How Do Pelvic Floor Muscle Contractions Elicited by 2 Different Delivery Methods of Neuromuscular Electrical Stimulation Compare With Volitional Contractions in Supine and Standing in Nulliparous Continent Women?

Ruth M. Maher, PT, PhD, DPT, WCS, BCB-PMD¹
Dawn M. Hayes, PT, PhD, GCS²

ABSTRACT

Objective: This study compared volitional pelvic floor muscle (PFM) contractions with those elicited by 2 delivery methods of neuromuscular electrical stimulation (NMES) in 2 positions using transabdominal ultrasound (TAUS) imaging to assess bladder base elevation (BBE).

Study Design: A repeated-measures design.

Background: Pelvic floor exercises and NMES are prescribed to improve PFM contraction. However, the evidence regarding efficacy of transvaginal NMES (TvNMES) in eliciting a contraction has been limited by inadequate description of how PFM contraction was determined.

Methods and Measurement: Six healthy females were recruited for this preliminary study. Volitional PFM and NMES-elicited contractions were assessed in the supine and standing positions; order was randomly assigned with at least a 24-hour washout period. An NMES unit with a vaginal electrode (TvNMES) and a device using externally applied electrodes embedded in a garment (EES) were used. PFM activity was assessed via BBE using TAUS imaging. Two-way repeated analysis of variance was used, with statistical significance being \( P < .05 \).

Results: Greater BBE was seen for EES versus TvNMES \( (P = .004) \) in both positions. Volitional PFM contractions elicited greater BBE than TvNMES in both positions \( (P = .003) \) and were not significantly different when compared with EES \( (P = 0.98) \). Comparison between interventions in 2 positions resulted in statistically significant difference favoring the standing position \( (P = .002) \).

Conclusion: The EES device in this study was shown to facilitate significantly greater BBE than a TvNMES device and was well tolerated by the healthy participants. More importantly, EES elicited a contraction similar to volitional PFM contractions.

Key Words: pelvic floor electrical stimulation, ultrasound imaging, urinary incontinence pelvic floor dysfunction

INTRODUCTION

The nonsurgical treatment of stress urinary incontinence (SUI) is multidimensional, with options including simple lifestyle modifications, physical therapy, and pharmacological therapies. Physical therapy interventions for SUI are commonly based on performance of pelvic floor exercises (PFEs). There is good evidence that PFEs are effective in decreasing the associated signs and symptoms of SUI, with up to 70% of women experiencing symptom resolution with PFEs.¹⁻³ However, success is highly correlated with compliance and the ability to achieve an effective contraction of the appropriate muscles in an appropriate manner.³ Several investigators have reported that approximately one-third of women initially contract the gluteal muscles, hip adductors, or abdominal muscles when asked to “squeeze as if trying to stop the flow of urine.”⁴⁻⁹ However, Henderson et al⁵ reported that 84% of women with SUI and 85% of their continent counterparts contracted their pelvic floor muscle (PFM) on first attempt when given a verbal prompt as verified by digital palpation. In addition, some studies have postulated that incorrectly performed PFEs may increase the stress on the ligaments and fascia and worsen symptoms of prolapse and potentially promote incontinence.⁴,¹⁰⁻¹²

¹Department of Physical Therapy, School of Pharmacy and Health Professions, Creighton University, Omaha, Nebraska.
²Oncology Quality & Accreditation, Northside Hospital Cancer Institute, Atlanta, Georgia.

Ruth M. Maher is one of the patent holders for the externally applied NMES garment (INNOVO) used in this study, which she developed during her PhD at University College Dublin, Ireland. She receives yearly royalties via an IP agreement and is also a member of the Clinical Advisory Board for Atlantic Therapeutics, Galway, Ireland. Dawn M. Hayes has no conflicts of interest or sources of funding to report.

DOI: 10.1097/JWH.0000000000000099
This suggests that it may be necessary to employ strategies to facilitate PFM contractions and to provide feedback in order to confirm that appropriate contractions of the PFM are taking place in order to enhance the impact of PFEs as an intervention. Neuromuscular electrical stimulation (NMES) has been widely employed as a strategy for enhancing/facilitating PFM contractions. While many studies have shown a beneficial effect of transvaginal NMES (TvNMES) that is comparable with other conservative interventions for SUI, there are others that have failed to show a clear benefit when compared with other therapies or used adjutantly with PFEs.\textsuperscript{13–18}

Most studies seem to use 50 Hz as the treatment frequency but show considerable variability regarding pulse duration/width, size of electrode, and stimulating surface area in addition to different treatment times.\textsuperscript{15–18} Consequently, the ideal electrical parameters for pelvic floor stimulation have not yet been well established\textsuperscript{19} and the use and effectiveness of delivered TvNMES are potentially limited by the patient’s tolerance to the stimulation intensity, pain, and/or bleeding.\textsuperscript{20–24}

Several preliminary studies with a new NMES device (Innovo, Atlantic Therapeutics, Galway, Ireland), which uses an array of large externally applied stimulating electrodes embedded in a garment (EES) to elicit PFM contractions, have provided very promising results in patients with SUI, noting significant reduction in associated symptoms, improved PFM strength, improvements in quality of life, and acceptable subject comfort levels.\textsuperscript{25–27} However, the effectiveness of this protocol in terms of eliciting a PFM contraction has not been compared with volitional PFM contractions in healthy continent women or those with SUI.

Since deficits in PFM coordination, strength, and endurance are all evident in women with SUI when compared with those without,\textsuperscript{28,29} this preliminary study sought to initially establish how PFM contractions elicited with 2 methods of NMES (TvNMES and EES) compared with volitional PFM contractions. While many studies have shown a beneficial effect of transvaginal NMES (TvNMES) that is comparable with other conservative interventions for SUI, there are others that have failed to show a clear benefit when compared with other therapies or used adjutantly with PFEs.\textsuperscript{30–33}

Study participants were also evaluated whether they could subjectively acknowledge when either method of NMES elicited a PFM contraction while the effect of stimulation was visualized with TAUS imaging.

### METHODS AND MEASURES

#### Design

The method of PFM contraction and the effect of 2 different positions were examined in a 3 (EES vs TvNMES vs volitional) × 2 (standing vs supine) repeated-measures design.

#### Participants

A convenience sample of 6 healthy, nulliparous, continent students (mean age = 24.8 years, SD = 2.6) were recruited from one physical therapy department. The participants completed a short medical screening questionnaire and were prescreened by the researchers based on the inclusion and exclusion criteria presented in Table 1. The study was approved by the institutional review board, and all participants signed a consent form prior to the initiation of testing. All participants underwent a standardized bladder-filling protocol to allow for delineation of structures during ultrasound imaging.\textsuperscript{34} Participants were asked to void no less than 1 hour prior to the initiation of testing, after which they were instructed to drink 500 mL of water. Participants were then screened in the supine and standing positions to determine whether they could appropriately perform a volitional PFM contraction resulting in elevation of the bladder base when visualized with TAUS imaging.\textsuperscript{12,34,35}

#### Equipment and Protocol

The study consisted of the following testing conditions, each performed in the supine and standing positions:

<table>
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<tr>
<th>Table 1. Inclusion and Exclusion Criteria</th>
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<tr>
<td><strong>Inclusion</strong></td>
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<tr>
<td>English-speaking</td>
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<td>18-45 years of age</td>
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<td>Nulliparous female</td>
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<td>Ability to perform a pelvic floor muscle contraction and describe the contraction</td>
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Research Report

Journal of Women’s Health Physical Therapy © 2018 Section on Women’s Health, American Physical Therapy Association

(1) volitional PFM contraction; (2) transvaginal NMES using a vaginal electrode (TvNMES); and (3) NMES using an externally applied garment (EES). The order of testing and positions was randomly assigned, with a minimum of 5 minutes between each position change and a 24-hour washout period enforced between each testing condition where no further stimulation or volitional PFM contractions were performed. Study participants were asked not to perform volitional contractions during NMES or during the washout period.

The TvNMES protocol used a Pathway STM-10 (The Prometheus Group, Dover, New Hampshire) with a vaginal electrode, and the other protocol used a new device (Innovo, Atlantic Therapeutics, Galway, Ireland), which used an array of 8 surface electrodes applied to the buttocks and proximal anterior and posterior lower extremities embedded in a garment that is wrapped around the pelvis and proximal thighs (Figure 1). Each stimulator delivered a 50-Hz pulse. The EES device used a ramp up/down time of 0.5 seconds, with an on/off time of 5/4 seconds, respectively, and a 620-μs pulse duration. The TvMES protocol used a ramp up/down time of 2/1 seconds, with an on/off time of 5/5, respectively, with a 300-μs pulse duration. The vaginal electrode stimulation surface area was 2.31 cm$^2$, and the surface area of the externally applied electrodes was 1536 cm$^2$. The intensity of each NMES protocol was based on the participant’s maximal tolerated level recorded in milliamperes. Participants were also asked to verbalize when they perceived a PFM contraction was occurring, and 3 consecutive repetitions of each testing protocol were used for data analysis.

Outcome Measure: TAUS Imaging

We used TAUS imaging since it is noninvasive and has been determined to be a valid and reliable method in the assessment of PFM function. Sherburn et al$^{38}$ reported a 100% agreement between TAUS imaging and digital palpation in identifying a correct PFM contraction in the sagittal and transverse planes. In addition, Sherburn et al$^{38}$ reported intraclass correlation coefficients for within-session interrater reliability ranges of between 0.86 and 0.88 and for inter-session interrater reliability between 0.81 and 0.89. A significant correlation has also been shown between TAUS imaging and perineometry ($r = 0.72$).$^{39}$

A Sonosite 180 plus (Sonosite, Bothell, Washington) ultrasound device with a 3.5-MHz curvilinear array transducer was used to acquire images transabdominally (TAUS) of BBE as an indicator of PFM function. All US data were acquired by one investigator. The transducer was oriented in the transverse plane on the midline of the body suprapublically as described by Thompson et al.$^{12,34}$ The transducer was then manipulated until a clear image of the bladder base was visible. A marker placed at rest and at the end of all PFM contractions was used to measure bladder base displacement (in centimeters) via on screen calipers to determine PFM function, with the average of 3 consecutive contractions used for data analysis. Participants were blinded to all ultrasound imaging to ensure that participant performance was not affected by visual biofeedback.

Data Analysis

Normality was examined for each of the continuous variables. Two-way repeated analysis of variance was used to assess bladder displacement using EES, TvNMES, and volitional PFM contractions across 2 different positions (standing and supine). Homogeneity of variance was evaluated using Mauchley’s test of sphericity. A P value of less than .05 was considered statistically significant. Statistical analyses were performed using SPSS for Windows, version 18.0. Minimal Detectable Change (MDC) for TAUS measurement of BBE was calculated from previous research as being 1.0 mm or 0.1 cm.$^{38}$

RESULTS

There was a statistically significant main treatment effect on BBE (Wilks $\lambda = 0.128$, $F_{2,4} = 13.6$, $P = .016$).

Figure 1. External neuromuscular electrical stimulation (EES) garment with embedded electrode array. Image shows the electrode position around the pelvis and proximal thighs once the garment is put on appropriately.
There was also a statistically significant positional effect in which BBE was greater in the standing position than in the supine position (Wilks’ $\lambda = 0.136$, $F_{1.5} = 31.67$, $P = .002$) (Table 2). External electrical stimulation (EES) and volitional PFM contraction created the greatest BBE (0.84 cm, SD = 0.13; and 0.84 cm, SD = 0.01) compared with TvNMES (0.11 cm, SD = 0.12 cm) (Figures 2 and 3). Changes in BBE for EES and volitional PFM exceeded the MDC of 0.1 cm whereas those for TvNMES were equal, thus providing evidence for clinical significance in favor of volitional PFM contractions and those elicited by EES.

Significant pairwise differences were noted between volitional PFM contraction and TvNMES ($P = .003$) and between EES and TvNMES ($P = .004$); however, there was no significant difference between BBE elicited by volitional contractions and EES (Table 2). Pairwise comparisons revealed that BBE was significantly greater in the standing position (0.89 cm, SD = 0.13; $P = .002$) than in the supine position across all testing interventions (Figures 4 and 5; Table 2).

Average intensity among participants was as follows: EES was 43 mA in the standing position and 40 mA in the supine position, and TvNMES was 26 mA in the supine position and 28 mA in the standing position. All participants reported the sensation of a PFM contraction using both devices. TAUS imaging showed evidence of PFM contractions elicited by EES in all participants, but only one of the 6 participants demonstrated a PFM contraction with TvNMES.

**DISCUSSION**

This preliminary study used TAUS imaging to compare PFM contractions across different conditions. We found that the EES protocol elicited a PFM contraction that was equivalent in function as assessed by BBE to a volitional contraction and more effective than that elicited using a TvNMES protocol in a group of healthy, nulliparous, continent women. These effects were observed in both positions studied using TAUS evaluation of contraction. Future work is needed to investigate whether the findings noted in this sample of women would be replicated in those with SUI.

The acute sensation experienced and described by all participants while using TvNMES was described as a “tightening or squeezing” in the perineal area. However, TAUS imaging confirmed that only one of 6 participants had a visible PFM contraction with TvNMES despite all participants verbalizing the occurrence of PFM contractions. This one participant could tolerate a higher intensity in all positions when compared with the remaining participants. For EES, intensity tolerance was greater across all participants when compared with TvNMES. This was most likely due to the difference in current density, as the average current density of TvNMES (11.26 mA/cm$^2$ in the supine position and 12.12 mA/cm$^2$ in the standing position) exceeded that of EES (0.03 mA/cm$^2$) in both positions.

NMES stimulates muscles indirectly, that is, through their motor nerves. The motor nerve is most susceptible to stimulation at the point where it branches to enter the muscle, known as the motor

### Table 2. Subject Position: Standing Versus Supine

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean Difference, cm</th>
<th>95% CI of Mean Change</th>
<th>$P$</th>
<th>Effect Size ($\eta_p^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing vs supine</td>
<td>0.57</td>
<td>0.31–0.84</td>
<td>.002</td>
<td>0.86</td>
</tr>
<tr>
<td>Type of intervention: Volitional vs external NMES (EES) vs transvaginal NMES (TvNMES)</td>
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</tr>
<tr>
<td>Volitional vs EES</td>
<td>−0.002</td>
<td>−0.31 to 0.31</td>
<td>.98</td>
<td>…</td>
</tr>
<tr>
<td>Volitional vs TvNMES</td>
<td>0.728</td>
<td>0.39–1.1</td>
<td>.003</td>
<td>0.87</td>
</tr>
<tr>
<td>EES vs TvNMES</td>
<td>0.731</td>
<td>0.36–1.1</td>
<td>.004</td>
<td>0.87</td>
</tr>
</tbody>
</table>

Abbreviations: EES, external electrical stimulation; NMES, neuromuscular electrical stimulation; TvNMES, transvaginal neuromuscular electrical stimulation.

![Figure 2](image-url)
point (MP). Therefore, the closer the electrode is to the MP, the less current it should take to stimulate the muscle through its nerve, given the proliferation of sodium channels and lower impedance.\(^{40}\) However, the location of the deep and superficial PFM makes it difficult to find the MPs in addition to ensuring uniform contact transvaginally to facilitate a contraction. In addition, the stimulating surface area on the transvaginal electrode is restricted because of the dimensions of the vaginal space.

While previous studies have indicated that larger electrodes produce stronger motor responses and less pain than smaller electrodes, few studies if any report the electrode size, current density, or indeed the position of the participant during the NMES intervention.\(^{40-42}\) Larger electrodes are also more comfortable for thicker fat layers and deeper nerves.\(^{43}\) This preliminary study showed that the EES protocol that used an extremely large stimulating surface area around the pelvis and proximal lower extremities elicited an appropriate PFM contraction that elevated the bladder base more than stimulation via TvNMES. TvNMES elicited a PFM contraction in one participant despite all participants reporting the sensation of a contraction. This finding is consistent with that of a study by Bø and Maanum,\(^{14}\) who reported and observed via perineal motion an appropriate PFM contraction occurring in one of 9 subjects using TvNMES despite most subjects perceiving a PFM contraction had occurred.

High current density can cause pain/discomfort, which can be a limiting factor to increasing intensity sufficient to elicit a muscle contraction.\(^{44,45}\) All participants in this study reported discomfort with TvNMES and none with EES. BBE elicited with EES was similar to that of volitional PFM contractions in this group of healthy participants. This is an interesting finding and infers that the new EES device used in this study elicits a similar PFM contraction to that induced volitionally when determined functionally via BBE viewed with TAUS imaging. We did not assess strength of contraction; however, studies have reported a moderate positive correlation between elevation of the bladder base on TAUS imaging and PFM strength.\(^{39}\)

Most studies reporting on the use of NMES in those individuals with SUI rarely, if ever, report the

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**Figure 3.** Effect of subject position on bladder base elevation.

**Figure 4.** Effect of subject position on bladder base elevation during volitional pelvic floor muscle contraction in the standing and supine positions. Volitional contraction in standing (VST) shows greater bladder base elevation (1.19 cm) than volitional contraction in the supine position (VSUP) (0.18 cm). On-screen calipers determined the amount of bladder base elevation.
position in which the participant received the intervention, that is, supine or standing. Several studies have reported that participant positioning influences PFM resting tone and recruitment in continent and incontinent women. This effect has been noted in the deep and superficial muscles of the pelvic floor to possibly accommodate for the increased amount of intra-abdominal pressure created by the trunk musculature. In addition, larger BBEs assessed via TAUS have been reported in the standing position when compared with the supine and hook-lying positions. Our findings noted a significant positional effect using NMES favoring the standing position.

We also postulate that current density, variability in vaginal dimensions, variability in pelvic floor innervation, and a positional effect may explain why few subjects had visible contractions on TAUS with TvNMES. These factors may alter the current path from the supine to standing positions, thus affecting muscle recruitment in addition to difficulty keeping the electrode in situ in the standing position. In fact, a positional change of more than 10 mm of the vaginal electrode has been shown to affect maximal urethral response to electrical stimulation. In addition, there may be asymmetry in innervation to the PFM, variability regarding location and sensitivity of peripheral nerves. Of particular interest are 2 studies that entailed detailed microdissection with staining to determine the innervation and morphology associated with levator ani innervation. Barber et al suggested that the levator ani is not innervated by the pudendal nerve but by innervation that originates from the sacral nerve roots (S3-S5), whereas Shobeiri et al reported that the levator ani nerve was derived from S3 and S4 ventral sacral foramina, with the pudendal nerve (S2-S4) not providing any innervation of the levator ani muscle. This variability in innervation may determine whether TvNMES can elicit a motor response in some individuals and may explain the equivocal findings regarding the efficacy of TvNMES in pelvic floor conditions such as SUI.

Limitations
Since many of those with SUI have difficulty volitionally performing a PFM contraction in the supine and/or standing positions, we decided to recruit only nulliparous continent women. We believe that our study participants served an appropriate purpose in this study, which focused on the most beneficial NMES intervention with associated parameters to elicit a PFM contraction that was similar to a volitional PFM contraction. Consequently, the generalizability of our findings is unknown, given the small sample size and inclusion of only healthy, nulliparous, young females.

CONCLUSION
The findings of this preliminary study provided evidence to support that the EES method for eliciting both a PFM contraction and volitional PFM contractions was superior to TvNMES in all study participants in the supine and standing positions, with the latter producing the most BBE. Participants found TvNMES to be very uncomfortable. This finding is supported by other studies and effects compliance with treatment protocols using TvNMES and ultimately outcomes. No discomfort was reported with EES, and the device elicited PFM contractions in all subjects. Furthermore, the assumption that a PFM contraction is occurring based on subjective perception using pelvic floor NMES should be reconsidered, given our findings in this preliminary study. We recommend that TAUS imaging, digital palpation, or observation of the perineum be utilized to confirm a PFM contraction. Further studies are required on a larger population and in those with SUI before results can be generalized.