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MEASUREMENT OF FEMALE MAXIMUM ISOMETRIC LEVATOR ANI MUSCLE STRENGTH UNCONFOUNDED BY INTRAABDOMINAL PRESSURE.

Hypothesis / aims of study

Accurate measurements of maximum voluntary isometric contraction strength (MVS) of the levator ani muscle have been a longstanding challenge. This is partly due to the rise in intra-abdominal pressure (IAP) that often accompanies a pelvic floor muscle contraction acting directly on the measurement device. We have re-designed an instrumented speculum [1] to shorten the upper bill so that, upon vaginal insertion, its tip does not protrude dorsal to the pubic symphysis thus limiting exposure to IAP (Fig. 1). We have called this instrumented speculum the 'Levator Ani Strength Sensor' (LASS). This study tested the validity and reliability of the LASS with the following hypotheses:
H1 (discriminant validity) - Levator MVS (in Newtons) measured with the LASS will not positively correlate with the simultaneous increase in IAP.
H2 (contrasting groups validity) - Women who, on palpation, have more levator ani muscle strength, will have significantly higher MVS measurements compared to those with poor strength on palpation.
H3 (reliability) - MVS measurements taken with the LASS at baseline and at one month will demonstrate acceptable test-retest repeatability.

Study design, materials and methods

A single group of women with incontinence recruited for an experimental RCT completed a clinical pelvic exam at baseline and again at 1-month follow-up. The LASS was instrumented with strain gages near the root of each bill so as to measure levator force and symphyseal reaction force, respectively, acting normal to each bill in the sagittal plane. The LASS was covered with a disposable condom and inserted into the vagina to the proper depth by a research trained nurse-practitioner. A 6 F Millar urodynamics catheter was placed in the bladder (at the baseline visit only) to independently measure IAP during measurement of MVS with LASS. Participant coaching on pelvic floor contraction was limited to a simple verbal request to "contract your pelvic muscles on the ready, set, go". Levator MVS was calculated as the difference in the peak force reading measured during maximal voluntary contraction minus the force measured in air prior to speculum insertion. Subjectively, we also asked women to repeat the contraction without the LASS and palpated the levator ani to categorize strength as 'poor', 'fair', 'good', or 'excellent'. Data analyses for discriminant and contrasting groups validity relied on graphical portrayal of data, correlation and t-tests. We collapsed digital assessment into dichotomous groups: poor/fair or good/excellent muscle strength to create extreme groups for the contrasting groups analysis.

Results

Forty seven of the 49 women measured at baseline completed both visits. Mean age was 54.3 (range 20-83) years; the majority was Caucasian, educated, and middle/upper income. A significant negative correlation was found between MVS and IAP readings ($r = -.31$, $p = .043$,) supporting H1. A sample reading with exceptionally high IAP, measured as intra-vesical pressure per the catheter in the bladder, is shown in Figure 2. The mean (SD) force developed by women with good/excellent muscle strength ($n = 38$) was significantly greater at 3.8 (1.7) N compared to 1.9 (0.8) N in the group with poor/fair muscle strength ($n = 11$) ($p = .001$) supporting H2. H3 was supported in that the between-visit coefficient of repeatability (± 2 X the SD_{diff}) was ± 3.1 N; $r = .58$, ($p = .000$).

Interpretation of results

The LASS demonstrated discriminant validity (H1) and contrasting groups validity (H2). Test-retest repeatability (H3) was similar to previously reported instruments [2, 3]. To our knowledge this is the first device that minimizes the confounding affects of IAP on the accurate assessment of isometric levator MVS.

Concluding message

The results suggest that the LASS is a valid and reliable instrument for estimating levator ani muscle strength with minimal artifact from IAP in women with incontinence.

Figure 1. Lateral view of the Levator Ani Strength Sensor (LASS). The upward broad white arrow ("LA") shows the force developed by the levator ani, the downward broad white arrow ("SP") shows the equal and opposite reaction force developed by the symphysis pubis. The black arrows show how IAP acts on the upper and lower surfaces of the lower blade, cancelling the effect of one another so as to cause no net force on the device.

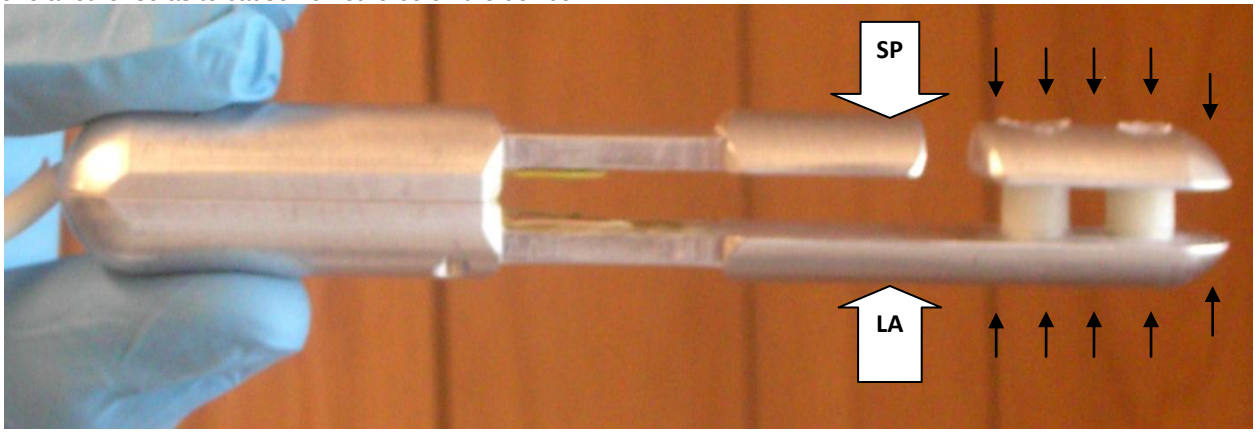
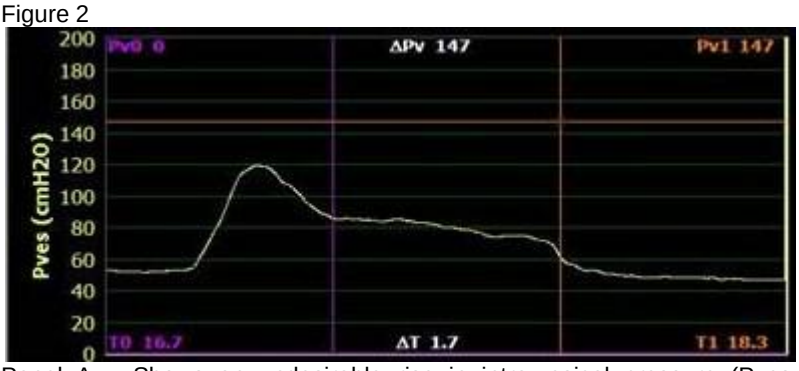
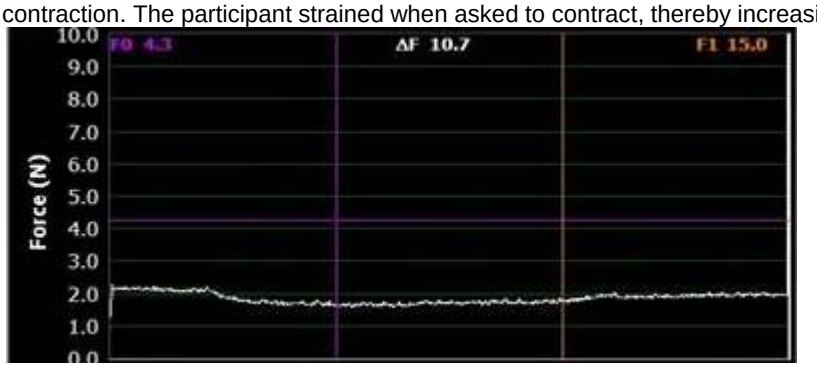


Figure 2



Panel A – Shows an undesirable rise in intra-vesical pressure (Pves cmH2O) during this woman's attempt at pelvic floor contraction. The participant strained when asked to contract, thereby increasing intra-abdominal pressure.



Panel B – Shows maximal voluntary strength (force in Newtons) measured with the Levator Ani Strength Sensor (LASS) simultaneous with measurement of intra-vesical pressure shown in Panel A. The LASS appropriately measures no rise in force production from the levator. This woman's levator muscles were non-palpable bilaterally on exam.

References

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2. Dumoulin C, Bourbonnais D, Lemieux MC. Development of a dynamometer for measuring the isometric force of the pelvic floor musculature. Neurourol Urodyn 2003; 22: 648-53
3. Miller JM, Ashton-Miller JA, Perruchini D, DeLancey JOL. Test-retest reliability of an instrumented speculum for measuring vaginal closure force Neurourol Urodyn 2007; 26: 858-63

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Michigan IRB-Med**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**