INTRA-RATER RELIABILITY OF VAGINAL PRESSURE MEASUREMENT OF MYOMED 932.

Hypothesis / aims of study
A variety of devices have been developed and made commercially available to measure pelvic floor muscle (PFM) strength (1). Manometers measuring squeeze pressure and dynamometers measuring force directly are the most commonly used measurement tools. However, the dynamometers are still not commercially available and vaginal squeeze pressure measurement is therefore still the most commonly used method in clinical practice. Ideally, before taken into use, all measurement tools should be tested for reliability and validity. The purpose of the present study was to investigate intra-rater reliability of vaginal squeeze pressure measurement component of a widely used PFM strength measurement tool: Myomed 932 (Enraf-Nonius, Delft, Netherland).

Study design, materials and methods
This was a test-retest intra-rater reliability test. Twenty women volunteered to participate in the study. Mean age was 43.8 years (range 29-63), 12 having regular menstrual cycles and 8 were peri-or postmenopausal. Nineteen were parous. Mean body mass index (BMI) was 26.2 (range 20.4-40.0). Mean parity was 2.1 child (range 0-4). Thirteen women exercised their PFM presently but at different levels, 7 did not exercise their PFM. The subjects were informed briefly of pelvic floor function and instructed to focus on their PFM as much as possible during the contractions. Abdominal muscle contraction, observed as a small hallowing of the abdomen, was allowed if no movement of the pelvis was visible (2). The subjects were tested in supine position with the knees bent and legs slightly apart. The examiner tested the subjects for correct PFM contraction with vaginal palpation with one finger. Only subjects performing correct contraction (squeeze and elevation of the PFM felt around the finger) were included in the study. The pressure probe was 9 cm in length and 3 cm in diameter. A silicon ring was placed at the end of the probe to control for right depth of insertion as it stopped at the introitus vaginae. The subjects inserted the pressure probe themselves into the vagina. A condom was put over the probe to ensure hygiene for each participant. The condom did not influence the pressure readings. The middle third of the probe was soft, having the sensitivity for pressure changes during contraction and relaxation and corresponds to the localization of the PFM in the middle third of the vagina (3). The examiner controlled for correct/proper placement. The probe was connected to the equipment (Myomed 932) with an airfilled tube. The readings were given in hPa, and showed lowest, highest and mean pressure (including resting pressure). The subjects were asked to perform 8 close to maximum contractions with a holding period of 5 seconds with 10 seconds rest between each contraction. The examiner controlled for correct contraction during the test. The interval between the test-retest was 2-7 days to minimize a possible effect of different phases of the menstrual cycle. The 12 women having regular menstrual cycles were all tested in the first half of their cycles. Each woman was tested approximately at the same time on both days.

The results are expressed as mean (for the 8 contractions) with 95% confidence intervals and ranges. Correlation analysis was calculated using Intraclass correlation coefficient (ICC), a group average coefficient of variation (CV%) for paired measurements was used to report the intrarater reliability of the strength measurements. Bland Altman plot was done (fig.1). A paired t-test was calculated to check for systematic bias.

Results
There was no statistically significant difference between test one and test two (p=0.789):
mean 34.05 hPa (95% CI: 29.65-38.45) and mean 34.35 hPa (95% CI: 30.86-37.84). The measurements ranged from 18-52 hPa interindividually on day 1 and 24-50 hPa on day 2.

Intraclass correlation coefficient (ICC) was 0.830; p<0.001 and CV% was 10.2%.
Interpretation of results
The ICC test showed strong correlation although the CV% indicate that there is some degree of intra-individual variation. When measuring physiological function like muscle strength one can expect confounding variables e.g. fatigue, different types of stress (work, personal) and motor learning effects of the first test to interfere with results. The t-test indicates that the learning effect was not significant in this test.

Concluding message
This test-retest intra-rater reliability study for Myomed 932 showed a strong correlation for test one and two. Hence, this apparatus can be used in clinical trials assessing PFM strength. However, to ensure validity of pressure measurements of PFM, observer should always control for right placement of the probe and simultaneous inward movement of the perineum during contractions.

References
1. Physical Therapy (2005) 85, 3; 269-282
3. Neurourol Urodyn (1992) 11; 107-113

FUNDING: None
HUMAN SUBJECTS: This study was approved by the National Bioethics Committee, Reykjavik, Iceland. (ref.number 06-070) and followed the Declaration of Helsinki Informed consent was obtained from the patients.