Journal of Pelvic, Obstetric and Gynaecological Physiotherapy, Autumn 2017, **121,** 23–35

CLINICAL PAPER

Does an innovative vaginal biofeedback device accurately compare with real-time transperineal ultrasound for measuring the direction of urethral movement?

S. E. McCarthy & K. Khan
Faculty of Health Studies, University of Bradford, Bradford, UK

Abstract
Optimal voluntary pelvic floor muscle contraction (VPFMC) has lift and squeeze components; however, there are no validated tools in physiotherapy practice that provide biofeedback for both simultaneously. This study compares a vaginal biofeedback (VBFB) device containing a tri-axial accelerometer and a force-sensitive resistor with real-time transperineal ultrasound (TPUS) with respect to measuring the direction of urethral movement. Fifteen asymptomatic adult females were recruited for the study, and data collection in private physiotherapy practice was approved by a university research ethics committee. Pelvic floor muscle strength was assessed vaginally using the modified Oxford scale (MOS). Using simultaneous TPUS and VBFB, five maximal VPFMCs and five Valsalva manoeuvre images were captured on TPUS, and the angles of proximal urethral inclination (PUI) and internal urethral meatus position (IUMP) were measured. The VBFB device stored pitch angle and force (N) measurements on its online database. Primary outcomes (pitch and PUI) were compared for percentage agreement and agreement using Cohen's kappa coefficient (κ). Correlations between pitch, PUI, N, IUMP and the MOS were assessed using Spearman's rho (ρ) ($P<0.01$). Subgroups of VPFMC and Valsalva were similarly analysed. Strong agreement (95.33%, κ = 0.92) and correlation (ρ = –0.653, $P<0.01$) were found between VBFB (pitch) and TPUS (PUI). The agreements between pitch and PUI were 96% and 94.67% for VPFMC and Valsalva, respectively. Secondary outcomes demonstrated significant ($P<0.01$) correlations between IUMP, and both PUI (ρ = 0.669) and pitch (ρ = –0.673). Pitch and PUI both correlated for VPFMC (ρ = 0.384). Pitch correlated with MOS (ρ = 0.422) and N (ρ = 0.318) for VPFMC, and with N for Valsalva (ρ = –0.534). Proximal urethral inclination was associated with IUMP (ρ = 0.504) for Valsalva. The VBFB device exhibited high levels of agreement and significant correlation with TPUS in the assessment of the direction of urethral movement.

Keywords: biofeedback, pelvic floor muscle exercises, transperineal ultrasound.

Introduction

Pelvic floor disorders such as urinary incontinence (UI), faecal incontinence (FI), pain during sexual intercourse (dyspareunia) and pelvic organ prolapse (POP) affect more than one in four women worldwide (Durnea *et al.* 2014; Wu *et al.* 2014; Lipschuetz *et al.* 2015), with some studies reporting an incidence of up to 66% (Schettino *et al.* 2014). These disorders are not limited to elderly, overweight, pregnant or multiparous females, for whom these characteristics are common risk factors (Wu *et al.* 2014), but have also been found in women who are nulliparous (Durnea *et al.* 2014), primiparous (Lipschuetz *et al.* 2015) and high-level athletes (Thyssen *et al.* 2002; Schettino *et al.* 2014). The stigma associated with these conditions may

Correspondence: Sinéad McCarthy, Physiotherapy Department, Mercy University Hospital, Grenville Place, Cork T12 WE28, Ireland (e-mail: sineadmccarthypelvichealth@gmail.com).

lead to under-reporting (Dumoulin & Hay-Smith 2010; Price *et al.* 2010), and the symptoms can have a significant impact on the quality of life (QoL) of the individual (Kocak *et al.* 2005).

In an extensive cross-sectional study in the USA, Sung *et al.* (2010) found that the costs associated with female pelvic floor muscle (PFM) dysfunction were both significant and steadily increasing. Urinary incontinence is more common in females than males (Corcos *et al.* 2006; Milsom *et al.* 2009). Pelvic floor muscle training (PFMT) has been shown to be an effective intervention for stress urinary incontinence (SUI) (Dumoulin *et al.* 2007), which is the most common type of PFM dysfunction in women (Bø & Borgen 2001). The National Institute for Health and Care Excellence guidelines for the management of women with UI (NICE 2013) recommend PFMT as the first-line treatment for SUI and mixed UI. Pelvic floor muscle training has also been proven to be beneficial for faecal incontinence (Mahony *et al.* 2004) and POP symptoms (Hagen *et al.* 2014).

Background

As described by Kegel (1948), an effective, functional PFM contraction (PFMC) must comprise of both a squeeze around the openings of the urethra, vagina and anus, and also an upward lift of the perineum. These are the clinical criteria used by physiotherapists grading PFM strength on the modified Oxford grading scale (MOS) (Laycock 1994). Laycock & Jerwood (2001) further validated both these squeeze and lift components as vital elements of PFM strength assessment, and developed a reproducible technique for testing PFM performance using digital vaginal examination. The recommended method of assessing this combination of squeeze and lift is via a digital vaginal assessment (NICE 2013). This allows an appropriately trained practitioner to ascertain the quality of both the squeeze and lift components of the PFMC, and give feedback regarding technique to the person performing the exercise (Bø & Finckenhagen 2001; Peschers *et al.* 2001). Described as a cranioventral lift (CVL), this lift-and-squeeze movement of the PFMs in an upward and forward direction was subsequently demonstrated by Dietz *et al.* (2001, 2002, 2004) using real-time transperineal ultrasound (TPUS).

A questionnaire-based study conducted in the UK by Mason *et al.* (2001a, b) referred to the widespread practice of distributing written instructions for PFM exercises (PFMEs) to women in the antenatal and postnatal periods, as did Fine *et al.* (2007) in the USA. The latter authors found that just 10% of women received a digital vaginal examination during their PFME instruction up to 6 months postpartum. Mason *et al.* (2001a, b) reported that this was rated as unsatisfactory by women, and resulted in a poor quality of PFMT. The literature shows that up to 50% of women could not perform a correct PFMC on vaginal assessment following minimal verbal instruction (Thompson & O'Sullivan 2003; Talasz *et al.* 2008; Vermandel *et al.* 2015). In a randomized controlled trial (RCT) investigating SUI on pad-testing, Tsai & Liu (2009) found that PFMT following digital vaginal examination was more effective than PFMT based solely on written information.

In clinical practice, the importance of vaginal biofeedback (VBFB) was emphasized in a seminal study by Bump *et al.* (1991), who found that only 49% of women could perform an ideal PFMC after brief verbal instruction. In fact, 25% were performing an action that might have been detrimental to their continence status. This correlated with the previous results of Bø *et al.* (1988), and subsequently, Thompson & O'Sullivan (2003), who respectively found that 17% and 25% of women were creating a downward movement of the PFMs instead of the required elevation. Similarly, Talasz *et al.* (2008) and Vermandel *et al.* (2015) respectively reported that 44.9% and 33.4% of women who claimed to be able to perform a PFMC were unable to do so correctly with only minimal instruction. Following childbirth, this figure rose to 52.2% (Vermandel *et al.* 2015). However, Vermandel *et al.* (2015) found that verbal instruction from a trained physiotherapist improved PFMC in 74% of women who were assessed using perineal observation. Similarly, Henderson *et al.* (2013) demonstrated that brief verbal instruction alongside a digital vaginal examination improved the PFME technique in 78% of 120 women who had been found to be incorrectly contracting their PFMs.

Biofeedback, either in the clinic or via a device for home use, has been suggested as a method of enhancing patient awareness of muscle function, effort during training and the importance of adherence to a training programme over time (Herderschee *et al.* 2013). Used as an adjunct to PFMEs as part of a physiotherapy intervention, VBFB was shown to be of some benefit to patients in a systematic review of 1583 women in 24 trials examining VBFB in PFMT for UI (Herderschee *et al.* 2013). Sixteen of the trials analysed compared PFMT plus VBFB with PFMT alone, and found a slightly reduced amount of UI in the VBFB group. Another systematic review of 22 trials emphasized the importance of assessment and confirmation of a correct PFMC before commencement of a PFMT regime for UI and/or FI in antenatal and postnatal women (Boyle *et al.* 2012). The evidence for adjunctive VBFB in terms of effectiveness over PFMEs alone, symptom improvement and QoL remained inconclusive in two other good-quality (Level 1 evidence) RCTs (Mørkved *et al.* 2002; Aukee *et al.* 2004). However, the benefits of VBFB as an additional strategy to improve compliance with a home exercise intervention (Bump *et al.* 1991) and correct PFM isolation (Lee & Choi 2006; Ibrahim *et al.* 2015), and therefore, theoretically improve the efficacy of a PFMC, have been shown.

Accurate PFM isolation potentially reduces substitution or compensation by parts of the global musculature system, such as the abdominal, gluteal or thigh muscles, the attachments of which do not appear to provide specific support to the pelvic organs or promote continence. This correct isolation of the PFMs has been shown to improve UI symptoms (Russell *et al.* 2005). It has also been demonstrated that adjunctive VBFB in PFMT enhances awareness and isolation of the PFMs (Rao *et al.* 2007), and therefore, self-efficacy in exercise. A comprehensive search of the literature found no research-based evidence to validate any of the VBFB tools designed for home use that can provide simultaneous feedback to women regarding both the lift and squeeze components of a PFMC, and therefore, give them information about their exercise technique.

Real-time ultrasound is a reliable, repeatable (Thompson *et al.* 2005) and non-invasive method of assessing this CVL of the PFM in clinical and research settings. Dietz *et al.* (2002) found equivocal validity and reliability with regard to the use of each of three measurements of levator activity via TPUS: displacement of the internal urethral meatus (IUM); change in the angle between the symphyseal axis and margin of the IUM; and change in the axis of the proximal urethra. Pregazzi *et al.* (2002) proved good repeatability in ultrasound measurements of the urethral angle during both PFMC and the Valsalva manoeuvre. This evidence indicates that TPUS imaging should be a reliable tool for validating measurements of PFM CVL and downward displacement.

Figure 1. The wireless vaginal biofeedback device and data application (© Chiaro Technology Ltd, used with permission).

The aim of the present pilot feasibility study was to ascertain whether a VBFB device employing tri-axial accelerometry and vaginal force sensor technology showed agreement and correlation with TPUS in measurements of urethral movement direction. The participants were a volunteer convenience sample of women who were asymptomatic for PFM dysfunction. This new instrument (see Fig. 1) has not previously been validated in this regard. If it is found to be comparable to TPUS, which is known to be a valid clinical tool, this device would potentially be adjunctive to a woman's home exercise programme for PFMT by giving VBFB on PFME technique.

Participants and methods

Fifteen asymptomatic adult females (mean age = 34.8 years, range = 28–53 years) were recruited through convenience volunteer sampling.

Table 1. Inclusion and exclusion criteria: (BBUSQ) Birmingham Bowel and Urinary Symptoms Questionnaire; and (ICIQ-VS) International Consultation on Incontinence Questionnaire – Vaginal Symptoms

Inclusion criteria	Exclusion criteria
Females over 18 years of age	Known current urinary tract or vaginal infection
Asymptomatic on the BBUSQ and ICIQ-VS	Pregnant at the time of data collection
Adequate English language and literacy skills, and cognition/understanding to participate in the trial	Less than 6 weeks postnatal
	History of any bladder, bowel, gynaecological or pelvic floor surgery
	Inability to provide informed consent

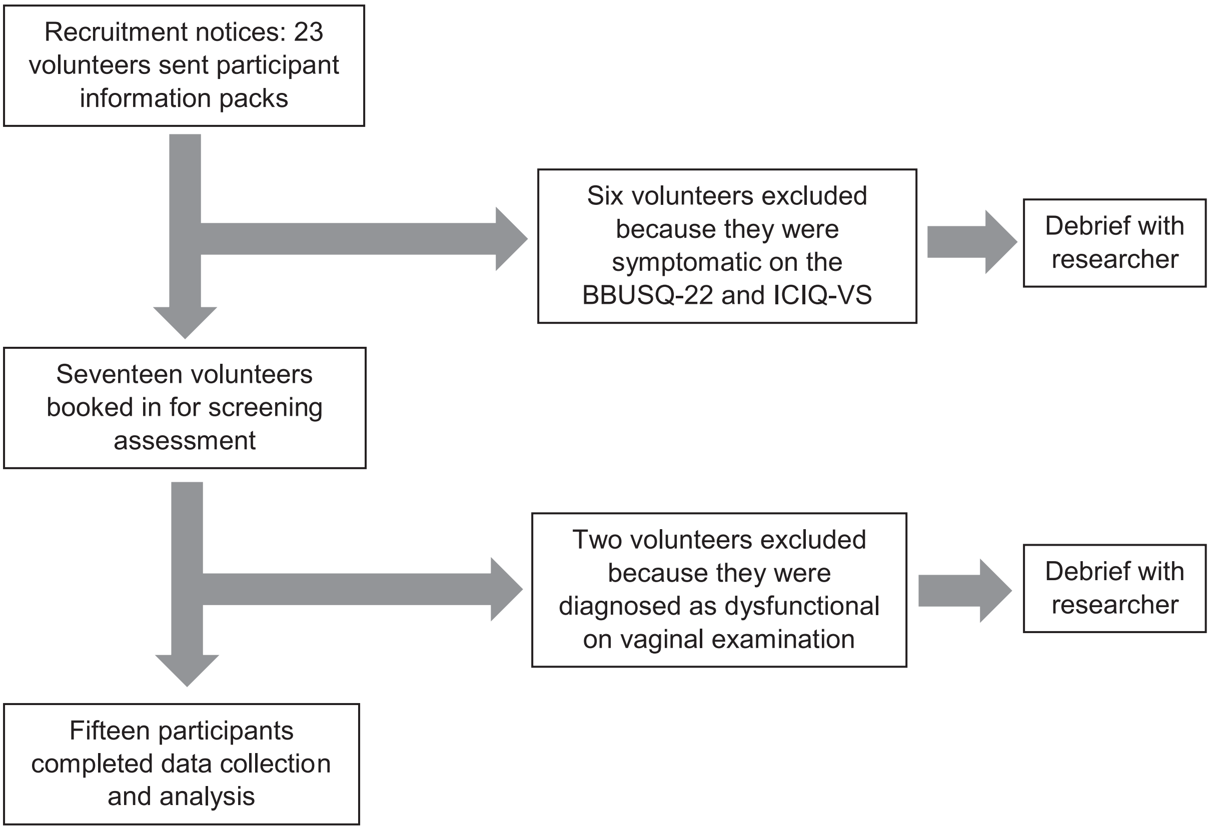

Figure 2. Screening and recruitment process: (BBUSQ-22) Birmingham Bowel and Urinary Symptoms Questionnaire; and (ICIQ-VS) International Consultation on Incontinence Questionnaire – Vaginal Symptoms.

The inclusion and exclusion criteria are outlined in Table 1. The screening and data collection were conducted in a private physiotherapy practice, and the study was granted approval (E521) by the Research Ethics Committee of the University of Bradford, Bradford, UK.

Pelvic floor muscle strength was assessed using digital vaginal examination. Progression to data collection required participants to achieve a minimum of a Grade 3 PFMC on the MOS (Laycock 1994; Laycock & Jerwood 2001), with a holding time of at least 5 s and a score of 2 (complete voluntary relaxation) on the Messelink scale from (0) absent, (1) partial to (2) complete (Messelink *et al.* 2005). A Grade 3 PFMC was deemed the minimum grade at which a PFMC discernibly demonstrates both the lift and squeeze components (Laycock & Jerwood 2001). This process was continued with consecutive volunteers until the present study had achieved a sample of 15 eligible participants (see Fig. 2). Women who were excluded were given the opportunity to debrief with the researcher (S.E.M.), and receive information regarding appropriate follow-up services as they required.

A convex TPUS scanner (HS-1500, Honda Electronics Co., Ltd, Toyohashi, Japan) and the VBFB device (Elvie, Chiaro Technology Ltd, London, UK) were used simultaneously while images were captured at rest and for a maximal 5-s vaginal PFMC (VPFMC) and a 5-s Valsalva manoeuvre (five times for each action). Angles of proximal urethral inclination (see Fig. 3), and the IUM position (IUMP) in relation to the symphysis pubis (see Fig. 4) were measured and recorded at rest, and for each of the 10 actions.

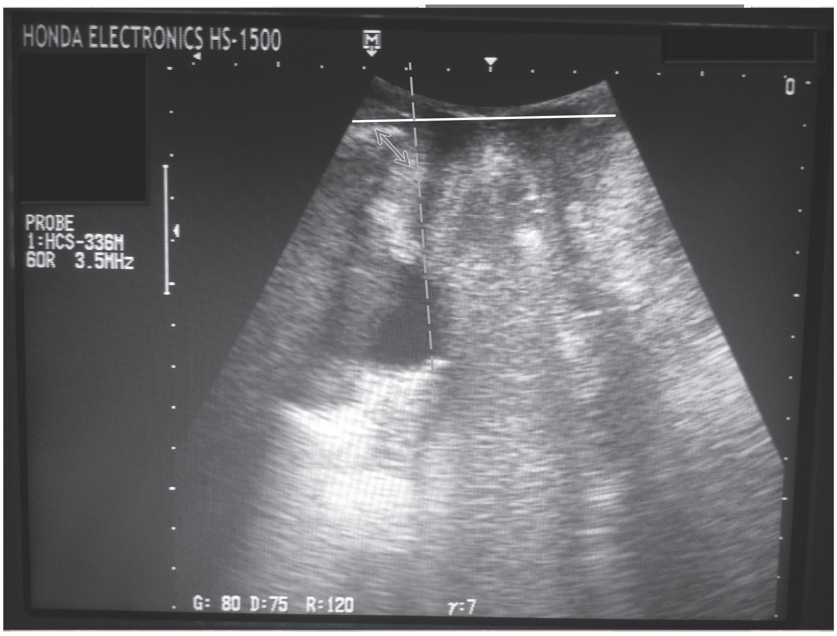

Figure 3. Angle created by a line through the central axis of the symphysis pubis crossing another through the central axis of the proximal third of the urethra.

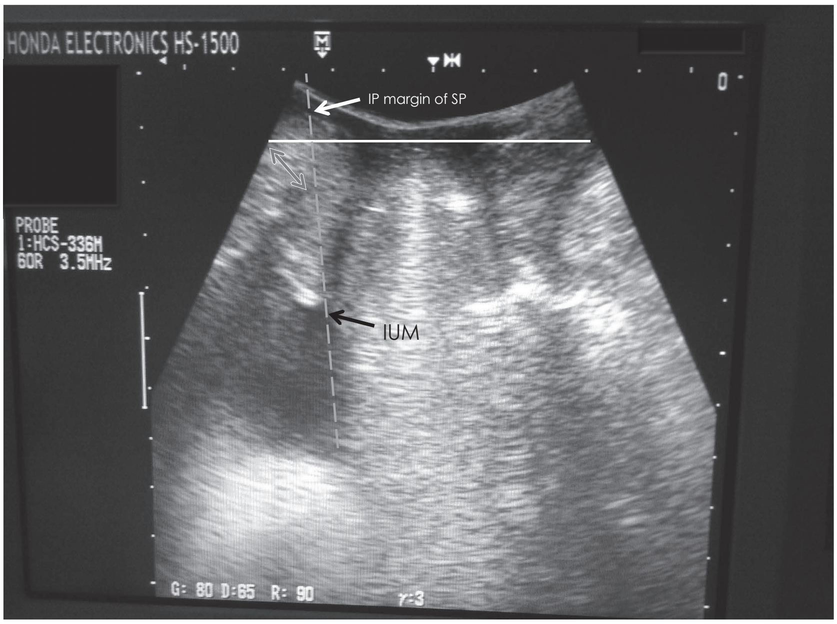

Figure 4. Angle created by a line through the central axis of the symphysis pubis (SP) crossing another from the internal urethral meatus (IUM) to the inferoposterior (IP) margin of the SP.

The change in angle (°), whether positive or negative, was deemed indicative of the direction of PFM movement. Pitch angle (°) and force (N) measurements were concurrently stored on a central online server via the VBFB device and its research application.

Using categorical data, the primary outcomes, i.e. pitch and proximal urethral inclination (PUI), were compared for percentage agreement and level of agreement with Cohen's kappa coefficient (κ). The percentage agreement of each action with the verbal instruction was also calculated for both pitch and PUI, and within the VPFMC and Valsalva subgroups. The data were categorized using the reasoning that pitch angle changes were expected to be positive and negative figures for a VPFMC and a Valsalva manoeuvre, respectively. This assumption was made because the pitch angle reading of the tri-axial accelerometer within the VBFB device is measured as the longitudinal axis of the device relative to the horizontal plane. Using the same anatomical reasoning, and evidence from the published literature (Schaer *et al.* 1995, 1996; Sendag *et al.* 2003; Dietz 2004), a change in the angle of the PUI axis was expected to be a negative figure

Table 2. Changes recorded in the outcome variables: (VPFMC) voluntary pelvic floor muscle contraction

Change	Outcome variable: Pitch	Proximal urethral inclination	Force (N)	Internal urethral meatus position
Median:				
150 actions	1	1	0.16	0
VPFMC	6	–15	0.21	–4
Valsalva manoeuvre	–8	17.5	0.09	6
Mode:				
150 actions	3	20	0.01	–2
VPFMC	3	–25	0.00	–2
Valsalva manoeuvre	–9	20	0.01	7
Range (minimum–maximum):				
150 actions	–21–15	–50–52	0–2.12	–19–26
VPFMC	1–15	–50–36	0–0.57	–19–16
Valsalva manoeuvre	–21–1	–8–52	0–2.12	–4–26

Table 3. Agreement between the primary outcomes: (PUI) proximal urethral inclination; (VPFMC) voluntary pelvic floor muscle contraction; (SE) standard error; and (N/A) not applicable

Comparison	Numerical agreement	Percentage agreement	Cohen's kappa coefficient (κ ± SE)
Pitch versus PUI:			
150 actions	143/150	95.33	0.92 ± 0.032
VPFMC	72/75	96.00	N/A
Valsalva manoeuvre	71/75	94.67	N/A
Pitch versus instructed action:			
150 actions	148/150	98.66	0.97 ± 0.019
VPFMC	75/75	100.00	N/A
Valsalva manoeuvre	73/75	97.33	N/A
PUI versus instructed action:			
150 actions	145/150	96.66	0.93 ± 0.029
VPFMC	72/75	96.00	N/A
Valsalva manoeuvre	73/75	97.33	N/A

for a VPFMC and a positive figure for a Valsalva manoeuvre when looking at the TPUS data.

Correlations between the outcomes for pitch, PUI, N, IUMP and MOS were assessed using Spearman's rho (ρ) ($P < 0.01$) because the data were non-normally distributed. Subgroups of the VPFMC and Valsalva data were also analysed for any relationships between the variables. As this was a pilot study, it was also postulated that recommendations would be elicited for future research if the feasibility of the use of this tool was proven.

Results

A total of 23 participants were screened in the present study following distribution of recruitment notices. Data collection was carried out over a 10-week period, and involved 15 eligible volunteers (see Fig. 2). The participants had a mean age [± standard deviation (SD)] of 34.8 ± 8.1 years and a mean (± SD) MOS score of 4.000 ± 0.366. The changes that were recorded in the four outcome variables are shown in Table 2. Table 3 outlines the level of agreement between the primary outcomes, i.e. pitch and PUI, and for each of these in comparison to the verbally instructed action.

A strong significant correlation (ρ = –0.653, $P < 0.01$) was found between the VBFB device and TPUS for pitch and PUI (see Fig. 5). Proximal urethral inclination and IUMP significantly correlated (ρ = 0.669, $P < 0.01$). Pitch and IUMP also correlated (ρ = –0.673, $P < 0.01$).

Pitch and PUI correlated for VPFMC (ρ = 0.384, $P < 0.01$) (see Fig. 6), but not for Valsalva (ρ = –0.041, $P = 0.73$) (see Fig. 7). Pitch demonstrated correlation with MOS (ρ = 0.422, $P < 0.01$) and with N (ρ = 0.318, $P < 0.01$) for VPFMC, and with N for Valsalva (ρ = –0.534, $P < 0,01$). Proximal urethral inclination was associated with IUMP (ρ = 0.504, $P < 0.01$) for Valsalva.

Discussion

A wireless vaginal device that connects via Bluetooth to a smartphone application has been created with the aim of providing women with real-time biofeedback about their PFME technique.

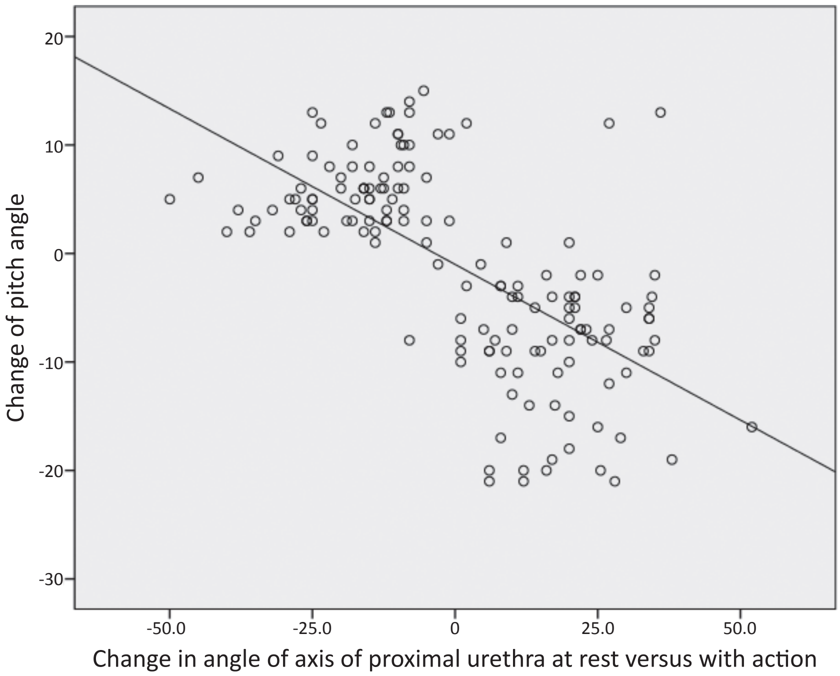

Figure 5. Relationship between the change of pitch angle and the change in the angle of the proximal urethral axis for 150 actions.

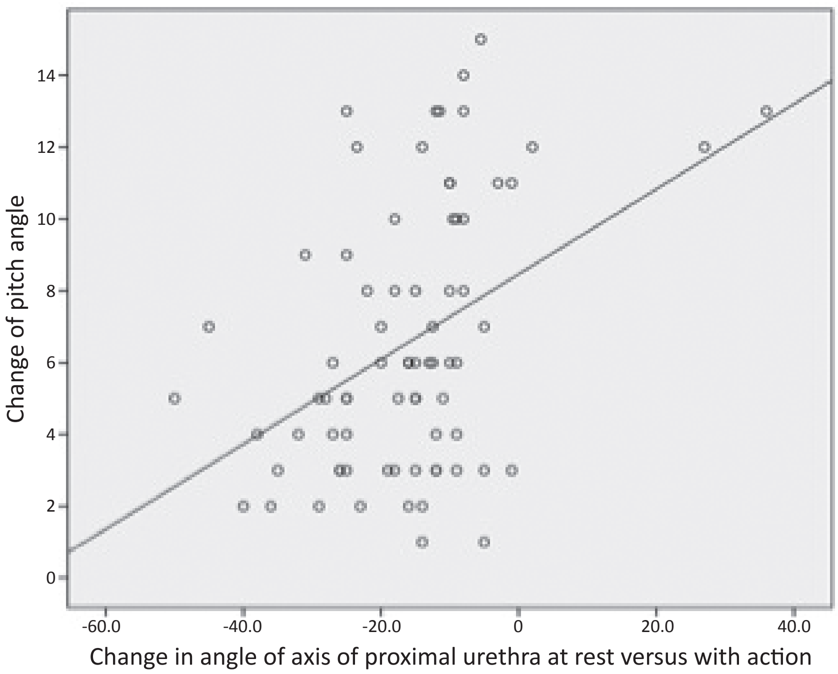

Figure 6. Relationship between the change of pitch angle and the change in the angle of the proximal urethral axis for 75 vaginal pelvic floor muscle contractions.

This device is novel in that, as well as having a force-sensitive resistor, it contains a tri-axial accelerometer that can give direction-specific feedback, and therefore, potentially identify whether a woman is creating downward displacement of her PFMs rather than a CVL. Transperineal ultrasound, which has been proven to be a valid and reliable tool for measuring PFM movement direction, was used to determine whether this new VBFB device would potentially provide women with accurate information.

The findings of the present pilot study demonstrated that there was a high and statistically significant level of agreement, and a large degree of correlation, between the data from TPUS (PUI) and the VBFB device (pitch) for 150 measurements of PFM movement direction in a sample of asymptomatic adult women. The Cohen's kappa

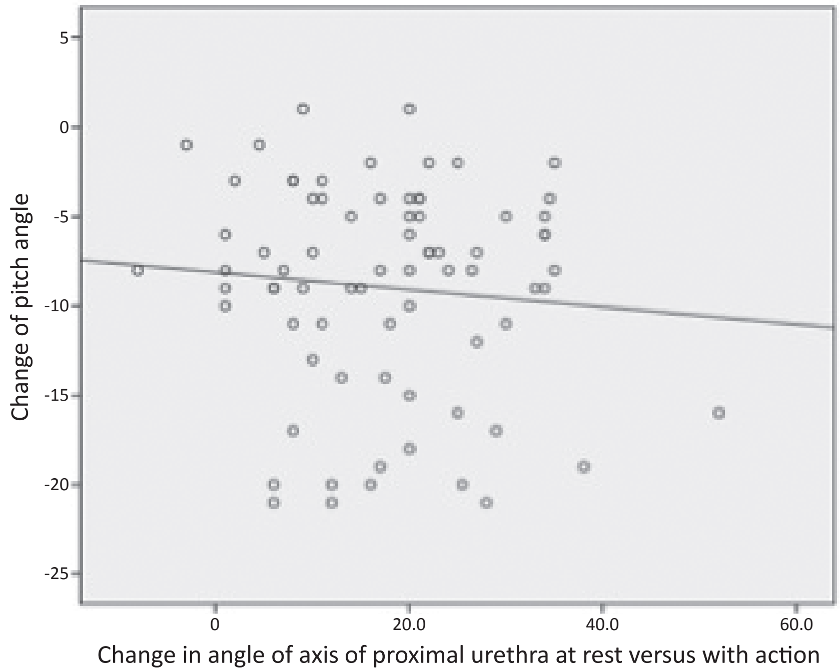

Figure 7. Relationship between the change of pitch angle and the change in the angle of the proximal urethral axis for 75 Valsalva manoeuvres.

statistical interpretation indicated an almost perfect level of agreement. For 75 VPFMCs, the primary outcomes also demonstrated a significant positive correlation. In the analysis of the secondary outcomes, a significantly strong correlation between the VBFB device (pitch) and a second measurement from the TPUS of PFM movement direction (IUMP), previously validated by Dietz *et al.* (2002), was also shown.

Transperineal ultrasound has previously been validated as having high reliability and reproducibility in the measurement of PFM movement direction, bladder neck position and displacement of the bladder neck with PFM activity (Schaer *et al.* 1995; Dietz *et al.* 2001, 2002; Peschers *et al.* 2001; Thompson *et al.* 2005). Two indicators of PFM movement (PUI and IUMP) were chosen for the analysis of the TPUS images in the present study, and these demonstrated a strong significant correlation, as per the work of Dietz *et al.* (2002). Each of these measures used the central axis of the symphysis pubis as a fixed bony reference line to calculate the change in urethral angle, as did previous work by Schaer *et al.* (1995) and Dietz (2004). The use of the symphysis pubis as a reference point has shown good inter- and intra-rater reliability in measurements of PFMCs and Valsalva manoeuvres (Schaer *et al.* 1995; Peschers *et al.* 2001; Dietz 2004). However, Armstrong *et al.* (2006) questioned the reliability of the central axis of the symphysis pubis as a reference line because of: the mobility of the probe on the perineum between the images captured; and the distortion effect of soft tissues associated with contractions of the PFMs. It is possible that this may help to explain why, in the present study, PUI and IUMP were positively correlated for 150 measures overall, and for 75 Valsalva manoeuvres, but not for 75 VPFMCs.

In contrast with the recent works of Rostaminia *et al.* (2015) and van Delft *et al.* (2015), the present authors did not find any significant correlations between vaginal palpation scores of PFM strength on the MOS, and either of the measures of PFM movement direction (PUI or IUMP) from the TPUS. However, as a result of the small sample size of this pilot, caution must be applied because the present findings also contradict the bigger studies of Dietz *et al.* (2002) and Thompson *et al.* (2006a), who found strong and moderate correlations, respectively, between ultrasound measurements of bladder neck mobility, and scores on vaginal palpation and perineometry. Transperineal ultrasound evaluates muscle action, contractility and, potentially, range of movement, rather than strength (Peschers *et al.* 2001). Although the Cohen's kappa statistic shows a very high level of agreement between pitch and PUI changes for 150 actions, the correlations appear slightly less impressive. This may be because these methods appear to agree very well in terms of movement direction, i.e. binary data indicating either a negative or a positive change, but not quite as much with regard to the magnitude of the movement in either direction, or as mentioned, the strength or force generated. Therefore, it is possible that there is an apparent relationship between measures of PFM movement direction, but not of its magnitude, as per Peschers *et al.* (2001) and Sherburn *et al.* (2005). Interestingly, a significant moderate correlation was shown between the change in pitch measured by the VBFB device and the MOS for VPFMCs, and between pitch and N for both VPFMCs and Valsalva manoeuvres. This perhaps indicates a link between PFM movement and the force, or strength, generated, which is more in line with the findings reported in the literature. This could suggest that the VBFB device is more sensitive to these measurements, and may have highlighted this link more effectively than the TPUS in the small sample involved in the present study, which possibly merits further investigation.

A correct PFMC is an inward lift and squeeze around the urethra with resultant urethral closure, stabilization and resistance to downward movement (Bø & Finckenhagen 2001). Based on the findings of Bump *et al.* (1991) and Thompson *et al.* (2006b), Whittaker *et al.* (2007) stated that improper performance of PFMEs might actually facilitate urine leakage. The subset of Valsalva data generated by the present study demonstrated that increased PFM force (N) was significantly correlated with a pitch change indicating downward displacement of the PFMs during a Valsalva manoeuvre. This finding shows that an increase in pressure does not mean that a CVL of the PFMs is occurring, and agrees with the findings of Thompson *et al.* (2006b). This reiterates the importance of assessing vaginal squeeze (e.g. by perineometry or electromyography), and also underlines that it is necessary to ascertain the direction of the PFM movement to be certain of the quality and benefit of the PFMC.

The primary outcome measures correlated strongly for 150 actions and 75 VPFMCs, but did not reach a significant correlation for 75 Valsalva manoeuvres. Reflexive co-contraction of the PFMs in response to an increase in intra-abdominal pressure may create some divergent outcomes in measures of PFM movement direction with Valsalva manoeuvres (Thompson *et al.* 2004; Haylen *et al.* 2010; Lovegrove Jones *et al.* 2010). Another potential explanation for the discrepancy between VPFMCs and Valsalva manoeuvres is that, despite vaginal examination and feedback regarding correct PFMC and Valsalva manoeuvre technique, it is possible that some women proved inconsistent in their response to an instructed action (Thompson *et al.* 2005). Moreover, given that the VBFB device showed 98.66% agreement with the instructed action, while TPUS showed 96.66%, it may also be proposed that the device is more sensitive and reliable than TPUS in capturing muscle activity at specific time points, as previously mentioned. Further research involving larger studies is warranted to confirm this possibility.

The findings of the present study demonstrate the ability of this vaginal device to give accurate biofeedback to women about their PFMEs, and therefore, establish its potential value as an adjunct to a prescribed home intervention of PFMT. Dietz & Shek (2008) and Lowenstein *et al.* (2010) reported that PFM strength was negatively correlated with PFM and sexual dysfunction at any age. A review by Mitchell *et al.* (2012) found that it was not reductions in muscle mass but a decline in muscle strength with ageing that was a greater risk for disability. This demonstrates the need for maintaining PFM strength in women to compensate for normal age-related changes, and prevent any deficits in the pelvic floor support system, as suggested by Alves *et al.* (2015). This theory, which proposes a need for ongoing strengthening, was further reinforced by a study by Kennis *et al.* (2013), who had previously stated that intensive exercise could not prevent age-related decline in muscle strength once exercising ceased. Sartori *et al.* (2015) found that age has less, if any, effect on the PFM strength profiles of continent women in comparison to those suffering from incontinence. As a result, it appears crucial that women who are, or have been, symptomatic for PFM dysfunction continue to maintain the strength of their PFMs as they grow older. Therefore, it is pertinent that they learn how to do PFMEs accurately (Henderson *et al.* 2013), get feedback from an appropriate practitioner (Vermandel *et al.* 2015), and then have the ability and confidence to adhere to a home exercise programme (Sacomori *et al.* 2015). This programme may well be a life-long project, as suggested by the findings of Wisdom *et al.* (2015), who concluded that skeletal muscle behaves in a "use it or lose it" fashion. This also correlates with the results of Campbell *et al.* (2013), who demonstrated that reduced skeletal muscle cross-sectional area and volume was associated with disuse.

Chen & Tzeng (2009) found that a woman's belief in her own ability to perform PFMEs is an important predictor of adherence to an exercise programme. Motivation to continue with a prescribed practice is enhanced by repetition, and by receiving feedback regarding the success and improvement of this practice (Rosenbaum 2011; Siu & Lopez 2012). Therefore, the results of the present study demonstrating the validity of the ability of a new VBFB device to give accurate information to women regarding their PFME technique at home has positive implications for persisting with of practitioner-prescribed exercise programmes, and suggest that it has a role in symptom management and prevention.

Limitations

The present findings cannot be extrapolated to either women who are symptomatic of any pelvic floor disorders or over a wide age range. Furthermore, the visual feedback, which would normally come from both TPUS and the smartphone application connected to the VBFB device, was unavailable to participants in the present study. Usually, in clinical practice, using TPUS for biofeedback gives visual reassurance to patients about the quality of their actions. This methodological limitation may have affected the consistency of the participants' performance. It is acknowledged that any conclusions drawn from this pilot study should be interpreted with some caution because of the small sample size and single researcher (S.E.Mc.C.).

Recommendations

The reliability and validity of this VBFB device as a measurement tool should be assessed in a population with bladder and/or bowel symptoms, as well as the elderly, bariatric and multiparous, and those with varying degrees of PFM dysfunction and pain. In future research, it would be valuable to investigate PFM movement in response to functional tasks, and also different loading scenarios and positions, using the VBFB device. The vaginal device, being wireless, comfortable and seemingly accurate, would potentially allow researchers to investigate PFM activity during a variety of occupational duties and physical exercises, and an array of postures and physiological loading scenarios. It may also be useful to include a validated measure of patient comfort or satisfaction in the form of a patient-reported outcome measure in future research involving this device.

Conclusion

The findings of the present pilot study revealed that an innovative VBFB tool exhibited high levels of agreement and significant correlation with TPUS, a previously validated and reliable method of assessing urethral movement direction as a result of PFM activity. Its potential to give women accurate information about their home exercise programme of PFMT, as prescribed in physiotherapy practice, was determined. There is a significant amount of published literature that supports the benefits of directional biofeedback, visual reinforcement and proprioceptive input in PFMT. Mastery of performance, which gives a sound sense of self-efficacy, allows women to continue with home exercises confidently, and may potentially prevent PFM dysfunction and/or symptoms in the future. The outcomes of the present study suggest that this VBFB device may allow women to attain mastery of performance in a non-clinical setting, and therefore, potentially achieve an ongoing and perhaps longer-term benefit from their practitioner-prescribed PFMT programme, which can reduce the symptoms of or prevent future PFM disorders.

Disclaimer

The VBFB device used in the present study is commercially available to the public. The researcher in the present study (S.E.Mc.C.) had no affiliation with, is completely independent of and did not receive remuneration of any kind as a result of this research from Chiaro Technology Ltd, or any individuals or groups connected with this organization.

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Sinéad McCarthy completed her undergraduate studies at Trinity College, Dublin, Ireland, in 2006. She first gained experience in women's health and continence physiotherapy at University Hospital, Limerick, Ireland, where she completed rotations and subsequently worked in the role of acting senior physiotherapist in women's health and continence in the University Maternity Hospital, Limerick. In 2011, Sinéad moved to Melbourne, Australia, where she gained experience in private physiotherapy practice before moving back to London UK, in 2013. She then worked as a specialist women's and men's health physiotherapist and team lead with Six Physio. Sinéad completed the University of Bradford MSc in Continence for Physiotherapists in 2016, and the present primary research was part of her course submission, for which she gained a distinction. She is now practicing as a continence care senior physiotherapist at the Mercy University Hospital in Cork, Ireland, and also in private practice.

Karen Khan has both a clinical and academic background, formerly in nursing and subsequently in midwifery. She completed her BA(Hons) in Midwifery and MA in Women's Studies at the University of York, York, UK, in 2000 and 2005, respectively. Karen was a senior lecturer at the University of York until 2014, when she moved to join the School of Midwifery and Reproductive Health at the University of Bradford. She is currently undertaking a part-time PhD exploring the influence of labour ward culture on student and mentor perceptions of patient safety. Karen supervises a range of MSc final projects for students within the Faculty of Health Studies.