Romero Culleres G[1], Peña Pitarch E[2], Jane Feixas C[1], Vilaseca Grané A[1], Arnau Bartes A[1], Montesinos Muñoz J[1], Sirvent Batalla G[1], Ticó Falguera N[1], Dalmau Garcia C[1], Abenoza Guardiola M[1]
1. Althaia Xarxa Assistencial de Manresa, 2. Escola Politecnica Superior d'Enginyeria de Manresa (UPC)

RELIABILITY AND VALIDITY OF A NEW VAGINAL DYNAMOMETER TO MEASURE PELVIC FLOOR MUSCLE STRENGTH IN WOMEN WITH URINARY INCONTINENCE

Hypothesis / aims of study
Though several studies of pelvic floor muscle assessment have been performed, there is still no general consensus on the most appropriate diagnostic method. Vaginal digital palpation using the Oxford Grading Scale is the most common method for evaluating pelvic floor muscle (PFM) strength. The technique is simple but it lacks reliability and validity. Measuring intravaginal pressure using a manometer also has limitations because it does not selectively record PFM strength. As a result, both methods estimate PFM strength only indirectly [1-3]. The aim of this study was to test the diagnostic reliability and validity of a new vaginal dynamometer for measuring PFM strength.

Study design, materials and methods
Test-retest study. One hundred and twenty-two women with stress urinary incontinence (SUI) were recruited. Patients were excluded if they had a history consistent with urge urinary incontinence or pelvic organ prolapse, pregnancy, previous urogynecological surgery or neurological conditions. The local ethics committee approved the protocol and patients gave signed informed consent. Examinations were conducted with the participants in the lithotomy position. PFM strength was evaluated three times in all women. The first examination comprised digital palpation carried out by a physician and quantified by the modified Oxford scale, and then two dynamometer measurements. PFM strength was recorded in Newtons (N). The second assessment was performed by a physiotherapist, and the third by a midwife who used digital palpation quantified by the modified Oxford scale and dynamometry measured in Newtons. Dynamometry measurements were performed by a new prototype dynamometer (patent number P201130449) comprising a speculum in which an inductive displacement sensor (LVDTSM210.10.2.KTmodel, Schreiber) is attached to a spring of known stiffness constant (k). Subjects were given guided instructions by the researcher on how to perform a PFM contraction. Two measurements were recorded: one initial value of baseline musculature response during 30 seconds, and the maximal voluntary strength during 10 seconds.The Cohen's Kappa index with quadratic weighting was used to assess the inter-rater agreement on the modified Oxford Grading Scale. The intraclass correlation coefficient (ICC) was calculated to assess the intra- and inter-rater reliability of the dynamometry measures. Bland & Altman plots and survival-agreement plots were also used. The diagnostic validity of the dynamometer in comparison to the gold standard (the modified Oxford Grading Scale) was assessed using a ROC analysis.

Results
Mean age was 55 years old (range 33-78); 54.9% of subjects were menopausal, 96.7% multipara and all were suffering from SUI.

Table 1. Patient distribution according to the modified Oxford scale.

	Physician		Midwife		Physiotherapist	
	n	%	n	%	n	%
No contraction (0)	9	7.4	7	5.8	12	9.8
Very weak contraction (1)	30	24.6	41	33.9	35	28.7
Weak contraction (2)	49	40.2	39	32.2	42	34.4
Moderate contraction: maintenance of pressure (3)	29	23.8	29	24.0	27	22.1
Good contraction: maintenance of pressure with resistance (4)	5	4.1	5	4.1	6	4.9

The Cohen's Kappa indexes for the digital palpation were 0.73 (95% CI: 0.63-0.83) between physician and midwife, 0.76 (95% CI: 0.72-0.85) between physician and physiotherapist, and 0.81 (95% CI: 0.75-0.87) between midwife and physiotherapist.
Intra-rater ICC, assessed through the two measurements performed by the physician with the vaginal dynamometer in similar conditions, was 0.93 (95% CI: 0.90-0.95). The inter-rater ICC was 0.92 (95% CI: 0.89-0.97).
Figure 2. Intra-rater reliability according to the Bland & Altman Plot.
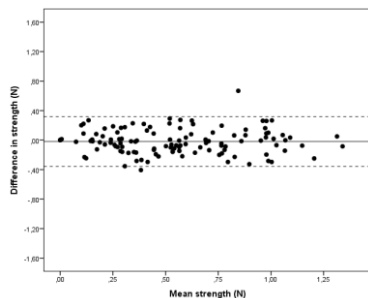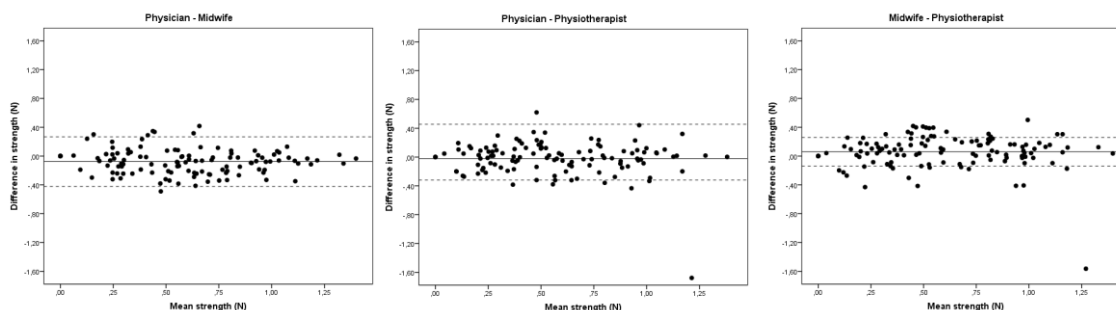
Figure 3. Inter-rater reliability according to the Bland & Altman Plot.

The intra-rater and inter-rater reliability disagreements were distributed in a similar way between the highest and lowest strength values (Figures 2 and 3). Differences were homogeneous along the horizontal axis. In 77% of patients the difference between the two measurements was 0.2 N or lower.

The results for the diagnostic validity of the dynamometer with regard to digital palpation calculated using the ROC analysis showed an area under the curve of 0.81 (95%CI: 0.73-0.89) for the physician, 0.84 (0.77-0.91) for the midwife and 0.79 (0.71-0.88) for the physiotherapist (figure 4).

Figure 4. ROC curve.
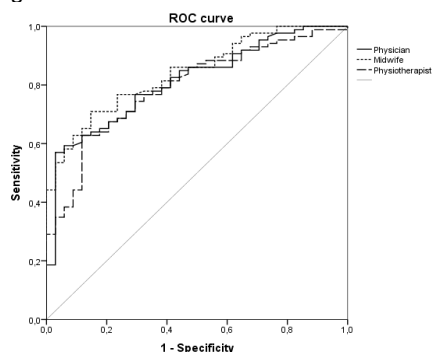
Interpretation of results
The results suggest that vaginal dynamometry is a reliable and valid instrument for quantifying PFM strength. The validity achieved with digital palpation was acceptable but because of its subjectivity this technique presents lower levels of inter-rater reproducibility.

Concluding message
Measurements of PFM maximum strength with the new vaginal dynamometer showed very good intra- and inter-rater reliability and showed good diagnostic validity compared with the modified Oxford Grading Scale. Our results support its use as a diagnostic instrument in clinical practice.

References
1. Physical Therapy 2005:85(3):269-282
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