Test- Retest reliability of an instrumented elastometer for measuring passive stiffness of the Levator Ani muscle.

Kruger, J.,1 Nielsen, P.,1 Dietz, H.P.,2 Taberner, A.1

1. The University of Auckland, New Zealand 2. Sydney Medical School – Nepean, University of Sydney

Background

• Clinical evidence demonstrates strong associations between vaginal birth, the incidence of levator ani (LA) muscle injury, and the development of pelvic organ prolapse 1.

• Strain of the LA muscles during delivery of the fetal head is considerable, and trauma to the muscle has been shown to occur in 10-30% of women delivering vaginally 1,2.

• The inherent elasticity of the muscle clearly plays a role in the ability of the muscle to accommodate the fetal head.

• Developing measures to identify a-priori, those who are most likely to suffer from injury during vaginal birth should be a high research priority.

Aim

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, in a test re-test series.

Materials and Method

• 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 with a data acquisition device that communicates with a laptop computer via a USB connection (USB-6009, National Instruments).

• Measurements of speculum displacement and force, provides feedback to the user via a strip chart with a force- displacement graph. The tip of the speculum is wider than the neck, (26mm compared to 18mm) which reduces 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 was assessed in 12 volunteers. Participants were tested twice, 3 to 5 days apart using the same protocol. The speculum was inserted to the level of the puborectalis muscle, orientated in the coronal plane. 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:

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.

Results

Mean age of 12 participants was 44.3 years (range 26 to 58 years). BMI 26 kg/m2 (range 20.4 to 33.7 kg/m2). Two were nulliparous, median number of vaginal deliveries 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. High Intraclass correlation co-efficient for both tests between Days indicate minimal variability of the measurements.

Concluding message

This second generation elastometer has proven 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.

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References:

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