline, and following 4 and 8 weeks of surface NMES training

	Baseline Values	4 Week Follow-Up	8 Week Follow-up	Within Subjects Level of Significance	Observed Power
IIQ-7 Score	56.4±12.5	32.8±13.1	15.9±5.3	P<0.0001	1.00
Leaks in last 5 days	19.4±8.1	1.1±1.7	0.4±0.7	P<0.0001	1.00
Jumping Jack Test (g)	3.5±2.8	0.75±1.0	0.3±0.7	P<0.05	0.65

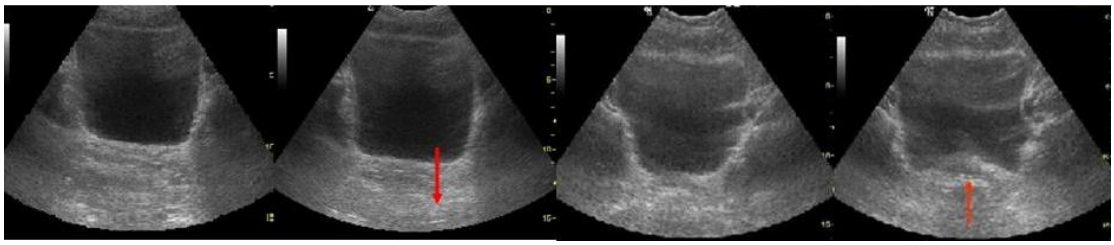
Table 2. Post hoc comparisons.

	Baseline Values vs. 4 Week Follow-Up	Baseline Values vs. 8 Week Follow-Up	4 Week Follow-Up vs. 8 Week Follow-Up
IIQ-7 Score	P = 0.0009	P = 0.0000009	P = 0.001
Leaks in last 5 days	P = 0.0002	P = 0.00009	P = 0.28
Jumping Jack Test (g)	P = 0.05	P = 0.009	P = 0.19

Post hoc comparisons carried out using 2-sided paired t-tests

Interpretation of results

The results of this pilot study show that externally applied stimulation can provide significant outcomes for those with stress urinary incontinence in a very short period of time. At baseline, sonography confirmed no subjects could volitionally contract the PFM appropriately. Sonography showed no encroachment of the PFM on the bladder in sitting or standing. Indeed most subjects performed valsalva which was evidenced by caudal displacement of the bladder in the transverse plane. Imaging performed throughout the study showed that application of the novel stimulator facilitated an appropriate PFM contraction in standing for all subjects. At the cessation of stimulation subjects could volitionally perform an appropriate PFM in supine and standing and reported having a better awareness of the PFM. All stimulation was performed in standing. We believe this is a more functional position to train the PFM since symptoms associated with stress urinary incontinence are more evident in standing.



a. b. c. d.

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

Concluding message

Urinary incontinence is a world wide problem and its prevalence is difficult to assess. Although most people associate loss of control to old age, it is not a normal or natural part of aging. More importantly incontinence causes a significant social and psychological impact on the lives of women. Studies show that SUI is the most prevalent type of incontinence in women under 60 years of age and that the majority of women respond to simple measures such as pelvic floor exercises (1). The clinical use of NMES in promotion of muscle strengthening is long established with many devices specifically manufactured for the treatment of pelvic muscle weakness. Many 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 (2,3). The novel NMES device in this study was shown to be effective in reducing or ablating the symptoms associated with stress urinary incontinence and in eliciting a PFM contraction in standing. The device is non invasive and can be used as a home treatment.

References

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**UCD Research Ethics Committee, University College, Dublin, Ireland**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**