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TEST- RETEST RELIABILITY OF AN INSTRUMENTED ELASTOMETER FOR MEASURING PASSIVE STIFFNESS OF THE LEVATOR ANI MUSCLE.

Hypothesis / aims of study

Clinical evidence demonstrates strong associations between vaginal birth, the incidence of levator ani (LA) muscle injury, and a decrease in muscle function (1). Imaging modalities such as ultrasound and magnetic resonance imaging have provided insight into the nature of LA injury, confirming that it is significantly implicated in the development of pelvic organ prolapse (2). Strain of the LA muscles during delivery of the fetal head is considerable, and childbirth related trauma to the muscle has been shown to occur in 10-30% of women delivering vaginally (1,2). Thus, developing measures to identify *a-priori*, those who are most likely to suffer from injury during vaginal birth should be a high research priority. The inherent elasticity of the muscle clearly plays a role in the ability of the muscle to accommodate the fetal head. However, measuring passive stiffness of the muscle in vivo remains challenging.

The aim of this study was to further develop and test a novel elastometer (3), designed to estimate *in vivo* passive stiffness produced by the puborectalis component of the LA muscle, where it passes in close contact with the lateral walls of the vagina, from its origin on the pubic ramus.

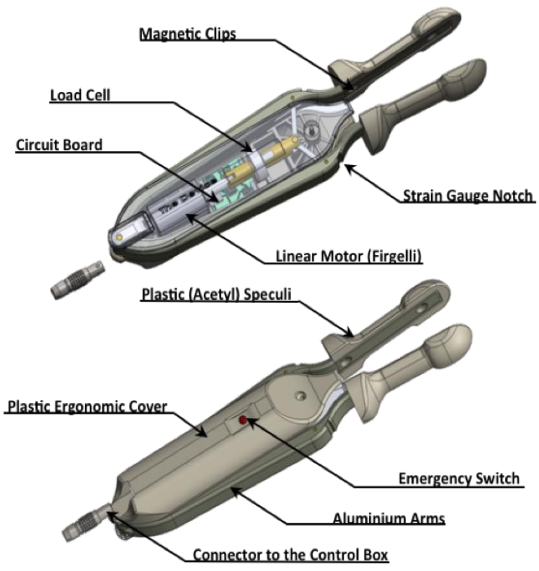
Study design, materials and methods

The elastometer used in this study is a more sophisticated version of a previously developed first-generation device (3). The current version of this instrument (Figure 1) boasts enhanced aesthetics and patient friendliness compared to our previous device. Notably, our elastometer can now implement user-defined measurement protocols under automatic computer control in order to measure the force-displacement characteristics of the LA muscle.

The device consists of a hand-piece comprising two aluminium arms, with detachable acetyl plastic speculum ends, actuated by a DC servo mechanism via a load cell. A load cell amplifier and displacement transducer are integrated into the hand-piece, providing force and speculum separation measurements. The hand-piece is connected to a control box that communicates with a laptop computer via a USB connection. The control box contains a data-acquisition device (USB-6009, National Instruments), motor drive circuit, and battery-based power supply. A custom MSWindows application implements a closed-loop motor control algorithm on the laptop, records measurements of speculum displacement and force, and provides feedback to the user. The laptop user-interface displays speculum separation and force on a strip chart, together with a force-displacement graph.

The design of the speculum end of the elastometer is such that the tip is wider than the neck, (26mm compared to 18mm) to reduce the likelihood of perineal muscles confounding measurement of passive stiffness. Magnetic clips attach the speculum ends to the device which allows for easy cleaning, and provides the facility of attaching speculums of various sizes.

Reliability and repeatability of the elastometer was assessed in 12 volunteers. None of the participants had had vaginal surgery, or any contraindications for vaginal examination. All participants were tested twice, 3 to 5 days apart using the same protocol. The speculum was inserted to the level of the puborectalis muscle (2-4 cm from the introitus) orientated in the coronal plane. After initial familiarisation with the device *in situ*, recording of the data commenced. All participants were encouraged to remain relaxed during the experiment. Data acquisition was automated with the device opening in 20 stepwise increments, to the desired separation, over 60 seconds. Data were collected at a frequency of 100 Hz. Averaged data over a three second period gave 21 data points per test. The procedure was repeated three times, with the initial run being considered as a preconditioning step and not used for data analysis. Statistical analysis was carried out using “R” version 2.12.2 (Copyright (C) 2011 The R Foundation for Statistical Computing). Results from Day 1 were compared with the re-test results using Bland/Altman repeated measures to determine any bias and limits of agreement and Intraclass correlation co-efficient (ICC) to determine reliability across tests and Days.



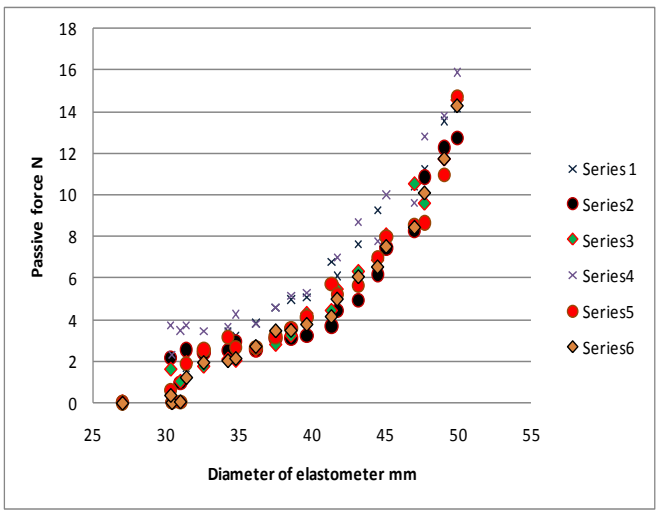


Figure 1. Schematic diagram showing components of elastometer

Figure 2: Representative plot from one subject. Series 1 -3 are from Day1. Series 4-6 are from Day 2. 1 and 4 were considered a preconditioning step.

Results

The mean age of the 12 participants was 44.3 years (range 26 to 58 years), BMI 26 kg/m^2 (range 20.4 to 33.7 kg/m^2). Two of these were nulliparous, with the median number of vaginal delivery being 2. Data was visualised in graphic form for each subject across all tests for both days. A representative plot from one subject is shown in Figure 2. ICC's for the second and third tests respectively were 0.92 (CI 0.89- 0.93), and 0.86 (CI 0.82-0.89). Limits of agreement (from repeated measures Bland Altman) were -2.79 N to +2.31 N, with a mean difference of -0.21 N.

Interpretation of results

Repeated Bland Altman demonstrates minimal bias with the mean difference close to zero at -0.12 N. The 95% limits of agreement range was slightly over 4 N, and likely to be due to biological variability. The high Intraclass correlation co-efficient for both tests between Days indicate minimal variability of the measurements.

Concluding message

This second generation elastometer has proved reliable and consistent in the measurement of passive stiffness of the puborectalis muscle in this group of volunteers. These results confirm satisfactory performance of the instrument in preparation for future studies validating this method in clinical and research settings.

References

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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**