



Does a 5-minute bout of INNOVO™ affect volitional Pelvic Floor Muscle Contraction in women who are unable to contract – A Proof of Concept Study



Ruth M. Maher

Philadelphia College of Osteopathic Medicine, Department of Physical Therapy, Suwanee, GA, USA

HYPOTHESIS / AIMS OF STUDY

Despite a myriad of teaching methods, between 30% - 70% of women with pelvic floor dysfunction (PFD) cannot perform appropriate pelvic floor contractions. Teaching and learning the appropriate contraction is challenging and may be related to kinesthetic impairments resulting in difficulties executing the motor task of pelvic floor muscle (PFM) recruitment. This kinesthetic impairment may be related to a lack of visual stimuli since the PFM are out of sight. Some evidence suggests neuromuscular electrical stimulation (NMES) may be better than no treatment for SUI. This study aimed to determine if NMES delivered externally in a pair of shorts (INNOVO) with a large surface area of integrated novel conductive ink electrodes provided a sufficient sensorimotor stimulus to enhance volitional PFM function in healthy women who could not contract their PFM.

STUDY DESIGN, MATERIALS AND METHODS

Ten healthy women aged 23 – 58 (mean 35 years) with a mean BMI of 25.1 kg/m² who could not perform a volitional PFM contraction assessed via transabdominal ultrasound (TAUS) participated. Exclusion criteria included those who could perform an appropriate PFM contraction, were pregnant, had a neurological disease, pelvic organ prolapse, lumbopelvic surgery, recurrent urinary tract infections, and cardiac pacemaker.

A bladder-filling protocol facilitated the delineation of structures during TAUS of bladder-base displacement (BBD) in millimeters (mm) under five conditions: pre-NMES volitional contractions in supine and standing, INNOVO NMES in standing, and post-NMES volitional contractions in supine and standing with at least a 5-minute washout period between INNOVO and post-NMES conditions.

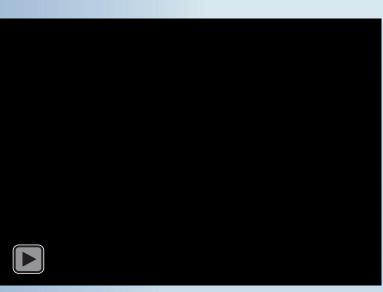


Figure 1. Illustration of INNOVO's multipath

SPECIFICATIONS

- Surface Area: 8 electrodes 1200cm²
- Current Density: 0.189 mA/cm²
- Frequency: 50Hz
- Pulse duration: 620µs
- On:Off time: 5 secs : 5 secs
- Treatment time: 5 minutes, 30 contractions

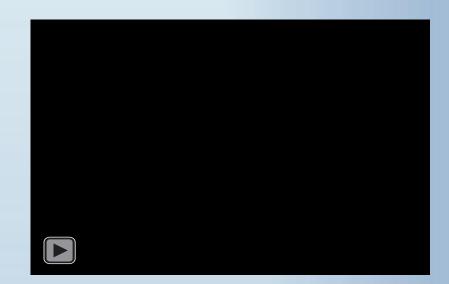
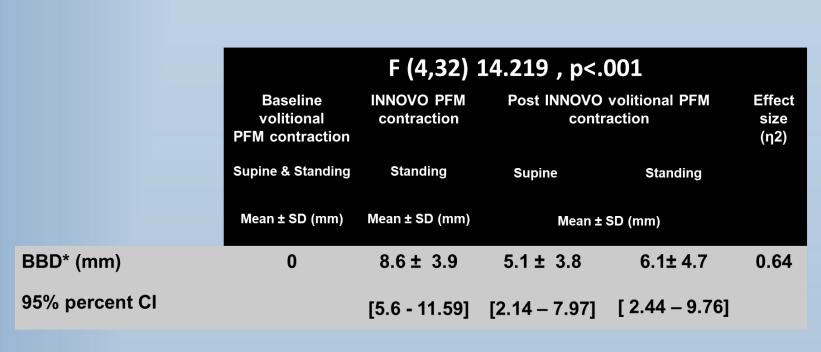


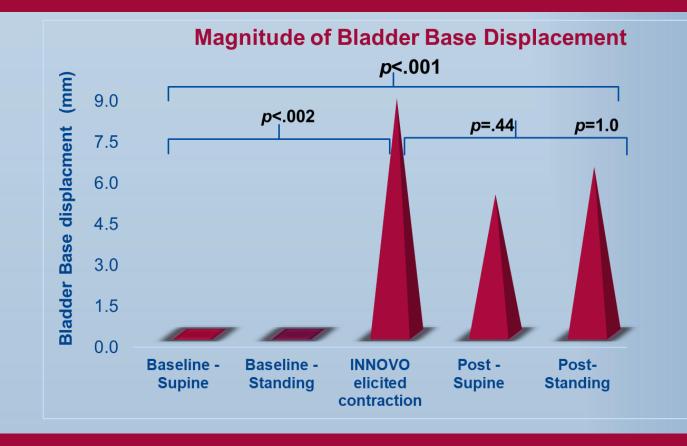
Figure 2. Transperineal ultrasound of INNOVO elicited pelvic floor contractions in standing.

Participants were blinded to TAUS and verbally cued to perform volitional PFM contractions pre and post-INNOVO NMES. No verbal cues were given during INNOVO NMES, delivered at each participant's maximum tolerable amplitude (mA) to elicit a PFM contraction confirmed by a cranial displacement of the BBD observed with TAUS.

RESULTS



BBD – Bladder Base displacement



INTERPRETATION OF RESULTS

- A 5-minute bout using INNOVO NMES provided a significant sensorimotor stimulus that facilitated awareness of pelvic floor function and improved
 the ability to contract the PFM in supine and standing.
- High NMES amplitudes elicit a motor response and induce a cortical facilitation effect. In contrast, low amplitudes are associated with a cortical inhibitory effect, thus showing an amplitude-based dose effect.
- Studies report that NMES-elicited contractions recruit proprioceptive receptors by stimulating muscle spindles and Golgi tendon organs that send afferent information to the somatosensory cortex.
- Consequently, the presence or lack of a contraction directly impacts the somatosensory cortex and, ultimately, cortical excitability as determined by motor-evoked potentials (MEP).

CONCLUDING MESSAGE

- INNOVO elicited contractions that significantly improved PFM function in women who initially could not volitionally contract their PFM.
- Since increased strength cannot explain this improvement, it is plausible that INNOVO stimulated many proprioceptive and kinesthetic receptors in addition to sensory afferents, which led to an immediate change in motor response.

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