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# Intravaginal pressure profile of continent and incontinent women

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## ABSTRACT

A well-functioning pelvic floor muscle plays an important role in maintaining urinary continence. The aim of this study was to describe and compare the intravaginal pressure profile using a multisensor device along the vaginal length in women with and without urinary incontinence (UI), while performing pelvic floor muscle tasks. Fifty-four adult pre-menopausal women (31 continent and 23 incontinent) participated in this cross-sectional observational cohort study. The intravaginal pressure profile was assessed at rest, during maximum and sustained pelvic floor muscle contractions, using the Pliance<sup>®</sup> multisensor device. Between-group comparisons were performed considering the overall pressure and the pressure profile of 10-subregions along the vaginal length. In the overall pressure assessment, women with UI presented lower pressures at rest, similar pressures during maximum contraction and lower capacity to maintain pressure during sustained contraction compared to those in the continent group. The pressure profile assessment showed between-group differences that were consistent throughout tasks, with the incontinent group presenting lower pressures than the continent group, specifically in the mid-vaginal length, around 3-4 cm from the vaginal opening. We observed consistent deficits in pressure generation in incontinent compared to continent women, precisely in the region of the pelvic floor muscles. With this protocol and novel instrument, we obtained a reliable and consistent intravaginal pressure profile of continent and incontinent women. This approach could assist clinicians in the assessment of pelvic floor muscle function and foster a better understanding of the urinary incontinence mechanism.

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# 1. Introduction

The pelvic floor is defined as the structures located within the bony pelvis, including the urogenital and anorectal viscera, the pelvic floor muscles (PFMs) and their connective tissues, nerves and blood vessels (Bø et al., 2017). PFMs, especially the levator ani muscle, are critical to protect the pelvic connective tissues from overloads, interacting with the endopelvic fascia to maintain continence and provide pelvic organ support (Ashton-Miller and DeLancey, 2007). Rises in intra-abdominal pressure, which occur during coughing, lifting a weight, or other physical exercises, exert a caudal (downward) force on both the bladder and the urethra. To counterbalance this force, voluntary or reflex contraction of PFMs result in a constriction and inward movement of the pelvic openings (Bø et al., 2017).

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25–45% of the adult female population (Milsom et al., 2017). PFMs play a well-established role in maintaining UI during effort tasks: first, by supporting pelvic organs and restricting downward displacements of the bladder neck (Bø, 2004); second, by compressing the urethra distally, causing the urethral pressure to increase prior to and during efforts, thereby preventing urine leakage (Delancey, 1988; Miller et al., 2001). Objective assessments of PFM function are necessary to set training roals, provide feedback and document changes regarding

Urinary incontinence (UI) is a common dysfunction, affecting

a woman's ability to contract and relax PFMs. Yet it has been a challenge for clinicians and researchers, having no currently defined "gold standard" measuring instrument.

The most commonly used tools to assess PFM function mainly consist of "air balloon type" intravaginal manometers, which provide an overall pressure of the intravaginal cavity during a PFM contraction or relaxation (Deegan et al., 2018). Apart from giving an indirect measure of PFM function, the validity of these measurements can be questionable for two main reasons: first, because the air balloon does not offer resistance for isometric







PFM contractions; and second, because they only provide an overall resultant pressure of a large intravaginal area, without taking into account that the vaginal cavity is subjected to forces from sources other than PFMs. For instance, contractions from abdominal muscles, as well as straining maneuvers, have been shown to result in increased upper intravaginal pressure (Coleman et al., 2012; Peschers et al., 2001). It is possible, therefore, that the pressure profile along the vaginal length might be as important as its magnitude for the continence mechanism.

A new intravaginal assessment technique was recently proposed using the Pliance<sup>®</sup> multisensor device (a non-deformable cylinder covered by a 10  $\times$  10 matrix of capacitive transducers), shown to provide reliable and valid pressure profiles along the vaginal length, distinguishing PFM contractions from rising intraabdominal pressure (Cacciari et al., 2017). Thus, we aim to apply this technique to describe and compare the intravaginal pressure profile of women with and without UI while they perform different PFM tasks.

# 2. Methods

## 2.1. Design

This is a cross-sectional observational cohort study involving continent, and stress or mixed incontinent women.

## 2.2. Participants and procedures

Fifty-four adult women (mean age 38.7 [range 20–54]) attending regular checkups at the University Hospital's urogynecology clinic were recruited for this study from January 2015 to January 2016. Women were included if: non-virgins; with no history of pregnancy within the past year; in pre-menopausal status (with monthly menstrual cycles); not using hormone supplements; with body mass index (BMI) lower than 30 kg/m<sup>2</sup>, and with no history of PFM training or of any medical conditions that could interfere with PFM function.

This study was approved by the Ethics Committee of the School of Medicine of the University of São Paulo (protocol n.023/14). After providing written informed consent, the participants completed a sociodemographic questionnaire to confirm their eligibility criteria, including age, body mass, stature, sexual status, history of pregnancies (gravidity) and deliveries (vaginal or cesarean section) and regularity of their menstrual cycle.

An experienced physiotherapist performed a PFM function assessment by vaginal bidigital palpation (Power, Endurance and Fast components of the Laycock PERFECT scheme) (Laycock and Jerwood, 2001), during which the participants were taught to properly contract their PFM and asked to perform a maximal PFM contraction. Women who presented a Power less than 3/5 (muscle tension with observed in-drawing of the perineum and anus) were not included in this study to ensure that correct PFM contractions were equally acquired by participants of both groups. Furthermore, evidence suggests that PFM maximum strength is not the best parameter to distinguish between continent and incontinent women. Participants were also excluded if they presented a pelvic organ prolapse stage above II on the POPQ scale (Haylen et al., 2016) during the clinical examination to avoid bias in the pressure profile between groups.

Participants were classified into a continent group (CoG) or an incontinent group (InG), using specific UI severity domains of the King's Health Questionnaire. This is a GRADE  $A^+$  (Diaz et al., 2017) condition-specific questionnaire validated in Portuguese (Tamanini et al., 2003) with domains for UI symptoms and UI-specific quality of life measures, with scores ranging from 0 to

100. Women reporting no symptoms of UI of any type (score 0/100) were included in CoG (n = 31). Participants reporting symptoms of either stress or mixed UI, with at least mild scores (score > 33/100) (Hebbar et al., 2015) for either severity of UI symptoms (*severity measures domain*) or the impact of these symptoms on quality of life (*incontinence impact domain*), were included in InG (n = 23). Those with only urgency UI symptoms or with lower scores on severity and impact of UI symptoms were not included in this study in order to make a clear distinction between groups.

## 2.3. Biomechanical assessment

The Pliance<sup>®</sup> multisensor device (MLA-P1, Pliance<sup>®</sup> System; novel; Munich, Germany) used to evaluate the spatiotemporal distribution of pressures along the vaginal cavity consists on a non-deformable cylinder covered by a 10  $\times$  10 matrix of capacitive transducers. Each transducer individually calibrated by the manufacturer to obtain a measurement range of 0.5–100 kPa and a measurement resolution of 0.42 kPa (Cacciari et al., 2017).

We measured both the overall pressure, considering the pressure resultant of the entire sensor matrix, and the pressure profile along 10 sensor subsets (ring 1 to ring 10) to map the pressure distribution throughout the vaginal length. For the latter, we divided the sensor matrix into ten rings (each one composed of a 10-sensor perimeter surrounding the cylinder), providing a map of the vaginal cavity along its depth. Pressure-related variables were acquired at 50 Hz. The instrument with the sensor matrix disposition and a diagram of the sensor subsets (rings) are illustrated in Fig. 1.

Prior to data acquisition, the instrumented probe was warmed to body temperature ( $\sim$ 37 °C), calibrated and covered with two



**Fig. 1.** Instrumented sensor probe: Pliance<sup>®</sup> System (Novel, Munich, Germany) including (from left to right) battery, multi-channel analyzer and intravaginal probe: Ertacetal<sup>®</sup> cylinder covered with capacitive transducers placed in a matrix configuration ( $10 \times 10$ ).

hypoallergenic and non-lubricated condoms, following previously validated protocol (Cacciari et al., 2017). Briefly, in a previous study under a controlled condition (pressure measurements under a 1-m water column) using the same protocol of sensor calibration and protection (with the two condoms), all sensors have been shown to be equally active, measuring uniformly equal pressures, thus guaranteeing the validity of the pressure profile obtained (Cacciari et al., 2017). The inner condom was marked at the length of 7 cm to standardize the depth of insertion in the vaginal cavity and attached with tape to the sensor base to prevent any movement. The outer condom was lubricated with hypoallergenic gel to avoid discomfort during probe insertion.

To guarantee test reproducibility, the probe was always inserted with the same orientation and with a 7-cm depth from the hymenal caruncle according to reference marks and held in place by the assessor to avoid any displacement. The probe was sterilized and cleaned according to the manufacturer's instructions and the requirements of the University Hospital Infection Commission.

After a one-minute accommodation period, the participants were asked to accomplish three tasks, in the same order. The first was the rest task, where participants were asked to relax their PFMs and remain silent while breathing normally for 10 s. The second task was the maximum task, where participants performed a series of two maximum PFM contractions and were instructed to "squeeze" and "lift" their PFM as hard as possible (Bø, 2003). Each of the two maximum tasks lasted three seconds. The third was the sustained contraction task, where participants performed a series of two sustained contractions and were instructed to sustain a maximal PFM contraction for 10 s while breathing normally. Between each trial and task, participants rested for 1 min to avoid fatigue. All participants received standardized verbal encouragement: the assessor repeated "contract, contract, contract" to stimulate maximal PFM contractions throughout the maximal and sustained contraction tasks. For all tasks, the start of the data acquisition was manually initiated a few seconds before the verbal command.

#### 2.4. Data analysis

Data was acquired and exported to ASCII format using the Pliance<sup>®</sup> System x/E software (Novel; Munich, Germany). Data

was then filtered (8 Hz low pass, 4th order Butterworth) and analyzed using a custom-designed program (MathWorks; Natick, MA). The mean of the two trials was used for each pressure variable calculated for the *maximum* and *sustained contraction tasks*.

For the *rest task*, a matrix of baseline values was calculated as the mean pressure achieved in each sensor during a selected 2second steady-state window (baseline matrix). Overall peak pressures during rest were considered as the maximum value of this baseline matrix. The pressure profile at rest was considered as the peak pressure obtained in each one of the 10 sensor rings of the baseline matrix.

For the *maximum task*, the temporal series matrix was first subtracted from the rest baseline matrix. Maximum overall peak pressures were considered as the maximum value of the peak pressuretime series of the entire matrix. The pressure profile for this task was considered as the peak pressure obtained in each one of the 10 sensor rings (at the same instant of the overall peak pressure).

For the sustained contraction task, the temporal series matrix was first subtracted from the rest baseline matrix. Peak pressuretime integrals were calculated from the entire sensor. A 10 s fixed time interval of the peak pressure-time series was set for further analysis. This interval started at the onset of the participant's sustained contraction, defined as the instance at which the pressure rose higher than 2 standard deviations plus the baseline value, and ended after 10 s. From this fixed time interval, we analyzed a subset of data starting from the first observed peak pressure within this interval till the end of the fixed interval (Fig. 2). For the pressure profile of this task, pressure-time integrals were calculated for the 10 sensor rings (in the same interval used for the peak pressure-time integrals of the entire sensor matrix). The duration of the peak pressure plateaus were also calculated in seconds from the overall peak pressure time series, representing the longest duration of the sustained contraction maintained above 50% and 75% of the peak pressure achieved during the maximum task (Fig. 2). These thresholds were chosen considering the usual reported deficits in force maintenance in UI women.

#### 2.5. Statistical analysis

For all variables (except for discrete and categorical variables – gravidity, parity, vaginal delivery and PFM digital assessment



**Fig. 2.** Example of the pressure-related variables calculated for each task. For the *maximum task*, the peak pressure was calculated from the peak pressure-time series of the entire matrix (as an overall pressure) and from 10 sensor rings (as a pressure profile). For the *sustained contraction task*, the maximal duration of two plateaus (representing 75% and 50% of the peak achieved during the *maximum task*) was calculated only from the overall peak pressure-time series, and pressure-time integrals were calculated both for the overall pressure and for the pressure profile (considered as the area under the curve in a window starting from the first peak and ending after 10 s from the contraction onset).

scores), normal distribution (Shapiro-Wilk test) and homoscedasticity (Levene Test) were achieved. The significance level was set to 0.05. Between-group (continent and incontinent) comparisons of descriptive variables were made using student *t*-tests (age, BMI) and Mann-Whitney U tests (gravidity, parity, vaginal delivery and PFM functions digital assessment scales).

Because we found statistical differences between groups for age, BMI and parity (Table 1), we calculated the correlation between these three variables and all dependent pressure-related variables, in order to identify potential co-variates that would serve as inputs for ANCOVA tests. The Pearson coefficients revealed that none of the correlations were significant or at least moderate ( $r_{age}$  range from 0.01 to 0.25, p > 0.05;  $r_{BMI}$  range from 0.01 to 0.17 p > 0.05; and  $r_{parity}$  range from 0.01 to 0.33 p > 0.05). Therefore, between-group comparisons were conducted by independent t-tests for overall pressure-related variables. Pressure profile related variables were compared between and within groups with mixed model analysis of variance (2 groups, 10 subregions). If a significant difference was found, Newman–Keuls post-hoc tests were performed.

To better appreciate the significance of the data, effect sizes were evaluated with Cohen d coefficients. We considered coefficients smaller than 0.40 to be small effects; between 0.40 and 0.75, moderate effects; and greater than 0.75, large effects (Thalheimer and Cook, 2002).

In *a posteriori* power calculation using the significant comparison with the lowest effect size was performed. Given the evaluated sample size, an alpha error of 5%, and an effect size of 0.51 – moderate effect (based on the peak pressure from the *rest task*), the statistical power  $(1 - \beta)$  obtained was 0.96 with *t*-test.

#### 3. Results

The demographic and clinical descriptions of the study groups are presented in Table 1. InG participants were significantly older,

#### Table 1

Anthropometric, demographic and clinical characteristics of the continent (CoG) and incontinent (InG) groups.

Variables	CoG (n = 31)	InG (n = 23)	р
Age <sup>1</sup> [years]	35.3 [31.5-38.9]	48.2 [44.7-51.7]	<0.01
Body mass index <sup>1</sup> [kg/m <sup>2</sup> ]	23.4 [21.8-25.0]	27.5 [25.9-29.1]	< 0.01
Parity <sup>2</sup>	0 (0-1)	2 (0-2)	< 0.01
Gravidity	1 (0-2)	2 (0-2)	< 0.01
Vaginal delivery <sup>2</sup>	0 (0-0)	0 (0-1)	0.35
Vaginal palpation			
Power <sup>2</sup> [0–5]	3 (3-5)	3 (2-4)	0.65
Endurance <sup>2</sup> [s]	4 (2-8)	5 (2-10)	0.57
Fast <sup>2</sup> [valid cycles*/10]	8 (4-10)	7 (3-10)	0.42
King's Health Questionnaire			
Incontinence Impact <sup>2</sup> [/100]	0 (0-0)	66.7 (68-100)	< 0.01
Severity Measures <sup>2</sup> [/100]	0 (0-0)	41.7 (25-50)	<0.01

<sup>1</sup> Mean [95% confidence intervals]; student *t*-test.

<sup>2</sup> Median (interquartile interval); Mann-Whitney U test.

\* Number of recognizable contractions on vaginal palpation.

with higher body mass index and parity, as expected for incontinent women due to the common risk factors in this population.

For the *rest task*, InG presented lower overall peak pressure than CoG (25% lower, moderate effect) (Table 2). The pressure profile approach revealed more accentuated differences between groups, with InG having lower pressures specifically in the mid-vaginal length in comparison to CoG (25% lower in ring 4, p = 0.010; 36% lower in ring 5, p < 0.001, and 27% lower in ring 6, p = 0.033) (Fig. 3, and Supplementary Material).

For the *maximum task*, there were no differences between groups for the overall peak pressure (Table 2). However, with the spatial stratification of the pressure profile, InG presented lower pressures in ring 5 when compared to CoG (46% lower, p < 0.001), again in the mid-vaginal length (Fig. 3, and Supplementary Material).

For the *sustained contraction task*, InG presented lower overall pressure-time integrals (27% lower, moderate effect), with reduced capacity to sustain their intravaginal pressure plateau when compared to CoG (31 and 43% lower plateau duration, moderate and large effects, for the 50 and 75% of the maximum contraction plateau's respectively) (Table 2). When considering the pressure-time integrals of the pressure profile, pressure distribution patterns did not present an interaction effect between groups and subregions, although between-group differences were still detected. Still, lower values were observed for InG in ring 5 (34% lower, p = 0.049) (Fig. 3, Supplementary Material).

#### 4. Discussion

The overall pressure assessment shows that incontinent women have lower pressures at rest, similar pressures during maximum contraction and lower capacity of maintaining pressure during sustained contraction compared to those in the continent group. With the pressure profile approach, it was possible to identify more specific and accentuated between-group differences that were consistent across all tasks. This approach demonstrated that stress UI symptoms are related to region-dependent differences in intravaginal pressure profiles, with InG presenting lower pressures in the mid-vaginal length.

At rest, we observed 25% lower overall pressures in InG compared to CoG. With the pressure profile approach, this baseline between-group difference reached up to 36% lower values for InG in the mid-portion of the vaginal cavity (rings 4–5). Ideally, a baseline tone composed of active constant PFM activity and passive viscoelastic properties of the PFM muscles and their surrounding tissues is thought to keep the urogenital hiatus closed against the opening action of the intra-abdominal pressure (Morin et al., 2010; Ashton-Miller and DeLancey, 2007). Our results suggest that, from the start, InG lacked this baseline resistance to counterbalance the constant downward action of the intra-abdominal pressure.

Other studies found similar (24–45%) lower resting intravaginal force or pressures in women with UI compared to continent control groups (Morin et al., 2004; Shishido et al., 2008). However,

#### Table 2

Overall pressure-related variables, t and p-values and effect sizes, acquired during the rest, maximum and sustained contraction tasks for the continent (CoG) and incontinent (InG) groups.

PFM tasks		CoG (n = 31)	InG (n = 23)	t	р	Cohen d Effect Size
Rest	Peak pressure [kPa]	9.0 [7.7–10.3]	6.7 [5.7–7.7]	2.60	0.010	0.51
Maximum	Peak pressure [kPa]	46.0 [39.2-52.7]	41.3 [32.8-49.9]	0.86	0.394	0.17
Sustained contraction	Pressure-time integral [kPa.s]	295.3 [254.9–335.7]	214.3 [166.3-262.4]	2.59	0.011	0.51
	50% plateau [s]	7.1 [6.4–7.9]	4.6 [3.8-5.4]	4.76	< 0.001	0.81
	75% plateau [s]	3.0 [2.3–3.8]	1.7 [1.2–2.2]	2.67	0.005	0.53

Mean [95% confidence intervals]; student t-test.



**Fig. 3.** Pressure profile: pressure distribution in 10 sensor rings, representing the pressure distribution along the depth of the vaginal cavity. Data presented as mean and standard error. CoG: control group; InG: incontinence group; mixed ANOVA for repeated measures (*rest task*: p < 0.001 for the interaction effect (group × subregion), with a group effect of p = 0.053 and a subregion effect of p < 0.001; *maximum task*: p < 0.001 for the interaction effect (group × subregion), with a group effect of p = 0.258 and a subregion effect of p < 0.001; *sustained contraction* task: p = 0.316 for the interaction effect (group × subregion), with a group effect of p = 0.002 and subregion effect of p < 0.001; \*Newman-Keuls post hoc (p < 0.05).

there is no consensus in the literature on this issue (Chamochumbi et al., 2012; Devreese et al., 2004; Verelst and Leivseth, 2007). This lack of agreement could be explained by differences in measuring devices between studies, in which the force or the pressure was assessed in different portions or orientations of the vaginal cavity. Clearly, PFM function measurements are dependent on the vaginal aperture (Dumoulin et al., 2004; Verelst and Leivseth, 2007) and the location of the sensor unit throughout the depth of the vaginal length (Devreese et al., 2004; Shishido et al., 2008). Therefore, it is difficult to compare or combine absolute values from studies using different methodologies, especially when no spatial distinction of pressures is available (Bø et al., 2005).

During the maximum contraction of the PFMs, there were no differences between groups regarding overall intravaginal pressures. However, InG presented lower pressures than CoG in the pressure profile analysis, again specifically in the mid portion of the vaginal cavity (ring 4, 46% lower). Previous studies found no differences between PFM maximum contractions in continent and incontinent women, using objective intravaginal pressure and force measuring tools (da Roza et al., 2013; Morin et al., 2004). However, differences were present in specific sensor orientations or depths of insertion, with higher between-group differences observed at the anteroposterior mid-portion of the vaginal length (Chamochumbi et al., 2012; Shishido et al., 2008). In the present study, the pressures obtained among InG were approximately half of the value exerted by CoG in a potentially crucial region for the continence mechanism. Not being able to generate enough pressure in the mid portion of the vagina may have a direct impact in the continence function, as the PFM are expected to compress the distal portion of the urethra, leading to an increase in the urethral pressure prior to and during efforts tasks, determinant to prevent urine leakage (Delancey, 1988; Miller et al., 2001). These results could explain the lack of constriction of the pelvic floor structures often reported in stress or mixed UI patients during effort tasks, resulting in leakage episodes. Therefore, as observed during rest, the pressure profile approach is paramount to distinguish PFM function between continent and incontinent women.

Furthermore, lower capacity to sustain a PFM contraction has been reported in incontinent women in studies using either digital palpation scales (Devreese et al., 2004) and force (Morin et al., 2004) or pressure units (Amaro et al., 2005; Thompson et al., 2006). Here, we observed that InG presented not only shorter plateaus of overall pressure maintenance, but also an altered pressure profile, with lower pressure time integrals markedly in the midvaginal length (ring 5, 26% lower). PFMs are expected to compress the urethra to maintain continence during prolonged activities such as carrying a weight from one location to another. The lower pressure maintenance observed in the InG reinforces the recommendation to assess, train and include prolonged PFM contractions in this population.

It is important to acknowledge that the study groups were not balanced for age, BMI and parity, which are known risk factors pelvic floor dysfunction and could be confounders of the obtained results. However, neither of these potential co-variables were significantly or at least moderately correlated to any of the calculated pressure-related variables, which strengthen the assumption that UI might be the main factor related to the pressure profile differences found between groups.

To our knowledge, this is the first study to compare the pressure profiles of continent and incontinent women in ten different depths along the length of the vaginal cavity with a high-spatial resolution pressure probe in a single time frame. The main results support previous findings of studies using either pull-through techniques (Shishido et al., 2008), a sleeve sensor measuring the pressure in two depths of the vaginal canal (Guaderrama et al., 2005) or a tactile high-definition manometer (Raizada et al., 2010). These studies all reported a high intravaginal pressure zone in the mid-portion of the vaginal cavity during PFM contractions, defined as axial and circumferential asymmetric. In a previous study using the same new sensor, we observed higher pressures in the mid-antero-posterior zone of the vaginal cavity during PFM contractions, as opposed to a more cranial and diffuse pattern observed during straining maneuvers (Cacciari et al., 2017). These findings suggest that our measurement protocol can distinguish PFM function from other pressure sources unrelated to the continence mechanism. Additionally, according to simultaneous imaging assessments of the pelvic floor structures, the observed pattern represents the main resultant pressure of PFMs acting to tighten the levator hiatus and clamp the urethra to maintain continence (Raizada et al., 2010).

By stratifying the pressure profile in sub-regions, we were able to pinpoint the area in which the main between-group differences are observed, validating the assumption that the intravaginal pressure profile pattern is more sensitive in the detection of alterations related to the continence mechanism than an overall pressure magnitude assessment. However, it is important to acknowledge that regardless of the methodology or measuring tool, it is impossible to discriminate specific muscle functions using only intravaginal force or pressure units, either considering the entire vaginal cavity area, or isolating measurements by regions (e.g. rings) or planes (e.g. sagittal or transverse). The measured force/pressure is always a sum of the active and passive components from PFMs, comprised of smooth muscles in fasciae and vaginal wall and passive mechanical forces from connective tissues (Verelst and Leivseth, 2007). Another limitation of this study is that the participants were only tested in the lying position, while stress UI episodes mainly occur during dynamic conditions such walking, jumping or running. However, if main group differences were observed in low-stress conditions, it would be reasonable to expect these differences to be maintained or increased in situations of higher stress. It is important to acknowledge that the probe itself distorts in some way the tubular structure of the vagina, thus possibly interfering in its pressure profile. However, both groups were submitted to the same interference, which should reduce its influence in the group comparison. And finally, our probe dimensions (length and diameter) correspond to intra-vaginal force measuring devices in the literature, which favors further comparisons with the literature (Ashton-Miller et al., 2014; Dumoulin et al., 2003).

This study conveyed important information that could help explain the mechanism of UI in women. A 10 by 10 sensor matrix allows a range of analysis possibilities, including the pressure profile assessment along the anteroposterior or laterolateral planes of the vaginal cavity, which should be further investigated. In addition, further studies are needed to compare tasks involving different sources of intravaginal pressure variation (including coughs or abdominal exercises) in this population, to better characterize the PFM pressure pattern in continent and incontinent women during daily living activities.

#### 5. Conclusions

The pressure profile assessment showed between-group differences that were consistent through all tasks. The incontinent group exhibited lower pressures than the continent group, specifically in the mid-vaginal length, around 3–4 cm from the vaginal opening. This is the first study to distinguish the pressure profiles of continent and incontinent women along the length of the vaginal cavity with a high-spatial resolution pressure probe in a single time frame. This indicates a focalized deficit in pressure generation in this group, precisely where PFMs are expected to tighten the levator hiatus and clamp the urethra to maintain continence.

#### **Ethical approval**

The study was approved by the Ethics Committee of the School of Medicine of the University of São Paulo (protocol n.023/14).

# **Declaration of Competing Interest**

The authors affirm that this study has not received any funding/ assistance from a commercial organization that could lead to a conflict of interest.

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## Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbiomech.2019.109572.

#### References

- Amaro, J.L., Moreira, E.C., De Oliveira, M.G., Padovani, C.R., 2005. Pelvic floor muscle evaluation in incontinent patients. Int. Urogynecol. J. 16, 352–354. https://doi. org/10.1007/s00192-004-1256-3.
- Ashton-Miller, J.A., DeLancey, J.O.L., 2007. Functional anatomy of the female pelvic floor. Ann. N. Y. Acad. Sci. 1101, 266–296. https://doi.org/10.1196/ annals.1389.034.
- Ashton-Miller, J.A., Zielinski, R., Miller, J.M., DeLancey, J.O.L., 2014. Validity and reliability of an instrumented speculum designed to minimize the effect of intra-abdominal pressure on the measurement of pelvic floor muscle strength. Clin. Biomech. 29, 1146–1150. https://doi.org/10.1016/ j.clinbiomech.2014.09.011.
- Bø, K., 2004. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work?. Int. Urogynecol. J. 15, 76–84. https://doi.org/10.1007/s00192-004-1125-0.
- Bø, K., 2003. Pelvic floor muscle strength and response to pelvic floor muscle training for stress urinary incontinence. Neurourol. Urodyn. 22, 654–658. https://doi.org/10.1002/nau.10153.
- Bø, K., Frawley, H.C., Haylen, B.T., Abramov, Y., Almeida, F.G., Berghmans, B., Bortolini, M., Dumoulin, C., Gomes, M., McClurg, D., Meijlink, J., Shelly, E., Trabuco, E.C., Walker, C., Wells, A., 2017. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Int. Urogynecol. J. 28, 191–213. https://doi.org/ 10.1007/s00192-016-3123-4.
- Bø, K., Raastad, R., Finckenhagen, H.B., 2005. Does the size of the vaginal probe affect measurement of pelvic floor muscle strength? Acta Obstet. Gynecol. Scand. 84, 129–133. https://doi.org/10.1111/j.0001-6349.2005.00676.x.
- Cacciari, L.P., Pássaro, A.C., Amorim, A.C., Geuder, M., Sacco, I.C.N., 2017. Novel instrumented probe for measuring 3D pressure distribution along the vaginal canal. J. Biomech. 58, 139–146. https://doi.org/10.1016/j.jbiomech.2017.04.035.
- Chamochumbi, C.C.M., Nunes, F.R., Guirro, R.R.J., Guirro, E.C.O., 2012. Comparison of active and passive forces of the pelvic floor muscles in women with and without stress urinary incontinence. Rev. Bras. Fisioter. 16, 314–319. https://doi.org/ 10.1590/S1413-35552012005000020.
- Coleman, T.J., Thomsen, J.C., Maass, S.D., Hsu, Y., Nygaard, I.E., Hitchcock, R.W., 2012. Development of a wireless intra-vaginal transducer for monitoring intraabdominal pressure in women. Biomed. Microdevices 14, 347–355. https://doi. org/10.1007/s10544-011-9611-x.
- da Roza, T., Mascarenhas, T., de Araujo, M.P., Trindade, V., Jorge, R.N., 2013. Oxford Grading Scale vs manometer for assessment of pelvic floor strength in nulliparous sports students. Physiotherapy 99, 207–211. https://doi.org/ 10.1016/j.physio.2012.05.014.
- Deegan, E.G., Stothers, L., Kavanagh, A., Macnab, A.J., 2018. Quantification of pelvic floor muscle strength in female urinary incontinence: A systematic review and comparison of contemporary methodologies. Neurourol. Urodyn. 37, 33–45. https://doi.org/10.1002/nau.23285.
- Delancey, J.O.L., 1988. Structural aspects of the extrinsic continence mechanism. Obstet. Gynecol. 72, 296–301.
- Devreese, A., Staes, F., de Weerdt, W., Feys, H., Van Assche, A., Penninckx, F., Vereecken, R., 2004. Clinical evaluation of pelvic floor muscle function in continent and incontinent women. Neurourol. Urodyn. 23, 190–197. https://doi. org/10.1002/nau.20018.
- Diaz, D.C., Robinson, D., Bosch, R., Costantini, E., Cotterill, N., Espuña-Pons, M., Kocjancic, E., Lemos, N., Tarcan, T., Yoshida, M., 2017. Patient-reported outcome assessment. In: Abrams, P., Cardozo, L., Wagg, A., Wein, A. (Eds.), Incontinence. ICI-ICS International Continence Society, Bristol, UK, pp. 541–598.
- Dumoulin, C., Bourbonnais, D., Lemieux, M.-C., 2003. Development of a dynamometer for measuring the isometric force of the pelvic floor musculature. Neurourol. Urodyn. 22, 648–653. https://doi.org/ 10.1002/nau.10156.
- Dumoulin, C., Gravel, D., Bourbonnais, D., Lemieux, M.C., Morin, M., 2004. Reliability of dynamometric measurements of the pelvic floor musculature. Neurourol. Urodyn. 23, 134–142. https://doi.org/10.1002/nau.10175.
- Guaderrama, N.M., Nager, C.W., Liu, J., Pretorius, D.H., Mittal, R.K., 2005. The vaginal pressure profile. Neurourol. Urodyn. 24, 243–247. https://doi.org/ 10.1002/nau.20112.
- Haylen, B.T., Maher, C.F., Barber, M.D., Camargo, S., Dandolu, V., Digesu, A., Goldman, H.B., Huser, M., Milani, A.L., Moran, P.A., Schaer, G.N., Withagen, M.I.J., 2016. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Organ Prolapse (POP). Neurourol. Urodyn. 35, 137–168. https://doi.org/ 10.1002/nau.22922.
- Hebbar, S., Pandey, H., Chawla, A., 2015. Understanding King's Health Questionnaire (KHQ) in assessment of female urinary incontinence. Int. J. Res. Med. Sci. 3, 531. https://doi.org/10.5455/2320-6012.ijrms20150301.
- Laycock, J., Jerwood, D., 2001. Pelvic floor muscle assessment: the PERFECT scheme. Physiotherapy 87, 631–642. https://doi.org/10.1016/S0031-9406(05)61108-X.

- Miller, J.M., Perucchini, D., Carchidi, L.T., DeLancey, J.O.L., Ashton-Miller, J.A., 2001. Pelvic floor muscle contraction during a cough and decreased vesical neck mobility. Obstet. Gynecol. 97, 255–260. https://doi.org/10.1016/S0029-7844 (00)01132-7.
- Milsom, I., Altman, D., Cartwright, R., Lapitan, M.C., Nelson, R., Sjöström, S., Tikkinen, K.A.O., 2017. Epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP) and anal Incontinence (AI). In: Abrams, P., Cardozo, L., Wagg, A., Wein, A. (Eds.), Incontinence. ICI-ICS International Continence Society, Bristol, UK, pp. 1–141.
- Morin, M., Bourbonnais, D., Gravel, D., Dumoulin, C., Lemieux, M.C., 2004. Pelvic floor muscle function in continent and stress urinary incontinent women using dynamometric measurements. Neurourol. Urodyn. 23, 668–674. https://doi. org/10.1002/nau.20069.
- Morin, M., Gravel, D., Bourbonnais, D., Dumoulin, C., Ouellet, S., Pilon, J.F., 2010. Application of a new method in the study of pelvic floor muscle passive properties in continent women. J. Electromyogr. Kinesiol. 20, 795–803. https:// doi.org/10.1016/j.jelekin.2009.10.004.
- Peschers, U.M., Fanger, G., Schaer, G.N., Vodušek, D.B., DeLancey, J.O.L., Schuessler, B., 2001. Bladder neck mobility in continent nulliparous women. Br. J. Obstet. Gynaecol. 108, 320–324. https://doi.org/10.1016/S0306-5456(00)00066-8.
- Raizada, V., Bhargava, V., Jung, S.-A., Karstens, A., Pretorius, D., Krysl, P., Mittal, R.K., 2010. Dynamic assessment of the vaginal high-pressure zone using highdefinition manometery, 3-dimensional ultrasound, and magnetic resonance

imaging of the pelvic floor muscles. Am. J. Obstet. Gynecol. 203, 172.e1–172.e8. https://doi.org/10.1016/j.ajog.2010.02.028.

- Shishido, K., Peng, Q., Jones, R.C.L., Omata, S., Constantinou, C.E., 2008. Influence of pelvic floor muscle contraction on the profile of vaginal closure pressure in continent and stress urinary incontinent women. J. Urol. 179, 1917–1922. https://doi.org/10.1016/j.juro.2008.01.020.
- Tamanini, J.T.N., D'Ancona, C.A.L.D., Botega, N.J., Netto Júnior, N.R., 2003. Validação do "King's Health Questionnaire "para o português em mulheres com incontinência urinária Validation of the Portuguese version of the King's Health Questionnaire for urinary incontinent women. Rev. Saúde Pública 37, 203–211. https://doi.org/10.1192/apt.01.12.
- Thalheimer, W., Cook, S., 2002. How to calculate effect sizes from published research: A simplified methodology. Work. Res. 1–9. https://doi.org/10.1113/ jphysiol.2004.078915.
- Thompson, J.A., O'Sullivan, P.B., Briffa, N.K., Neumann, P., 2006. Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze pressure measurements. Int. Urogynecol. J. 17, 624–630. https://doi.org/ 10.1007/s00192-006-0081-2.
- Verelst, M., Leivseth, G., 2007. Force and stiffness of the pelvic floor as function of muscle length: A comparison between women with and without stress urinary incontinence. Neurourol. Urodyn. 26, 852–857. https://doi.org/ 10.1002/nau.20415.