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Development of a Dynamometer for Measuring the Isometric Force of the Pelvic Floor Musculature

Chantale Dumoulin,[1]* D. Bourbonnais,[1] and M.-C. Lemieux[2]

[1] *School of Rehabilitation, Faculty of Medicine, University of Montreal, Montreal, Canada*

[2] *Department of Obstetrics and Gynecology, Maisonneuve-Rosemont Hospital, Montreal, Canada*

Aims: The aim of this study was to design and develop a dynamometer providing a direct measurement of pelvic floor muscle (PFM) strength. **Materials and Methods:** Two pairs of strain gauges were mounted on the moveable branch of a dynamometric speculum allowing measurements at different vaginal apertures. Linearity, repeatability, independence of the site of application of the resultant force to the lower branch of the speculum and hysteresis were tested by means of in vitro calibration studies. **Results:** The linearity proved excellent over a range of 0–15 N with regression coefficients close to unity between imposed loads and voltage outputs. The slopes and intercepts of the regression lines were not significantly different between repeated sessions, indicating the high reliability of these in vitro measurements. The slopes and intercepts of the calibrations, using the same repertoire of loads imposed at three locations on the moving branch of the dynamometer, were not significantly different, confirming that the force measurement is independent of the site of the force application. Hysteresis was considered to be minimal. **Conclusions:** This study demonstrates that the dynamometer provides reliable measurements. The new device thus appears to have conceptual and measuring advantages over conventional methods and seems to be a very promising instrument for measuring pelvic floor strength. *Neurourol. Urodynam. 22:648–653, 2003.*

Key words: calibration; dynamometry; evaluation; muscle strength; pelvic floor

INTRODUCTION

Since the purpose of physical therapy treatment of stress urinary incontinence (SUI) is to strengthen pelvic floor muscles (PFM), reliable direct measurement of the strength of the musculature is essential for assessing the effects of such treatment. Until now, physiotherapists have relied on either digital assessment or indirect sources of measurement such as surface electromyography (EMG) and pressure perineometry for this purpose [Shull et al., 1999].

Digital assessment is widely used because of its simplicity and low cost but has the disadvantage of being based on the subjective estimation of strength by an evaluator [Shull et al., 1999]. Even if digital examination is mandatory to teach PFM contraction correctly, it does not demonstrate the inter-rater reliability qualities of a clinical research instrument [Bo and Finckenhagen, 2001].

Although less subjective than digital assessment, surface EMG measurements remain an indirect indicator of muscle strength. The principal weakness of this approach is that recordings from an intra-vaginal surface EMG do not ensure absence of cross-talk coming from the electrical activity of other skeletal musculature [Peschers, 2001].

Pressure measurements also provide an indirect indicator of muscle strength. Any increase in abdominal pressure, such as during coughing or a Valsalva manoeuver, or even with active contraction of the hip adductors or abdominal muscles may influence the pressure reading [Shull et al., 1999; Peschers, 2001]. Thus, pressure will increase without any indication of the origin of the applied force on the probe, which affects the validity of the measurement.

Recognizing the importance of direct measurements of the pelvic floor strength for evaluation of the effects of SUI treatment aimed at strengthening the PFM, we have recently designed and developed a dynamometer for this purpose

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Abbreviations: EMG, electromyography; PFM, pelvic floor muscles; SUI, stress urinary incontinence.

Work was performed at: Maisonneuve-Rosemont Hospital and Montreal Rehabilitation Institute, Montreal, Canada.

Chantale Dumoulin is a Student Member of the Research Centre of the Montreal Rehabilitation Institute, Montreal, Canada.

D. Bourbonnais is an Affiliated Researcher at the Research Centre of the Montreal Rehabilitation Institute, Montreal, Canada.

M.-C. Lemieux is an Assistant Professor, Faculty of Medicine, University of Montreal, Canada.

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*Correspondence to: Chantale Dumoulin, Research Centre, Montreal Rehabilitation Institute, 6300 Darlington, Montreal, Quebec, Canada, H3S 2J4. E-mail: dumoulin@sympatico.ca

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which offers unique features compared to existing apparatus [Caufriez, 1993; Rowe, 1995; Sampselle et al., 1998]. The objective of this article is to describe the new dynamometer design. The originality of this dynamometer, its characteristics, and clinical application will be presented.

MATERIALS AND METHODS

General Description of the Dynamometer

The new PFM dynamometer comprises a dynamometric speculum and a computerized central unit.

Dynamometric Speculum

The speculum (Fig. 1) comprises two aluminum branches. When the upper branch of the speculum is fixed, the other branch can be slowly opened by an adjustable screw allowing the pelvic floor forces to be measured at different introital vaginal antero-posterior diameters. The distance between the two branches can be adjusted from minimum (5 mm) to 40 mm. Once the aperture has been determined, a second screw fixes the moveable branch of the speculum during measurement.

The resultant force exerted by the PFM on the speculum is measured on the basis of cantilever principle using two pairs of strain gauges (EA-13-125PC-350) glued on each side of the moveable lower branch of the speculum. PFM contraction induces a strain which is measured by the gauges, causing the electrical resistance to change; the latter, in turn, is measured as a voltage variation. The strain gauges are mounted in a Wheatstone bridge, using a differential arrangement [Avril, 1984; Bourbonnais et al., 1993] such that only the voltage difference between the two opposite pairs of strain gauges is measured. Under these conditions, the voltage difference remains constant wherever the same force is applied on the branch of the speculum. This ensures that the force is measured independent of its exact site of application to the lower branch of the speculum in the vagina (Fig. 2).

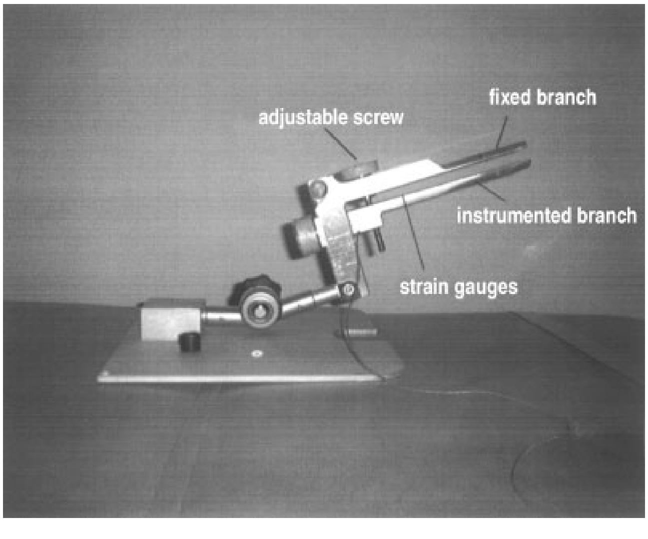

Fig. 1. Dynamometric speculum.

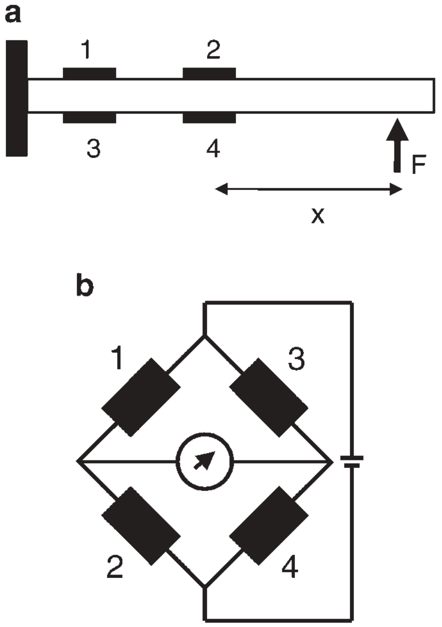

Fig. 2. **a**: Spatial arrangement of the strain gauges depicted from the side of the lower branch of the dynamometer. Two pairs of gauges (1 and 3) and (2 and 4) are mounted in a differential arrangement to monitor the force (F) exerted in vertical axis. This arrangement ensures that the force (F) is measured independently of the exact site of the application of the force, i.e., independently of the value of x. **b**: The two pairs of gauges are connected to a full Wheatstone bridge as illustrated.

Central Unit

The central unit consists of a laptop computer (Toshiba Satellite Celeron 400 MHz) and a PCMCIA acquisition card (DAQCard-700 by National Instruments Corporation). Voltage values from the strain gauge amplifiers (Analog Devices model 2B31) are digitized at a frequency of 50 Hz. The voltage values are then converted into units of force using the factor obtained during the calibration procedure. A computer program (Numeri) was developed to present the PFM force measurements in written data and graph form (Fig. 3).

Originality of the Dynamometer

The originality of this dynamometer is revealed in the following features:

1. The dynamometer is designed to take direct measurements of the PFM strength at different openings of the speculum, thereby allowing measurement at different muscle lengths.

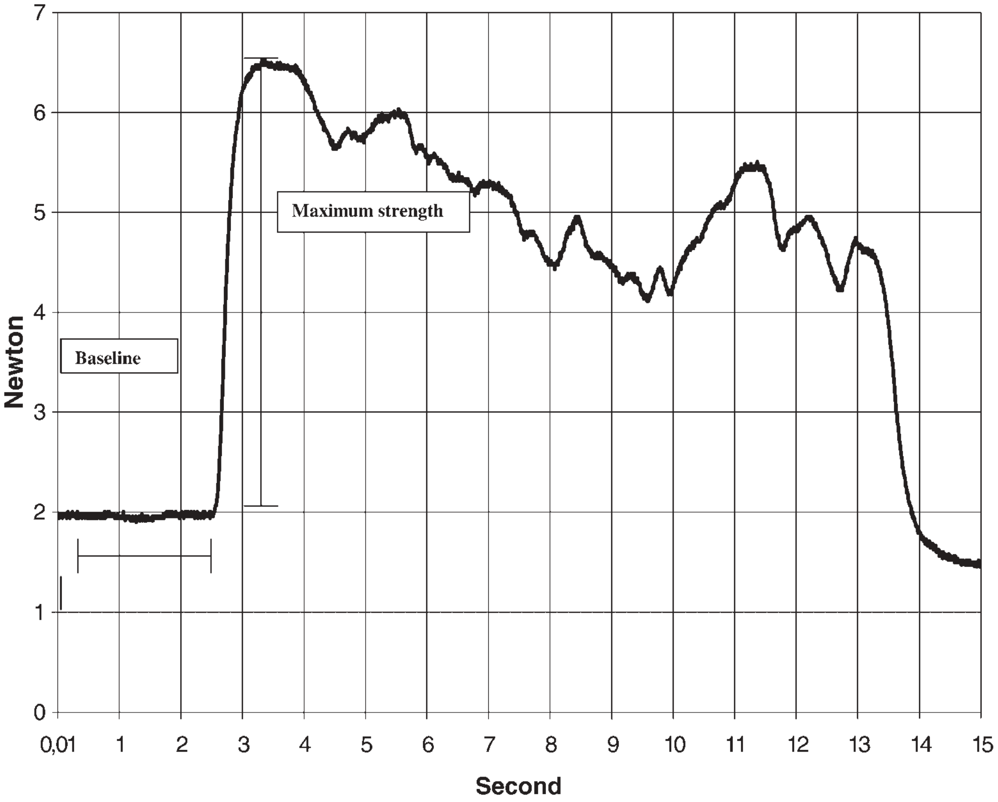

Fig. 3. Recording of pelvic floor passive strength (baseline) and maximal strength.

In studies of human muscular strength, it is well known that the maximum force varies with muscle length [Lieber, 1992]. In general, the highest contraction force occurs at the greatest possible muscle length, while, conversely, the contraction force is weakest at short muscle length [DiNubile, 1991]. To be able to differentiate weak from strong muscle or identify the effect of treatment on muscle strength, measurements in static evaluation are generally taken at a muscle length where maximal force can be expected [Gravel et al., 1990], the new dynamometer design offers this possibility.

2. The new dynamometer is designed to take direct measurements of the pelvic floor passive strength (baseline or passive resistance given by the PFM) at a given opening of the speculum. Introital vaginal aperture is often increased after vaginal delivery [Small and Wynne, 1990] and is associated with a reduction in PFM strength [Schussler and Anthuber, 1994]. The evaluation of PFM passive strength at a given introital vaginal antero-posterior diameter (Fig. 4) is a parameter that could add to the understanding of SUI secondary to PFM weakness.

Clinical Application

For the evaluation of the PFM function, the patient adopts a supine position, hips and knees flexed and supported, feet flat, on a conventional gynecologist's table. The evaluator prepares the instrument to be used for the measurement by covering each branch with a latex condom and lubricating it with a hypo-allergen gel. Then the two branches of the measuring device are brought to minimum and inserted into the vaginal cavity in an antero-posterior axis to a depth of 5 cm. According to Bo [1992], the muscular mass of the pelvic floor is located some 3.5 cm from the opening of the vaginal cavity. The 5-cm depth therefore allows the peri-vaginal portion of the pelvic floor to squeeze the lower branch of the dynamometer while the upper branch presses underneath the pubic bone to provide stability. In this position (with the branches of the dynamometer closed), the evaluator can measure the passive and active force of the PFM (baseline and maximal muscular strength, respectively). The next step is to separate the two branches using a screw so that measurements can be taken at different dynamometer openings. For example, PFM strength can be taken first with both dynamometer branches at minimum opening (5 mm), then with a 1.5 cm opening between the two branches of the speculum (Fig. 4). All trials are recorded on a portable computer (central unit). At the end of the measurement session, the condoms are discarded and the dynamometric speculum is disinfected.

Calibration

The dynamometer was assessed for linearity, repeatability, ability to measure the resultant force independently of its point of application on the branch of the speculum, and hysteresis.

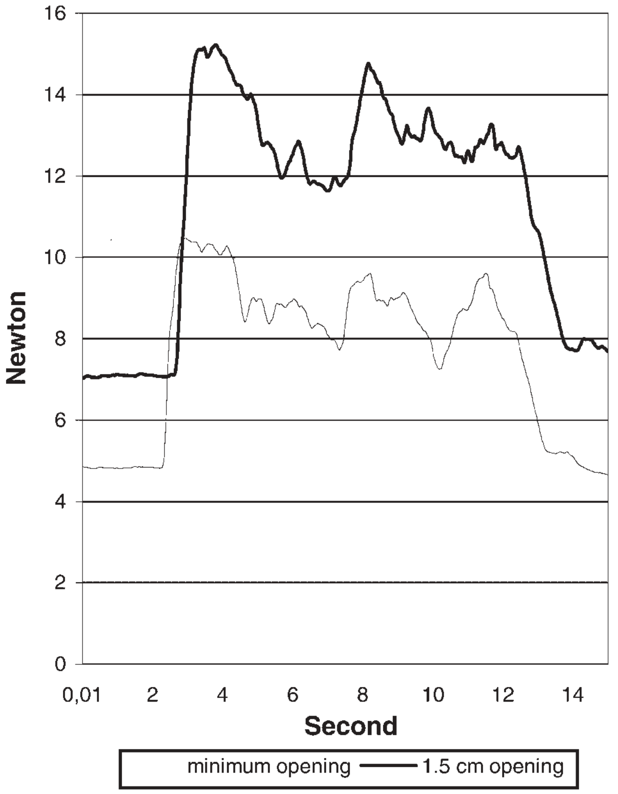

Fig. 4. Recording of a pelvic floor passive strength (baseline) and maximal strength at two different dynamometer openings (minimum opening, and at 1.5 cm opening) in a single subject.

1. The linearity of the dynamometer was tested by applying increasingly greater loads (0–15 N), using 10 calibrated loads, on the instrumented branch of the speculum and measuring the voltage output given by the dynamometer. The range of loads was chosen to cover the range of force of the PFM as measured in a pilot study of continent and incontinent women [Morin et al., 2000]. Linear regression analysis was used to compute the factors (slope and intercept) converting the force value to a voltage output.
2. To evaluate repeatability, the loading protocol was repeated twice with the same loading technique. The calibration results were then fitted to two linear-regression equations. To evaluate whether these two equations were significantly different, we used a simple statistical method to compare simple linear regression equations. The *slopes* and *elevations* of the two linear-regression functions were compared using a method that involved the use of a Student's *t* test, in a fashion analogous to that of testing for differences between two population means [Zar, 1984].
3. To verify that the differential arrangement of the gauges ensures that the force is measured independently of its exact site of application to the lower branch of the speculum, successive loading of the transducers using the same loading technique was done at distances of 2.5, 3.5, and 4.5 cm from the tip of the lower branch of the speculum. Again, the calibration results were fitted with linear regression equations and the *slopes* and *elevations* of the linear regression function at 2.5 and 4.5 cm were compared to the 3.5-cm linear regression function [Zar, 1984].
4. The hysteresis was computed by dividing the maximum difference in voltage output between the two loading conditions by the maximum scale output recorded with the highest load. The result is reported as a percentage.

The methods, definitions, and units of this study conform to the standards recommended by the International Continence Society, except where specified [Abrams et al., 1988].

RESULTS

Linearity

The voltage output for a loading trial at 3.5 cm was characterized by a simple linear regression function, $y = ax + b$, where $a = 19.807$ N/V and $b = 0.0375$ N. The value of the coefficient of determination (R^2) was 0.999. Therefore, the voltage output of the strain gauges during the imposed force was observed to be highly linear over a range of 0–15 N.

Repeatability

The voltage output for the two successive loading trials at 3.5 cm was characterized by an x/y plot of the two sets of measurements and by two simple linear regression functions, as presented in Figure 5. The slope and elevation of both

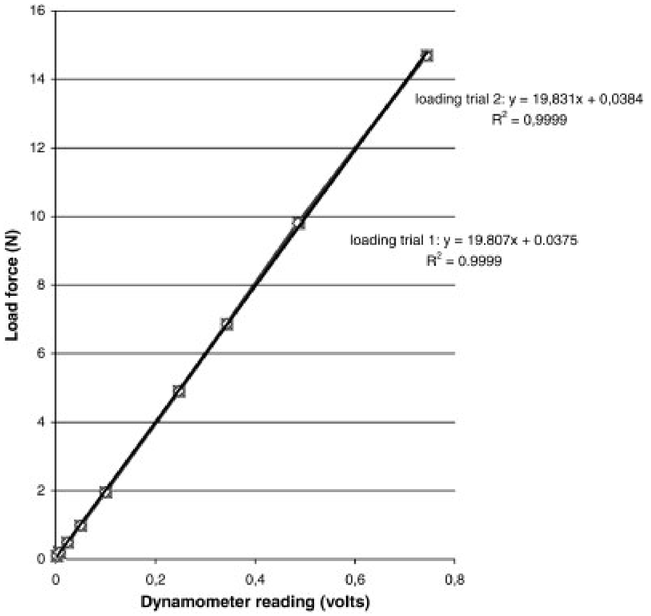

Fig. 5. Repeatability: voltage output of the strain gauges during imposed force for two successive loading trials at 3.5 cm. Results of each loading trial when fitted with a first-order linear regression.

regressions were not significantly different [$t = -0.12$; $P > 0.50$ and $t = -0.1$; $P > 0.50$, respectively].

Independence of the Site of Application of the Resultant Force to the Lower Branch of the Speculum

The x/y plot, the regression equation and the coefficients of determination for calibrations at three different locations on the moving branch of the dynamometer (2.5, 3.5, and 4.5 cm) were computed and are presented in Figure 6. Furthermore, the slopes and elevation of two linear regression functions (2.5 and 4.5 cm) were compared to the slope of the 3.5-cm linear regression. The slope and elevation at 2.5 cm were not different from those measured at 3.5 cm [$t = 0.21$, $P > 0.50$; $t = -0.27$, $P > 0.50$] respectively. Similarly, the slope and elevation at 4.5 cm were not different from those at 3.5 cm [$t = -0.004$, $P > 0.50$; $t = 0.036$, $P > 0.50$] respectively.

Hysteresis

The device exhibited minimal hysteresis of 0.00006%. Furthermore, the output of the strain gauges was found to drift by less than 0.003 N in 1 h of continuous service.

DISCUSSION

The calibration results suggest that the voltage outputs of the apparatus are linearly related to applied forces. Repeated calibration with dead weights has shown that the force measurements are also repeatable. Furthermore, calibration performed by applying forces at different locations on the moving branch of the dynamometer confirms that the measurement is independent of the site of application of the resultant force.

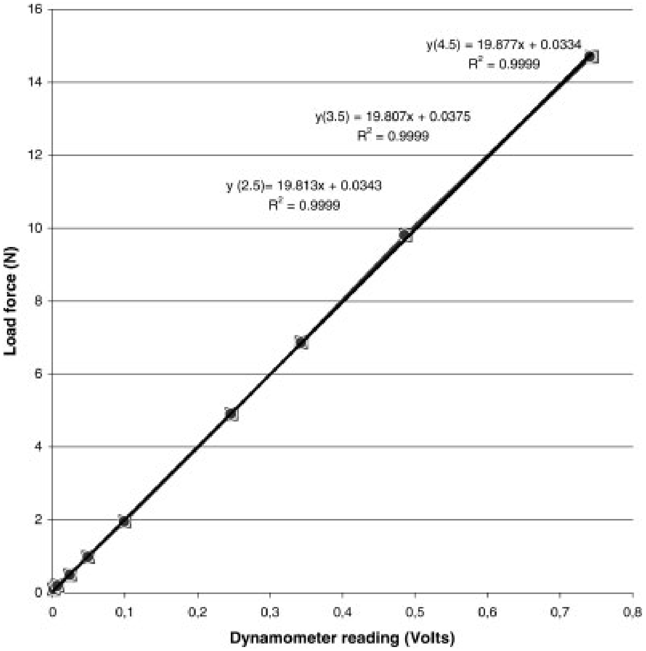

Fig. 6. Independence of site of the application: Slopes and regressions obtained for calibrations at three different locations on the moving branch of the dynamometer (3.5, 4.5, and 2.5 cm). The results of each loading trial were then fitted with a first order linear regression.

Sources of Error

The strain exerted on a single pair of strain gauges mounted on a cantilever structure will vary according to the distance between the site of application of the force and the location of the gauges. In this case, the site of application of force needs to be known in order to calibrate the arrangement. Since the intra-vaginal location of the PFM varies across subjects and is difficult to determine, it could constitute an important source of error in the PFM force measurement. However, this source of error was eliminated by using two pairs of strain gauges in a differential arrangement, which makes the measurements independent of the point where force is applied on the lower branch of the dynamometer.

Another source of error is the orientation of the force of the PFM relative to the longitudinal axis of the dynamometer branch. If the resultant force is not oriented perpendicular to the branch of the dynamometer, only a component of the force will be measured. This component will vary as a co-sinusoidal function of the angle from the perpendicular line. We identified two error components which could change the perpendicular orientation of force with respect to the dynamometer branch. First, the error component related to the natural orientation of the PFM pulling action with respect to the natural angle of the vagina. Based on current anatomical knowledge [DeLancey, 1988], we assume that the orientation of the PFM pulling action is perpendicular to the natural angle of the vagina (angle between the horizontal and longitudinal axes of the vagina). Second, the error component related to the orientation of the dynamometer in the vagina. During dynamometric evaluation, the branches of the speculum are carefully inserted into the vagina to ensure that they will follow the natural longitudinal axis of the vagina. However, if the orientation of the branches did not respect the longitudinal axis of the vagina, it would change the perpendicular orientation of the force of the PFM with respect to the branch of the dynamometer. In order to evaluate this error component, we tested the PFM maximal strength in one subject using different angulations of the dynamometer. Maximum PFM strengths were similar between the different angulations tested within 5° of the natural vaginal angle. However, when dynamometer angulations differed by 10° from the natural vaginal orientation, the subjects reported discomfort and the PFM strength measurements were much lower. This suggests that pain will influence strength measurements. Considering that measurements must be taken without patient discomfort, we assume that maximum angulation errors in relation to the natural vaginal orientation are small, probably 10° at most. We identified that a shift of 10° will introduce a maximal error of 1.5% (cos 10°) on the force measurement.

Potential use of the dynamometer. Dynamometers are valuable tools for the assessment of muscle function [Bohannon, 1990]. The new dynamometer has several advantages over other devices for measuring PFM strength. First, as opposed to manual testing, it provides an objective measurement of the PFM strength. Second, this dynamometer provides a direct indication of PFM strength as opposed to EMG and pressure measurements. The new dynamometer may prove to be a useful tool for evaluating PFM directly and more accurately than ever achieved before.

Finally, there is also some evidence to suggest that the dynamometer could be used in a rehabilitation setting to enhance PFM strength by providing feedback during PFM training.

Limits of the device. Although the supine position does not represent the position in which SUI generally happens, dynamometric measurements in this position offer better stabilization than a more representative position of SUI signs and symptoms, namely standing. In terms of clinical use, the dynamometer does not lend itself to measuring muscle forces in women presenting an unperforated hymen, significant organ prolapse, excessive vaginal scarring or PFM hypertonicity, which would affect insertion of the dynamometer branches into the vagina.

CONCLUSION

This study demonstrates that the dynamometer accurately measures forces applied to its instrumented branch. The new device thus appears to have considerable conceptual and measurement advantages over conventional methods and seems to be a very promising instrument for measuring PFM strength.

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