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Validity and Reliability of an Instrumented Speculum Designed to Minimize the Effect of Intra-abdominal Pressure on the Measurement of Pelvic Floor Muscle Strength

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Abstract

Background—Existing clinical measurements of pelvic floor muscle strength are contaminated by crosstalk from intra-abdominal pressure. We tested an improved instrumented speculum designed to minimize this crosstalk. The hypotheses were that the speculum yields: 1) maximum vaginal closure forces unrelated to intra-abdominal pressure, 2) discriminatory validity between women who have strong vs. weak pelvic floor muscles, and 3) acceptable test-retest reliability.

Methods—Maximum voluntary vaginal closure force was measured in 40 incontinent women (20–77 years) using the improved instrumented speculum on two visits spaced one month apart. At the baseline visit, intra-abdominal pressure was also estimated via intra-vesical catheterization during the vaginal closure force measurement. Subjective estimate of pelvic floor muscle strength was also assessed using digital palpation by a skilled examiner to determine group placement as “strong” (n=31) or “weak” (n=9).

Findings—Vaginal closure force was not significantly correlated with intra-abdominal pressure ($r = -.26$, $p = .109$). The groups with subjectively scored strong and weak pelvic floor muscles differed significantly by mean [SD] maximum vaginal closure force (3.8 [1.7] vs. 1.9 [0.8] N respectively, $p < .01$.) Across both time points the mean vaginal closure force was 3.42 [1.67] N with a range of .68 to 9.05 N. Mean Visit 1 and Visit 2 vaginal closure force scores did not differ (3.41 [1.8] and 3.42 [1.6] N, respectively). The vaginal closure force repeatability coefficient was 3.1 N.

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Interpretation—The improved speculum measured maximum vaginal closure force without evidence of crosstalk from intra-abdominal pressure, while retaining acceptable discriminant validity and repeatability.

Keywords

vaginal closure force; levator ani; strength; instrumented speculum; repeatability

Introduction

Measuring the ability of the levator ani to close the levator hiatus and distal vagina using a voluntary pelvic muscle contraction is an essential component of the functional assessment of pelvic floor disorders. Challenges remain, however, in the accuracy of measuring vaginal closure force (VCF) with any degree of validity or repeatability. This is partly due to the wide variety in genital anatomy (Lloyd et al., 2005), variation in the skill with which women can volitionally recruit the levator muscle (Miller et al., 2007) and the “noise” or “crosstalk” on the measuring of VCF caused by the rise in intra-abdominal pressure (IAP) that often accompanies a levator ani contraction.

Scoring systems such as the digital measure (Brink et al., 1989) and the Oxford scale (Laycock & Jerwood, 2001) subjectively quantify the pelvic muscle contraction and use scales such as “zero” to “five” or “poor,” “fair,” “good” or “excellent.” Digital palpation measurement of maximal voluntary contraction has the advantages of simplicity and low cost. However, these scoring systems are subjective and categorical in nature, have limited reliability (Frawley et al., 2006) and may not demonstrate the level of reproducibility needed in the research setting (Bö & Finckenhagen, 2001). Additionally, these scoring systems are reliant upon the examiner having previously assessed a wide range of pelvic muscle strengths to provide the foundation necessary for subjective comparison.

In an effort to obtain more objective measurements of maximum voluntary pelvic muscle strength, several different types of measurement instruments have been developed. The first, reported by Kegel (Kegel, 1948), was an intra-vaginal pressure perineometer. There have been various iterations of the pressure perineometer, but all contain intravaginal balloon catheters intended to measure pelvic muscle strength. These measurements suffer from three artifacts. First, the compliance of the balloon means that the device fails to measure levator muscle force isometrically, raising the possibility of systematic bias due to striated muscle’s length-tension and force-velocity relationships. Second, the fact that intravaginal squeeze pressure is known to vary along the vagina (Guaderrama et al., 2005) can be an issue. This may result in a lack of adequate differentiation between the effect of contraction of the levator ani muscles, the abdominal wall muscles, and gluteal muscle contraction (Peschers et al., 2001). Third, because of where they are placed, none of these devices differentiate between the effect of an intra-abdominal pressure rise, and a pelvic floor muscle contraction (see below).

An alternate to the pressure perineometer is the intra-vaginal instrumented speculum. This was designed by Ashton-Miller et al. (2002) to measure VCF isometrically via a pair of parallel strain-gauged bills. The reliability and validity of a similar device was reported by

Dumoulin et al. (2003 & 2004), while the test-retest reliability of the Ashton-Miller et al. (2002) device was reported by Miller et al. (2007). The latter authors demonstrated within-visit repeatability that improved by the third visit, but between-visit repeatability was more difficult to demonstrate given the lack of motor control women commonly experience in consistently isolating and maximally contracting their levator ani muscle. The instrument has proven adequate for identifying patients with levator muscle weakness (DeLancey et al., 2007). More recently, acceptable intra-class correlation of a bidirectional dynamometer, a speculum-type instrument designed to measure pelvic floor muscle strength has been reported (Nunes et al., 2011).

Although both the perineometer and instrumented speculum have helped to advance the field of pelvic floor muscle strength measurement, neither has adequately minimized the effect of crosstalk on the measurement of levator contraction force (here called the ‘signal’) from rises in intra-abdominal pressure (the ‘noise’). Intra-abdominal pressure (IAP) particularly confounds both measures when women have weak, injured or atrophied levator muscles, i.e., when the ratio of signal-to-noise (S-N) is low. In these cases, an inability to perform adequate levator contraction results in two potential outcomes when a woman is asked to contract her pelvic floor muscles. One is that the woman simply fails to recruit her levator ani muscles because she “can’t find them” (low VCF signal). The other is that she responds, but recruits other muscles (e.g., abdominal wall muscles and gluteus), some of which can result in a rise in IAP (high noise). This rise in IAP “noise” will be registered by a balloon perineometer as a pelvic muscle contraction, and would significantly augment the VCF unless a restriction is placed on how much IAP is permissible during the measurement, as for example the 5 cm H₂O limit on IAP rise imposed by Morgan et al. (2005) in recognition of this problem.

To address the above challenges the configuration of the Ashton-Miller et al. (2002) instrumented speculum was modified so as to render its VCF measurement less sensitive to IAP (see Methods), thereby improving the S-N ratio of the measurement. The purpose of this study was to test the improved instrumented speculum *in vivo* for validity and repeatability in measuring VCF by means of the following hypotheses: 1) the improved speculum VCF measure will be unrelated to IAP, 2) the improved speculum will demonstrate discriminatory validity between women who have strong vs. weak pelvic floor muscles, and 3) the improved speculum will demonstrate acceptable test-retest reliability.

2. Methods

2.1 Instrumented Speculum

The improved instrumented speculum (Fig. 1) evolved from the original instrumented speculum (Ashton-Miller et al. 2002), which is similar in size and shape to a Pederson speculum. This original speculum has two rounded aluminum bills, 7 cm long and 2.5 cm wide, cantilevered from a handle in parallel with one another with pairs of waterproof strain gauges near their roots. Each pair of gauges was connected to a Wheatstone bridge circuit in a differential shear beam configuration so that the change in voltage across the bridge was proportional to a shear force applied normally to the axis of each bill. Static weights ranging up to 20 N were applied normal to each bill to calibrate the transducer.

However, a limitation of this original speculum was that the VCF measurement is susceptible to crosstalk from IAP acting parallel to and in the same direction as these two forces. This problem, highlighted in Morgan et al. (2005), was temporarily managed by developing a ‘work around’ that limited the allowable increase in IAP on the instrumented speculum to 5 cmH₂O or less. This work around, however, required IAP monitoring from a separately placed urodynamic catheter capable of measuring IAP within the bladder. To avoid the invasiveness of the catheter, the mechanical design of the original speculum design was modified to eliminate IAP cross talk.

The resulting modified instrumented speculum differs from the original instrumented speculum in that the upper bill of the speculum is divided in two: the distal end of the now “divided” upper bill is rigidly attached to the distal end of the lower bill (Fig. 1). The proximal “short” portion of the upper bill nearest the handle is then positioned in the mid-sagittal plane so that its tip lies immediately dorsal to the inferior aspect of the symphysis pubis (Fig. 2). Thus positioned, the IAP acts normally on both the cranial and caudal surfaces of the modified lower bill that extend dorsal to the pelvic symphysis, thereby minimizing the net force across the modified lower bill due to IAP. The resultant force on the speculum then reflects the VCF with little crosstalk from IAP. Otherwise, the design, strain gauges and their location, their wiring and signal conditioning are as described previously (Ashton-Miller et al., 2002).

When used in the clinical setting the improved instrumented speculum is first covered with a non-latex disposable condom externally lubricated with a water-soluble gel. The handle of the instrumented speculum is held between the clinician’s gloved fingertips horizontally in the air while its transducer output is balanced to zero. It is then gently introduced into the vagina along the distal axis to a depth of approximately 5 cm. The correct depth of insertion of the speculum is found iteratively in the following manner. The speculum is first be inserted “too far” so that when the subject strains down to increase IAP without contracting her pelvic floor muscles, a VCF signal increase is seen on the real time graphical display, indicating that the shorter bill is recording IAP. While the subject strains down, the speculum is then withdrawn distally until a location is reached at which a graphical display of the VCF no longer shows any influence of the IAP signal increase. This indicates that the insertion depth of the tip of the shorter superior bill is now adjacent to the arcuate pubic ligament just below the symphysis pubis, where, by design, IAP can only act on the proximal (more dorsal) half of the superior bill (Fig. 2). Hence, at this location, the reaction force from the pubic symphysis is uncontaminated by the effect of IAP. With the speculum correctly placed, VCF is then measured during a maximum volitional levator ani contraction or “Kegel effort.”

2.2 Participants

Data for this analysis were collected from 40 female research participants who were incontinent by self-report. These participants served as a control group in a parent study. Inclusion criteria for the control group in this parent study included: female, 18 years of age or older, ability to read and write English, self-reported urinary incontinence during coughing, and at least two episodes of leakage at home noted on diary during a consecutive

three day period. Exclusion criteria for this same parent study control group were history of untreated urinary tract infection, surgery within the past year for urinary incontinence or pelvic organ prolapse, current pregnancy or pregnancy within the last year, history of pronounced pain or discomfort with pelvic exam, history of neurological conditions, history of incomplete bladder emptying or greater than 12 leakage episodes on 3-day diary. To be included in this sub-analysis of the improved instrumented speculum, additional inclusion criteria included complete data across two time points on variables under consideration. This study was approved by the University of Michigan Institutional Review Board and each participant gave written, informed consent prior to participating.

2.3 Procedures

Each participant had two clinical visits spaced about a month apart, with no intervention employed between visits. Women completed standard demographics questionnaires, a voiding diary, and questionnaires on bladder habits.

Throughout the study, the clinical data were collected by a single nurse practitioner with extensive experience in performing pelvic exams in both the clinical and research settings. At Visit 1, a urethral catheter (8 Fr. Gaeltec® dual-microtip urodynamics catheter, Medical Measurements Inc., Hackensack N.J.) was inserted in order to independently monitor IAP within the bladder simultaneously with the improved instrumented speculum VCF measures. We felt it was unnecessary to show the IAP and LA force relationship twice for the same woman so these bladder catheter measures were only conducted at the first visit to lessen participant burden and risk of infection.

Measurements with the improved vaginal speculum were taken at both visits. Research participants were positioned comfortably in a semi-recumbent lithotomy position. We first asked women to contract while the examiner palpated the levator ani muscle digitally through the vaginal sidewall and categorized the subject's overall strength subjectively as 'poor,' 'fair,' 'good,' or 'excellent.' The instrumented speculum was then introduced vaginally and positioned as described above. The subject was asked again to "contract your pelvic floor muscles, on the ready, set, go" with the resultant VCF being measured by the speculum in the mid-sagittal plane (Figs. 1 and 2). Because these women functioned as control participants in the parent study, they were given only a one-sentence verbal instruction to "contract or squeeze" the pelvic floor muscles for speculum measures. Even if the participant inadvertently strained when asked to contract, coaching was limited to a single verbal correction and one additional attempt. Readings for both urethral and vaginal catheters were stored digitally and coded later by a trained and blinded research assistant, and not by the nurse who was conducting the examination.

2.4 Data Analysis

VCF was calculated as the difference in the peak force measured during maximal voluntary contraction minus the baseline force measured in air prior to insertion. IAP was measured at the first visit as the absolute value of IAP measured simultaneously with VCF. We examined the data from women who performed as outliers on IAP to characterize their parallel data on IAP and VCF graphically.

Because women who have poor pelvic muscle tone are prone to straining down when asked to “contract the pelvic floor muscles,” we hypothesized that IAP and VCF would be unrelated when using the improved instrumented speculum. In other words, strain-induced IAP readings would not influence VCF readings using this improved speculum. The statistical analysis used to test this hypothesis was a Pearson’s correlation.

In order to provide two groups for contrasting groups analysis, data from the digital palpation assessment of levator ani muscle strength (Brink et al 1994) (here graded as excellent, good, fair, poor) were collapsed into dichotomous groups: excellent/good and fair/poor. We used independent t-tests to ascertain if there was a significant difference in VCF measurements between the two groups.

To assess the repeatability of the VCF measures using the improved instrumented speculum, the Bland and Altman (1999) method of analysis was used. This method involves obtaining descriptive statistics that show the mean, minimum and maximum of the readings across visits, the mean difference between the measures obtained at the two clinic visits, and the standard deviation of that difference. The coefficient of repeatability is then calculated as two times the standard deviation of the theoretical difference of zero, a value that is interpreted as 95% of the sample falling within the limit of the coefficient of repeatability. This statistical analysis offers the advantage of remaining in the original units of measurement (in this case, Newtons of force), a comparison to the full range of values shown within the sample, and offers clinicians and researchers a pragmatic approach to judge whether or not there is acceptable repeatability of the measures. Throughout all of the analysis, a p-value of 0.05 was considered significant.

3. Results

Mean participant age was 53.7 (range 20–77) years with the majority (80%) being Caucasian. Mean body mass index was 29.8 kg/m² with a range of 19.0 to 55.8 kg/m². Mean number of vaginal deliveries was 1.9 (range 0 – 9). Mean ($\pm$ SD) leakage episodes per day by participant diary was 2.9 ± 2.8 .

When simultaneous IAP and VCF measurements were displayed on the same time base, there was no evidence for cross talk of the IAP signal onto the VCF signal in any of the activities studied. For example in Figure 3, we show the two signals displayed for a subject at rest (at left), during a Kegel contraction (center) and during a Valsalva (at right). In the center panels, the force on the speculum is clearly uncorrelated with the steady P_{ves} signal. At right, the onset of the rise in P_{ves} leads the rise in the force on the speculum by at least 0.25 secs and when P_{ves} peaks, varies and then falls back to resting values those changes are not reflected in the speculum signal.

We compared measures of women with good/excellent muscle strength ($n = 31$) to those with poor/fair muscle strength ($n = 9$) to provide a contrasting groups approach to validity. The groups did not differ significantly by age, BMI or vaginal deliveries (Table 1). Women with poor/fair muscle strength had significantly more daily leakage episodes (5.0 per day) than women with good/excellent muscle strength (2.3 per day). The mean VCF of women

with good/excellent muscle strength was significantly greater at 3.8 ± 1.8 N compared to 2.0 ± 0.8 N in the group with poor/fair muscle strength ($p < .01$).

Repeatability of the improved instrumented speculum was analyzed using VCF measurements at both visits. The Visit 1 VCF was 3.41 ± 1.8 N and Visit 2 was 3.42 ± 1.6 N which were not significantly different ($p = .969$) with a Pearson's correlation of .603. Mean VCF score using both time points was 3.42 ± 1.67 with a range of .68 to 9.05 N. The mean difference (m_d) between VCF scores from Visit 1 to Visit 2 was .01 with a standard deviation of the difference of 1.5. The intra-individual differences in Visit 1 and Visit 2 VCF measures were distributed evenly above and below zero in the Bland-Altman plot (Fig. 4). The repeatability coefficient for the between-visit VCF measures using the improved speculum was ± 3.1 N.

4. Discussion

The goal of this study was to test the reliability and validity of the improved instrumented speculum. The results show a device whose design minimizes the confounding effects of IAP on the accurate assessment of isometric levator ani contraction, measured as VCF. By assessing the correlation between peak VCF and IAP readings, we were able to demonstrate that the improved instrumented speculum was able to discriminate between a rise in the VCF resulting from an actual pelvic muscle contraction and a rise in IAP.

Validity of the improved instrumented speculum was also upheld when, using a contrasting groups approach, the VCF readings were compared for women in the upper half range demonstrating excellent/good levator ani muscle strength versus those in the lower half range with fair/poor levator ani muscle strength, as judged by a common subjective clinical method for assessing pelvic muscle strength. Given the poor motor control of the levator ani, and limited sample size, we did not consider the use of more than two groups justified for this validation.

One of the main challenges to accurately quantify pelvic floor muscle strength in research is the frequent rise in the IAP exhibited when women attempt to contract their levator ani (Bump et al., 1991). This is because the effort made to contract these muscles is accompanied by co-contraction of the abdominal wall musculature, and sometimes diaphragm, thereby increasing IAP. Most existing devices that have been designed to measure pelvic floor muscle strength cannot discriminate increases in IAP from increases in VCF caused by levator muscle contraction. The one exception is the method used by Morgan et al. (2005), who limited the permissible rise in IAP, which helped to maintain a relatively high S-N ratio, but might have limited the maximum levator contraction force if a woman was used to cocontracting levator and abdominal muscles (Madill & McLean 2005). We did not design this study to compare measures from the improved instrumented speculum with other perineometers in the same woman because the latter would not be expected to correlate due to the influence of IAP on them.

The across-visit coefficient of repeatability of the improved speculum was 3.1 (.68 to 9.05) N which compared favorably to the across-visit repeatability 6.9 (2.5–10.8) N of the previously reported instrumented speculum Miller et al., (2007). We did not utilize women

who were trained at contracting their pelvic floor muscles, thus some of the between-visit variability we measured was likely due to a lack of motor coordination rather than variability introduced by the speculum itself. On the other hand, the typical patient with incontinence is not necessarily highly-trained or able to be consistent in contracting her pelvic floor muscles, therefore the repeatability measures most likely reflect what might be expected in such a patient population.

In this study repeatability of measures were assessed using data from two different visits, rather than repeat measures on the same visit. Although these were control participants, just being involved in a study of incontinence and pelvic floor muscle strength may have increased their awareness of their pelvic floor muscles, as reflected by the non-significant increase in VCF between the visits. Limitations of the instrumented speculum are that it is difficult to position if the woman is standing upright so postural load cannot reliably be measured. Use of the device presently requires the expense of a laptop and the instrument itself, but a smart phone could alternatively be used for a readout. The device requires use of a disposable condom. Despite these limitations, the improved instrumented speculum overcomes many of the prior limitations for measuring levator force and has application for both research and clinical use. In clinical application for instance, women attempting pelvic floor muscle training could be given an actual score and be motivated to quantifiably “improve” her score with pelvic muscle training. In research applications, the improved instrumented speculum could be used for determining cut-points for strength scores in regard to the decision to use pelvic floor muscle training to help reduce pelvic floor symptoms.

5. Conclusions

We conclude that the improved instrumented speculum provides a valid measure of VCF, it minimizes artifact due to cross-talk from intra-abdominal pressure, and is equivalent to other instruments in repeatability over two points in time.

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Highlights

- We developed an improved instrumented speculum to measure vaginal closure force.
- The improved speculum measurements were unconfounded by intra-abdominal pressure.
- We compared speculum measurements to subjective measures of pelvic muscle strength.
- The improved speculum had acceptable discriminant validity and repeatability.

Figure 1.
Photograph of the improved instrumented speculum. Note that the bills of the speculum are covered by a condom in actual use.

Figure 2.

The upward red arrow (“LA Force”) illustrates the line of action of the levator ani force; the downward black arrow (“Pubic Bone Rxn Force”) shows the line of action of the corresponding reaction (‘Rxn’) force from the inferior symphysis pubis. The short black arrows represent the IAP, acting normal to the upper and lower surfaces of the compound lower bill; these pressures null one another out so as to minimize the net force on that bill due to IAP. Minimizing this net force also minimizes the effect of IAP on the measured VCF. The short black lines near the root of each bill show the location of the strain gauges.

Figure 3.

Temporal histories of the intra-abdominal pressure (P_{ves} , bottom row) and the vaginal closure force ('Force') on the speculum (top row) in a subject performing three different activities: resting (left), during a maximum volitional contraction of the pelvic floor muscles ('Kegel Hold'), and during a maximum Valsalva effort (right). Evidence for P_{ves} not affecting the measurements of force measured with this speculum comes from the lack of a correlation between the upper and lower traces in the Kegel Hold (at center) and at right in the Valsalva. Note in the Kegel Hold how the force rises at 'a' and 'c' without P_{ves} rising, and the increase to a peak in force at 'b' followed by a decline that is not reflected in the P_{ves} trace below which instead remains steady after 'b.' In the Valsalva note the increase in the rate of increase in force beginning at 'd,' but a rate decrease in P_{ves} beginning at the same time point.

Figure 4.
Between-visit difference in VCF (N) for each research participant, ordered chronologically.

Table 1

Mean (SD) values for age, body mass index (BMI), parity status, incontinence status and maximum voluntary vaginal closure force (VCF), by group.

	Participants with Poor/Fair LA Strength (n = 9)	Participants with Good/Excellent LA Strength (n = 31)	
Age (years)	54.1 (13.3)	52.4 (13.5)	t = .32 p = .75
BMI (Kg/m ²)	31.8 (9.5)	29.3 (6.8)	t = .87 p = .39
Number of vaginal deliveries	2.44 (.88)	1.77 (2.2)	t = .90 p = .38
Average leakage episode per day	5.0 (4.8)	2.3 (1.5)	t = 2.7 p = .01
VCF (N)	2.0 (.77)	3.8 (1.8)	t = 3.0 p = .004*

*
p<.01