

# The Efficacy of a New Pelvic Floor Neuromuscular Electrical Stimulator compared to a Sham Modified version in eliciting Pelvic Floor Muscle contractions in healthy female subjects - A Validation study using Ultrasound Imaging.

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## Objective

Neuromuscular electrical stimulation (NMES) of the pelvic floor (PFM) is a popular adjunctive intervention to pelvic floor exercises (PFE) in those with stress urinary incontinence (SUI). The purpose of this study was to demonstrate that a new NMES device elicits PFM contractions and a sham does not and secondly, that the sham is considered a credible therapy by users for use in an upcoming RCT.

## Background

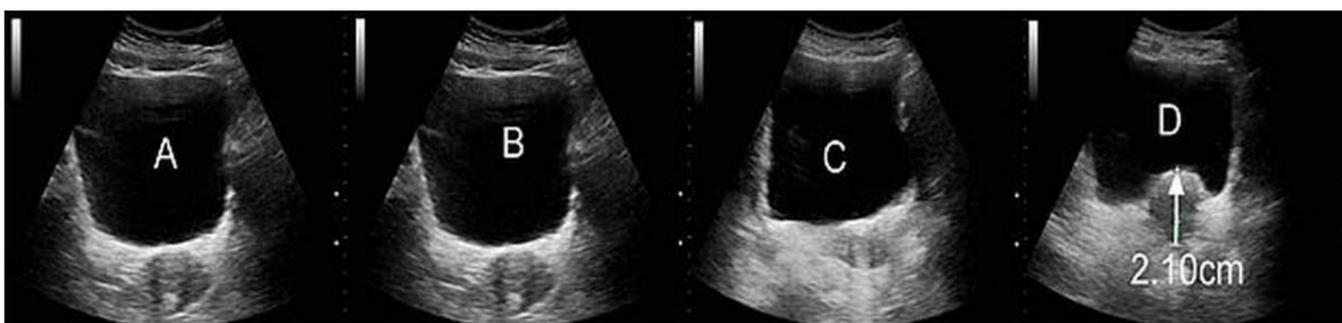
While PFE are effective in increasing PFM strength, their location make it difficult to confirm an appropriate contraction occurs. Less than half of those given instructions can contract their PFM, consequently adjunctive therapies such as NMES are frequently used.<sup>1</sup> The evidence regarding NMES for SUI is somewhat equivocal<sup>2</sup> and the subjective perception of an NMES elicited contraction should not be relied upon as studies show PFM contraction occurs in only 11 – 16%.<sup>3,4</sup>

## Methods

Twenty healthy females with a mean age of 34.8 years (SD 16.3) and mean BMI of 25.4 kg/m<sup>2</sup> (SD 5.7) were recruited for this study. This was a controlled, single-centre, cross-over study and all subjects provided informed consent to receive Treatment A and B. Treatment A and B's stimulating surface area were 1202cm<sup>2</sup> and 1260cm<sup>2</sup>, respectively, and parameters were modified to produce a sensory response (Treatment A) and motor response (Treatment B). Ultrasound (US) data were acquired transabdominally and appropriate PFM contraction was defined as one which resulted in cranial displacement of the bladder. Subjects were blinded to US imaging and bladder displacement was assessed using on-screen callipers. US data was also verified by a blinded independent assessor. Additionally, subjects completed feedback questionnaires to determine whether users perceived a valid treatment.

## Results

Contractions were observed for all participants during Treatment B and none were apparent for Treatment A (Fig. 1). Mean displacement for Treatment B was 0.96 cm (SD 0.53) and 1.04 cm (SD 0.58) with respect to unblinded and blinded assessment. Direct comparison of both assessments for Treatment B indicates that unblinded measurements were systematically smaller than the blinded measurements, with a mean (95% CI) difference of -0.08 cm, p=0.007. Though statistically significant, this difference is small, representing 8% of the mean value. 13 subjects thought Treatment A was 'an effective treatment' and 7 were 'not sure'. 15 believed Treatment B was 'an effective treatment' and 5 were 'not sure'. There was no clear preference for either treatment. 10 preferred Treatment A (50%), 7 preferred Treatment B (35%) and 3 had no preference (15%). When subjects were asked to compare effectiveness of treatments, 10 thought Treatment A was 'less effective' than Treatment B, 1 thought they were 'equally effective' and 9 didn't know'.



**Figure 1.** US images comparing Sham treatment A (A & B) to New NMES Treatment B (C & D). A: shows resting position of bladder; B shows no bladder displacement during treatment; C shows resting position of bladder; D shows bladder displacement of 2.10cm

## Conclusion

Treatment B consistently elicited a PFM contraction and the sham (Treatment A) did not. Unblinded and blinded assessment gave identical results for each treatment. One of the key contributors to effective PFM training is confirmation of a correct volitional contraction. The same should apply when using NMES. If NMES does not elicit a contraction, then there is no benefit in using it to increase strength or endurance of the PFM. This study showed that Treatment B elicited a contraction in 100% of the subjects whereas the Treatment A failed to elicit contractions despite being perceived as a potential treatment intervention.

## References

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