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WHAT GOES UP MUST COME DOWN? AN ANALYSIS OF THE PERIFORM PLUS INTRAVAGINAL SENSOR WITH INDICATOR USING SIMULTANEOUS ULTRASOUND IMAGING AND SURFACE ELECTROMYOGRAPHY IN HEALTHY CONTINENT WOMEN.

<u>Hypothesis / aims of study</u>

The purpose of this study was two-fold. Firstly, to determine if direction and amount of displacement of the external indicator of the Periform Plus sensor confirms if an appropriate pelvic floor muscle (PFM) contraction is occurring (Fig. 1). Secondly, to determine if displacement of the indicator is associated with direction and displacement noted on ultrasound imaging (US) and pelvic floor muscle (PFM) activity.

<u>Study design, materials and methods</u>

This was an observational pilot study. 5 healthy college aged continent women who could volitionally perform an appropriate volitional pelvic floor muscle (PFM) contraction were recruited for this study. Each subject completed a bladder filling protocol to allow for delineation of the bladder from the pelvic floor fascia and associated PFM. An appropriate PFM contraction presented as cranial displacement of the bladder by the PFM when assessed in the transverse plane with ultrasound imaging (US). Subjects completed 5 PFM contractions of 5 seconds on and 5 seconds off in 4 randomly ordered positions (supine, hooklying with knees at 90° of flexion, supine with feet flat against a wall and standing). Two minutes rest was provided between each testing position. All US imaging was acquired in the transverse plane using a curvilinear transducer. Direction (cranial or caudal) and amount of displacement by the Periform Plus indicator was assessed in centimetres while simultaneous sEMG was acquired. Subjects were blinded to US imaging and EMG.

<u>Results</u>

During PFM contractions the external indicator moved downwards in all subjects regardless of the position of testing. Hooklying with knees bent produced the greatest mean displacement of the Periform Plus indicator. Cranial displacement on US imaging was seen for most subjects in all positions (Table 1). Caudal displacement was noted in two subjects; one subject for supine and supine feet flat against the wall; and the other for supine. These positions were associated with higher EMG values and greater displacement of the Periform indicator for these subjects.

Table 1.
The effect of position on Periform displacement, US displacement and EMG

Position	***Mean Periform Indicator displacement (cm)†***	***Direction of Ultrasound Displacement ↑↓***	***Mean Maximal EMG (µV)***
Supine	2.34 ±1.30	60% ↑ **=>** 40%↓	125.01 ± 70.72
Supine feet flat at wall	2.30 ±1.43	80% ↑ **=>** 20%↓	106.94 ± 51.92
Hooklying knees@90°	2.47 ±1.34	100%↑	92.24 ± 55.11
Standing	2.30 ±1.56	100%↑	94.76 ± 50.84

† all displacement was down
↑ cranial displacement on US imaging
↓ **c**audal displacement on US imaging

Figure 1.
Periform ® PLUS EMG sensor and indicator illustrating the direction the indicator should go during a PFM contraction (**x** denotes incorrect contraction occurs if the indicator goes up; √ denotes correct contraction occurs if the indicator goes down); **a.** Shows indicator level when PFM at rest and b. Shows downwards (caudal) displacement during a PFM contraction in standing.

Interpretation of results
The Periform Plus intravaginal sensor provides instructions for use which state that an appropriate PFM contraction occurs when the indicator moves down or away from the body (Figure 1). This determination is based on the `Q-Tip Test` developed by Crystle et al (1).
The results of this study showed that despite all subjects displacing the indicator downwards during a PFM contraction, US imaging displacement was not in agreement. Two subjects exhibited caudal displacement of the bladder on US imaging in supine and supine feet flat against the wall testing positions in addition to increase PFM EMG activity (Fig 2). Caudal displacement on US is usually associated with a strategy which results in co-activation of the abdominals with a concomitant increase in intra-abdominal pressure (IAP). The increase in EMG activity could suggest the PFM were eccentrically contracting to accommodate for the increase in IAP (2). The greatest displacement of the indicator was noted in the hooklying positions with knees at 90° of flexion indicating that position did have an effect.

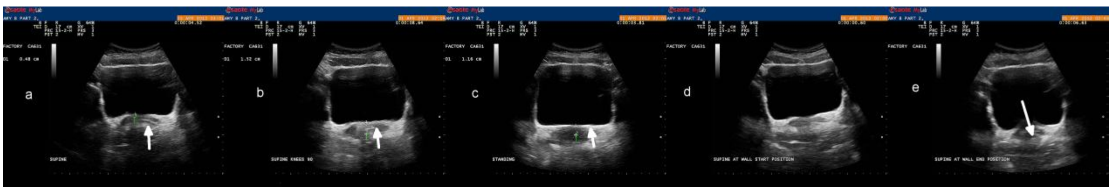

Figure 2.
US images showing PFM contraction in **a.** Supine; **b.** supine knees @ 90; **c.** standing ; all showing cranial encroachment (white arrow); **d.** shows PFM at start and **e.** end of contraction supine with feet flat against wall; showing caudal displacement with white arrow.

Concluding message
Few if any studies have used ultrasound imaging to confirm if vaginal biofeedback devices do provide appropriate feedback to the user. This study showed that the direction of the indicator on the Periform Plus did not always correlate with the direction of displacement on US imaging. The literature has shown that less than half of those given only verbal instructions are able to appropriately contract their PFM and that those who perform an inappropriate PFM contraction could potentially promote incontinence (3). Various training/biofeedback aids are available in an effort to teach or facilitate appropriate PFM contraction in the home. While co-activation of the deep abdominal muscles has been shown to occur during a PFM contraction, increases in IAP can have an impact on a compromised pelvic floor and cause urinary leakage and other pelvic floor dysfunctions. Clinicians or end users should not solely rely on biofeedback devices as a means of confirming appropriate PFM contractions without monitoring for strategies which excessively involve abdominal muscle recruitment and further compromise a pelvic floor dysfunction.

References
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Disclosures
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