LICIA PAZZOTO CACCIARI

Análise da distribuição multivetorial de cargas do assoalho pélvico feminino em diferentes populações

Tese apresentada à Faculdade de Medicina da Universidade de São Paulo para obtenção do título de Doutora em Ciências

Programa de Ciências da Reabilitação

Orientadora: Profa. Dra. Isabel de Camargo Neves Sacco

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Aos meus pais e ao Gui,
com muito amor

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NORMATIZAÇÃO ADOTADA

Esta tese está de acordo com as seguintes normas, em vigor no momento desta publicação:

Referências: adaptado de *International Committee of Medical Journals Editors* (Vancouver).

Universidade de São Paulo. Faculdade de Medicina. Divisão de Biblioteca e Documentação. *Guia de apresentação de dissertações, teses e monografias*. Elaborado por Anneliese Carneiro da Cunha, Maria Julia de A. L. Freddi, Maria F. Crestana, Marinalva de Souza Aragão, Suely Campos Cardoso, Valéria Vilhena. 3a ed. São Paulo: Divisão de Biblioteca e Documentação; 2011.

Abreviaturas dos títulos dos periódicos de acordo com *List of Journals Indexed in Index Medicus*.

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RESUMO

Cacciari LP. *Análise da distribuição multivetorial de cargas do assoalho pélvico feminino em diferentes populações* [tese]. São Paulo: Faculdade de Medicina, Universidade de São Paulo; 2017.

Apresentamos nesta tese a compilação de dois artigos científicos aceitos para publicação, que serão reproduzidos e discutidos em diferentes sessões apresentadas a seguir. Os objetivos gerais desta tese são desenvolver um instrumento inovador para a análise biomecânica do assoalho pélvico (AP) , capaz de fornecer um perfil preciso da distribuição de pressões ao longo do canal vaginal, e caracterizar o potencial de coordenação espacial desse grupo muscular em uma população de mulheres treinadas na técnica de Pompoarismo. Para o primeiro objetivo, nós desenvolvemos um sensor com alta resolução tridimensional para a avaliação do perfil espaço-temporal de pressões no canal vaginal. Para isso, o mapeamento obtido da distribuição intravaginal de pressões foi (i) testado entre avaliadores, tentativas e sessões de avaliação para verificação da confiabilidade e repetitividade do instrumento e protocolo de coleta; (ii) comparado à avaliação digital da força do AP, e (iii) caracterizado e diferenciado entre duas tarefas opostas: a contração máxima do AP e manobra de Valsalva (considerada como um esforço máximo de expulsão com movimento caudal do AP). Para o segundo objetivo, com o novo sensor nós comparamos dois grupos de mulheres: praticantes e não praticantes de uma técnica específica de coordenação da musculatura do AP, o Pompoarismo. O sensor consiste em um cilindro de Ertacetal® não deformável envolvido por uma matriz de sensores capacitivos calibrados individualmente (MLA-P1, pliance System; novel; Munique, Alemanha). O cilindro, com 23,2 mm de diâmetro e 8 cm de comprimento, contém uma área sensora de 50 cm^2 (10x10 elementos de 7,07 mm^2, com *gap* de 1,79 mm entre cada sensor). Cada sensor apresenta amplitude de medida entre 0,5 e 100 kPa, e resolução de 0,42 kPa, o que possibilita mensurações unidirecionais com alta resolução espacial e testada baixa e uniforme resposta à temperatura. O perfil de pressão intravaginal foi descrito com base em duas diferentes abordagens considerando: (i) o pico de pressão da matriz inteira e (ii) a distribuição da pressão ao longo de diferentes sub-regiões do canal vaginal, obtidas por divisões da matriz sensora em “anéis”, “planos”, ou subáreas (caudal, média e cranial). Coeficientes de correlação intraclasse indicaram excelente repetitividade inter e intra avaliador para a área total e medial, com confiabilidade moderada para as áreas cranial e caudal. A correlação entre os picos de pressão e a força obtida pela avaliação digital do AP foi moderada [coeficiente de Spearman r=0,55 ($p<0,001$)]. O Perfil espaço-temporal de pressões do canal vaginal foi completamente diferente entre a contração máxima do AP e a Valsalva (ANOVA medidas repetidas, dois fatores), com a contração muscular resultando em pressões notavelmente maiores na porção anteroposterior média do canal vaginal. Considerando o potencial de coordenação e distribuição espacial da pressão intravaginal, observamos no grupo de mulheres praticantes de pompoarismo uma maior capacidade de sustentação da força muscular (40% maior, efeito moderado, p=0,04), além de menores contribuições relativas da porção média e plano anteroposterior, e maiores contribuições das porções caudal e cranial e planos latero-laterais da pressão intravaginal, que se mostrou de modo geral mais simetricamente distribuída em relação ao grupo controle. Com este protocolo e instrumento inovador foi possível obter um mapeamento de alta resolução, confiável e capaz de distinguir o perfil de distribuição de pressões ao longo de diferentes porções do canal vaginal, e caracterizar tarefas e padrões de coordenação muscular em diferentes grupos de mulheres.

Descritores: biomecânica; assoalho pélvico; cargas internas; mulheres; treinamento

ABSTRACT

Cacciari LP. Investigation of the multivectorial load distribution of the pelvic floor in different female populations [thesis]. São Paulo: Faculdade de Medicina, Universidade de São Paulo; 2017.

This thesis is presented as a compilation of two scientific papers accepted for publication, reproduced in different sections. The general purpose of this thesis is to develop a novel instrumented probe for pelvic floor muscle (PFM) biomechanics assessment, capable of providing a precise high spatial 3D resolution pressure profile of the vaginal canal, and to map the spatial coordination potential of these muscles in a trained female population. For the first objective, we developed a novel device for assessing the spatiotemporal pressure profile of the vaginal canal. The pressure profile was (i) tested for reliability and repeatability, (ii) compared to the PFM digital assessment, and (iii) characterized and compared between two opposite tasks: maximum contraction and Valsalva maneuver (maximum intra-abdominal effort with downward movement of the pelvic floor). For the second objective, we assessed and compared two groups of asymptomatic women using the newly developed device: practitioners and non-practitioners of a specific coordination training of the PFM, the Pompoir technique. The developed probe consists of a non-deformable Ertacetal® cylinder, covered by a matrix of individually calibrated capacitive sensors (MLA-P1, pliance System; Novel, Munich, Germany). The cylinder is 23.2 mm in diameter and 8 cm in length, and its sensing area is 70.7 mm^2 (10x10 matrix of sensing elements, each with 7.07 mm^2 in size and 1.79 mm gap between them). The capacitive sensors have a measurement range of 0.5–100kPa, and a measurement resolution of 0.42 kPa, enabling unidirectional measurements with high spatial resolution, and tested low uniform and linear response to temperature variations. The pressure profile was described based on two different approaches, either considering the peak pressure of the entire sensor matrix or the pressure distribution along different sub-regions of the vaginal canal, obtained by divisions of the sensor matrix in “rings”, “planes” or major areas (caudal, mid and cranial) throughout the vaginal length. Intraclass correlation coefficients indicated excellent inter- and intra-rater reliability and intra-trial repeatability for the total and mid-areas, with moderate reliability for the cranial and caudal areas. There was a moderate correlation between peak pressure and PFM digital palpation [Spearman’s coefficient $r=0.55$ ($p<0.001$)]. Spatiotemporal profiles were completely different between the maximum contraction tasks compared to Valsalva (2-way ANOVAs for repeated measures), with contraction resulting in notably higher pressures in the mid-anteroposterior portion of the vaginal canal. Regarding the effect of Pompoir training, the trained group presented better ability to sustain the achieved pressure for a longer period (40% longer, moderate effect, $P=0.04$) also having smaller relative contributions from the mid-region rings and anteroposterior plane, and greater contributions from the caudal and cranial rings and latero-lateral plane, with more symmetrical pressure distribution patterns in comparison to the control group. With this protocol and novel instrument, we obtained a high-resolution and highly reliable innovative 3D pressure distribution map of the pelvic floor, capable of distinguishing vaginal sub-regions, planes, rings, tasks and characterizing coordination patterns of the PFM following a specific training protocol.

Descriptors: biomechanics; pelvic floor; internal loads; woman; training

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 (PFM) and their connective tissues, nerves and blood vessels (Bø et al. 2017a). PFM, especially the levator ani muscle, are critical to protect the pelvic connective tissues from overloads, interacting to the endopelvic fascia to maintain continence and provide pelvic organ support (Ashton-Miller and DeLancey 2007).

The levator ani muscle is a complex structure with five origin-insertion pairs and three basic sub-regions: (i) the iliococcygeus, consisting in a flat layer that connects the pelvic sidewalls near the sacrum; (ii) the pubovisceral, comprised itself of three origin-insertion pairs, that attaches the walls of the pelvic organs and the perineal body to the pubic bone on either side of the symphysis (puboperineal, the pubovaginal and the puboanal), and (iii) the puborectalis, that form a sling around and behind the rectum, just above the external anal sphincter (Kearney et al. 2004; Ashton-Miller and DeLancey 2007).

The normal function of the PFM is defined as a level of constant resting tone (except just before and during voiding and defecation), that should be symmetrical and with the ability to voluntarily and involuntarily contract and relax (Bø et al. 2017a). This constant resting tone keeps the urogenital hiatus closed by compressing the vagina, urethra, and rectum against the pubic bone, pulling the pelvic floor structures in a ventro-cephalic direction (Ashton-Miller and Delancey 2009).

Rises in intra-abdominal pressure, which occur during coughing, lifting, or other physical exercises, exert a caudal (downward) force on both the bladder and the urethra. To counterbalance this force, further voluntary or reflex contraction of the PFM result in a constriction and inward (ventro-cephalic) movement of the pelvic openings (Bø et al. 2017a), increasing the compression force to maintain continence and support of the pelvic floor structures (Ashton-Miller and DeLancey 2007). During a cough, for example, normal PFM function was shown to produce a timely compression of the pelvic floor and additional external support to the urethra, reducing its displacement, velocity, and acceleration (Jones et al. 2010).

More precisely, during maximum voluntary contraction the pubovisceral and puborectalis portions of the levator ani muscle increase the vaginal closure force by 46%, further compressing the rectum, distal vagina, and urethra behind the pubic bone distally, to elevate these structures and close the genital hiatus, accounting for the constriction and inward components of the PFM function (Kearney et al. 2004; Ashton-Miller and Delancey 2009). Finally, the iliococcygeus portion of the levator ani muscle elevates the central region of the posterior pelvic floor, acting mainly as a support diaphragm, having a small contribution to the ventral displacement of the pelvic organs (Ashton-Miller and Delancey 2009). When both constriction and lifting components are combined, a resultant force in the ventro-cephalic direction helps to compress the rectum, vagina, and urethra, from back to front, balancing the caudal force that is naturally exerted by the gravity, and further augmented by effort tasks that result in increases in intra-abdominal pressure (Ashton-Miller and Delancey 2009).

In addition to maintaining pelvic organ support, and bowel and bladder continence, pelvic floor structures have a critical role in sexual satisfaction (Rosenbaum 2007). Female sexual function is defined not only by physical health, but also by emotional, mental and social wellbeing in relation to sexuality (World Health Organization 2015). Although acknowledging its multifactorial etiology, some authors related the PFM tonus and voluntary contraction capacity to genital arousal and orgasmic functions, describing the vagina as a contractile organ, exhibiting electrical activity in the form of slow waves, which together with active contractions of the PFM stimulates sexual excitement and pleasure for both men and women (Shafik 2000; Shafik et al. 2004). PFM contractions have also been hypothesized to lead to genital responses that would facilitate sexual performance, such as (i) vaginal constriction, which helps to maintain penile rigidity, and promote clitoral and cervical stimulation; (ii) vaginal elongation together with uterine elevation, which contribute to the adequate adaptation of the penis in the vaginal canal (Shafik 2000), and (iii) increase in vulvovaginal blood flow, which contribute to a better arousal, lubrication and orgasm (Lavoisier et al. 1995). All these responses are related to PFM functionality, therefore biomechanical capabilities of the PFM such as cranial-caudal coordination, spatiotemporal symmetry of action, along with strength and resistance, are necessary for targeting sexual function.

Several pelvic floor symptoms have been described, and can be classified into (i) urinary incontinence symptoms, (ii) bladder storage symptoms, (iii) sensory symptoms, (iv) voiding and postmicturition symptoms, (v) pelvic organ prolapse symptoms, (vi) symptoms of sexual dysfunction, (vii) symptoms of anorectal dysfunction, (viii) pelvic pain and (ix) lower urinary tract infection (Haylen et al. 2010). Most of those symptoms are associated to PFM dysfunctions (Messelink et al. 2005), wherein the force-generating capacity of the PFM seem to be related to symptoms of urinary incontinence (Jones et al. 2010; Luginbuehl et al. 2015), fecal incontinence (Lewicky-Gaupp et al. 2010; Tibaek and Dehlendorff 2014), pelvic organ prolapse (DeLancey et al. 2007; Friedman et al. 2012) or sexual dysfunctions (Lowenstein et al. 2010; Martinez et al. 2014; de Menezes Franco et al. 2016). Besides the magnitude of PFM force-generating capacity, other force/pressure related parameters have been found to be different between symptoms or treatment protocols, such as force velocity and endurance (Morin et al. 2004a), symmetry (Deindl et al. 1994), coordination between superficial and deep PFM contractions (Devreese et al. 2007) and overall spatial distribution of pressures along the vaginal wall (Peng et al. 2007). Altogether these variables other than maximum strength should be added to the PFM assessment in both clinical and research settings.

Pelvic floor symptoms are common conditions affecting more than one fourth (MacLennan et al. 2000; Kepenekci et al. 2011; Wu et al. 2014) of adult women. Particularly urinary and anal incontinence are common in the female population, with a prevalence of about 16–17% and 9%, respectively (Nygaard et al. 2008; Wu et al. 2014), although depending on the definition and study population, the prevalence can be much higher. Female sexual dysfunction is also age-related, progressive, and highly prevalent, with 40 to 45% of adult women presenting at least one symptom including low sexual interest, desire or arousal (sexual excitement and sexual pleasure); lubrication problems; orgasmic dysfunctions (inability to achieve an orgasm, markedly diminished intensity of orgasmic sensations, or marked delay of orgasm during any kind of sexual stimulation); and dyspareunia (persistent or recurrent pain during sexual activity) among others (Lewis et al. 2010). Up to one in seven women have surgery for pelvic organ prolapse (POP) or urinary incontinence in their lifetime (Olsen et al. 1997; Smith et al. 2010; Løwenstein et al. 2015). Furthermore, as the population ages, the number of women suffering from pelvic floor symptoms is expected to increase, resulting in a large social, medical and economic burden (Wu et al. 2011).

Kegel (1948) was the first to report training of the PFM to be effective in the management of urinary incontinence in women. Though PFM motor-capacity training has been an important part of Chinese Taoism exercises for more than 6,000 years, aiming to stimulate circulation in the sexual organs, energize the pubic region and promote self-awareness (Chang 1986). Up to date, PFM exercises are widely recommended as first line conservative management for women with all types of urinary incontinence (Dumoulin et al. 2015). Some studies also indicated that PFM training have a positive impact on sexual functions by increasing self-confidence, desire, lubrication, orgasm, and satisfaction (Bø et al. 2000; Beji et al. 2003; Dean et al. 2008; Zahariou et al. 2008), although it has been suggested that more high quality clinical trials would be necessary to confirm these findings (Bø 2012; Ferreira et al. 2015). Most recently, benefits of PFM training were reported for anal incontinence (Johannessen et al. 2017), and for the prevention and reduction of symptoms and severity of pelvic organ prolapse (Hagen and Stark 2011; Hagen et al. 2017), pointing out that intervention for treatment and prevention of these dysfunctions should be encouraged on the basis of it being safe and done easily by most women.

Moreover, a recent study (Alperin et al. 2016) found that aging itself results in substantial decrease in the predicted force production and fibrosis in all PFM, suggesting that PFM training should be prescribed as a preventive strategy for all women, as means for mitigating the impact of aging before the development of significant fibrotic changes. However, no study investigated the effects of PFM training in asymptomatic women, which could be of great interest to better understand the potential of this muscle group, and clarify the advantages of recommending PFM training as a preventive measure for several pelvic floor symptoms.

Therefore, an objective evaluation of PFM, assessing its physical and mechanical capabilities – such as strength, coordination, resistance, symmetry, relaxation and contraction rates, among others – is necessary to be able to properly intervene and give feedback regarding a woman's ability to contract their PFM and to document changes in PFM function and biomechanical capabilities throughout an intervention protocol (Bø and Sherburn 2005). However, there is still no gold standard method for this purpose and measuring tools are still a topic of debate.

We believe that PFM assessments with clinical relevance should be made by an objective, reliable, and multidimensional mechanical tool capable of measuring the magnitude and spatiotemporal distribution of pressures along the vaginal canal, taking into account the PFM 3D flexible structure, the directions of PFM contractions and, more precisely, its ventro-cephalic resultant force.

In the following sections, some of the available measuring tools, as well as their strengths and limitations will be described, and the rationale for building a new measuring tool will be presented, proposing a method for objectively distinguishing

PFM contractions from intra-abdominal pressure increases, and to assess the PFM’s biomechanical capabilities, such as force, pressure, coordination, resistance, symmetry, relaxation and contraction rates in different regions of the vaginal canal.

1.1. Assessment of pelvic floor muscle function

In clinical practice, PFM function is commonly assessed by digital palpation scales (e.g., PERFECT scheme proposed by Laycock and Jaerwood (2001)), which remains the first choice of assessment among clinicians, mainly because it is fast, requires no equipment, and selectively depicts PFM activity (Peschers et al. 2001b). Furthermore, most validated digital palpation scales have the advantage of providing information on both the squeeze and lift components of the PFM contraction (Laycock and Jerwood 2001), with some of them also accounting for muscle tone, endurance (Devreese et al. 2004), and left-right and anteroposterior symmetry of contraction (Slieker-ten Hove et al. 2009).

However, the digital palpation assessment has the disadvantage of being a subjective method with limited reproducibility. Digital palpation scales have been considered less sensitive than objective techniques to quantify sustained contractions (Frawley et al. 2006) and to differentiate variations in discrete force (Morin et al. 2004b). Additionally, although substantial agreement have been reported between two raters in one study (Van Delft et al. 2013), others reported limited reliability even for experienced examiners (Bø and Finckenhagen 2001; Ferreira et al. 2011; Sartori et al. 2015). Bo and Finckenhagen (2001) reported that an available definition of “weak”, “moderate”, “good”, and “strong” muscle contractions does not seem to be specific enough to reliably reproduce the evaluation of PFM strength, concluding that vaginal palpation can be mandatory when teaching correct PFM function, but may not be reproducible, sensitive or valid enough for scientific purposes.

For the objective assessment of the PFM function, the existing (defined) devices can be classified as manometers, dynamometers, electromyographers (EMG) or imaging techniques, such as ultrasound and magnetic resonance imaging (MRI) (Bø and Sherburn 2005; Bø et al. 2017a). So far, there is no perfect instrument or gold standard for the PFM strength assessment; however, each method has its advantages and disadvantages, and some of them will be discussed in the following sections.

1.1.1. Manometry

Manometers are among the most popular devices of PFM function assessment, mainly because they are easy to handle, there are several commercially available options, and they are considered an inexpensive alternative to obtain objective measures of PFM function. The first “air balloon type” manometer designed to measure PFM function has been presented by Kegel (1948). At that time, the new device was named “perineometer”, and was considered an instrument devised to register muscle contraction. Perineometers offered great value as a visual aid for guiding patients during PFM exercises, functioning mainly as a biofeedback tool, encouraging patients to continue the exercises until the desired result was attained.

However, the use of perineometers as an objective measuring tool of PFM strength has been widely discussed, mostly because intra-abdominal pressure variations might interfere with the validity of measurements. For example, it has been shown that during tasks that raise intra-abdominal pressure the recorded vaginal pressure increases regardless of PFM contraction, suggesting that the obtained measures may not be specifically related to PFM strength (Bø et al. 1990b; Peschers et al. 2001b; Thompson et al. 2006a).

Nevertheless, a degree of imprecision does not preclude its value as a simple, inexpensive, and painless way to reliably assess general PFM function (Hundley et al. 2005). One of the suggested techniques described to avoid misleading measurements is to assure that PFM contraction is simultaneously accompanied by an observable inward movement of the balloon catheter (which is considered to be a sign of correct PFM contraction) (Bø et al. 1990a, 1990b). Previous studies have found substantial agreement of vaginal squeeze pressure measured by perineometers with digital assessment of the PFM function (Isherwood and Rane 2000; Riesco et al. 2010), and also with morphometric parameters assessed by transperineal ultrasound during maximal voluntary PFM contraction (Volløyhaug et al. 2016). However, the concordance of measurements with different commercially available perineometers ranged from poor to moderate, which makes it hard to compare results acquired with different equipments (Barbosa et al. 2009). One possible explanation is that pressure measurements of vaginal squeeze differ depending on the size of the vaginal probe used (Bø et al. 2005). Therefore, results from published studies using various probes are hard to be compared or combined (Bø et al. 2005).

One of the main concerns about the commercially available perineometers is that their intravaginal balloon catheters are made of highly pliable materials, which can be problematic since their radial compliance hinders isometric measurements of PFM contraction (Ashton-Miller and Delancey 2009). Furthermore, not only PFM force is highly related to vaginal canal distension, but PFM length affects the reliability of those measurements, with vaginal apertures of 24-40 mm being considered ideal for reducing the standard error of measurement (Dumoulin et al. 2004a; Verelst and Leivseth 2004b).

Several variations of perineometers have been applied to differentiate PFM contraction among women with a range of pelvic floor symptoms. Specifically, when comparing women with and without symptoms of urinary incontinence, it has been found that these symptoms are related to (i) lower vaginal squeeze pressure during maximal PFM contraction (Mørkved et al. 2004; Amaro et al. 2005; Thompson et al. 2006b; Hilde et al. 2013); or (ii) lower PFM endurance, defined either as the duration of a sustained maximal contraction (Amaro et al. 2005; Thompson et al. 2006b) or the pressure-time integral (Hilde et al. 2013). Also, the amount of vaginal pressure obtained during maximum PFM contraction was considered a strong predictor of stress urinary incontinence (Baracho et al. 2012). Nevertheless, some of these findings are not unanimous in the literature. For instance, (i) peak pressure was not different between young continent and incontinent women (da Roza et al. 2013), and also (ii) when comparing PFM contraction to a Valsalva maneuver (maximum intra-abdominal pressure effort with downward movement of the pelvic floor) vaginal squeeze pressure increased during both tasks, with no difference in the pressure measured either between tasks or when comparing continent and incontinent women (Thompson et al. 2006a).

Considering other PFM symptoms, reduced vaginal squeeze pressure assessed by perineometers was also related to (i) symptoms of anal incontinence, (ii) pelvic organ prolapse (Friedman et al. 2012), (iii) levator ani structural damages caused by after vaginal delivery (Hilde et al. 2013), and (iv) symptoms of sexual dysfunction (e.g., satisfaction and lubrication) either in young nulliparous (Martinez et al. 2014) or in post menopausal women (de Menezes Franco et al. 2016). Therefore, perineometers do not seem to be the instrument of choice to distinguish PFM contractions from intra-abdominal pressure rises, or to describe the pressure profile along different portions of the vaginal canal as they do not have adequate precision or resolution to evaluate symmetry, coordination or the lift component of the PFM function.

Improved manometry devices and prototypes

A completely different methodology to improve precision in the pressure assessments was presented by three different research groups. In the first case (Guaderrama et al. 2005), a four-channel water-perfused manometry catheter (4.5 mm) was used to map the pressure profile of the vaginal canal. As a solution to measure pressures along the depth of the vagina, the proposed device was motor-driven pulled through the vagina at constant withdrawal speed of 8 mm/s. In the second case (Raizada et al. 2010), the proposed device consisted of a high-definition manometry probe (10 mm diameter with a pressure sensitive part of 64mm), instrumented with 256 tactile sensitive microtransducers forming a continuous grid in both the axial and circumferential directions, with the advantage of mapping the vaginal canal all at once, without the need to be pulled through. Finally, the last mentioned proposed instrument (Egorov et al. 2010) was designed to measure the elastic properties of the vaginal wall through a "tactile imaging" technique (considered a translation of manual palpation into a digital image). For that a tactile array probe prototype was developed, comprising 120 capacitive sensors, and "computerized palpations" of the vaginal canal were achievable by pressing the probe head against different portions of the vaginal wall (Egorov et al. 2010). However, these devices are either not commercially available, or have limited accessibility and high cost.

From the results of these studies, one can easily conclude that the vaginal pressure profile is more complex than what was previously described, with an asymmetry of force/pressure distribution in both the longitudinal and the circumferential directions of the vaginal wall (Guaderrama et al. 2005; Raizada et al. 2010), highlighting the importance of a spatial-temporal assessment of the PFM function. More specifically, at rest or during PFM contraction, the anteroposterior maximum pressures were found to be 50-65% greater than the lateral ones (Guaderrama et al. 2005), and image findings support that PFM contraction result in a high-pressure zone of 3-4 cm length that compresses the pelvic organs against each other from back to front and also against the back of the symphysis pubis (Jung et al. 2007). Furthermore, (i) the anterior peak pressure was found to be greater than the posterior one, especially during PFM contractions; (ii) the vaginal high-pressure zone was also found to be longer in the posterior portion of the vaginal wall, compared to the anterior and lateral directions; (ii) the size of the vaginal high-pressure zone was found to increase in all directions with PFM contraction, with this increase being maximal in the posterior wall; and (iv) the posterior peak pressure point was reported to move together with the anorectal angle, around 7 mm in the ventro-cephalic direction during PFM contraction (Raizada et al. 2010).

Most recently, a new pressure device was proposed (Schell et al. 2016), consisting of an array of eight pressure sensors mounted onto a flexible printed circuit board (80 mm length and of 20 mm width), which allow the device to conform to the anatomy of the vagina. In addition to its flexibility and flat-shape that seems to conform to the anatomy of the vagina, this device has the advantage of being wireless, with data transmitted via Bluetooth to an Android tablet with reported real-time display and user feedback, which appears to allow data acquisition in different body positions in a more ecological environment. However this device is still under testing and validation, and it is also not yet commercially available.

1.1.2. Dynamometry

Dynamometers are found to be capable of providing a precise measure of vaginal force and its derivative variables, which are considered to be a more direct assessment of the PFM strength (Morin et al. 2004; Constantinou and Omata 2007). At least five dynamometer prototypes have been proposed by different research groups from different countries, proven to be reliable and also tested either across groups of women with and without pelvic floor symptoms or following PFM treatment protocols (Dumoulin et al. 2003; Verelst and Leivseth 2004b; Constantinou and Omata 2007; Nunes et al. 2011; Ashton-Miller et al. 2014).

Some other instruments have been proposed, but they are still under development or have not been tested across pelvic floor symptoms or treatments, with only reliability studies found in the literature so far (Saleme et al. 2009; Jean-Michel et al. 2010; Arora et al. 2015; Kruger et al. 2015; Martinho et al. 2015; Schell et al. 2016). Therefore, in the following paragraphs, the first dynamometers, mentioned in the beginning of this sub-section, will be discussed.

Most of the initially proposed dynamometer devices can be categorized as “speculum type dynamometers” (Dumoulin et al. 2003; Verelst and Leivseth 2004b; Nunes et al. 2011; Ashton-Miller et al. 2014), and some of them have the advantage of being suitable to measure the intravaginal force along different apertures of the vaginal canal (Verelst and Leivseth 2004b; Nunes et al. 2011).

Dumoulin et al. (2003), in Canada, developed an instrumented speculum comprised of two aluminum branches. While the upper branch is fixed, the other can be slowly opened allowing the pelvic floor forces to be measured at different introital vaginal anteroposterior diameters (from 19 to 54 mm). Here, the resultant force exerted by the PFM on the speculum is recorded by two pairs of strain gauges, and the difference between them is acquired and used for analysis.

Verelst and Leivseth (2004b), in Norway, proposed a prototype consisting of two semi-round branches meant to shift mutually parallel to each other, so the opening can be changed from 30 to 50 mm. Strain gauges were glued to one of the branches, with no specifications of number or arrangements. The main difference between this and the aforementioned device is that the first, on one hand, is fixed to a metal base, which can make it uncomfortable to the patient if not properly adjusted to the vaginal canal angle; while the second, on the other hand, seems to require someone to hold it during the evaluation, which could also be a source of random artifacts in the measure.

A third speculum type dynamometer was designed by Nunes et al. (2011), in Brazil. This prototype consists of a stainless steel speculum instrumented with two pairs of strain gauges (fixed on the inferior and lateral sides of the branches) in a way that both the anteroposterior (sagittal plane) and left-right (frontal plane) directions of the intravaginal force could be assessed. Likewise, the first two previously described prototypes, this device was designed to perform measurements under variable-openings of the vaginal canal, although the aperture range was not specified.

One of the main limitations of the three previously described devices is that only the resultant force of the whole vaginal canal is measured, even though it is in both directions (anteroposterior and left-right), which makes it unlikely to depict PFM contractions from other artifacts, such as intra-abdominal pressure rises. To overcome this limitation, Ashton-Miller et al. (2014), in United States, designed a fourth dynamometer without evidence of crosstalk from intra-abdominal pressure, while retaining acceptable discriminant validity and repeatability for the assessment of PFM strength. This device is an improved model that evolved from an original instrumented speculum developed by the same group (Ashton-Miller et al. 2002), which was similar in size and shape to a Pederson speculum. The difference is that the upper bill of the speculum was divided in two along its length. The proximal “short” portion of the upper bill, closest to the handle, was designed to be positioned immediately dorsal to the inferior aspect of the symphysis pubis, thereby minimizing the net force across the modified lower bill originated from intra-abdominal pressure variations. This device, however, only measures the resultant force of the PFM in a fixed aperture of the vaginal canal (25 mm).

Finally, in a different approach, a directional multi-sensor vaginal probe was designed by Constantinou and Omata (2007), also in United States. This probe is completely different from the speculum type dynamometers presented until now. Here, the force transducer is supported by a leaf spring, which can be compressed by the force applied by PFM contractions, incorporating the measurement of both force and displacement of the vaginal wall. For that, four pairs of force/displacement transducers were assembled to enable the measurement of anterior, posterior, left and right vaginal wall movement with reference to a fixed central axis. Another novelty of this sensor is that it was designed to be manually pulled through (2 cm/s) the vaginal canal while simultaneously recording the position of the probe and the force/displacements along the vaginal walls in the four mentioned directions. The advantage of this approach is the possibility to acquire the force and displacement across the whole length of the vaginal canal, as with some of the pressure devices presented before (Guaderrama et al. 2005; Raizada et al. 2010). The main disadvantage of this device is that it does not allow acquirements of the pressure-time profile of the vaginal canal all at once, requiring it to be pulled through, which can be considered a source of bias when describing pressure patters in different portions of the vaginal length.

Because PFM maximum strength increases depending on the vaginal introitus opening, dynamometers apertures and diameters directly affect the reliability of PFM measurements (Dumoulin et al. 2004a; Verelst and Leivseth 2004b). Therefore, it is particularly hard to combine findings from different studies using different devices formats and openings. Regarding this matter, intravaginal force measurements at 24 mm of anteroposterior vaginal-opening presented a higher reliability with lower standard error of measurements (Dumoulin et al. 2004a) compared to narrower or wider opening options; while for the transverse plane, a left-right 40 mm vaginal opening provided the most reliable outcome (Verelst and Leivseth 2004b).

In regards to the relationship between dynamometer measurements and digital palpation, the magnitude of mean forces increased proportionally to increments in digital palpation scores with moderate correlation between the two techniques (Morin et al. 2004b). According to the authors, this result reveals a relevant sensitivity of the objective assessment provided by dynamometry, which seems to be a better option to detect discrete changes of PFM strength over time and/ or after treatments than digital palpation. Most of the presented dynamometer devices have several advantages when compared to pliable perineometers, but lack in precision or resolution to assess symmetry, coordination or even the lift component of the pelvic floor function. Furthermore, none of the abovementioned devices are capable of mapping the spatio-temporal pressure distribution across different portions of the vaginal canal, which would be recommended considering the reported asymmetric distribution of forces along the vaginal length (Jung et al. 2007).

Description of force parameters in women with pelvic floor dysfunctions

All of these dynamometers were used to investigate the effect of some pelvic floor symptoms and dysfunctions in PFM force parameters (Morin et al. 2004a; Verelst and Leivseth 2004a, 2007; Peng et al. 2007; Shishido et al. 2008; Lewicky-Gaupp et al. 2010; Chamochumbi et al. 2012; Miller et al. 2015; Cyr et al. 2017), with most of the studies focusing on symptoms of urinary incontinence (Morin et al. 2004a; Verelst and Leivseth 2004a, 2007; Peng et al. 2007; Shishido et al. 2008; Chamochumbi et al. 2012).

When compared to a control group, women with symptoms of urinary incontinence presented similar time to fatigue (defined as time to 10% decline of the initial reference force) (Verelst and Leivseth 2004a) and vaginal cavity aperture value (maximum vaginal opening that the volunteer could tolerate, without discomfort or pain); but lower (i) PFM force normalized by the body weight as a function of the transverse diameter of the vagina (Verelst and Leivseth 2004a); (ii) endurance (considered as the area under the force-curve from 10 to 60 s of PFM contraction); (iii) rate of force development; and (iv) number of rapidly repeated contractions (taken during 15s) (Morin et al. 2004a).

For the passive force (tonus) and the maximum PFM force, the reports are conflicting. Two studies did not find differences in tonus between controls and women with urinary incontinence symptoms (Verelst and Leivseth 2004a; Chamochumbi et al. 2012) and three others reported lower tonus in the incontinent group (Morin et al. 2004a; Peng et al. 2007; Shishido et al. 2008). Similarly, one study did not find differences in the PFM maximum force between groups (Morin et al. 2004a), while four others reported lower force in the incontinent group (Verelst and Leivseth 2004a;

Peng et al. 2007; Shishido et al. 2008; Chamochumbi et al. 2012). These conflicting findings could be explained by the fact that each study used a different measuring device, for which the force was considered in different portions or orientations of the vaginal canal. Therefore, we can conclude that the assessment of PFM should not be restricted to maximal force, and should definitely acknowledge the asymmetry of the force spatial distribution along different portions of the vaginal wall.

1.1.3. Electomyography

Surface electromyography (EMG) assessing the neuromuscular function of the PFM is widely used as a biofeedback tool, with many commercially available options, guiding clinical practice during PFM treatment protocols (Aksac et al. 2003; Aukee et al. 2004; Auchincloss and McLean 2009). This feedback is thought to help isolating specific PFMs and to motivate the participants by displaying the PFM activity and progress. Bipolar electrodes are usually placed on the surface of the perineum or inside the urethra, vagina or rectum (Bø et al. 2017a). However, it is important to acknowledge that the large surface area of the available electrodes may result in cross-talk from adjacent muscles and other artifacts (Bø et al. 2017a). This limitation is particularly relevant when assessing PFM, considering that the pelvic floor is a complex structure, comprised of multiple innervation zones with large inter-individual variability (Enck et al. 2004; Cescon et al. 2014), several muscle layers and muscle insertions, contained in a concave three-dimensional (3D) architecture (Ashton-Miller and DeLancey 2007).

Between-trials and between-days reliability findings performed with two commercially available intravaginal EMG devices suggested that, although it is acceptable to use PFM surface EMG as a biofeedback tool for training purposes, it is not recommended as an objective PFM function assessment for between-subject comparisons or as an outcome measure between-days (Auchincloss and McLean 2009). In addition, when surface EMG was compared to other assessment techniques, such as perineometers, digital evaluation or perineal ultrasound, both EMG and pressure perineometers did not to selectively depict PFM activity from intra-abdominal pressure rises (Peschers et al. 2001a).

Nevertheless, recent high-density surface EMG prototypes have presented reliable measurements of the PFM activity in different regions of the vaginal canal (Voorham-van der Zalm et al. 2013), and showed to be capable of providing a comprehensive mapping of innervation zones of the pelvic floor and sphincter muscles (Peng et al. 2016). These devices have yet to be tested either across patients or following treatments. However, it is interesting to mention that a different asymmetry pattern was found in the PFM activation, with women presenting significantly higher average EMG values on the right side of the pelvic floor compared to the left side (Voorham-van der Zalm et al. 2013). In addition, innervation zones were also found not to be strictly left–right symmetric, with up to 10 motor units detected by the vaginal probe, which varied in location and number among individuals (Peng et al. 2016).

Surface EMG is usually recommended to measure the activity of large, superficial muscles, and it is important to take into consideration the signal-to-noise ratio, which is inversely related to the thickness of the tissue between the sensor and the muscle fibers, and highly related to the EMG sensor direction relative to muscle fibers (Merletti et al. 2009). As previously described, PFM are a complex structure with multiple origins and insertions, therefore, having multipennate fiber patterns (with angles ranging from 41° to −43° relative to the horizontal (Betschart et al. 2014)), which makes reliable and reproducible acquisition of muscular activity signal patterns a real challenge, specially when considering comparisons across individuals with different muscular trophisms, or following interventions. Another important consideration to be made is that pre and post treatment comparisons using EMG are compromised due to changes in trophism and to inevitable changes in the position of electrodes, altering the muscle sample that is being assessed, and therefore, compromising the reliability of the method for this purpose.

1.1.4. Imaging techniques

Imaging techniques such as magnetic resonance imaging (MRI) or ultrasound (US) have been increasingly used in the evaluation of pelvic floor disorders (Dietz 2010; Pontbriand-Drolet et al. 2015). MRI presents an advantage of providing clear and detailed images of pelvic floor anatomy, remaining the most promising tool for studying details of urethral movement (Perez et al. 1999); whereas US enables dynamic measurements of the pelvic floor morphometry and function (Dietz et al. 2002), which could further elucidate the etiology and pathophysiology of pelvic floor symptoms.

Some of the main advantages of transperineal US compared to MRI are the lower cost, better visualization of moving structures, convenience for real time visual biofeedback of PFM contractility (Dietz et al. 2001). Additionally, it is a non-invasive assessment, which is an advantage compared to other objective assessments of PFM function, especially for older women, or women with sexual dysfunction symptoms (van Delft et al. 2015).

Three-dimensional or four-dimensional transperineal US can measure the reduction in the area and in the anteroposterior diameter of the levator hiatus, which result mainly from the ventral component of PFM contraction (Brækken et al. 2008; van Delft et al. 2015). Although other morphometry parameters, such as cranio-ventral shift of the bladder neck or the pelvic floor organs (Dietz et al. 2001, 2002; Thompson et al. 2006b) may not reflect PFM strength strictly, they account for the result of both the constriction and inward components of PFM action (Peschers et al. 2001b; Brækken et al. 2009).

Studies comparing assessments of PFM contraction by transperineal US and digital palpation presented moderate-to-strong correlations between PFM strength and morphometric parameters of the pelvic floor structure. PFM strength was, for example, associated to a higher bladder neck cranio-ventral displacement (Dietz et al. 2002; Thompson et al. 2005), thicker pubovisceral muscles (Brækken et al. 2014) and smaller levator hiatus dimensions (Brækken et al. 2014; Albrich et al. 2016; Volløyhaug et al. 2016). However, up to date, only one classification scale was recently proposed for the PFM strength assessment using ultrasound measurements (Volløyhaug et al. 2016).

Nevertheless, US morphometric parameters may not be sensitive enough to discriminate subtle variations in PFM function, mainly because the measures of displacement are crucially dependent on tissue compliance or elasticity rather than only muscle strength or resistance (Chen et al. 2011). In support of this hypothesis, a reduced PFM contractility detected by digital palpation was better related to levator ani muscle injuries (Guzmán-Rojas et al. 2014), and to subjective and objective measures of pelvic floor organ descent (Oversand et al. 2015) than any sonographic morphometric parameter of PFM function.

When imaging measurements were done prior to and after PFM treatment protocols, pelvic floor morphometric changes were often accompanied by symptoms or function improvements. More specifically, although it cannot directly assess strength improvements, imaging studies provided some insights into the possible anatomical mechanisms through which physiotherapy enables the PFM to minimize urine leakage, or prolapse symptoms. US images were capable of detecting some changes in the morphology and anatomy of some structures post PFM treatment, such as (i) reduction in levator ani muscle surface area at rest, and during contraction, suggesting increase in levator ani passive tone and strength (Dumoulin et al. 2007); (ii) reduction in the anorectal angle and increase in the bladder neck height at rest, during contractions or Valsalva maneuvers, suggesting improved pelvic organ support (Madill et al. 2013); (iii) hypertrophy of the striated urethral sphincter (Madill et al. 2015); (iv) increases in PFM volume and reduction of the levator hiatus dimension, elevating the resting position of the bladder and rectum (Brækken et al. 2010), suggesting changes in the strength and resistance of these muscles.

1.2. Rational for the development of a new measurement device of PFM function

From this brief literature review, we conclude that an objective assessment of PFM physical and functional capacities are indubitably necessary, for clinicians and researchers, when choosing treatment orientation or evaluating outcomes. However, up to date, there is no gold standard method of evaluation, and although different measuring prototypes have been recently proposed, comparisons between them are challenging, and their results are hard to be compared or combined.

Most authors suggest assessing PFM strength using vaginal dynamometers, considering it a better method as they measure force directly (Dumoulin et al. 2003; Verelst and Leivseth 2004a; Constantinou and Omata 2007; Saleme et al. 2009; Nunes et al. 2011; Ashton-Miller et al. 2014; Parkinson et al. 2016; Romero-Cullerés et al. 2017). However, none of the aforementioned dynamometer prototypes are available to be commercialized, and they appear to be used only in a research scenario.

Among the commercially available options, manometers and EMG are not the best choice for an objective PFM assessment, since they do not selectively depict PFM activity from confounding artifacts effectively (Peschers et al. 2001a). In addition, both options lack the ability to adequately evaluate the spatiotemporal differentiation of PFM function along the vaginal canal, providing only a single univectorial measurement of the resultant force acting on the vaginal walls, which reveal little about the quality, symmetry or different biomechanical capabilities of the PFM (Bø and Sherburn 2005; Guaderrama et al. 2005; Shishido et al. 2008).

Imaging techniques seem to be the most effective way to investigate both the constriction and inward mechanisms of PFM action (Brækken et al. 2009), but they have limited accessibility and high cost. Also, as discussed previously, they are not the best option to discriminate subtle variations in PFM function, mainly because the measures of displacement are crucially dependent on tissue compliance or elasticity rather than just muscle strength or endurance (Chen et al. 2011; Guzmán-Rojas et al. 2014; Oversand et al. 2015).

Ideally, a device designed to assess the PFM function should take into account its flexible, 3-D, deformable surface and should analyze both the force distributed through various regions of the vaginal canal (latero-lateral and anteroposterior directions; caudal, mid and cranial areas) (Devreese et al. 2004) and the capacity to coordinate contractions in a symmetrical way and with proper spatial distribution.

One of the main goals of the present study was to develop a PFM assessment device that (i) is specific enough to provide force and pressure parameters in order to distinguish between patients and follow-up on treatment outcomes; (ii) could precisely map the pressure profile along the entire vaginal canal; and (iii) could be commercialized and used by researchers and clinicians in a simple and easy way.

We chose to start from a sensor matrix of capacitive transducers that was already commercially available for other purposes rather than intravaginal measures (pliance sensor mat, Novel; Munich, Germany). To be sure it was suitable for PFM assessments, the device was extensively tested and had to be adapted to the specific characteristics of this particular application, considering parameters such as sensor length, format, and diameter; range of pressure measurement across the sensor matrix; sampling frequency; spatial and temporal resolution; electronic resolution; and sensitivity. It was a great advantage to start from something that is already highly precise, with low sensitivity to temperature variations (Kernozek et al. 2002; Janura et al. 2009) and with a commercially available and easy to use software, with a friendly interface that does not require special training to be handled.

The idea of building this equipment won a prize in the University of Sao Paulo contest for innovative ideas (*Olímpiada USP Inovação*), promoted by the *Agência USP Inovação*, and also won the most promising proposal award in an international conference (Expert Scientific Meeting- Cambridge, USA 2014) specifically aimed at investigations of load distribution on the human or animal bodies.

In the following conference, in 2016 (Expert Scientific Meeting- Lisbon, Portugal 2016), a full-length paper presenting the results obtained with this new instrument on a Pompoir trained population was selected by a prominent panel of experts as *the Art in Science Award* winner, which was the main prize given in this event. This paper was accepted by the *Clinical Biomechanics* journal and it is presented in a separate section of this thesis.

2. OBJECTIVES

The general purpose of this study is to develop a novel instrumented probe for PFM biomechanics assessment, capable of providing a precise high spatial 3D resolution pressure profile of the vaginal canal, to distinguish PFM contractions from intra-abdominal pressure rises, and to map the spatial coordination potential of these muscles in a trained asymptomatic female population.

2.1. Specific aims

Our specific aims were to:

(i) verify the association between the PFM functional assessment score by a digital assessment scale (Oxford grading) and the biomechanical parameters measured by the new device;

(ii) verify the reliability (intra- and inter-rater) and repeatability (among trials) of the new device and assessment protocol;

(iii) characterize the spatiotemporal pressure profile along the entire vaginal canal of healthy women during the performance of two opposite tasks: PFM maximum contraction, and a Valsalva maneuver (maximum intra-abdominal pressure effort with downward movement of the pelvic floor);

(iv) investigate the potential coordination of the different portions of the PFM in asymptomatic women trained in the Pompoir technique.

2.2. Hypotheses

Our hypotheses were that with this novel instrument would be able:

(I) to reliably map the pressure profile along the vaginal canal, differentiating the PFM contraction from intra-abdominal pressure rises,

(II) and to describe the potential capabilities of the PFM function in an asymptomatic trained population, distinguishing spatial symmetry and coordination patterns along the length of the vaginal canal.

3. METHODS

The results of this study will be published in two accepted papers. Therefore, this thesis is being presented as a compilation of scientific papers, reproduced in the following sections.

The first study was accepted and published online by the *Journal of Biomechanics* (impact factor of 2.43, https://doi.org/10.1016/j.jbiomech.2017.04.035) and presents the results of the test-retest reliability study of the novel instrumented device, together with differentiation of the 3-D pressure distribution map of the vaginal canal during two tasks, PFM maximum voluntary contraction and Valsalva maneuver (Cacciari et al. 2017).

The second study was accepted by the *Clinical Biomechanics* journal in may 2017 (impact factor of 1.64) and presents the potential capabilities of the PFM function, comparing asymptomatic women with and without experience on a specific training program for the PFM strength and coordination, the Pompoir technique

Additionally, a research internship was included as part of the PhD project development, which took place at the *Laboratoire Incontinence et Veillissement* (Montreal, Canada). During the internship, data on an investigation using imaging technique as a tool to assess PFM functionality and responses of two types of PFM training protocols in the management of female urinary incontinence was analyzed. Along with the experience in assessing PFM characteristics and properties using US imaging, the results of a randomised clinical trial with women aged 60 years or older suffering from urinary incontinence symptoms are still to be published, but one abstract containing some of these findings will be presented in the International Continence Society meeting (Florence, 2017). This internship and learning experience, supervised by Dr. Chantal Dumoulin, also resulted in a Cochrane review aiming to determine the effectiveness of training in the management of female urinary incontinence, which is also to be published in the first semester of 2017. A second abstract containing a summary of this Cochrane review update will also be presented in the International Continence Society meeting (Florence, 2017). These results are in the annex section of this thesis.

4. ACCEPTED PAPER 1

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Novel instrumented probe for measuring 3D pressure distribution along the vaginal canal

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Abstract

We developed an intravaginal instrumented probe (covered with a 10x10 matrix of capacitive sensors) for assessing the three-dimensional (3D) spatiotemporal pressure profile of the vaginal canal. The pressure profile was compared to the pelvic floor (PF) digital assessment, and the reliability of the instrument and repeatability of the protocol was tested. We also tested its ability to characterize and differentiate two tasks: PF maximum contraction and Valsalva maneuver (maximum intra-abdominal effort with downward movement of the PF). Peak pressures were calculated for the total matrix, for three major sub-regions, and for 5 planes and 10 rings throughout the vaginal canal. Intraclass correlation coefficients indicated excellent inter- and intra-rater reliability and intra-trial repeatability for the total and medial areas, with moderate reliability for the cranial and caudal areas. There was a moderate correlation between peak pressure and PF digital palpation [Spearman's coefficient r=0.55 (p<0.001)]. Spatiotemporal profiles were completely different between tasks (2-way ANOVAs for repeated measures) with notably higher pressures (above 30kPa) for the maximum contraction task compared to Valsalva (below 15kPa). At maximum contraction, higher pressures occurred in the mid-antero-posterior zone, with earlier peak pressure onsets and more variable along the vaginal depth (from rings 3 to 10-caudal). During Valsalva, the highest pressures were observed in rings 4 to 6, with peak pressure onsets more synchronized between rings. With this protocol and novel instrument, we obtained a high-resolution and highly reliable innovative 3D pressure distribution map of the PF capable of distinguishing vaginal sub-regions, planes, rings and tasks.

Keywords: pelvic floor, reliability, pressure distribution, vaginal closure force, levator ani, strength.

Introduction

The pelvic floor (PF) has been poorly studied from a biomechanical perspective probably because of its complex structure comprised of many muscle layers, multiple muscle insertions in endopelvic organs and fascia (Ashton-Miller and DeLancey 2007) with concave format in a three-dimensional (3D) architecture.

Although objective assessment of PF muscles (PFM) physical and functional capacities is highly recommended (Abrams et al. 2010), a gold standard method and equipment are still topics of debate. PFM assessments of clinical relevance should be made by an objective, reliable, and multidimensional mechanical tool capable of measuring the magnitude and spatiotemporal distribution of pressures inside the vaginal canal, taking into account the PF 3D flexible structure, and the relative direction of PFM contractions.

In clinical practice, digital palpation is the technique most often used to evaluate the quality of PFM function (Laycock and Jerwood 2001). However, palpation is less sensitive than other techniques for quantifying sustained contractions (Frawley et al. 2006), for differentiating variations in discrete force (Morin et al. 2004b), and has limited reliability even for experienced examiners (Sartori et al. 2015). The most regularly used quantitative methods include EMG, manometers, and dynamometers (Bø and Sherburn 2005). In particular, manometers and dynamometer measurements are considered more direct and objective assessments of PF function than digital palpation (Bø and Finckenhagen 2001; Barbosa et al. 2009; Rahmani and Mohseni-Bandpei 2011; Ribeiro et al. 2016) and have been used for several purposes

(Theofrastous et al. 2002; Dorey et al. 2004; Quartly et al. 2010; Friedman et al. 2012; Middlekauff et al. 2016; Torelli et al. 2016; Bø et al. 2017b).

Dynamometers are capable of providing precise maximum force and its derivative variables (Morin et al. 2004; Constantinou and Omata 2007); whereas manometers are usually made of highly pliable materials, which can be problematic. Furthermore, univectorial measurements obtained by manometers or by dynamometers reveal little about the quality, symmetry, or cranial movement direction of PFM contractions (Schaer et al. 1995; Bø and Sherburn 2005; Haylen et al. 2010). Moreover, surface EMG does not provide an objective measurement of force, endurance, or symmetry, and assessment is rather questionable and difficult to perform reliably because PFM architecture includes multiple innervation zones (Peschers et al. 2001b; Enck et al. 2004; Cescon et al. 2014).

In general, the literature points out that all aforementioned methods lack the proper spatiotemporal differentiation of PF functions along the vaginal canal and do not effectively differentiate PFM contractions from intra-abdominal pressure increases or adjacent muscle contractions (Peschers et al. 2001b; Guaderrama et al. 2005; Shishido et al. 2008).

Recently, new equipment has emerged, such as a pressure sensor developed by van Raalte and Egorov (2015) to record tissue deformation patterns from the vaginal walls. However, it does not cover the entire vaginal canal, the resulting pressure maps are merely tactile images (a translation of the digital sensation of touch in to a digital image), and it is necessary to rotate the probe to get spatial pressure distribution;

therefore, one cannot measure spatial and time distribution simultaneously, reducing repeatability.

To improve the understanding of PF function and the pathophysiology of urogynecological dysfunctions, we propose a novel instrumented non-deformable probe (pliance sensor mat type: MLA-P1; novel; Munich, Germany) for PF assessment and test (i) its association with a clinical evaluation scale (Oxford grading); (ii) its reliability (intra- and inter-rater) and repeatability (among trials); and (iii) its ability to characterize the spatiotemporal pressure profile along the entire vaginal canal and to differentiate between a PFM maximum contraction, which is clinically relevant to investigate, and a Valsalva maneuver (maximum intra-abdominal pressure effort with downward movement of the PF), which can be performed by women instead of a proper PFM contraction in clinical evaluations (inward movement).

Methods

Participants

This cross-sectional study included 26 healthy women [37.0 (10.8) years, 62.6 (9.0) kg, 162.4 (7.2) cm, 23.8 (3.9) kg/m^2] with regular menstrual cycles, median (Interquartile range): 0 parity (number of children- 0–1), 3 (from 0 to 5) modified Oxford grading scheme (Laycock and Jerwood 2001). Exclusion criteria included body mass index higher than 30kg/m^2; history of pregnancy within the past year; history of urogynecological or neurological dysfunctions, untreated urinary tract infections or surgery for urinary incontinence or pelvic organ prolapse; pelvic organ prolapse stage higher than II (most distal portion of the prolapse situated between 1cm above and below the hymen) (Haylen et al. 2016). This study was approved by the Ethics Committee of the School of Medicine of the University of São Paulo (protocol n.023/14), and all subjects provided informed consent.

Biomechanical assessment

The spatiotemporal pressure distribution of the vaginal canal was evaluated using a fully instrumented non-deformable probe, consisting of an Ertacetal® cylinder [tensile modulus of elasticity of 2,800 MPa (according to ISO 527-1/-2)], covered by a 10 x 10 matrix of individually calibrated capacitive sensors (MLA-P1, pliance System; novel; Munich, Germany). The cylinder is 23.2mm in diameter and 8cm in length, and its sensing area is 70.7x70.7mm (10x10 sensing elements of 7.07x7.07mm, with 1.79mm gap between them). The capacitive sensors have a measurement range of 0.5–100kPa, and a measurement resolution of 0.42kPa, enabling unidirectional measurements with high spatial resolution (Fig.1). This equipment and software are easy to use, with a friendly interface that do not require special training to handle.

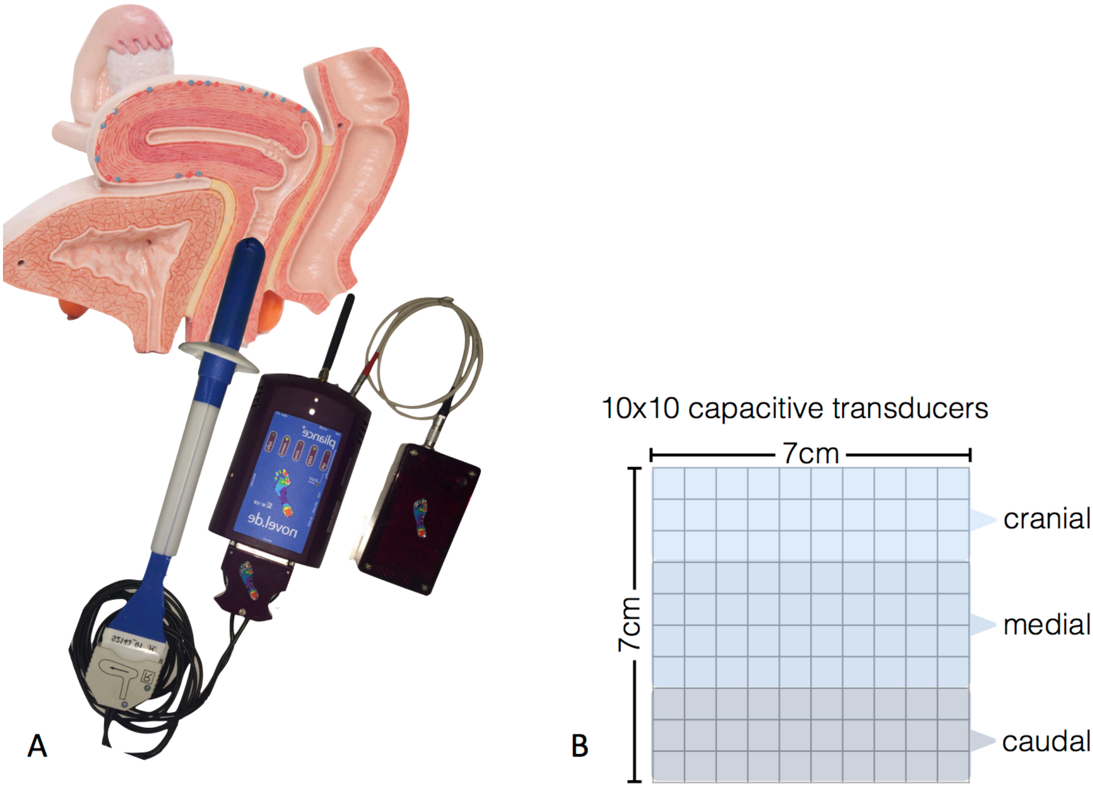

Figure 1. A- pliance System (Novel, Munich, Germany) intravaginal instrumented probe: hard plastic cylinder covered by capacitive transducers placed in a matrix configuration (10x10). B- Sensor matrix diagrams representing three major areas: caudal (first three lines of sensors), medial (four mid sensor lines), and cranial (last three lines of sensors).

Capacitive sensors are notoriously highly precise, with low temperature variation (Kernozek et al. 2002; Janura et al. 2009). However, when it comes to measuring pressures inside the body we considered it necessary to test its uniformity and linearity in response to temperature. Therefore, we built a 1-meter water column instrumented with a thermometer (Fig. 2). To better understand the effect of the temperature in which the instrumented probe was calibrated, we tested it under two conditions: (1) probe calibration under room temperature (around 20°C) and (2) probe calibration under body temperature (around 37°C). The instrumented probe was covered with two non-lubricated condoms, and data collection was performed with water temperatures ranging from 15 to 40^{o}C in 5–10^{o}C increments. We observed that at 9.81kPa (1-m water column) all sensors were active, measuring uniformly equal pressures for both conditions. Nevertheless, for the condition in which the sensor was calibrated under body temperature, we could observe more linearity of peak pressure changes (regression equation y=10.09–0.06*x; R^2=0.88; Pearson correlation r=0.94;), compared to the condition in which the probe was calibrated under room temperature (regression equation y=10.86–0.06*x; R^2=0.79; Pearson correlation r=0.89), with peak pressure changing linearly and only slightly in temperatures varying from 20 to 40^o.

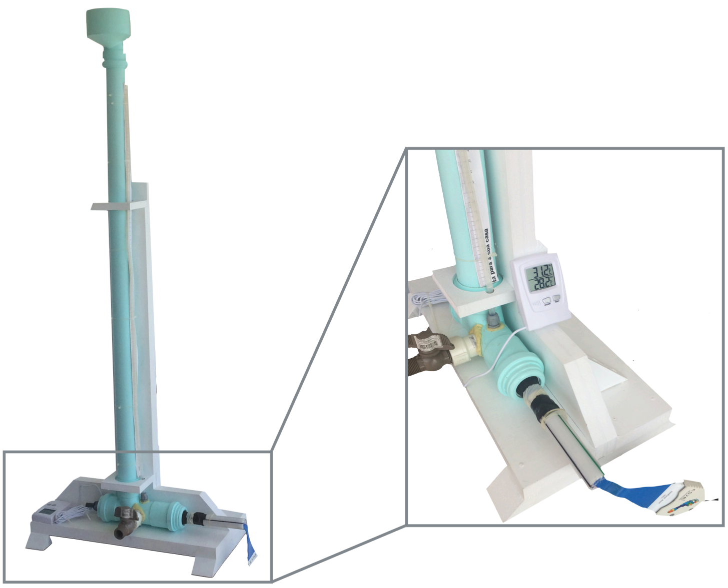

Figure 2. Temperature test setup for assessing the uniformity and linearity of the pressure measurement along the instrumented probe in a controlled condition. Figure on the left- 1-meter column of water. Detail – location of probe insertion to be tested and digital thermometer.

Pressure-related variables were acquired at 50Hz as the women performed two tasks while breathing normally, with a 1-min rest period between trials and tasks. The first task— maximum contraction—was similar to the POWER assessment from the PERFECT scheme (Laycock and Jerwood 2001), and consisted of two trials of PF maximum contractions maintained for 3 seconds each, where the participants had to "lift" and "squeeze" their PF as hard as possible (Bø 2003); the second task—the Valsalva maneuver—consisted of two trials of maximum intra-abdominal pressure effort leading to a downward movement of the PF, maintained for 5 seconds each. The start of the measurements was manually synchronized just after the verbal command given for each tasks. Later, during the data processing, each signal was cut-in a custom-written MATLAB function to isolate the pressure time-series corresponding to the beginning of PF contraction.

The instrumented probe was warmed to body temperature and covered with a hypoallergenic, non-lubricated condom, which was marked at a length of 7cm to ensure standardized depth of insertion. A second condom was placed over the first to prevent skin contact with the ink used for the marking. The probe was sterilized and cleaned according to the manufacturer's instructions and the requirements of the University Hospital Infection Commission. The instrumented probe was always inserted into the vaginal canal with the same orientation, following the marks, 7cm from the hymeneal caruncle~~.~~

To test the reliability and repeatability (intra- and inter-raters and trials), a subset of 15 participants were tested twice. At the first visit, participants were assessed by two trained physiotherapists (evaluators 1 and 2) with an hour interval between assessments. One week later, at a second visit, volunteers were re-assessed by evaluator 1.

Data analysis

Data were filtered (8Hz low pass, 4th order), and analyzed using a custom-designed math function. From the peak pressure-time series, we calculated peak pressures [kPa] (highest pressure value in a subset of sensors): (A) in 5 planes – 20 sensors each, with each plane (36^o apart from each other) representing a sum vector of pressures from two 10-sensor lines diametrically opposed along the cylinder (Peng et al. 2007); (B) in 10 rings, each one composed by the 10-sensor perimeters surrounding the cylinder; and (C) in three major areas: cranial (corresponding to the first 3 lines of sensors from the vaginal opening), medial (4 mid-lines of sensors), and caudal (3 last lines of sensors) (Fig.1B). Regarding the variables described in A and B above, our rational was based on the anatomy and biomechanics of the pelvic floor muscles. Normal forces measured along the circumference of the vaginal canal are thought to act together (i.e. to constrict and lift the pelvic floor structures during the PFM contraction), regardless of the orientation of each individual force. By this means, we considered that adding together the pressures from opposite sides of the vaginal wall would provide a better directional overview of the resultant forces acting on the vaginal canal. Similar approaches were proposed by Peng et al. (2007) and Shishido et al. (2008), however, in both cases the sensor device used consisted of only four force transducers that were manually pulled thought the vaginal canal. In our study, when analyzing together the pressure matrix divided by planes and axes, it is possible to have a complete map of the load distribution along the vaginal length, differentiating the pressure patters on the two opposite tasks.

Peak pressure onset in each ring was also determined from the instant (% time series) at which the peak pressure-time series of each sensor ring achieved a pressure value higher than 2 standard deviations from its baseline pressure. The mean value for each task (from 2 trials) was considered for statistical purposes.

Statistical analysis

Given the sample size evaluated (n=26), an alpha error of 5%, and a moderate effect size of 0.45 (d) (based on peak pressure in the total area), the statistical power (1-β) obtained was 0.77 for the t-test used. For all variables, normal distribution (Shapiro Wilk test) and homoscedasticity (Levene Test) were achieved. For comparisons of peak pressure between tasks (Valsalva and maximum contraction) and among rings (10), planes (5), or major areas (3), we used 2-way ANOVAs for repeated measures. For comparisons of the peak pressure onset among rings within each task, we used ANOVAs for repeated measures, and for comparisons between tasks in each ring, we used paired t-tests. For reliability testing, we calculated (a) the Intra-class Correlation Coefficient$_{2,1}$ (ICC); (b) the standard error of prediction (SEP) for inter-rater comparisons; for intra-rater and intra-trial comparisons, we used (c) ICC$_{3,1}$; and (d) standard error of measurements (SEM). An alpha error of 5% was adopted for all comparisons. For the correlation between the peak pressure from the entire matrix and the Oxford grading scheme we used the Spearman correlation.

Results

Fig.3 shows different pressure profiles for both tasks. For the maximum contraction, the highest pressures (above 30kPa) were observed in the mid-antero-posterior zone (2–4cm from the vaginal introitus), whereas for the Valsalva, the highest pressures were markedly lower (below 15kPa) and in the upper portion of the antero-posterior zone (4–5cm from the vaginal introitus), with notably high pressures along the whole cranial circumference of the vaginal wall compared to other regions, although not significant.

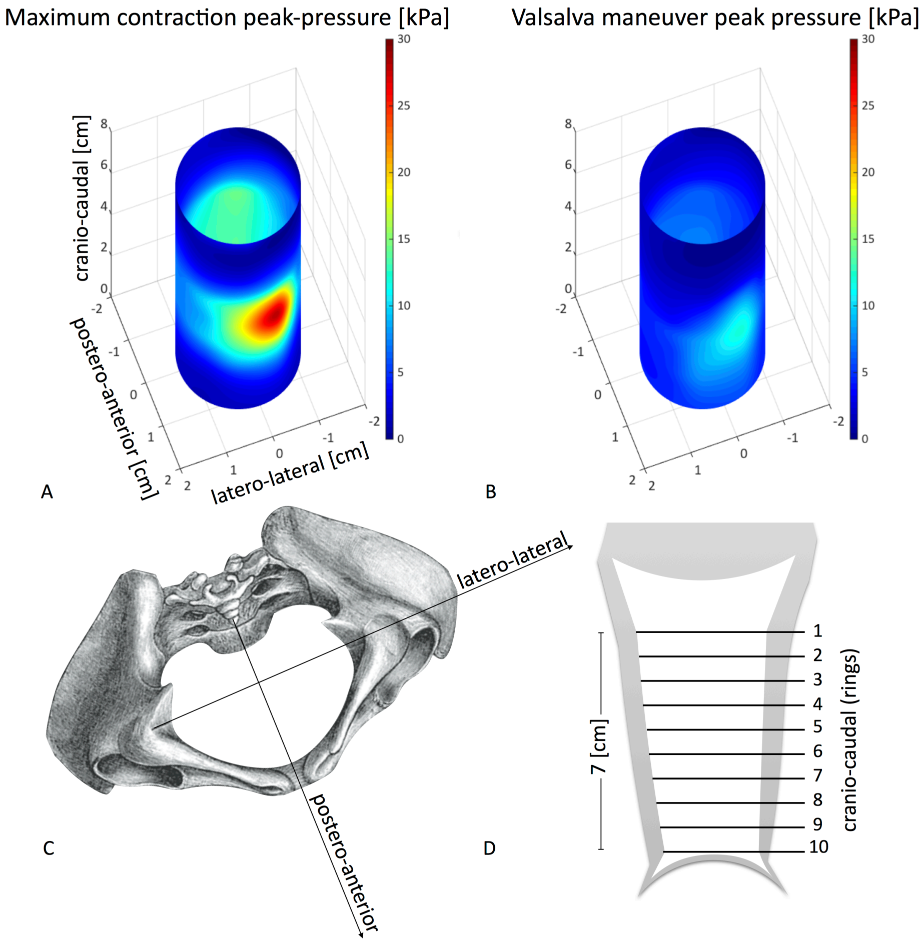

Figure 3. 3D diagram of the matrix peak pressure mean among participants (n=26) for maximum pelvic floor contraction (A) and valsalva maneuver (B). For both graphs, x and y planes represent latero-lateral and antero-posterior planes of the pelvis, respectively (C). The z axis represent the depth of the vaginal canal, being 7 the hymenal caruncle, and 1 the most cranial portion achieved by the instrumented probe (D).

Peak pressure by planes and rings

There was a significant interaction effect between tasks and planes ($p<0.001$, $F=14.87$), with higher pressures in all 5 planes during maximum contraction as opposed to those that occurred during the Valsalva. Intra-task comparisons between planes showed, for the maximum contraction, higher pressures in planes 2 and 3 (corresponding to the antero-posterior plane), and for the Valsalva, higher pressures also in plane 2 compared to planes 1, 4-5, and plane 3 compared with plane 5 (Fig.4a).

For the analysis by rings, there was a significant interaction effect between the tasks (maximum contraction–and Valsalva) and rings ($p<0.001$, $F=17.34$), with higher pressures in rings 4 to 8 during maximum contraction as opposed to Valsalva. For the maximum contraction, intra-task comparisons between rings showed higher pressures in rings 4 to 8, with the highest in ring 6. For the Valsalva, higher pressures were observed in rings 4 to 6 compared to rings 1, 8, 9, and 10 (Fig.4b).

Peak pressure by major areas

There was an interaction effect between tasks and major areas in peak pressure ($F=42.267$, $p<0.001$). In both tasks, the medial area presented higher peak pressures than the cranial and caudal areas ($p<0.001$), which were different for the medial and caudal areas between tasks (Table 1).

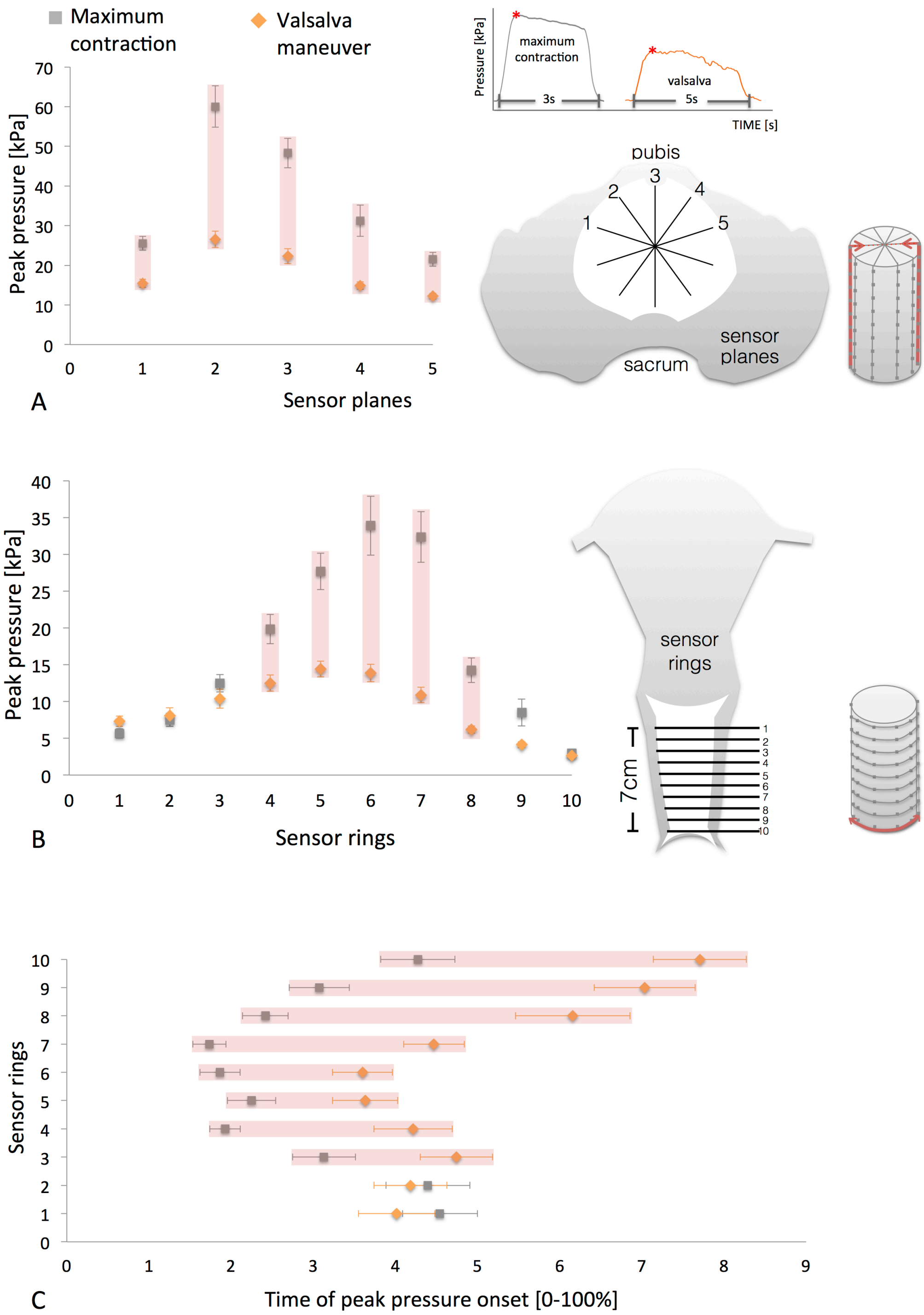

Figure 4. Peak pressure comparisons between tasks: maximum contraction (in grey) and valsalva maneuver (in orange). Mean and standard errors (n=26), differences between tasks (univariate ANOVAs) highlighted in pink (*P*<0.05). A- peak pressures among planes (sum vector of pressures from two 10-sensor lines diametrically opposed along the vaginal depth). B- peak pressures among rings (10-sensor perimeters surrounding the vaginal circumference). C- onset of peak pressure-time series for each ring (instant in % time that each sensor ring achieved a pressure value higher than 2 standard deviations from baseline).

Peak pressure onset by rings

Peak pressure onset was always later in the Valsalva compared to the maximum contraction–for rings 3 to 10 ($p<0.05$) and we observed contractions with more synchronicity in the activation of the rings in the Valsalva. For maximum contraction, rings were different from each other in 21 out of 45 possible comparisons ($F=12.443$; $p<0.001$); for instance, ring 1 was different from rings 3 to 8, ring 2 was different from rings 4 to 8, ring 3 was different from ring 10, rings 4 to 7 were different from rings 9 to 10, and ring 8 was different from ring 10. In contrast, in the Valsalva, only rings 1 and 2 were different from rings 9 and 10, respectively ($F=3.681$; $p=0.0005$). Only 3 differences were found among 45 possible differences. There were clearly three blocks of rings contracting at similar times in the Valsalva: rings 1, 2, 6, and 7 were the first block; rings 5, 4, and 3 were the second block; and rings 8, 9, and 10 were the third and last block, in order of contraction. Whereas for the maximum contraction task, three different blocks were identified: rings 5, 6, 7, 8, and 3, in this order, in the first block; rings 9, 2, and 1 in the second block; and finally, ring 10 (Fig.4c).

Correlation of total peak pressure and Oxford grading

We observed a significant moderate correlation between digital palpation assessment and biomechanical assessment (peak pressure) [Spearman’s coefficient of Þ=0.5477 ($p<0.001$)]. Out of the 26 participants, 3 presented a score of 1 [peak pressure mean (95% confidence interval) [27.1kPa (16.50–37.78)], 2 presented a score of 2 [33.2kPa (-0.33–66.68)], 10 presented a score of 3 [54.1kPa (43.58–64.60)], 3 presented a score of 4 [61.1kPa (36.93–85.21)], and 8 presented a score of 5 [74.8kPa (61.52–88.15)].

Inter- and intra-rater reliability and inter-trial repeatability of peak pressure in major areas in the maximum contraction task

The intra-rater reliability for the maximum contraction task was excellent for the peak pressure in the total and medial areas. For the cranial area, the reliability was modest, and it was poor for the caudal area. The intra-trial repeatability was excellent for the peak pressure in the total, cranial, and medial areas ($ICC_{3,1}$ >0.86), however, we observed moderate reliability for the caudal area. The inter-rater reliability was excellent in the total and medial areas. For the cranial and caudal areas, the reliability was modest (Table 1).

Table 1. Peak pressure (kPa) mean and standard deviation in three major areas and in the total matrix area during Valsalva and maximum contraction. Intra class correlation coefficients and standard error of measurement and prediction between raters and trials of the maximum contraction task.

Peak Pressure (kPa)				Reliability Intra-rater		Reliability Intra-trials		Reliability Inter-rater		
Areas	**Valsalva**	**Maximum force**	**Tasks comparison**	**$ICC_{3,1}$**	**SEM**	**$ICC_{3,1}$**	**SEM**	**$ICC_{2,1}$**	**SEP $_{rater1}$**	**SEP $_{rater2}$**
Cranial	8.2 (4.3)	12.5 (8.5)		0.69	4.5	0.86	2.9	0.72	3.2	5.6
Medial	18.6 (11.7)$^{*\&}$	45.0 (22.4)$^{*\&}$	p^1<0.001	0.94	7.6	0.95	6.6	0.92	10.6	12.1
Caudal	6.4 (4.9)$^{\#}$	12.2 (9.7)$^{\#}$	F=42.267	0.12	11.6	0.70	6.2	0.50	10.7	10.7
Total	20.3 (13.2)	52.0 (24.2)		0.94	7.4	0.97	5.1	0.96	8.0	8.5

*[1] ANOVA 2-way (repeated measures), bonferroni post-hoc test. * represents the medial area different from the others in maximum contraction and valsalva; & represents the difference between tasks in medial area; # represents the difference between tasks in caudal area.*

Discussion

The proposed instrumented probe provided a precise 3D map of the pressure distribution profile of different areas, rings, and planes throughout the vaginal canal, and enabled a distinctive and high-resolution spatiotemporal analysis, enhancing the understanding of the function of the PF in dynamic tasks. This novel device also provided reliable measurements of PFM contractions for intra- and inter-rater and intra-trial comparisons.

The intra-rater, inter-rater, and intra-trial reliability for the medial and total areas of the vaginal canal were excellent, whereas for the cranial area, we found modest intra- and inter-rater reliability, but excellent intra-trial reliability. Although the caudal area showed moderate inter-rater and intra-trial reliability, intra-rater reliability was poor suggesting a greater individual variability in achieving maximum PF force, mainly because of the anatomical location of the PFMs (Jung et al. 2007); however, when comparing trial averages between sessions (intra-rater reliability), this variability was attenuated and the reliability became excellent. Peak pressures were slightly susceptible to changes, which were linearly predictable when the sensor was calibrated under body temperature.

Among clinicians, the most typical method for quantification of PF function is digital palpation because it is fast, requires no equipment, and selectively depicts PFM activity better than most available biofeedback devices (Peschers et al. 2001b). The moderate correlation observed between clinical and biomechanical assessment can be attributed to a possible lack of sensitivity of the clinical evaluation that could fail to differentiate discrete changes over time or treatments. Although peak pressures have increased accordingly with digital palpation rates, pressure value confidence intervals overlap between adjacent clinical grades. For instance, among 10 participants scored as 3 in Oxford grading (Laycock and Jerwood 2001) the peak pressure confidence interval could be attributed to both grades 2 and 4.

Several manometers (Barbosa et al. 2009; van Raalte and Egorov 2015; Ribeiro et al. 2016), dynamometers (Dumoulin et al. 2004a; Constantinou and Omata 2007; Saleme et al. 2009; Chamochumbi et al. 2012; Romero-Cullerés et al. 2017) and EMG techniques (Halski et al. 2013; Ptaszkowski et al. 2015) have been proposed to objectively quantify PF function. However, most of these methods were developed for research purposes, in contrast to the proposed sensor, which is already commercially available and has the advantage of differentiate the effects of maximum contraction of PFMs as opposed to an increase in intra-abdominal pressure (Valsalva) along the vaginal canal (Fig.3). Pressure profiles were completely different between tasks with notably higher pressures (above 30kPa) for the maximum contraction and lower pressures (below 15kPa) for the Valsalva, with an entirely different spatiotemporal pressure distribution pattern.

Furthermore, most of the assessment devices described in the literature measure only the resultant load of the entire vaginal canal; with this new device, it was possible to precisely map the vaginal spatiotemporal pressure profile with a high-resolution, distinguishing 5 planes and 10 rings (Fig.4). One major advantage of our proposed 100 capacitive sensors instrumented probe is the ability to measure the entire vaginal depth, which definitely provides a better spatiotemporal pressure profile and facilitates comparisons between anatomical regions. We consider a limitation of this study, and a suggestion for future studies, the lack of comparison of the new proposed device with other available measuring tools. More studies are now needed to confirm our results and compare the instrument with dynamometers or perineometers.

When comparing both tasks, we observed for the maximum contraction, higher pressures in the mid-antero-posterior zone (2–4cm from the vaginal introitus), 110–126% higher for all 5 planes, whereas in the Valsalva, the highest pressures were in the upper portion of the antero-posterior zone (4–5cm from the vaginal introitus). Along the rings, higher-pressures were again observed for the maximum contraction in the mid-portion [rings 4–8], and were even higher in rings 6–8 (130–197% above the obtained Valsalva pressure). Accordingly, the mid-region achieved higher-pressure rates for both tasks when the sensors were divided into the three major areas (caudal, medial, and cranial). These results detail the specific region of PFM force action and confirm previous findings of a mid-antero-posterior high-pressure zone in the vaginal canal (Guaderrama et al. 2005; Jung et al. 2007; Peng et al. 2007; Shishido et al. 2008).

In our study we observed a latero-lateral asymmetry during PFM contraction, with higher-pressure values shown in the 2nd plane (left anterior to right posterior) compared to the 4th plane (right anterior to left posterior). In healthy women the PFM have been thought to contract bilaterally as a functional unit (Shafik 1998), with no differences reported on vaginal pressure (Guaderrama et al. 2005) or ultrasound images between right or left sides (Weinstein et al. 2007). However latero-lateral asymmetries of the PFM were reported in a recent study using a multiple array EMG probe (Voorham-van der Zalm et al. 2013), with higher average EMG values obtained for the right side of the PF compared to the left side. Considering that PFM form a U-shaped loop around the urethra, vagina, and anus, the reported higher activation of the PFM left portion corroborates with the higher-pressure pattern observed here in the 2nd plane. This is the first time that the pressure profile of the vaginal canal has been evaluated with a high spatial 3D resolution probe, and it is possible that this slight symmetry difference was not reported before due to lack of resolution of the majority of the equipment's used to date.

Peak pressure onsets were different from rings 3 to 10 in the maximum contraction; the ring onsets were always late in the Valsalva compared to the maximum contraction, with more synchronicity in the activation of the rings in the Valsalva.

A limitation of our study is that we did not standardize the length of the vagina among women and the instrumented probe has a fixed length. Nevertheless, anthropometric factors such as height, weight, and body mass index cannot predict the anatomical configuration of the vaginal canal (Luo et al. 2016) and there are no correlations between vaginal length and these parameters. Here we made sure to cover the mid-portion of the vaginal canal for all participants (around 3.5 cm from the vaginal introitus), which was previously described as the most relevant region for PF muscle contraction (Guaderrama et al. 2005). With 100 sensors, we can be confident that the high-pressure zone observed in the mid-antero-posterior portion of the vaginal canal, would not be influenced by the size of either the vagina or the device length. Another limitation of our instrument is that it can only be used when the subject is lay down, and therefore it is not possible to assess the PFM in dynamic conditions such walking, jumping or running, what could provide more information about the continence mechanism.

With this protocol and novel instrument, we can obtain highly reliable measurements and high-resolution recording of the dynamic responses of the PFMs along the entire vaginal canal, as well as in different areas, planes, and rings, enabling an innovative 3D pressure distribution map for the female PF; this method has advantages among other commercially available instruments for measuring pressure in the vaginal canal, considering its high spatial 3D resolution. From a clinical perspective, this new device allows accurate and selective measurement of PFM performance and could have positive implications for clinical assessment and rehabilitation. In further studies, this novel instrument allows us to measure the load distribution in pregnant woman; to differentiate patterns of load distribution in different populations, training effect and tasks, leading us to a new era of measuring loads distribution of the pelvic floor muscles.

Conclusion

The novel instrumented probe has an excellent reliability and repeatability, is moderately associated with PFM digital assessment, and provides a high-resolution map of the dynamic and spatiotemporal pressure profile throughout the vaginal canal, differentiating the action of PFMs from intra-abdominal pressure increases.

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Conflict of interest statement

The research has been co-funded by CNPQ, CAPES and FAPESP. The fourth author (M.G.) works in novel gmbh and conducts this research supervised by Dr Isabel CN Sacco. All other authors are not associated to novel gmbh. Data were collected, analyzed and the paper written with no influence from the funding agencies or novel Company and no author will receive anything of value from the commercial product included in this paper.

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5. ACCEPTED PAPER 2

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High spatial resolution pressure distribution of the vaginal canal in pompoir practitioners: a biomechanical approach for assessing the pelvic floor

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Abstract

Background: Pompoir is a technique poorly studied in the literature that claims to improve pelvic floor strength and coordination. This study aims to investigate the pelvic floor muscles´ coordination throughout the vaginal canal among Pompoir practitioners and non-practitioners by describing a high resolution map of pressure distribution.

Methods: This cross-sectional, study included 40 healthy women in two groups: control and Pompoir. While these women performed both sustained and "waveform" pelvic floor muscle contractions, the spatiotemporal pressure distribution in their vaginal canals was evaluated by a non-deformable probe fully instrumented with a 10x10 matrix of capacitive transducers.

Findings: Pompoir group was able to sustain the pressure levels achieved for a longer period (40% longer, moderate effect, P=0.04). During the "waveform" contraction task, Pompoir group achieved lower, earlier peak pressures (moderate effect, P=0.05) and decreased rates of contraction (small effect, P=0.04) and relaxation (large effect, P=0.01). During both tasks, Pompoir group had smaller relative contributions by the mid-region and the anteroposterior planes and greater contributions by the caudal and cranial regions and the *latero-lateral* planes.

Interpretation: Results suggest that specific coordination training of the pelvic floor muscles alters the pressure distribution profile, promoting a more-symmetric distribution of pressure throughout the vaginal canal. Therefore, this study suggests that pelvic floor muscles can be trained to a degree beyond strengthening by focusing on coordination, which results in changes in symmetry of the spatiotemporal pressure distribution in the vaginal canal.

Keywords: pelvic floor muscle function, pelvic floor muscle training, muscle strength, vaginal pressure, women, biomechanics.

Introduction

Pelvic floor (PF) muscle training is widely recommended as first-line, conservative management for women with any type of urinary incontinence (Dumoulin et al. 2014) and as a treatment or prevention option for a variety of urogynecological dysfunctions (Freeman 2013) because these disorders have been linked to anatomical defects in structures that support the pelvic organs, including the levator ani muscle (Heilbrun et al. 2010). Urogynecological dysfunctions affect up to 67% of adult women (Kepenekci et al. 2011), depending mostly on age, childbirth status, body mass index (BMI), and family history (MacLennan et al. 2000; Swift et al. 2005; Wood and Anger 2014).

In addition to improving PF coordination and strength, PF muscle exercises are believed to improve sexual function by increasing self-confidence, desire, lubrication, orgasm, and satisfaction, although they have mostly been studied in women with urinary incontinence (Bø et al. 2000). Techniques involving strength and coordination training were first reported as treatment options for urinary incontinence in the mid-1900s (Kegel 1948), though reports indicate that PF motor-capacity training has been an important part of Chinese Taoism exercises for more than 6,000 years, aiming to stimulate circulation in the sexual organs, energize the pubic region, and promote self-awareness and sexual satisfaction (Chang 1986).

Although the deep and superficial layers of the PF muscles comprise different anatomical structures and innervation, clinically, they are assumed to act as a functional unit simultaneously as a mass contraction, to pull the pelvic floor structures in a ventro-cephalic direction*,* (Bø and Sherburn 2005), while Pompoir practitioners claim they can contract the PF muscles in layers, differentiating these layers as “rings” along the vaginal canal. If this is true, this practice would reveal patterns of pressure distribution in the vaginal canal that identify the action of these layers, or discriminate these rings. Training in the Pompoir technique has recently spread among women searching for improved self-awareness and sexual satisfaction. However, this practice has never been properly documented, and its outcomes in terms of pressure distribution along the PF structures have never been studied.

During the PF muscle contraction, a high-pressure zone is clearly identified at the mid-anteroposterior portion of the vaginal canal (Guaderrama et al. 2005). Given the presumed potential of Pompoir training to coordinate, strengthen the capacity of, and symmetrically distribute loads throughout different portions of the PF, one can assume that Pompoir practitioners would present a different coordination pattern than those without training experience that would result in a more homogeneous spatial and temporal pressure distribution along the vaginal canal.

Speed, timing, endurance, coordination and symmetry of the PF muscle contraction are thought to be just as important to urogynecological function as is their capacity to generate force (Bø 2004; Devreese et al. 2004). Therefore, techniques that favors training these physical capacities could enhance the trainability potential of the PF muscles in the pursuit of better sexual and continence functioning.

Assessing the PF muscles’ physical and functional capacities is still a matter of debate in the literature. Because of the complexity of the PF structure, whose format is concave with a three-dimensional (3-D) architecture, multiple origins and insertions (Ashton-Miller and DeLancey 2007), and great variability in the locations of its multiple innervation zones (Cescon et al. 2014), developing a quantitative, 3-D tool to discriminately assess various regions of the vaginal canal and PF muscle layers and functions is still ongoing. Digital palpation is the most-used technique to evaluate the quality of PF muscle function; however, palpation is less sensitive when quantifying sustained contractions (Frawley et al. 2006) or when differentiating variations in discrete force (Morin et al. 2004b) and has limited reliability when performed by different raters (Sartori et al. 2015).

Ideally, assessing the PF should take into account its flexible, 3-D, deformable surface and should analyze both the force distributed through various regions of the vaginal canal (latero-lateral, caudal, medial, and cranial) (Devreese et al. 2004) and the capacity to coordinate contractions in a symmetrical, spatially distributed way. However, the most regularly used methods in scientific and clinical investigations, including electromyography (EMG), intravaginal balloon catheters (perineometers), and dynamometers (Bø and Sherburn 2005), lack adequate spatiotemporal differentiation of PF functions along the vaginal canal and barely differentiate intra-abdominal pressure increases from PF-muscle contractions (Guaderrama et al., 2005; Peschers et al., 2001; Shishido et al., 2008). Perineometers are made of highly pliable materials, which can be problematic, since it has been shown that PF muscle force is related with vaginal canal distension (Dumoulin et al. 2004a). In addition, surface EMG assessments are rather questionable and difficult to perform reliably because PF-muscle architecture includes multiple innervation zones (Peschers et al. 2001b; Enck et al. 2004).

PF evaluations using a reliable-mechanical tool capable of measuring pressures magnitude, and their temporal and spatial distribution, would also improve the understanding of the pathophysiology of urogynecological dysfunctions. Thus, the purpose of this study was to investigate the potential coordination of the different portions of the PF in Pompoir practitioners by describing a high spatial (3D resolution) map of pressure distribution along the vaginal canal among practitioners and non-practitioners.

Methods

Participants

The eligibility criteria for all participants included age between 20–45 years, premenopausal status with monthly menstrual cycles, BMI no higher than 30 kg/m^2, not virgins, not currently pregnant, no history of pregnancy within the past year, no reported urogynecological dysfunction, no history of neurological or psychological conditions that could interfere with PF muscle function, no history of untreated urinary tract infections or surgery for urinary incontinence or pelvic organ prolapse, no pronounced pain or discomfort with pelvic exam, no pelvic organ prolapse stage higher than II (most distal portion of the prolapse situated between 1cm above and below the hymen) (Haylen et al. 2016), and the ability to contract the PF muscles correctly according to digital assessment (≥ 3 on the 0–5 modified Oxford grading scheme).

This cross-sectional study included 40 healthy adult women divided into two groups. The control group (CG, n = 23) comprised volunteers without any type of PF training or urogynecological physiotherapy practice [34.5 (8.9) yrs. old, 23.5 (3.1) kg/m^2, 164.1 (6.8) cm], modified Oxford grading scheme median 4 (IQR 3–5)]. The modified Oxford grading scheme defines the ability to contract the PF muscles in six categories (0-nil, 1-flicker, 2-weak, 3-moderate, 4-good and 5-strong) (Laycock and Jerwood 2001) and was checked by digital palpation by an experienced physiotherapist during the clinical assessment. The Pompoir group (PG, n = 17) comprised volunteers with at least 6 months of Pompoir training taught by the same professional [34.3 (8.7) yrs. old, 25.5 (4.1) kg/m², 162.1 (9.6) cm], modified Oxford grading scheme median 4 (IQR 3–5)].

This study was approved by the Ethics Committee of the School of Medicine of the University of São Paulo (protocol n.023/14), and all participants provided written, informed consent prior to participating.

The two groups were matched to guarantee similarity for features that represent risk factors for urogynecological dysfunctions (Wood and Anger, 2014), and that could interfere in the PF-muscle assessment results, including age (t = 0.07; P = 0.95), BMI (t =-1.05; P = 0.30), height (t=-0.81; P=0.14), modified Oxford grading scheme (z = -0.80; P = 0.45), parity (median 0, min-max 0–2, Z = 0.10; P = 0.90), and type of delivery (vaginal labor, Z=- 0.53; P = 0.74).

Clinical Assessment

The participants were interviewed and then clinically assessed by a trained physiotherapist (evaluator 1, who had 10 years of experience in women's health physiotherapy) to make sure they met the eligibility criteria. For the clinical evaluation, they were positioned supine with hips and knees flexed and feet flat on a conventional gynecologist's table in an isolated, private room with comfortable temperature and illumination. The participants received detailed instructions about correct PF muscle contraction with an inward movement of the perineum that tries to “squeeze” and “lift” the PF as they would to prevent urine or flatus loss (Messelink et al., 2005). The evaluator assessed the PF muscle function by digital palpation while the women performed a series of voluntary contractions using Laycock’s PERFECT assessment scheme (Laycock and Jerwood 2001). PERFECT is an acronym with P representing power (a measure of strength), E = endurance, R = repetitions, F = fast contractions, and finally ECT = every contraction timed. The scheme was developed to simplify and clarify the PF muscle assessment and was used here to quantify and qualify the pelvic floor muscle function.

Instrument

The spatiotemporal pressure distribution of the vaginal canal was evaluated using a fully instrumented probe, consisting of an Ertacetal® cylinder [tensile modulus of elasticity of 2.800 MPa (according to ISO 527-1/-2)], covered by a 10 x 10 matrix of individually calibrated capacitive transducers (MLA-P1, pliance System; novel; Munich, Germany). The cylinder is 23.2mm in diameter and 8cm in length, and its sensing area is 70.7x70.7mm (10x10 matrix of sensing elements, each with 7.07x7.07 mm in size, 0.6 mm in thickness, and 1.79 mm gap between them, coated with a protective layer of 0.3 mm). The capacitive transducers have a measurement range of 0.5–100kPa, and a measurement resolution of 0.42kPa, enabling unidirectional measurements along the vaginal canal (Figure 1A). All sensors were tested for accuracy before their first use by the manufacturer. Each individual sensor was checked in regards of measured vs.

applied pressure in a test session with at least 6 different values of pressure covering the whole range of expected values.

Reliability of the instrument

To ensure the reliability of the instrumented probe and the evaluator, we designed a test-retest protocol to guarantee the quality of the measurement and examiner. Prior to the main data acquisition, each participant repeated 3 tasks of maximum voluntary contraction, twice in the first day with different evaluators, and once more in a second day, one week apart. In the first visit, participants had their PF function assessed by a trained physiotherapist (evaluator 1) while performing three trials of maximally contracting their PF muscles. At least 1h after the first measurement, the objective PF assessment was repeated by evaluator 2. Both evaluators were trained physiotherapists specializing in woman's health and had 10 years of experience (evaluator 1) and 3 years of experience (evaluator 2) in clinical practice. One week later, at a second visit, volunteers were again assessed by evaluator 1 while performing the same task. Intra-rater, inter-rater, and inter-trial reliabilities for peak pressure were excellent (Hallgren 2012). (intra-rater standard error of measurements (SEM) = 10.54, $ICC_{3,1}$ = 0.86; inter-rater standard error of prediction (SEP) = 5.46, $ICC_{2,1}$ = 0.91; and inter-trials SEM = 9.07, $ICC_{3,1}$ = 0.907)

Data acquisition

Prior to each test, the instrumented probe was warmed to body temperature and covered with a hypoallergenic, nonlubricated condom. This condom was marked at the length of 7 cm to ensure standardized depth of insertion in the vaginal canal. To prevent skin contact with the ink used for the marking, a second condom was placed over the first, and it was appropriately lubricated with a warmed, hypoallergenic gel to minimize discomfort during insertion. Before and after each use, the device was sterilized and cleaned according to the manufacturer's instructions and the requirements of the University Hospital Infection Commission.

The instrumented probe was inserted always with the same orientation, 7 cm into vaginal canal from the hymeneal caruncle with the content measurement length of 8 cm. The depth of insertion was carefully ensured by matched anatomical (hymeneal caruncle and clitoris) references and the mark on the condom and along the probe. This insertion depth was chosen because the usual length of the vaginal canal of adult women is 8.9 ± 1.3 cm (Silveira et al. 2015) and we wanted to avoid discomfort during task performance. In addition, the PF muscles are known to act mainly in the first 6 cm of the vaginal canal (Shishido et al. 2008). After a 1-min accommodation period, if no discomfort was reported, the women were instructed to relax their PF muscles, remain silent and breathe normally for 10 sec while a baseline value was taken (baseline pressure, calculated as the mean pressure value for each transducer).

Pressure-related variables were acquired at 50 Hz while the women performed two different tasks with a 1-min rest period between both trials and tasks (Figure 1B). The first task (the endurance task) consisted of two sustained contractions; the second task (the wave task) consisted of three waveform contractions. During the endurance task, participants were asked to contract their PF muscles, as they had done in the clinical examination, and sustain the contraction for 10 s while breathing normally, similar to the PERFECT scheme endurance test (Laycock and Jerwood 2001). During the wave task, women were instructed to contract their PF muscles in a caudal-cranial direction for 2 s and then relax them in a cranial-caudal direction for 2 s. The cadence was controlled by a digital metronome. The wave task is usually undertaken in Pompoir practice and in strengthening training of the PF, and it is a coordination task in which the actions of all layers and regions of PF muscles must be coordinated to successfully accomplish the goal.

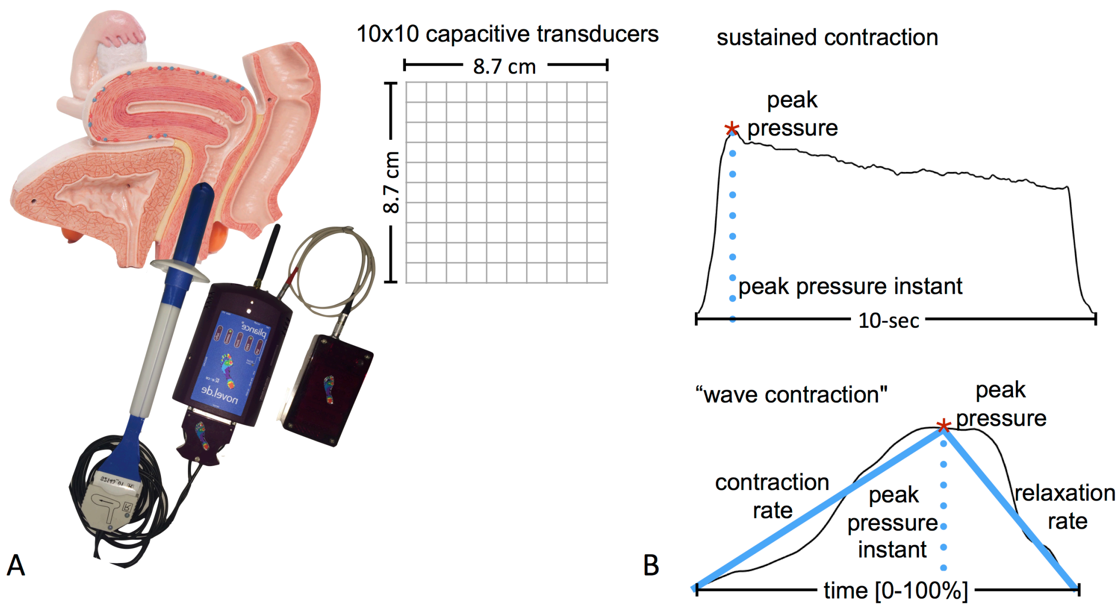

Figure 1. A- Pliance System (Novel, Munich, Germany). Intravaginal probe: Ertacetal® cylinder covered with capacitive transducers placed in a matrix configuration (10x10). B- Variables calculated from the peak pressure time-series. Sustained contraction: peak pressure and pressure instant. "Wave" contraction: peak pressure, pressure instant, contractions rate and relaxation rate.

Standardized verbal encouragement was given throughout the efforts (Caldwell et al. 1974), and only contractions that resulted in an inward movement of the perineum were recorded (Bø et al. 2009). Tasks were performed in the same sequence by all women, guaranteeing that the maximum voluntary muscle contraction necessary for the endurance task was not affected by any fatigue or learning effect produced by the wave coordination task.

Data analysis

Data was acquired and exported in ASCII format by Pliance System x/E software (Novel; Munich, Germany), further filtered (8Hz low pass, 4th order) and analyzed in a custom-designed function written in Matlab (MathWorks; Natick, MA). For the wave task, data was normalized to time [0–100%].

From the recorded pressure values, the following variables were calculated for the endurance task: (1) peak pressure [kPa] subtracted from the baseline pressure, (2) time to peak pressure [s] and (3) duration of the plateau [s], which represented the longest duration of the sustained contraction maintained above 90% of the peak pressure. For the wave task, the following variables were calculated: (1) peak pressure [kPa] subtracted from the baseline pressure, (2) time to peak pressure [%t], (3) contraction rate $\left[\frac{peak\ pressure - initial\ pressure}{time\ to\ peak\ pressure}\,\mathrm{kPa/\%t}\right]$ and (4) relaxation rate $\left[\frac{peak\ pressure - final\ pressure}{1 - time\ to\ peak\ pressure}\,\mathrm{kPa/\%t}\right]$.

We also analyzed pressure-time integrals of peak pressures and of the sum (total) of pressures in a) 5 planes (20 sensors each), with each plane (36^{o} apart from each other) composed by a sum vector of pressures from two 10-sensor lines diametrically opposed along the cylinder (Peng et al. 2007); and b) 10 rings, each one composed by 10-sensor perimeters surrounding the cylinder.

For the endurance task, the pressure-time integral was calculated in a fixed window of 8 s starting from time to peak pressure. For the wave task, the window was fixed at 50% of the contraction period starting from the instant at which the pressure rose higher than 2 standard deviations plus the baseline value. To better describe the relative contribution by each plane and ring to the pressure distribution along the vaginal canal, the pressure-time integral calculated only for the total pressure was normalized by the total pressure-time integral of the entire matrix (sum of all 100 sensors) in the same fixed windows used for each task.

Finally, for the wave task, onset of the peak pressure-time series in each ring was determined from the instant (% time series) at which each ring achieved a pressure value higher than 2 standard deviations from the baseline pressure.

Statistical analysis

Means of trials (two for the endurance task and three for the wave task) per subjects were used for statistical purposes. Given the sample size evaluated, an alpha error of 5%, and an effect size of 0.80 – large effect (d) (based on pressure-time integral), the statistical power (1- β) obtained was 0.79 with t-test.

For all variables, normal distribution (Shapiro Wilk test) and homoscedasticity (Levene Test) were achieved. Between-group comparisons of all anthropometric, clinical, and pressure-related variables (time series, peak pressure, and pressure-time integral by the entire matrix) were made by t-tests for independent samples, with the significance level set at 0.05. Between-group comparisons of pressure-time integrals and peak pressure onsets by planes and rings were conducted by multivariate ANOVAs (MANOVAs). If a significant difference was found, univariate ANOVAs were performed.

Cohen's d coefficients were calculated to express the effect size between groups for each task. We considered d coefficients smaller than 0.40 to be small effects; between 0.40 and 0.75, moderate effects; and greater than 0.75, large effects.

Results

Peak pressure time series of the entire matrix

For the endurance task, the Pompoir group sustained 90% of the achieved contraction for a longer period than the control group (40% longer, moderate effect). No differences between groups were identified for the peak pressure magnitude or the time to peak pressure (small effects).

For the wave task, the Pompoir group achieved lower, earlier peak pressures than the control group (moderate effect). The Pompoir group also had decreased contraction (small effect) and relaxation (large effect) rates (Table 1).

Table 1.Mean (standard-deviation) of the pressure-related variables of the time series of the entire matrix for endurance and wave tasks.

Peak pressure-time series	Control Group (n=23)		Pompoir Group (n=17)		t^1	P^1	Cohen's d
ENDURANCE TASK							
Peak pressure [kPa]	41.7	(21.5)	46.6	(28.8)	-0.63	0.53	0.20 (small)
Peak pressure instant [s]	2.63	(2.27)	1.85	(1.84)	1.15	0.26	0.38 (small)
Plato 90% [s]	1.29	(0.91)	1.90	(1.73)	-2.07	0.04	0.43 (moderate)
WAVE TASK							
Peak pressure [kPa]	40.5	(22.3)	27.4	(16.9)	2.02	0.05	0.67 (moderate)
Peak pressure instant [%t]	52.9	(8.9)	45.8	(12.3)	2.11	0.04	0.70 (moderate)
Contraction rate [kPa/%t]	0.71	(0.40)	0.57	(0.42)	1.10	0.28	0.35 (small)
Relaxation rate [kPa/%t]	-0.83	(0.52)	-0.46	(0.30)	-2.62	0.01	0.86 (large)

[1]independent samples t-test. Cohen's d effect size (Thalheimer and Cook 2002). Statistical differences between groups highlighted (P<0.05).

Pressure-time integrals by planes

Multivariate comparisons between groups and planes showed significant effects for both pressure-related variables for endurance task: total pressure-time integral (Wilks' Lambda = 0.83, F = 4.14, P = 0.004) and peak pressure-time integral (Wilks' Lambda = 0.86, F = 2.48, P = 0.039). Both group and planes also significantly affected the wave task's total pressure-time integral (Wilks' Lambda = 0.66, F = 12.25, P < 0.001) and peak pressure-time integral (Wilks' Lambda = 0.69, F = 8.48, P < 0.001). Between-group univariate analysis of total pressure-time integrals showed that for both tasks the Pompoir group had a smaller relative contribution by the anteroposterior planes and a greater contribution by the latero-lateral planes (Figure 2).

Between-group univariate analysis of the absolute peak pressure-time integrals showed that Pompoir group achieved higher values in the latero-lateral planes during the endurance task (33% higher in plane 1) and lower values in the anteroposterior planes during the wave task (25% lower in plane 3) (Table 2).

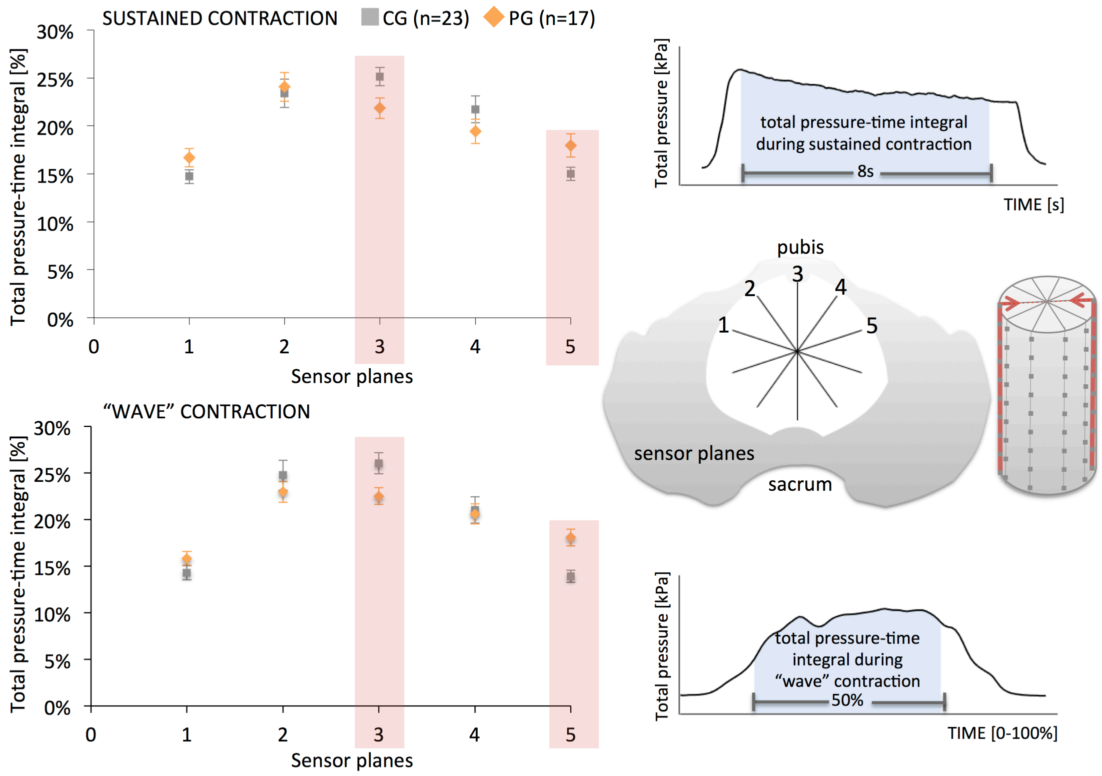

Figure 2. Mean total pressure-time integrals (standard error) for each one of the 5 planes for endurance (sustained contraction) and wave tasks normalized by the total pressure-time integral of the matrix (relative values %). On the right two representative plots illustrate the pressure-time integral window used for each task. CG= control group, PG= Pompoir group. Differences between groups (univariate ANOVAs) highlighted in pink (P<0.05).

Pressure-time integrals by rings

Multivariate comparisons showed significant effects of groups and rings for both pressure-related variables for the endurance task: total pressure-time integral (Wilks' Lambda = 0.60, F = 5.47, P < 0.001) and peak pressure-time integral (Wilks' Lambda = 0.78, F = 2.02, P = 0.043). In addition, for the wave task, both groups and rings significantly affected the total pressure-time integral (Wilks' Lambda = 0.56, F = 8.14, P < 0.001) and peak pressure-time integral (Wilks' Lambda = 0.76, F = 2.84, P = 0.004). Between-group univariate analysis of total pressure-time integrals showed that for both tasks, Pompoir group had smaller relative contributions by rings 6 and 7. Trained women also had greater contributions by the caudal and cranial extremities (rings 1, 9, and 10) for both the sustained contraction and the wave task (rings 1, 2, and 10) (Figure 3).

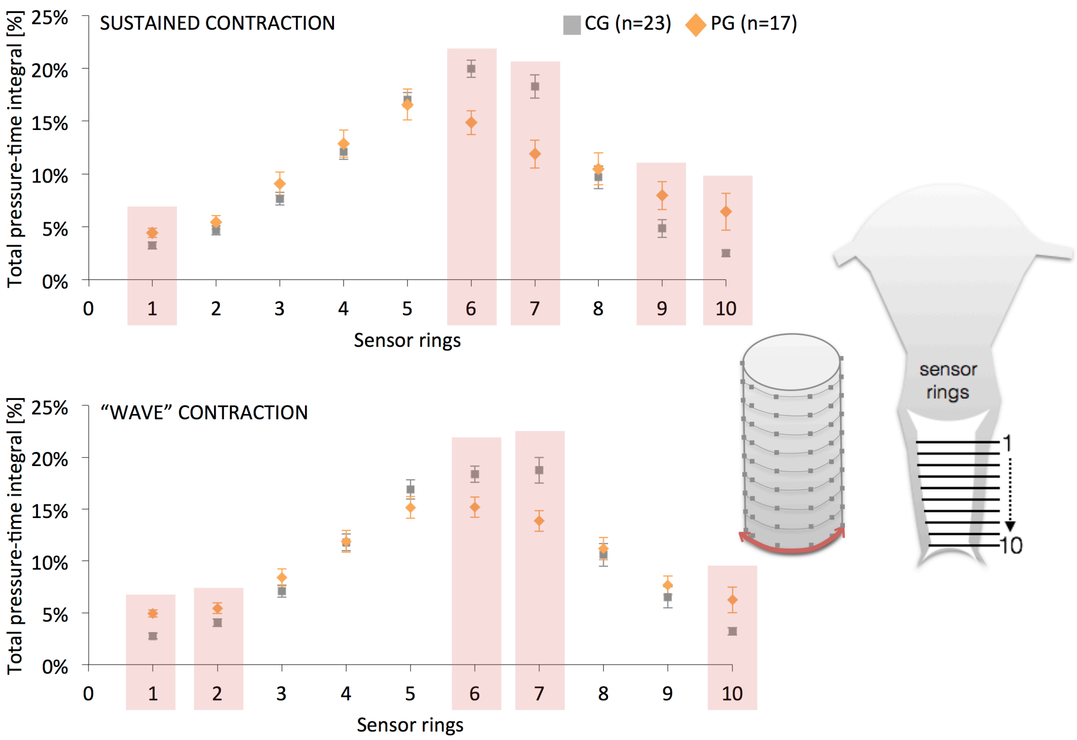

Figure 3. Mean total pressure-time integrals (standard error) for each one of the 10 rings for endurance (sustained contraction) and wave tasks normalized by the total pressure-time integral of the matrix (relative values %). CG= control group, PG= Pompoir group. Differences between groups (univariate ANOVAs) highlighted in pink (*P* <0.05).

Between-group univariate analysis of absolute peak pressure-time integral showed that Pompoir group achieved lower values in the mid-region (67% lower in ring 7) and higher in the most-caudal region (48% higher in ring 9 and 55% higher in ring 10), but only during the sustained contraction. For the wave task, Pompoir group had smaller absolute values in rings 7 and 9 relative to controls (Table 2).

Table 2. Mean (standard-deviation) of the peak pressure-time integral by planes and rings of endurance (kPa*s) and wave tasks (normalized in time, kPa*%t).

	ENDURANCE TASK [kPa*s]				Univariate ANOVA		WAVE TASK [kPa*%t]				Univariate ANOVA	
	CG (n=23)		PG (n=17)		F	*P*	CG (n=23)		PG (n=17)		F	*P*
Plane 1	141.3	(10.3)	187.9	(19.0)	5.4	0.02*	755.8	(71.8)	735.0	(67.6)	<0.1	0.83
Plane 2	265.2	(22.6)	336.5	(43.9)	2.5	0.12	1659.8	(174.2)	1200.6	(97.6)	5.2	0.03*
Plane 3	297.3	(23.9)	283.1	(30.1)	0.1	0.71	1520.4	(94.7)	1210.8	(103.1)	4.9	0.03*
Plane 4	271.4	(30.0)	244.7	(37.3)	0.3	0.58	1355.5	(181.0)	1102.3	(155.0)	1.1	0.29
Plane 5	152.7	(12.8)	188.2	(25.3)	1.9	0.17	755.5	(15.3)	881.5	(121.2)	0.7	0.40
Ring 1	30.9	(4.4)	36.7	(4.9)	0.7	0.39	146.4	(21.2)	171.2	(15.0)	1.3	0.25
Ring 2	45.8	(6.2)	50.9	(7.6)	0.3	0.60	211.8	(33.6)	222.9	(26.9)	0.1	0.74
Ring 3	74.5	(7.8)	92.0	(15.0)	1.4	0.26	366.4	(62.4)	366.9	(45.6)	<0.1	0.99
Ring 4	115.3	(12.3)	123.1	(15.8)	0.2	0.70	592.7	(82.2)	595.9	(79.2)	<0.1	0.97
Ring 5	156.7	(16.5)	181.6	(21.8)	0.9	0.36	868.9	(56.9)	801.9	(99.8)	0.3	0.60
Ring 6	190.4	(14.0)	189.5	(35.3)	<0.1	0.98	855.2	(152.1)	752.2	(86.9)	1.0	0.32
Ring 7	190.2	(19.2)	127.7	(21.7)	4.5	0.04*	1193.9	(95.9)	575.7	(61.2)	13.8	<0.01*
Ring 8	93.4	(13.5)	123.0	(27.4)	1.1	0.29	590.9	(92.3)	479.6	(76.7)	0.8	0.37
Ring 9	48.2	(12.3)	64.8	(11.9)	0.9	0.36	425.5	(21.3)	232.0	(23.2)	4.0	0.05*
Ring 10	21.7	(2.9)	35.2	(5.7)	5.3	0.02*	156.7	(15.3)	149.0	(13.9)	0.1	0.77

*Mean (SD), CP=control group PG=pompoir group. Univariate ANOVAs. Statistical differences between groups highlighted (*P<0.05).*

Onset of peak pressure-time series by rings

Multivariate comparisons showed significant effects of the onset of peak pressure-time series among groups and rings (Wilks' Lambda = 0.62, F = 2.15, *P* = 0.046). Between-group univariate analysis showed for Pompoir group later pressure increases in the most cranial portions (rings 1 and 2) and earlier in one of the caudal rings (ring 9) of the vaginal canal.

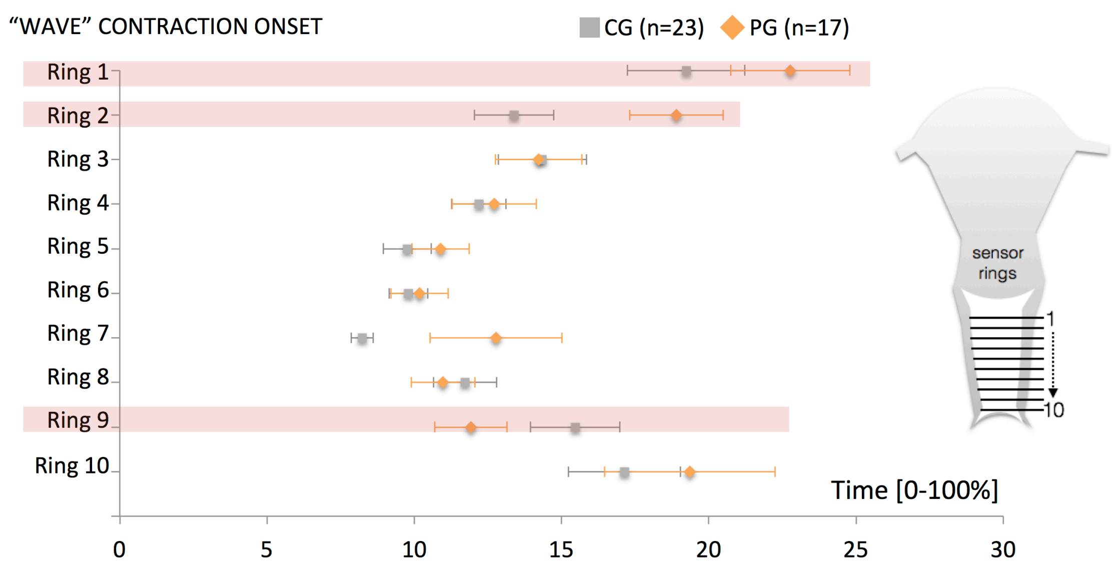

Figure 4. Onset mean of the peak pressure-time series (standard error) for each one of the 10 rings during the wave contraction task. CG= control group, PG= pompoir group. Differences between groups (univariate ANOVAs) highlighted in pink (*P* <0.05).

Discussion

Many studies have investigated the global function, strength, and endurance of PF muscles. Various equipment have been developed in an attempt to objectively measure PF muscle function, distinguishing pathologies, and treatment outcomes (Bø and Finckenhagen 2001; Dumoulin et al. 2003; Ashton-Miller et al. 2014), but no device has been built to characterize the pressure distribution along various portions of the vaginal canal. The present study aimed to describe the PF muscles´ capacity to produce pressure in the vaginal canal in women with experience in the practice of Pompoir, a technique that has been poorly studied in the literature. This technique specifically trains the coordinated contraction and relaxation of PF muscles and the spatiotemporal distribution of pressure along the vaginal canal. Our results indicated a more-symmetrical pressure-distribution pattern along the vaginal canals of Pompoir practitioners, which illustrates the effects of PF muscle training in asymptomatic women and its potential to improve coordination in this muscle group. To our knowledge, this is the first study to characterize the spatiotemporal pressure distribution of the PF muscles in a trained population.

For both tasks in both groups, PF muscle contraction resulted in higher contribution of the anteroposterior (planes 2–4) mid-pressure zone (rings 4–7, corresponding to the first 3–5 cm from the vaginal introitus) to the total pressure-time integral (figures 2-3). Similar results have previously been reported (Guaderrama et al. 2005), with the vaginal-pressure profile being described using infusion manometry and motorized pull-through and with a high-pressure zone of the vaginal canal being identified at the mid-anteroposterior portion. This pattern can be explained by the anatomical location of the PF muscles and their function of lifting the anal canal anteriorly to compress the vagina and urethra against the back of the pubic symphysis (Jung et al. 2007). Similar pull-through approaches with force transducers have indicated reduced pressures specifically in the anteroposterior direction of the vaginal wall, in incontinent women, which has been attributed to poorer PF muscle function and related to lower urethral-closure pressures, both characteristics of stress urinary incontinence (Peng et al. 2007; Shishido et al. 2008).

In the present study, Pompoir group displayed a more-homogeneous spatial-pressure distribution for both the wave and endurance-contraction tasks relative to the control group, with smaller relative contributions by the anteroposterior planes and greater participation of the latero-lateral planes while contracting the PF muscles. In addition, during both tasks, Pompoir group displayed a more-symmetrical distribution along the 10 rings measured throughout the depth of the vaginal canal, with less contribution by the mid-region and more by the cranial and caudal regions. These results suggest that women trained in Pompoir technique produce different pressures over a broader surface of the vaginal canal when contracting their PF muscles, distinguishing the contracted regions, which results in an improved capacity to generate pressures through the entire canal, when compared to controls.

For peak pressure-time series of the entire matrix, Pompoir group sustained the achieved peak for longer periods during the endurance task. During the wave task, Pompoir group achieved lower, earlier peak pressures, with a longer relaxation rate. Apparently, Pompoir practice promoted improved coordination of PF muscle-pressure production, improving control over gradually contracting and relaxing the PF. For this task, the participants were asked to contract their PF muscles in a caudal-cranial direction and then relax them in a cranial-caudal direction in a coordinated manner. The wave task was chosen to represent the coordination capacity of the PF muscles, which is usually part of the Pompoir practice.

In addition, for the wave task, differences between groups were observed in the onset of each ring contraction. It was clear that, for both groups, the mid-pressure zone of the vaginal canal (rings 4–7) was activated first, but the trained participants had earlier pressure increases at the most-caudal portions and later ones at the most-proximal portions of the vaginal canal, matching the solicited task. Altered contraction sequence of the PF muscles has previously been observed in incontinent women, with the majority of asymptomatic women contracting superficial muscles before the deep muscles, whereas incontinent women presented a reversed sequence (Devreese et al.

2007). In the present study, we observed an overall caudal-to-cranial pattern of pressure increases along the vaginal canal in both groups, but Pompoir training seemed to promote a subtle improvement in the separation and sequencing of the superficial and deep layers of the PF muscles. This could promote a better cranial lift of the pelvic organs, although this hypothesis needs to be confirmed by imaging studies.

It is not possible to confirm the influence of each muscle layer on the changes in the pressure profile that were achieved by coordination training, or whether this type of intervention has any advantages among other PF muscle training techniques, or would result in functional benefits for continence mechanisms or sexual satisfaction. We also acknowledge that variations in vaginal length were not taken into account for this analysis. Whereas there was no difference in body weight, height or BMI between groups, it was shown in a recent study that these anthropometric parameters are not correlated to vaginal dimension (Luo et al. 2016). Nevertheless, we made sure to cover the mid-portion of the vaginal canal for all participants (around 3.5 cm from the vaginal introitus), which was previously described as the most relevant region for PF muscle contraction (Guaderrama et al. 2005). With 100 sensors, we can be confident that the high-pressure zone observed in the mid-anteroposterior portion of the vaginal canal, would not be influenced by the size of either the vagina or the device length.

This is the first attempt to characterize the status of the pressure distribution in women that had their PF muscle trained, demonstrating that PF muscles can be trained to change its coordination capacity, besides improving its strength and endurance. Future studies should use a longitudinal design and combine investigation of the pressure profile with imaging techniques to achieve a better understanding of the effects of different coordination training protocols on urogynecological functioning.

Conclusion

Specific coordination training of the PF muscles, such as Pompoir practice, alters the vaginal pressure profile, promoting a more-symmetric pressure distribution throughout the entire vaginal canal, with greater contributions by the caudal and cranial extremities and the latero-lateral planes. To our knowledge, this is the first study to characterize the spatiotemporal pressure distribution of the PF muscle contraction in a trained population, and it demonstrates that PF muscles can be trained to a degree beyond strengthening by focusing on coordination, which results in changes in symmetry of the spatiotemporal pressure distribution in the vaginal canal.

Conflicts of 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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Authors' contributions

ICNS and LPC are the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. LPC, ACP, ACA, and ICNS were responsible for the study design, analysis and data interpretation and manuscript literature review. LPC, ACP, ACA were responsible for data collection. All the authors contributed with the manuscript and approved the final version. The material within has not been and will not be submitted for publication elsewhere.

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6. GENERAL DISCUSSION

The hypotheses of this study were that with this novel instrument we would be able to reliably map the pressure profile along the vaginal canal, differentiating the PFM contraction from intra-abdominal pressure rises, and would be able to describe the potential capabilities of the PFM function in an asymptomatic trained population, distinguishing spatial symmetry and coordination patterns along the length of the vaginal canal**.** The main findings were that the proposed instrumented probe has an excellent reliability and repeatability, with outputs that are moderately associated with PFM digital assessment, and provides a dynamic and high-resolution map of the spatiotemporal pressure profile throughout the vaginal canal, distinguishing the action of PFM from intra-abdominal pressure rises. We also verified that specific coordination training of the PFM, such as the Pompoir practice, alters the vaginal pressure profile, promoting a more-symmetric pressure distribution throughout the entire vaginal length, with greater contributions from the caudal and cranial extremities and the latero-lateral planes of the vaginal canal.

6.1. Advantages and applicabilities of the new device

Ideally, to test the validity or accuracy of a new proposed measurement device, it would be necessary to analyze how closely the results from the new method approximate from the current gold standard assessment of the PFM function (Streiner and Norman 2006). However, as discussed before, there is still no defined gold standard method for the assessment of PFM strength (Bø et al. 2005). In addition, among the commercially available devices, neither perineometers nor EMG provide a precise spatial distribution map of the forces acting along the vaginal canal, measuring only unspecific resultant forces or muscular activity patterns, which would make comparisons between the new equipment and other available devices challenging.

Up to date, digital palpation scales of PFM function are still the first choice of assessment for comparing patients and interventions (Devreese et al. 2004), but comparisons between digital and dynamometric or manometric assessments of the PFM strength already showed that objective force/pressure parameters seems to be more reproducible, sensitive and valid to detect subtle differences across or within individuals (Bø and Finckenhagen 2001; Morin et al. 2004b).

In our study, we found moderate correlation between the clinical and the objective assessment of maximum PFM strength [Spearman's coefficient of $\rho=0.5477$ ($p<0.001$)]. While peak pressures increased proportionally with digital palpation rates, pressure value confidence intervals overlapped between adjacent grades, supporting findings from previous dynamometric (Morin et al. 2004b) and manometric (Bø and Finckenhagen 2001) studies, which also reported moderate correlations (0.56 and 0.66 respectively) between these two measurements.

Regarding the reliability of the new device, we observed for the total area (considering the entire sensor matrix) intraclass correlation coefficients of 0.94 (intra-rater), 0.97 (intra-trials) and 0.96 (inter-raters), with a standard error of measurement varying from 5.1 to 8.5, corresponding to 10 to 16% of the mean value pressure achieved during maximum PFM contractions. Similar results were reported in a reliability study using a dynamometer (Dumoulin et al. 2004a), with dependability indexes varying from 0.69 to 0.88, and standard error of measurements ranging from 31 to 33% of the obtained mean force, depending on the number of trials used in the comparison, or on the opening of the vaginal canal. It is interesting to point out that, according to the cited study, measurements done at a dynamometer opening of 1 cm (corresponding to 24 mm of vaginal aperture) reached the best reliability indices and the lowest error of measurement compared to shorter or wider opening options (Dumoulin et al. 2004a). Here, we were not able to measure the force-length relationship of the PFM, but we took into account this reported optimal vaginal aperture length when building the equipment, choosing a cylinder with matching length to the previous report (23.2 mm in diameter).

Besides the good sensitivity and reliability of the new proposed device, one of its main advantages would be its ability to selectively differentiate between the PFM contraction action in the vaginal canal and intra-abdominal pressure rises. With the full map of the spatiotemporal distribution of pressures along the vaginal length, it was possible to observe a high-pressure zone at the anteroposterior mid portion of the vaginal canal, larger in area and higher in magnitude at the posterior and anterior vaginal walls, respectively. These results also support previous findings of studies using either pull-through techniques (Guaderrama et al. 2005; Peng et al. 2007; Shishido et al. 2008) or a tactile high-definition manometer (Raizada et al. 2010), in which a high-pressure zone was observed during PFM contraction, and defined as axial and circumferential asymmetry. According to simultaneous imaging assessment of the pelvic floor structures, the described pattern represents the resultant force of the PFM acting to compress the rectum, vagina, and urethra, from back to front, in a ventro-cephalic direction (Raizada et al. 2010).

This was the first study to map the spatiotemporal distribution of pressures during a task involving an opposite downward movement of the pelvic floor structures. A Valsalva maneuver is defined as forced expiration against a closed glottis, requiring contraction of the diaphragm and abdominal muscles in order to obtain markedly increased intra-abdominal pressure. When these pressure rises are accompanied by a relaxation of the PFM, they provoke a caudal force on both the bladder and the urethra, causing the levator hiatus to increase in length and volume (Ornö and Dietz 2007). During this task, co-activation of the PFM may be a substantial confounder, reducing pelvic organ descent (Ornö and Dietz 2007). To overcome this limitation it is recommended to provide digital, auditory or visual biofeedback to the participants, and to acquire sustained maneuvers held for at least 9s in order to avoid false-negative results (Ornö and Dietz 2007; Orejuela et al. 2012). With the novel proposed device, we were able to provide real-time visual and auditory feedbacks to the women during each assignment, and, within the obtained pressure map, it was easy to distinguish between contractions of the PFM and a Valsalva effort without any additional measures. On the other hand, these two opposite movements can hardly be differentiated by manometers or even EMG, which detect pressure rises or cross-talks from adjacent muscles indiscriminately (Peschers et al. 2001b), and rely on visual inspection of an inward movement of the perineum to assure a correct PFM contraction (Bø et al. 1990a, 1990b).

In our study, we presented several differences in the pressure distribution profile of these two opposite tasks. For instance, PFM contractions resulted in higher pressures mainly in the mid-anteroposterior direction of the vaginal canal, corresponding to 2–4cm from the vaginal introitus, again supporting findings of the PFM ventro-cephalic action on the pelvic organs (Raizada et al. 2010). Whenever a high-pressure zone was detected in the mid anteroposterior portion of the vaginal canal, we were able to recognize a PFM contraction pattern, which can be useful to better guide clinicians and patients during PFM assessments for training or comparisons purposes. Also, in our study we followed previous instructions of providing digital feedback of each task before data acquisition, and opted to ask the participants to hold their Valsalva maneuver for at least 5 s, in order to minimize their discomfort without having the risk of assessing sub-maximal efforts.

Ashton-Miller (2014) also presented a device designed to measure the maximum vaginal closure force without crosstalk from intra-abdominal pressure, but it consisted in a dynamometer capable of providing only the resultant force of the vaginal canal, and we believe that being able to map the pressure distribution pattern along the vaginal length can bring advantages that could objectively help clinicians and researchers when choosing treatment orientation or evaluating outcomes. In our study, we were able to differentiate tasks and groups not only by the resultant force, but also by the pressure distribution pattern from the vaginal canal. Previous studies also reported that spatial coordination patterns (Devreese et al. 2007) or symmetry and overall pressure distribution maps (Peng et al. 2007) can be useful when distinguishing PFM function between symptomatic and asymptomatic women, suggesting that variables other than resultant strength parameters should be added to the PFM assessment in both clinical and research settings.

6.2. Effects of Pompoir practice for PFM training on the 3D pressure profile map of the vaginal canal

PFM training is highly recommended for several pelvic floor dysfunctions (Bø et al. 2000; Beji et al. 2003; Dean et al. 2008; Zahariou et al. 2008; Hagen and Stark 2011; Bø 2012; Dumoulin et al. 2015; Ferreira et al. 2015; Hagen et al. 2017; Johannessen et al. 2017), with some authors recommending it also as a preventive measure for all women (Hagen and Stark 2011; Hagen et al. 2017), considering the high incidence of symptoms (MacLennan et al. 2000; Kepenekci et al. 2011; Wu et al. 2014). In addition, the conservative management is safe, with no contraindications, and easily performed by most women.

However, up to date, we have not found reports in the literature regarding the effects of PFM training on asymptomatic women, and the potential capabilities of the PFM in a trained population, particularly in a practice that claims to improve coordination, and strengthen the capacity of, and symmetrically distribute loads throughout the vaginal canal. Devreese et al. (2004) described a coordination pattern of PFM contraction that varied between continent and incontinent women, with coordination defined as superficial PFM contraction prior or simutaneously to deep PFM contraction. Apart from this study, usually only resultant strength parameters are assessed among individuals or following treatments, with the PFM being assumed to work as a functional unit (Bø and Sherburn 2005), with little objective information regarding coordination training techniques and its effects on the pelvic floor capability to selectively distinguish layers or portions of muscles in a coordinated way.

Considering the studies that evaluated the results of PFM training protocols specifically designed to treat urinary incontinence symptoms, no changes were observed between trained and controls for either maximum strength (Sampselle et al. 1998; Dumoulin et al. 2004b) or rapidity of PFM contractions (Dumoulin et al. 2004b). But improvements were reported for some other strength parameters, reveling that PFM exercises may result in (i) increased number of PFM contractions in 15 s; (ii) earlier PFM activation when coughing and (iii) better sustained contractions between repeated coughs (Madill et al. 2013). These results suggest that the PFM evaluation should assess, in both clinical and research settings, other parameters besides maximal strength, such as spatial and temporal force/pressure distribution, symmetry, endurance, agility, and coordination. However, again, no reports were found on the spatiotemporal load distribution pattern along the vaginal length, and the possible effects of the exercise on different regions of the vaginal canal.

The specific training technique studied in the present thesis is called Pompoir, which is thought to be a millenary practice from India, Japan, or Thailand and consists of using several exercises to coordinate the contraction and relaxation of various portions and layers of PFM along the entire vaginal canal in a rhythmic order (Alves 2013). Although for some authors PFM are expected to act simultaneously as a mass contraction (Bø and Sherburn 2005), Pompoir practitioners claim they can selectively distinguish PFM layers, called “rings”, along the vaginal length. Training in the Pompoir technique has recently spread among women searching for improved self-awareness and sexual satisfaction. However, this practice has never been properly documented, and its outcomes in terms of pressure distribution along the pelvic floor structures have never been studied untill today.

In order to differentiate Pompoir practitioners from non-practitioners, we chose to evaluate an exercise that is commonly taught in this practice, the “wave contraction”, which is part of the beginners and advanced classes and is considered a basis for several other exercise variations. During the wave task, women are expected to contract their PFM in a caudal-cranial direction and then relax them in a cranial-caudal direction, with it being considered a coordination task, where maximum contraction is not expected. We also chose to evaluate a commonly assessed task in clinical practice: a sustained contraction held for 10 s, which is part of the PERFECT scheme (Laycock and Jerwood 2001), and is considered an important capability for maintaining continence.

For the data analysis, we opted for two different approaches. Firstly, we described the pressure-time curve of these two tasks considering the entire sensor. Secondly, in order to properly map the vaginal canal, we divided the 100-sensor matrix in rings and planes, aiming to map the spatial distribution pattern along the vaginal length (10 rings), but also specify the orientation of the normal forces (5 planes) acting on the vaginal canal. Particularly for the orientation of force assessments, our rational was based on the anatomy and biomechanics of the PFM. Normal forces measured along the circumference of the vaginal canal are thought to act together (i.e. to constrict and lift the pelvic floor structures during the PFM contraction), regardless of the orientation of each individual force. Therefore, we considered that adding the pressures from opposite sides of the vaginal wall together would provide a better directional overview of the vaginal pressure profile. Similar approaches were proposed by Peng et al. (2007) and Shishido et al. (2008), however, in both cases the adopted sensor device consisted of only four force transducers that were manually pulled thought the vaginal canal. In our study, analyzing the pressure matrix divided by planes and rings simuteneously, we had a complete map of the load distribution along the vaginal length, which was thought to discriminate the coordination patterns between tasks and groups with high spatial 3D resolution.

Considering the entire sensor matrix, the main differences found between practitioners and non-practitioners were not related to the maximal strength, as reported in previous studies comparing continent and incontinent women, leading us to conclude that other physical and biomechanical capabilities of the PFM, besides strength, are more revealing when discriminating symptoms and assessing treatments effects (Morin et al. 2004a; Madill et al. 2013). We observed in the Pompoir group a better endurance in the sustained contraction task (time to 10% decline of the initial reference force (Verelst and Leivseth 2004a)) and a slower relaxation rate in the wave task. This finding suggests that Pompoir practitioners are able to sustain the achieved peak pressure for longer periods, indicating an improved coordination of pressure generation and maintenance, and better control when gradually contracting and relaxing the PFM.

Considering the analyzed rings and planes, we observed a more-symmetrical pressure-distribution pattern along the 5 planes and 10 rings of the vaginal canal in

Pompoir practitioners. We found smaller relative contributions by the anteroposterior planes and greater participation of the latero-lateral planes during PFM contraction in Pompoir practitioners. In addition, during both tasks, the Pompoir group presented less contribution from the mid-region rings and greater participation of the cranial and caudal rings when compared to the control group. These results suggest that women trained in Pompoir technique produce different pressures over a broader surface of the vaginal canal when contracting their PFM, distinguishing the contracted regions, which resulted in an improved capacity to generate pressures through the entire canal.

To our knowledge, this is the first study to characterize the spatiotemporal pressure distribution of the PFM in an asymptomatic trained population, although results should be interpreted with caution. It is not possible to confirm the influence of each muscle layer on the achieved changes in the pressure profile, or whether this type of intervention has any advantages when compared to other PFM training techniques, or even if it would result in any functional benefits for pelvic floor symptoms such as urinary incontinence or sexual dysfunctions. However, we would like to acknowledge that the description of the whole pressure profile along the vaginal length, in addition to all biomechanical parameters chosen to be analyzed, could be of great interest for clinicians and researchers. This is especially true because we could confirm that strength magnitude is definitely not the best parameter to characterize a population, and to consider only the resultant force acting within the vagina canal as treatment outcome, could mask possible spatial patterns of muscle activation that may bring important information for the field.

6.3. Clinical Implications

Pelvic floor dysfunctions are common conditions with one quarter of adult women reporting at least one disorder, resulting in a large social, medical and economic burden (Wu et al. 2011). In Brazil, out of 1500 women living in 7 different states, 29.3% presented symptoms of orgasmic dysfunction, 21.1% referred pain during sexual intercourse and 34.6% lack of sexual desire, which also increases with age (Abdo et al. 2002). Considering that, the search for medical care and treatment options, which is already high, is likely to increase as the population ages.

PFM training is the first line of conservative management for women with different symptoms of pelvic floor dysfunction (Bø et al. 2000; Beji et al. 2003; Dean et al. 2008; Zahariou et al. 2008; Hagen and Stark 2011; Brækken et al. 2015; Dumoulin et al. 2015; Hagen et al. 2017; Johannessen et al. 2017), promoting pelvic organ support and control of the continence mechanism, along with better awareness of the pelvic floor structures, self- confidence and libido. Pompoir practice is not particularly focused on treating or preventing pelvic floor symptoms, but on improving coordination capacities of the PFM, being reported by practitioners to promote benefits on sexual function and self-awareness. Most importantly, it was chosen here for being a poorly studied techinique from the biomechanical perspective, although recently spread in Brazil as an option for asymptomatic women aiming to better understand their PFM function.

The findings of this thesis suggest that the novel proposed device is a reliable tool, which can provide real-time visual and auditory feedbacks during pelvic floor assessments to better guide treatment outcomes, and also help clinicians and researchers to better understand the pressure profile of the vaginal canal in relation to different pathologies or treatment options. The pressure pattern assessment is already a reality for foot biomechanics, helping clinicians and researchers to map high-pressure zones and prescribe optimal footwear (Bus et al. 2011; Ulbrecht et al. 2014) and specialized treatment protocols (Sacco and Sartor 2016). We believe that adding this objective assessment either as a biofeedback or an outcome measure across symptoms or following treatments would be of great interest for this field, supporting clinicians on their practice and helping to better match women to the optimal intervention for their condition and individual characteristics.

6.4. General considerations and limitations

Voluntary PFM contraction assessments are highly recommended during routine examination for all women complaining of lower tract urinary symptoms, and it should account not only for the PFM strength assessment (static and dynamic), but also for its physical and biomechanical capabilities, expressed as the capacity to voluntarily relax the PFM (if absent, partial or complete), to sustain a maximal or sub-maximal contraction (endurance), to symmetrically contract the PFM, to homogeneously distribute loads throughout the vaginal canal, and to coordinate repeated contractions (Staskin and Kelleher 2013).

We believe that with this novel device and biomechanical analysis approach, it would be possible to better characterize the pressure profile along the vaginal canal, differentiating the spatial and symmetrical (or asymmetrical) distribution of forces resulting from PFM contractions or intra-abdominal pressure rises, aiding clinicians on their practice and researchers to better understand the relationship between PFM function and symptoms and treatment techniques. However, it is important to acknowledge that this is still a work in progress, with limitations and possible amendments to be made in future studies.

First, we would like to mention that variations in vaginal length were not taken into account in our analysis. Although there was no difference in body weight, height or BMI between groups, it was shown in a recent study that these anthropometric parameters are not correlated to vaginal dimension (Luo et al. 2016). Nevertheless, we made sure that the mid-portion of the vaginal canal was covered for all participants (around 3.5 cm from the vaginal introitus), which was previously described as the most relevant region for PFM contraction (Guaderrama et al. 2005). With 100 sensors, we can be confident that the high-pressure zone observed in the mid-anteroposterior portion of the vaginal canal, would not be influenced by the size of either the vagina or the device length. However, it would be important for future studies to take the vaginal length into account, specially if post menopausal women or women that went through hysterectomies, factors known to be negatively related to vaginal length, are to be included (Tan et al. 2006).

The sensor is embedded in a rigid and relatively long cylinder that is more comfortably used with the subjects in supine position. Assessing the PFM in dynamic situations, such as walking, jumping or running, would be more difficult. Among the described devices, only one of them (Schell et al. 2016) presented the advantage of being designed to be retained in the vaginal canal independent of someone holding the sensor, and with communication via Bluetooth enabling data acquisition in different positions in a more ecological environment.

Finally, we acknowledge that different training techniques would have to be compared in order to better understand the specific advantages of Pompoir training protocols, but here we were able to distinguish spatial and temporal differences between practitioners and non-practitioners, which can help to elucidate the PFM biomechanical characteristics, and which can be further used to compare results from different training protocols.

7. CONCLUSIONS

With this protocol and novel instrument, we obtained a high-resolution and highly reliable innovative 3D pressure distribution map of the pelvic floor, capable of distinguishing vaginal sub-regions, planes, rings, tasks and characterizing coordination patterns of the PFM following a specific training protocol. The proposed instrumented probe presented excellent reliability and repeatability and provides a dynamic and high-resolution map of the spatiotemporal pressure profile throughout the vaginal canal, discriminating the action of PFM from intra-abdominal pressure rises. We also verified that the Pompoir practice alters the vaginal pressure profile, promoting a more-symmetric pressure distribution throughout the entire vaginal length. We believe that a high spatial 3D resolution pressure profile of the vaginal canal, capable of mapping the spatiotemporal coordination patterns along the intravaginal walls can contribute to the clinical practice and help determining the optimal intervention for each patient's condition and individual characteristics.

8. ANNEX – ABSTRACTS TO BE PRESENTED IN THE ICS 2017

ICS

Abstract Title:

ASSOCIATION BETWEEN DIGITAL ASSESSMENT (FLEXIBILITY AND STRENGTH) AND ULTRASOUND MORPHOMETRIC PARAMETERS OF THE PELVIC FLOOR

Abstract Text:

Hypothesis / aims of study

Pelvic floor muscles (PFM) should have an adequate resting tone, symmetry and the ability to voluntarily and involuntarily contract with constriction and inward (ventro-cephalad) movement of the pelvic openings [1]. Decreases in muscle tone and strength are associated with either reduced contractile activity and/or passive stiffness, which are components of the mechanism related to pelvic organs descent and urinary incontinence (UI). PFM function is commonly assessed by digital palpation scales, with the disadvantage of being a subjective method with limited reproducibility. Transperineal ultrasound (TPUS) has been increasingly used as an objective and non-invasive method to assess both the constriction of the PFM muscle and the inward movement of the pelvic floor structure, however its relation to digital assessments of PFM function in UI women is still unclear. The aim of this study is to explore the relation between PFM digital assessment (flexibility and strength) and morphometric parameters measured by TPUS in women with UI.

Study design, materials and methods

This is a cohort study with 60 years or older women suffering from UI symptoms. Participants were recruited through community-based advertising. UI was defined as at least one weekly episode of involuntary urine loss during the preceding 3 months. The participants were asked to empty their bladders, and were positioned in supine. Digital and TPUS assessments of the PFM were conducted by an experienced physiotherapist. The flexibility of the vaginal opening (passive vaginal opening~~)~~ was measured with the index and, if possible, the middle finger inserted into the distal vagina to the proximal interphalangeal joints and abducted in the 3 and 9 o'clock plane. It was scored from 0 (less than one finger insertion) to 4 (two finger insertion with fingers abducted horizontally ≥2cm) [2]. PFM strength was assessed intra-vaginally with one finger, using the Modified Oxford Scale (MOS) with scores ranging from 1 to 5. PFM morphometry was evaluated using TPUS imaging (Voluson E8 Expert BT10; GE Healthcare) with a 3-/4-dimensional transperineal probe (RM6C next-generation matrix). Images were recorded at rest, during maximum PFM contraction and during cough. Each maneuver was performed twice and the ultrasound volume with the most effective contraction (i.e., most reduced levator hiatus antero-posterior diameter) and cough (i.e., most caudal displacement of the bladder neck (BN)) were considered for analysis. TPUS data was analyzed offline (4D View, Version 10.2; GE Healthcare) by an observer blinded to the digital assessment. Morphometry was assessed by measuring the following parameters in the midsagittal and axial planes (at the level of minimal hiatal dimensions) planes: (1) anorectal height, distance from the apex of the anorectal angle to a horizontal reference line passing by the inferior-posterior margin of the symphysis pubis, BN (2) x-axis and (3) y-axis related to the inferior-posterior margin of the symphysis pubis, (4) levator hiatus area, (5) levator hiatal antero-posterior and (6) transverse diameters.

The shift between rest condition and both tasks (cough and contraction) were calculated (rest – task), as well as the percentage of change for each variable ((rest – task)/rest %). BN cranioventral displacement was also calculated for contraction and cough as the hypotenuse of a right-angled triangle (square root: $\Delta BN\text{-}x^2+\Delta BN\text{-}y^2$).

The relationships between digital and TPUS assessments of PFM function were investigated using Pearson correlation coefficient and hierarchical stepwise regression by assessment condition (rest, contraction/couch). This method was used to explore how well digital assessment variances are explained by morphometric parameters of the pelvic floor TPUS evaluation.

Results

204 incontinent women were evaluated. Participants were aged between 60 and 84 (68 ± 5.6) years, mean BMI was 27.1 ± 4.6 Kg/m^2, parity ranged from 0 to 8 (median 2, interquartile range from 1 to 3) and the mean ICIQ-UI SF score was 12.3 ± 3.3. For the digital assessment, flexibility score ranged from 0.75 to 4 (median 2, interquartile range from 2 to

2.5) and MOS ranged from 0 to 5 (median 3, interquartile range from 3 to 4). Ultrasound morphometric parameters are shown in Table 1.

Associations between flexibility and morphometric parameters of the PFM during rest and cough are shown in Table 2. Using hierarchical regression by assessment condition (rest, cough) levator hiatus area at rest explained 10.9% of the variance in flexibility (Beta coefficient in the final model is β= 0.327; p<0.01). When adding variables in the cough condition to the model, BN cranio-ventral shift (β = 0.028; p = 0.700) explained additionally 0.1% of the variance, for a total explained variance of 11%.

Table 1 Morphometric parameters measured by transperineal ultrasound

Ultrasound assessment	*Rest*	*Std Dev.*	*Contraction*	*Std Dev.*	*shift*	*(%)*	*Cough*	*Std Dev.*	*shift*	*(%)*
Anorectal height [mm]	18.8	6.4	21.7	6.0	-2.9	(-15%)	15.6	7.2	3.2	(17%)
Bladder neck x [mm]	2.0	5.4	-2.8	6.1	4.8	(246%)	8.2	6.9	-6.3	(-321%)
Bladder neck y [mm]	23.6	4.2	25.2	4.8	-1.6	(-7%)	19.2	6.5	4.4	(19%)
Levator hiatus area mm2]	1433.3	318.2	1184.2	262.1	249.1	(17%)	1622.5	403.8	-189.2	(-13%)
Levator anteroposterior [mm]	53.5	7.5	44.9	6.7	8.6	(16%)	54.1	8.0	-0.6	(-1%)
Levator transverse [mm]	38.2	4.8	37.0	4.8	1.2	(3%)	41.2	5.6	-3.0	(-8%)

Bladder neck cranio-ventral shift [mm]: contraction 6.7 ± 4.6 and cough 9.2 ± 6.0.

Table 2 Pearson correlation coefficients and *p* values (flexibility *versus* morphometry)

	Rest	*Cough*		
Ultrasound assessment	*raw data*	*raw data*	*shift*	*% of change*
Anorectal height	r= -0.036; p=0.62	r= -0.055; p=0.44	r= 0.078; p=0.28	r= 0.107; p=0.13
Bladder neck x	r= 0.127; p=0.08	r= 0.269; p<0.01	r= -0.233; p<0.01	r=-0.022; p=0.77
Bladder neck y	r= 0.069; p=0.33	r= -0.131; p=0.07	r= -0.183; p<0.01	r= -0.181; p=0.01
Levator hiatus area	r= 0.353; p<0.01	r= 0.349; p<0.01	r= -0.161; p=0.03	r= -0.120; p=0.11
Levator hiatus anteroposterior	r= 0.275; p<0.01	r= 0.280; p<0.01	r= -0.101; p=0.16	r= -0.091; p=0.21
Levator hiatus transverse	r= 0.254; p<0.01	r= 0.298; p<0.01	r= -0.151; p=0.04	r= -0.129; p=0.08

BN cranio-ventral shift (r= 267, p<0.01); Statistically significant results are highlighted, p<0.05

Associations between strength (MOS) and morphometric parameters of the PFM during rest and contraction are shown in Table 3. Using hierarchical regression by assessment condition (rest, contraction), the anorectal height at rest explained 1.6% of the variance in strength (Beta coefficient in the final model is β= 0.135; p=0.052). When adding variables in the contraction condition to the model, anorectal height percentages of change (β = -0.324; p<0.001), levator hiatus anteroposterior shift (β = -0.726; p = 0.002) and percentages of change (β = 1.198; p<0.001) explained additionally 33.8% of the variance (p<0.001) for a total explained variance of 35.4%.

Table 3 Pearson correlation coefficients and *p* values (strenght *versus* morphometry)

	Rest	*Contraction*		
Ultrasound assessment	*raw data*	*raw data*	*shift*	*% of change*
Anorectal height	r= -0.128; p=0.07	r= 0.070; p=0.32	r= -0.326; p<0.01	r= -0.290; p<0.01
Bladder neck x	r= 0.016; p=0.82	r= -0.239; p<0.01	r= 0.363; p<0.01	r= 0.095; p=0.21
Bladder neck y	r= 0.029; p=0.68	r= 0.203; p=0.01	r= 0.201; p=0.01	r= 0.174; p=0.02
Levator hiatus area	r= 0.007; p=0.92	r= -0.274; p<0.01	r= 0.346; p<0.01	r= 0.421; p<0.01
Levator hiatus anteroposterior	r= 0.065; p=0.36	r= -0.319; p<0.01	r= 0.461; p<0.01	r= 0.511; p<0.01
Levator hiatus transverse	r= -0.044; p=0.54	r= -0.112; p=0.12	r= 0.103; p=0.15	r= 0.125; p=0.08

BN cranio-ventral shift (r= 0.357, p<0.01); Statistically significant results are highlighted, *p*<0.05

Interpretation of results

Higher PFM flexibility (passive vaginal opening) was associated with larger levator hiatus at rest. For the cough task, higher flexibility was related to more dorsally positioned BN and larger displacements of BN and levator hiatus. Levator hiatus area at rest contributed more to predicting PFM flexibility than any other morphometric parameter assessed during rest or cough, although with poor agreement. PFM strength was associated with smaller hiatus area and anteroposterior dimension, with more cranial and ventrally positioned BN and with higher shifts and percentages of change of almost all measured variables during contraction. Anorectal height, levator hiatus dimension shift and percentages of change during contraction were the variables that better contributed to the prediction of PFM strength, with fair agreement.

Concluding message

In older women with UI, increased flexibility was poorly associated with PFM morphometry during rest and cough. Higher PFM strength was fairly associated with increased constriction of the PFM and inward movement of the PFM structure during contraction.

Abstract Title:

PELVIC FLOOR MUSCLE TRAINING VERSUS NO TREATMENT OR INACTIVE CONTROL TREATMENTS FOR URINARY INCONTINENCE IN WOMEN: A COCHRANE REVIEW UPDATE

Abstract Text:

Hypothesis / aims of study

The objective of this study is to determine the effectiveness of pelvic floor muscle (PFM) training in the management of female urinary incontinence (UI). The following hypothesis was tested: that PFM training is better than no treatment, placebo, sham, or any other form of inactive control treatment. Because new trials are eligible for inclusion in the Cochrane systematic review (last updated 2014) (1), an update of current best evidence is needed.

Study design, materials and methods

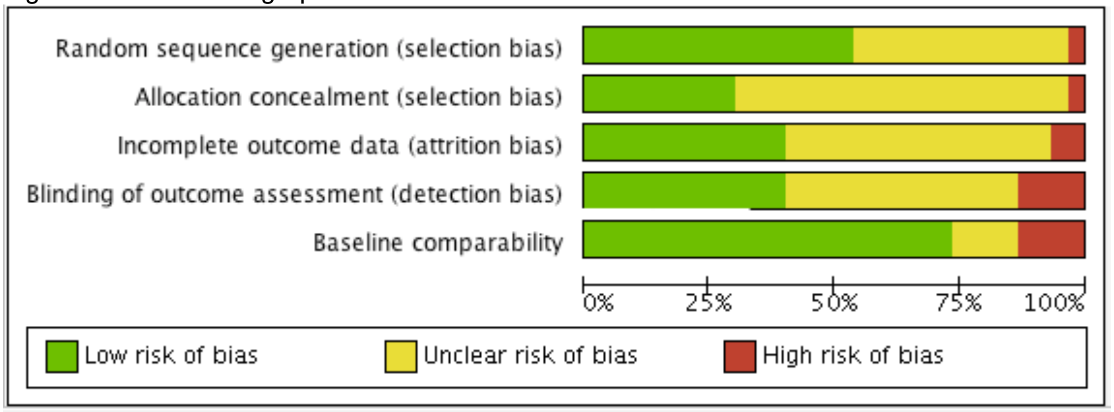
We searched (17 March 2017) the Cochrane Incontinence Group Specialised Register, which contain: trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and MEDLINE in process; hand searched journals and conference proceedings; and the reference lists of relevant articles. We included randomised or quasi-randomised trials in women with stress (SUI), urge (UUI) or mixed urinary incontinence (MUI), based on symptoms, signs, or urodynamics. One arm of the trial included PFM training. The comparator arm was no treatment, placebo, sham, or other inactive control treatment. Trials were sub-grouped by UI types. Outcomes of interest were patient reported measures, clinician reported measures, quality of life (QOL) and side effects. Two reviewers (LC and CD) independently assessed eligibility and methodological quality of trials. Any disagreement was resolved by discussion or arbitration with a third party (JHS). Two reviewers independently extracted data for the pre-defined outcomes (LC and CD). Meta-analysis was conducted when appropriate, in subgroups (by UI type), due to the heterogeneity of samples. For categorical outcomes we used risk ratio (RR) and for continuous outcomes we determined a mean difference, both with 95% confidence intervals (CI). A fixed effect model was used except if there was statistically significant heterogeneity in which case a random-effects model was considered. Risk of bias assessment was carried out as described in the Cochrane Handbook (2).

Results

Nine new trials were added in the update. In total, thirty trials involving 1788 women (918 PFM training, 870 controls) were included in the review; 26 trials (1526 women) contributed data to the meta-analysis. The trials were generally of small or moderate size and many were at moderate risk of bias, based on the trial reports. Risk of bias assessment showed that across all studies approximately 55% of trials had adequate random sequence generation and 30% had adequate allocation concealment. In 40% of trials there was low risk for attrition bias, and outcome assessors were adequately blinded. 75% of trials presented adequate baseline comparability (Figure 1).

Fourteen countries contributed studies to this review (USA, Brazil, UK, Japan, Turkey, Canada, Norway, Austria, China, Iran, Korea, Portugal, The Netherland, and Sweden). There was considerable variation in: interventions used (e.g., programs lasting from 1 to 24 weeks, with 8 to 500 PFM voluntary contractions per day); study populations (e.g., pre- and post-menopausal women, women with osteoporosis and also young volleyball athletes); and outcome measures (e.g., patient reported cure or improvement of symptoms, satisfaction, quantification of symptoms, specific and non specific QOL questionnaires, adverse effects, measures of PFM function and of adherence, among others). For the first time there were trials that reported on women with mixed UI only (n=1) and urge UI only (n=1), and trials that presented an intervention provided exclusively by a smartphone app (n=1).

Figure 1. Risk of bias graph.



In women with stress UI, cure was more likely with PFM training in comparison with inactive control (4 trials, RR 8.4, 95% CI 3.7 to 19.1, p<0.00001), and cure or improvement was more likely with PFM training in comparison with inactive control (3 trials, RR 6.3, 95% CI 3.9 to 10.3, p<0.0001). For women with mixed UI, one trial reported that PFM training is associated with better quality of life (ICIQ-UI-SF) in comparison with inactive control (MD -3.97, 95% CI -7.85 to -0.09, p<0.0001). For women with urge-predominant mixed UI one trial reported a greater reduction in the number of leakage episodes with PFM training in comparison with inactive control (MD -1.8m, 95% CI -2.7 to -1.0, p<0.0001). Finally, in trials with women with any type of UI, there was also moderate quality evidence that PFM training is associated with cure (3 trials, RR 5.5, 95% CI 2.9 to 10.5), or cure and improvement (2 trials, RR 2.4, 95% CI 1.6 to 3.5), in comparison with inactive control.

Interpretation of results

We found evidence that PFM training is better than no treatment, placebo, sham, or other inactive control treatment for women with stress UI, urge UI, mixed UI or UI of any type. The addition of nine new trials did not change the essential findings of the prior review. The wider range of populations, countries and secondary outcomes within these new trials emphasized the strength of recommendation for women with UI. Of note, in almost all new included trials, the PFM training protocols were described in more detail, with progressive training based on exercise physiology. Moreover, there were more use of patient reported symptoms and QOL outcomes, in line with recent recommendations (3).

Concluding message

Notwithstanding that long-term effectiveness of PFM training needs to be further researched, the updated review provides support for the widespread recommendation that PFM training be included as first-line conservative management programs for women with stress UI, mixed UI, urge UI and UI of any type.

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APPENDICES

APPENDIX A – Project approved by São Paulo Research Foundation (FAPESP)

INFLUÊNCIA DO TREINAMENTO PERINEAL E DA FUNÇÃO SEXUAL NA DISTRIBUIÇÃO MULTIVETORIAL DE CARGAS DO ASSOALHO PÉLVICO FEMININO

The influence of perineal training and sexual function on multidirectional load distribution of the female pelvic floor

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RESUMO

O assoalho pélvico é um conjunto de músculos, ligamentos e fáscias, localizado na região da pelve ainda pouco estudado do ponto de vista da biomecânica. Sua função é sustentar os órgãos pélvicos e garantir a continência urinária e fecal. Embora 45% das mulheres não sejam capazes de contrair o assoalho pélvico voluntariamente, a força e a capacidade de sustentação da contração dessa musculatura estão relacionadas à severidade da incontinência urinária e à satisfação sexual. O fator de risco mais bem estabelecido para disfunção e enfraquecimento da musculatura do assoalho pélvico é o parto vaginal. Os objetivos deste estudo são: (1) Investigar a relação entre a distribuição espaço-temporal das cargas do assoalho pélvico feminino e a técnica de pompoarismo, e (2) Investigar a relação entre a distribuição espaço-temporal das cargas no assoalho pélvico e a satisfação sexual. A distribuição espaço-temporal e multivetorial de cargas do assoalho pélvico será obtida por meio de um probe instrumentado por sensores capacitivos (Pliance System- Novel, Monique, Alemanha) e de um dinamômetro instrumentado por célula de carga; (EMG-system do Brasil 020653/ 2013 – São José dos Campos, SP/Brasil). Para responder ao primeiro objetivo, 20 mulheres primíparas que passaram pelo parto vaginal com e sem a preparação perineal serão avaliadas quanto à distribuição multivetorial de cargas. Para responder ao segundo objetivo, 20 mulheres nulíparas praticantes e não praticantes de pomporismo serão avaliadas pelo mesmo protocolo do primeiro objetivo. Após a palpação vaginal, a distribuição espaço-temporal da força da musculatura do assoalho pélvico será avaliada durante 3 contrações voluntárias máximas e uma contração sustentada. As medidas obtidas entre os diferentes grupos independentes de mulheres em cada objetivo serão comparadas por meio de análises de variância (ANOVA), seguidas de testes post hoc de Newman-Keuls. Será adotado p= 0,05 para diferenças significativas.

Descritores: assoalho pélvico; treinamento; força; mulheres; pressão; distribuição de cargas

ABSTRACT

The pelvic floor is a group of muscles, joints and fascia, forming the base of the abdomino-pelvic cavity, considered an understudied region of the body from a biomechanical perspective. Together these structures contribute to support the pelvic organs and to maintain urinary and faecal continence. Although 45% of the women are not capable to contract the pelvic floor voluntarily, the strength and the capacity to maintain the pelvic floor muscle contraction are related to the severity of incontinence and sexual satisfaction. The aims of the present study are to: (1) investigate the effect of a pompoir training practice on strength, endurance and coordination of these muscles; and to (2) investigate the effect of sexual dysfunction symptoms on strength, endurance and coordination of these muscles. A multidirectional spatiotemporal load distribution of the pelvic floor will be assessed by a probe fully instrumented with capacitive sensors (Pliancy System- Novel, Munich, Germany). To answer the first question, 20 women with and without symptoms of pelvic floor dysfunction; and to answer the second question 20 nulliparous that practiced or not the pompoir training will be assessed by the same protocol. After vaginal palpation, pelvic floor muscle strength will be evaluated during three consecutive maximal voluntary contractions and one sustained contraction. The variables will be compared between groups by analysis of variance (ANOVA) followed by Newman-Keuls post-hoc test. Alpha will be set at 0.05 for all analysis.

Descriptors: pelvic floor; training; strength; women; pressure; load distribution

1. CARACTERIZAÇÃO DO PROBLEMA

O assoalho pélvico feminino é uma região do corpo ainda pouco estudada do ponto de vista biomecânico. Esse conjunto de estruturas tem como função comum a sustentação dos órgãos pélvicos e a manutenção da continência urinária, mas também deve permitir a eliminação de resíduos, proporcionar prazer sexual, garantir a estabilidade lombo-pélvica e possibilitar o parto vaginal (1, 2). Disfunções do assoalho pélvico podem levar a quadros de prolapso, incontinência ou urgência urinária que afetam a qualidade de vida e resultam na necessidade de operação cirúrgica complexa e com alta taxa de reincidência (2).

Para que a contenção urinária seja mantida, a pressão de fechamento uretral deve ser maior que a pressão da bexiga, tanto durante o repouso quanto durante aumentos da pressão intra-abdominal (3). Essa pressão de fechamento uretral é mantida pela musculatura estriada do esfíncter uretral, pela musculatura lisa uretral e por elementos vasculares da submucosa (4, 5).

Outras estruturas ativas também são essenciais para o bom funcionamento do mecanismo de contenção, como o esfíncter uretral externo e o músculo elevador do ânus (pubococcígeo, puborretal, pubovaginal, e iliococcígeo). Esses último tem origem no púbis e ílio e inserção na vagina (porções laterais posteriores), no canal anal (porções laterais posteriores), no cóccix e na fáscia do músculo obturador interno (2).

O esfíncter uretral externo está ancorado ao músculo elevador do ânus e funciona como um ponto fixo para a sua contração. Desse modo, a funcionalidade de um é intimamente dependente da integridade do outro (7). A atividade basal do músculo elevador do ânus mantém o hiato urogenital fechado, impedindo o prolapso dos órgãos pélvicos pela compressão da vagina, uretra e reto contra o púbis, o assoalho e os órgãos pélvicos. Durante aumentos da pressão intra-abdominal, como na tosse, a contração do músculo elevador do ânus, juntamente com a contração do diafragma e do abdômen, movimenta a vagina e o reto ventral e cranialmente (8) gerando um aumento de tensão da fáscia endopélvica, necessária para o fechamento do lúmen uretral (2).

O músculo elevador do ânus é composto predominantemente por fibras do tipo I, com alta resistência à fadiga responsáveis pela manutenção do tônus basal do assoalho pélvico, mas também contém fibras do tipo II, responsáveis pela contração voluntária rápida que permite o fechamento adicional do canal em casos de maior demanda (9).

Considera-se que força de contração do elevador do ânus, assim como a habilidade de sustentar a contração máxima desse músculo, estão relacionadas à severidade da incontinência urinária (10) assim como a queixas gástricas e sexuais (11). No entanto, aproximadamente 45% das mulheres não é capaz de contrair o assoalho pélvico voluntariamente e apenas 27%, apresentam uma contração involuntária antes do aumento da pressão intra-abdominal (12).

1.1. DISFUNÇÕES DO ASSOALHO PÉLVICO

A Sociedade Internacional de Continência (13) define como incontinência a condição em que a perda involuntária de urina é um problema social ou higiênico, e considera como sintomas urogenitais mais comuns as incontinências urinárias de esforço e de urgência. A primeira é geralmente associada à fraqueza da musculatura do assoalho pélvico, e definida como a perda involuntária de qualquer quantidade de urina durante a execução de tarefas que provoquem aumento da pressão intra-abdominal, como a tosse ou o espirro. A segunda, também chamada de urge-incontinência, é definida como a perda de urina acompanhada ou precedida por uma forte urgência de urinar, geralmente explicada pela hiperatividade do músculo detrusor da bexiga. A combinação entre as incontinências de esforço e de urgência é classificada como incontinência mista. A bexiga hiperativa é uma disfunção uroginecológica caracterizada pela contração involuntária do músculo detrusor durante a fase de enchimento vesical, culminando em sintomas de urgência, com ou sem incontinência, geralmente acompanhados por aumento da frequência urinária. Apesar da diferença entre as causas e sintomas descritos, considera-se o treinamento supervisionado da contração adequada do assoalho pélvico como o tratamento conservador de primeira linha para estas disfunções, colaborando com os três tipos de incontinência (14, 15).

A incontinência urinária é uma disfunção comum, que acomete de 9 a 72% das mulheres de 17 a 79 anos (16), que varia de acordo com a idade (17-19), o número de partos (18, 20) o índice de massa corpórea (21, 22).

O parto vaginal é considerado o mais bem estabelecido fator de risco para disfunções do assoalho pélvico, principalmente quando associado ao uso de fórceps, ruptura do esfíncter anal, episiotomia, maior duração do 2o estágio do parto (23), excesso de peso do bebê, fraqueza do assoalho pélvico (24), presença de diabetes mellitus, alto índice de massa corpórea, idade, paridade, anestesia epidural (25), histórico de incontinência antes ou durante a primeira gravidez (26) ou ao excesso de mobilidade do colo vesical (27).

Estudos neurofisiológicos mostram que o parto vaginal pode causar denervação parcial dos músculos estriados do assoalho pélvico (28, 29), enquanto estudos de imagem mostram que o principal trauma ocorre no músculo pubococcígeo, acometendo de 20 a 40% de mulheres primíparas (30-32). Esta denervação parcial dos músculos do assoalho pélvico tem sido associada a alterações da ativação do elevador do ânus (33) e ao desenvolvimento de incontinências urinárias, fecais ou prolapsos (34).

1.2. AVALIAÇÃO DO ASSOALHO PÉLVICO

Nos cinco últimos anos, o número de trabalhos dentro da área da Fisioterapia relacionados à função e disfunção do assoalho pélvico aumentou razoavelmente (40% em relação aos 10 anos anteriores), tendo atualmente 160 trabalhos na base de dados da biblioteca nacional americana (Medline). Ainda assim, a produção científica da qualidade do assoalho pélvico sob o ponto de vista biomecânico ainda ocupa um posição pequena dentro do universo acadêmico, com apenas 29 trabalhos na mesma base de dados. Devido a grande complexidade dos músculos do assoalho pélvico e a íntima relação destes com disfunções uroginecológicas recorrentes em mulheres, a demanda por avaliações objetivas em biomecânica deve ser crescente.

A avaliação objetiva da ação muscular do assoalho pélvico é altamente recomendada pela Sociedade Internacional de Continência (13) como parte da avaliação de rotina de mulheres com queixas uroginecológicas, mas torna-se complicada por seu formato côncavo, com ação concêntrica (35) e inserções na fáscia endopélvica e órgãos, além da variabilidade nas suas não únicas zonas de inervação. O assoalho pélvico normalmente contrai simultaneamente como um sincício, mas a qualidade da contração e a contribuição de cada camada muscular podem diferir (36) e influenciar diretamente nos mecanismos de continência e outros tantos relacionados a esta região do corpo.

Subjetivamente a avaliação do assoalho pélvico pode ser feita por meio de observações clínicas (anatômica ou funcional), da quantificação dos sintomas (perda urinária), ou avaliação da qualidade de vida e socioeconômica (37) relacionadas à função do assoalho pélvico. Já avaliações objetivas podem ser obtidas por meio da palpação digital, da eletromiografia, da perineometria ou da dinamometria (36).

A palpação digital é uma avaliação rotineiramente utilizada na clínica, geralmente empregada em combinação com escalas de força muscular (38), mas que, embora prática, pode ser pouco sensível e específica, mesmo para examinadores experientes, devendo idealmente ser acompanhada de outras análises mais quantitativas da função muscular (39, 40).

A perineometria e a dinamometria são consideradas avaliações mais diretas e objetivas da função do assoalho pélvico (41, 42). Estas são geralmente empregadas como (a) biofeedback da pressão da cavidade vaginal durante o tratamento (43), (b) ferramenta diagnóstica da pressão para diferenciar grupos de pacientes (continentes e incontinentes) (18, 44), (c) resposta do sucesso ou não da terapia utilizada (45). Apesar de aparentemente correspondentes e serem ainda usadas na literatura sem distinção apropriada, a dinamometria é uma ferramenta mais sensível, precisa, direta e específica que a perineometria. A dinamometria é capaz de fornecer precisamente a força máxima, a taxa de desenvolvimento da força, a resistência de sustentação e de repetição das contrações (46-49), diferentemente da perineometria, já que o comprimento dos músculos do assoalho pélvico são influenciados diretamente pela alta complacência dos transdutores de pressão (perineometria) durante a avaliação (50) e consequentemente, a mensuração da força, resistência e taxas serão diretamente modificadas pela mudança de comprimento muscular.

No entanto, aumentos de pressão da cavidade abdominal refletem em aumentos da pressão uretral e vaginal, tornando complexa a diferenciação entre o que seria uma contração do assoalho pélvico ou da parede do abdômen (51). Além disso, a medida univetorial da pressão obtida por meio da perineometria ou da força no caso da dinamometria nos diz relativamente pouco sobre a qualidade, a simetria ou inclusive sobre o movimento cranial da contração muscular, mesmo este sendo considerado essencial para o mecanismo de contenção urinária (8, 51).

De acordo com a International Urogynecological Association (52) a avaliação da musculatura do assoalho pélvico deve incluir, além da avaliação da força máxima estática e dinâmica, a avaliação do relaxamento voluntário, da resistência ou endurance (capacidade de sustentar a força máxima ou quase máxima), da repetibilidade (número de contrações máximas realizadas em determinado tempo), da coordenação, do deslocamento cranial e da simetria da contração muscular. É portanto fundamental um diagnóstico feito a partir de uma ferramenta objetiva, fidedigna e multivetorial, capaz de identificar a magnitude, a distribuição espacial, temporal e a direção relativa da contração do assoalho pélvico. Esta forma de avaliação pode ser facilitada por um cilindro não deformável totalmente instrumentado por sensores capacitivos que tem alta linearidade com a medida de força/pressão exercida, que pode dar um mapa da distribuição destas forças e pressões numa série temporal. Este equipamento seria uma inovação de alta qualificação na avaliação da força e função do assoalho pélvico.

1.3. Terapêutica de disfunçoes do assoalho pélvico

O treinamento específico dos músculos do assoalho pélvico tem sido preconizado como padrão ouro no tratamento e na prevenção das disfunções uroginecológicas (53), sendo altamente recomendado para prevenção e tratamento de incontinências (54, 55) e de disfunções sexuais (56, 57). Embora o treinamento do assoalho pélvico tenha sido popularizado por Arnold Kegel em 1948, há relatos bem mais antigos de sua utilização que chegam a datar de 6.000 anos atrás (58).

Em mulheres com prolapso dos órgãos pélvicos, o treinamento supervisionado induziu alterações morfológicas do períneo, tais como: o aumento do volume muscular, redução da área do hiato urogenital e do comprimento muscular, elevação da posição da bexiga e do reto, além da redução da área do hiato e do comprimento muscular mesmo durante manobras que aumentavam a pressão intra-abdominal (59).

Para a incontinência urinária de esforço, o treinamento por exercícios é empregado para otimizar a sustentação dos órgãos pélvicos, principalmente a bexiga e a uretra, garantindo a continência por aumento da pressão intra-uretral (60) e prevenindo o prolapso durante o esforço (61). Foi demonstrado que com treinamento é possível contrair conscientemente a musculatura do assoalho pélvico antes e durante situações de aumento de pressão abdominal (como a tosse) (62), ao mesmo tempo que a hipertrofia adquirida do músculo elevador do ânus facilitaria uma resposta mais automática do assoalho pélvico frente a alterações da pressão intra-abdominal (58).

Para a incontinência urinária de urgência, acredita-se que o aumento da pressão intra-uretral, decorrente da contração voluntária do assoalho pélvico, seja responsável pela inibição da contração involuntária do músculo detrusor da bexiga (63), tornando possível o controle da frequência ou a redução dos episódios de perda urinária.

O treinamento do assoalho pélvico é também recomendado na prevenção de incontinências decorrentes da gravidez e do parto vaginal. Este treinamento tem o objetivo de preparar o assoalho pélvico para o parto vaginal podendo ser direcionado para um fortalecimento (54, 64, 65) e/ou para um alongamento da musculatura (66-68). Durante o parto vaginal, o assoalho pélvico se alonga de 3 a 4 vezes o seu tamanho original, o que pode levar ao rompimento de sarcômeros (microtrauma) ou mesmo à avulsão do elevador do ânus (macrotrauma) (69), o que justificaria a diminuição da pressão vaginal de repouso, de sua força e funcionalidade (70), além do aumento da prevalência de incontinência, que é três vezes maior em mulheres submetidas a parto vaginal (71).

Exercícios simples de fortalecimento e coordenação muscular do assoalho pélvico são preconizados também como prevenção e tratamento de disfunções sexuais, pressupondo-se que essas disfunções estejam relacionadas a alterações da força, resistência e coordenação da musculatura dessa região. Em alguns casos, as disfunções sexuais podem estar relacionadas à hipertonia associada ou não à fraqueza da musculatura do assoalho pélvico (72), disfunções estas que poderiam ser corrigidas com técnicas de relaxamento, alongamento, fortalecimento e coordenação muscular (73). Estas técnicas tem potencial para beneficiar a função sexual, incluindo excitação e orgasmo (74), assim como para reduzir a perda urinária durante a relação, trazendo benefícios para a qualidade de vida dessas pacientes (56).

O pompoarismo é uma antiga técnica oriental, derivada do tantra, que consiste na contração e relaxamento dos músculos vaginais, buscando como resultado autoconhecimento e o prazer sexual, sendo inclusive indicado como tratamento de incontinências urinária e fecal e lesões perineais relacionadas ao parto vaginal (75). No entanto até o momento, não encontramos na literatura nenhuma avaliação dos possíveis efeitos deste treinamento na força, coordenação e simetria da contração muscular perineal.

Considerando que o fortalecimento do assoalho pélvico é preconizado como prevenção e tratamento da maioria das suas disfunções uroginecológicas, supõe-se que mulheres continentes apresentem força, resistência e coordenação dessa musculatura maior e melhor em relação a mulheres de mesma idade, características antropométricas e condição gestacional, porém incontinentes, cuja pior qualidade de funcionamento do assoalho contribuiria para sua condição clínica.

2. RELEVANCIA DA PROPOSTA

Embora a função do assoalho pélvico seja fundamental para manutenção da qualidade de vida das mulheres, aproximadamente 45% delas não são capazes de contrair o assoalho pélvico voluntariamente e apenas 27%, apresentam uma contração involuntária antes do aumento da pressão intra-abdominal. Em muitos casos, a percepção da musculatura do assoalho pélvico é reduzida, o que, se não impossibilita, pelo menos dificulta a realização de tarefas aparentemente simples como a contração e o relaxamento dessa musculatura. A incontinência urinária é comum acometendo de 9 a 72% das mulheres de 17 a 79 anos, que varia de acordo com tipo de parto e o índice de massa corpórea. Ela tem sido frequentemente relacionada à fraqueza e a falta de coordenação da musculatura do assoalho pélvico. Da mesma forma que para as disfunções urinárias, a fraqueza dos músculos do assoalho pélvico pode causar disfunção sexual. Segundo a Organização Mundial de Saúde, a sexualidade humana forma parte integral da personalidade de cada um, é uma necessidade básica e um aspecto do ser que não pode ser separado dos outros aspectos da vida.

O treinamento desses músculos pode melhorar a função sexual e tem sido preconizado como padrão ouro no tratamento e na prevenção das disfunções uroginecológicas e sexuais. Porém, em alguns casos, mesmo mulheres capazes de realizar as contrações e o treinamento proposto, ainda permanecem com algum grau de disfunção. Devido a grande complexidade do assoalho pélvico e a íntima relação deste com as disfunções uroginecológicas, a demanda por avaliações objetivas em biomecânica deve ser crescente. Aperfeiçoar o conhecimento científico nesta área de pesquisa poderá beneficiar mulheres em diversas fases de sua vida, agindo principalmente na prevenção e promoção da saúde, princípios norteadores do nosso sistema de saúde, o qual devemos almejar.

Além disso, ao melhorar o conhecimento sobre o assoalho pélvico, inevitavelmente aborda-se a sexualidade, outro conceito deixado de lado pela maioria dos profissionais de saúde e que segundo a OMS, deveria ser considerada como direito humano básico. Desta forma, a atual equipe formada para desenvolver este projeto pretende unir o conhecimento e experiência clínica já estabelecidos há pelo menos 10 anos de investimento na área do projeto, com conhecimento biomecânico robusto de parte da equipe para o potencial êxito da proposta.

3. OBJETIVOS E HIPÓTESES DO PROJETO

3.1. OBJETIVOS

- Investigar a relação entre a distribuição espaço-temporal das cargas do assoalho pélvico feminino e a técnica de pompoarismo.
- Investigar a relação entre a distribuição espaço-temporal das cargas no assoalho pélvico e a satisfação sexual.

3.2. HIPÓTESES

- As mulheres praticantes de pompoarismo apresentarão maior magnitude de pressão, resistência e melhor distribuição de cargas, em relação às não treinadas.

- Mulheres com disfunção sexual apresentaram menor magnitude de pressão, resistência e alteração do padrão espacial de distribuição da pressão ao longo do canal vaginal

4. METODOLOGIA

4.1. DESENHO EXPERIMENTAL

Serão dois estudos laboratoriais transversais elaborados para responder os objetivos 1 e 2:

(1) Dois grupos independentes onde o fator treinamento de pompoarismo (fator independente) será apresentado em dois níveis em: (i) mulheres com treinamento de pompoarismo, (ii) mulheres sem treinamento de pompoarismo

(2) Dois grupos independentes onde o fator satisfação sexual (fator independente) será apresentado em dois níveis em: (i) mulheres sem insatisfação sexual relatada, (ii) mulheres com insatisfação sexual relatada.

Os grupos independentes e fator medida repetida serão relacionados com o grupo de variáveis dependentes provindas da avaliação da força e pressão. As hipóteses a serem testadas para os grupos (dependentes ou independentes) estudados nos objetivos 1 e 2 serão:

H0: $\lambda 1 = \lambda 2 = 0$ e

HA: no mínimo um $\lambda i \neq 0$,

onde λi, i = 1 e2 representando os efeitos do pompoarismo e da satisfação sexual.

4.2. CASUÍSTICA

Para responder ao objetivo 1 da proposta, serão avaliadas 20 mulheres nulíparas, igualmente divididas em 2 grupos: mulheres não praticantes e praticantes da técnica de pompoarismo há pelo menos 3 meses. Para responder ao objetivo 2 da proposta, serão recrutadas 30 mulheres igualmente divididas em 2 grupos: mulheres com disfunção sexual e mulheres sem disfunção sexual avaliadas e classificadas segundo o questionário Female Sexual Function Index (Anexo E). As voluntárias deste estudo serão recrutadas dentro do quadro de estudantes e funcionárias do departamento de Fisioterapia, Fonoaudiologia e Terapia Ocupacional da Faculdade de Medicina da USP, assim como do ambulatório de Fisioterapia do Hospital Universitário, e do serviço de ginecologia do mesmo Hospital. Todas as voluntárias serão informadas dos procedimentos desta pesquisa por meio de um termo de consentimento livre e esclarecido, elaborado conforme resolução 196/96 do Conselho Nacional de Saúde ficando uma cópia com o voluntário e outra com o pesquisador. Este termo obedece às características metodológicas e éticas orientadoras deste projeto.

Para ambos objetivos, serão consideradas elegíveis mulheres: com idade entre 18 e 55 anos, que não estejam no climatério ou menopausa, não virgens, com índice de massa corporal abaixo de 29 kg/m2, sem comorbidades neurológicas ou psicológicas que possam interferir na função do assoalho pélvico, prolapso genital acima de II de acordo com a classificação Pelvic Organ Prolapse Quantification (POP-Q), diagnóstico de vaginismo que impossibilite a avaliação intra-vaginal, infecção urinária, doenças venéreas, histórico de cirurgia vaginal ou abdominal e treinamento perineal.

4.3. Protocolo de Avaliação

O protocolo será desenvolvido no Laboratório de Biomecânica do Movimento e Postura Humana do Departamento de Fisioterapia, Fonoaudiologia e Terapia Ocupacional da Faculdade de Medicina da Universidade de São Paulo, sendo constituído das seguintes etapas: (1) avaliação inicial, em que explicaremos os objetivos do estudo e, após a assinatura do termo de consentimento, realizaremos uma entrevista para checagem dos critérios de elegibilidade, tanto por questionários específicos de sintomas urogenitais, quanto por meio de avaliação física, e (2) avaliação da distribuição de cargas do assoalho pélvico por meio de um sistema de sensores capacitivos Pliance System (Novel, Munique, Alemanha).

4.4. Avaliação Inicial

As voluntárias elegíveis serão convocadas para uma visita onde serão informadas do escopo do estudo. Caso concordem em participar do mesmo, assinarão o termo de consentimento livre e esclarecido aprovado pela Comissão de Ética. Em seguida responderão a três breves questionários digitalizados e auto-administráveis, com caráter investigativo sobre possíveis sintomas uroginecológicos ou sexuais para checagem dos critérios de elegibilidade (Anexo E).

O primeiro, King's Health Questionnarie, é de fácil compreensão, vastamente utilizado e validado para a língua portuguesa (16, 17), desenvolvido pelo King's College Hospital em Londres, especificamente para avaliar e diagnosticar sintomas uroginecológicos. O segundo, Female Sexual Function Index (FSFI), já validado no Brasil (18), proposto por Rosen et al., em 2000 (19), nos Estados Unidos, para ser um instrumento de avaliação epidemiológica que respeita a natureza multidimensional da função sexual feminina. O FSFI é um questionário breve, que pode ser auto-aplicado, e que se propõe a avaliar a resposta sexual feminina em seis domínios: desejo sexual, excitação sexual, lubrificação vaginal, orgasmo, satisfação sexual e dor. Sua escala varia de 2 a 36, sendo que quanto menor a pontuação, maior a disfunção relatada. Vamos considerar aqui como disfunção sexual scores menores que 26 (20). Por fim, as voluntárias preencherão também uma fixa de avaliação, que consiste em questões de caracterização da amostra (como massa, idade e estatura) e de checagem dos critérios de elegibilidade (como a paridade, e o histórico de comorbidades ou cirurgias que comprometam a função perineal).

Para a avaliação física as voluntárias receberão um avental e se posicionarão em decúbito dorsal com os joelhos fletidos, sobre uma maca. Em primeiro lugar, uma fisioterapeuta experiente dará instruções detalhadas sobre a contração dos músculos do assoalho pélvico e realizará, em seguida, o exame físico, constituído da inspeção do trofismo vaginal, distopias pélvicas, reflexos bulboesponjoso e anal, e da classificação funcional da musculatura do assoalho pélvico por meio da escala de Oxford (21)

Tabela 1- Avaliação subjetiva da contração muscular perineal- Escala Oxford

Avaliação subjetiva da contração muscular perineal – Esquema PERFECT

P	POWER	Grau 0 - sem contração perineal visível, nem à palpação (ausência de contração).
		Grau 1 - esboço de contração muscular não sustentada,
		Grau 2 - contração de pequena intensidade, mas que se sustenta.
		Grau 3 - contração moderada, com aumento de pressão intravaginal, comprimindo os dedos, e apresentando pequena elevação da parede vaginal.
		Grau 4 - contração satisfatória, que aperta os dedos do examinador, com elevação da parede vaginal em direção à sínfise púbica.
		Grau 5 - contração forte, compressão firme dos dedos do examinador com movimento positivo em direção à sínfise púbica.
E	ENDURANCE	a quantidade de tempo que a contração é mantida e sustentada, preferencialmente acima de 10 segundos.
R	REPETITIONS	número de contrações mantidas repetidas 6 vezes, com 4 segundos de descanso entre elas.
F	FAST	número das contrações rápidas (contração e relaxamento o mais rápido e o mais forte possível), medido após pelo menos um minuto de descanso, e acima de 10 contrações.

4.5. ANÁLISE DA DISTRIBUIÇÃO DE CARGAS

Caso enquadradas nos critérios de elegibilidade, as voluntárias passarão por uma avaliação objetiva da distribuição de cargas do assoalho pélvico por meio de um equipamento cilíndrico instrumentado com uma matriz de 10x10 sensores capacitivos (Pliance System - Novel, Munique, Alemanha). Esse equipamento tem resolução espacial de 1 cm^2 (Figura 1), e fornece sinal correspondente a força de preensão dos músculos do assoalho pélvico (leitura de 0 a 200 KPa), permitindo um diagnóstico objetivo, fidedigno e multivetorial, capaz de identificar a magnitude, a distribuição espacial, temporal e a direção relativa da deformação da parede vaginal. O comprimento do probe foi definido com base em um levantamento prévio do comprimento vaginal de 63 mulheres.

Figura 1- (A) probe vaginal cilíndrico com acabamento em cúpula e "trava" posicionada a 7cm do fim do sensor, coberto por matriz de 11x10 sensores capacitivos (Pliance System - Novel, Munique, Alemanha). (B) sistema Piance, com condicionador de sinais Bluetooth e bateria.

A avaliadora irá cobrir o probe com um preservativo não lubrificado, e utilizando-se de um lubrificante hipo-alergênico, irá inseri-lo 7cm ântero-posteriormente, para dentro do canal vaginal. Num primeiro momento, realizaremos a coleta de dados da força passiva do assoalho pélvico um minuto após a inserção do probe vaginal. Para isso, as voluntárias serão orientadas a respirar tranquilamente e relaxar o máximo possível seu assoalho pélvico. Como fizemos nos estudos piloto, utilizaremos esse parâmetro para checagem do tônus basal e futura calibração da força muscular. Em seguida realizaremos um treinamento da adequada contração perineal (não expulsiva) e instruiremos as voluntárias a contrair os músculos do assoalho pélvico o mais forte que puderem, sustentando essa contração por 10 segundos. Serão realizadas três contrações sustentadas de 10 segundos, com intervalo de um minuto entre as contrações. Por fim, após um intervalo de dois minutos, as voluntárias realizarão 10 contrações rápidas controladas por um metrônomo (uma contração por segundo) (figura 2). Após utilização, o probe será higienizado conforme orientação da Comissão de Infecção Hospitalar e do fabricante.

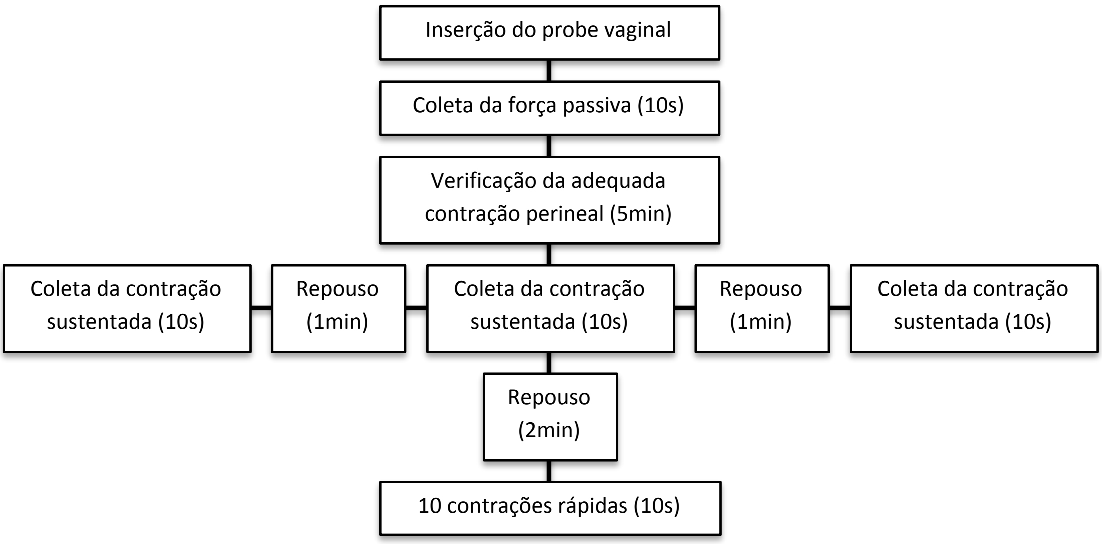

Figura 2- Fluxograma das etapas da coleta de dados.

4.6. ANÁLISE MATEMÁTICA

A aquisição, processamento e a exportação dos dados em ASCII será realizado por meio do software da Novel, Munique, Alemanha, e o tratamento matemático dos dados será feito por meio de uma rotina matemática em linguagem Matlab elaborada para este fim. As séries temporais de força e pressão serão analisadas separadamente para 8 áreas selecionadas (figura 3) e variáveis discretas calculadas, como a força e pressão máximas, integrais, taxas de força e forças relativas.

Cranial anterior	Cranial esquerda	Cranial posterior	Cranial direita
Caudal anterior	Caudal esquerda	Caudal posterior	Caudal direita

Figura 3. Regiões selecionadas para análise temporal da força e pressão da parede vaginal: anterior, posterior, esquerda e direita, todas elas divididas em nas regiões cranial e caudal

4.7. ANÁLISE ESTATÍSTICA

A priori, será verificada a normalidade dos dados por meio do teste de aderência de Shapiro Wilk. Com a finalidade de descrever o perfil da amostra, serão feitas tabelas de frequência para as variáveis categóricas e estatísticas descritivas para as variáveis biomecânicas estudadas. A posteriori, será realizada uma análise de variância one-way sendo o fator independente o grupo, seguidas de testes post hoc de Newman-Keuls. Serão consideradas as diferenças estatísticas com nível de significância igual a 5% ($\alpha = 0,05$). O tratamento estatístico será realizado no programa Statistica v.10 (Statsoft Inc.).

5. ETAPAS PARA O DESENVOLVIMENTO DO PROJETO - CRONOGRAMA

O projeto será desenvolvido em 4 anos:

Tabela 1 - Cronograma para as etapas do projeto.

Atividade / Período	2º sem 2013	1º sem 2014	2º sem 2014	1º sem 2015	2º sem 2015	1º sem 2016
Revisão e atualização de literatura	X	X	X	X	X	X
Importação do equipamento de pressão		X				
Treinamento da equipe no equipamento		X				
Definição do protocolo de coleta de dados			X			
Experimento piloto			X			
Coleta de dados			X	X		
Análise matemática e estatística das variáveis					X	
Interpretação e discussão dos resultados					X	X
Elaboração de artigos e textos de divulgação					X	X
Elaboração do texto final e relatório final						X

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APPENDIX B – ETHICS COMMITTEE APPROVAL

MEDICINA

USP

COMITÊ DE ÉTICA EM PESQUISA

APROVAÇÃO

O Comitê de Ética em Pesquisa da Faculdade de Medicina da Universidade de São Paulo, em sessão de **05/02/2014, APROVOU** o Protocolo de Pesquisa nº **023/14** intitulado: **"ANÁLISE DA DISTRIBUIÇÃO MULTIVETORIAL DE CARGAS DO ASSOALHO PÉLVICO FEMININO EM DIFERENTES POPULAÇÕES"** apresentado pelo **Departamento de FISIOTERAPIA, FONOAUDIOLOGIA E TERAPIA OCUPACIONAL**

Cabe ao pesquisador elaborar e apresentar ao CEP-FMUSP, os relatórios parciais e final sobre a pesquisa (Resolução do Conselho Nacional de Saúde nº 466/12).

Pesquisador (a) Responsável: Isabel de Camargo Neves Sacco
Pesquisador (a) Executante: Lícia Pazzoto Cacciari

CEP-FMUSP, 07 de Fevereiro de 2014.

R. Chammas.

Prof. Dr. Roger Chammas
Coordenador
Comitê de Ética em Pesquisa

Comitê de Ética em Pesquisa da Faculdade de Medicina
e-mail: cep.fm@usp.br

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: ANÁLISE DA DISTRIBUIÇÃO MULTIVETORIAL DE CARGAS DO ASSOALHO PÉLVICO FEMININO EM DIFERENTES POPULAÇÕES

Pesquisador: Isabel C. N. Sacco

Área Temática:

Versão: 3

CAAE: 17787813.1.0000.0065

Instituição Proponente: Faculdade de Medicina da Universidade de São Paulo

Patrocinador Principal: FUNDACAO DE AMPARO A PESQUISA DO ESTADO DE SAO PAULO

DADOS DO PARECER

Número do Parecer: 667.528

Data da Relatoria: 29/05/2014

Apresentação do Projeto:

Não foi realizada nenhuma alteração do Projeto. Apenas foi selecionada a segunda opção de submissão de emenda segundo orientação da Instituição Coparticipante, para que eles possam visualizar a documentação

Objetivo da Pesquisa:

Conforme parecer anterior

Avaliação dos Riscos e Benefícios:

Conforme parecer anterior

Comentários e Considerações sobre a Pesquisa:

Conforme parecer anterior

Considerações sobre os Termos de apresentação obrigatória:

Conforme parecer anterior

Recomendações:

Conforme parecer anterior

Conclusões ou Pendências e Lista de Inadequações:

Conforme parecer anterior

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Conforme parecer anterior

SAO PAULO, 29 de Maio de 2014

Assinado por:
Roger Chammas
(Coordenador)

APPENDIX C - AWARDS

Licia P. Cacciari
University of São Paulo
School of Medicine
Physical Therapy, Speech and Occupational Therapy Dept.
São Paulo
Brazil

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http://www.novel.de

Your Ref: Your Message: Our Ref: DJ Date: 9.8.2016

CERTIFICATE OF ATTENDANCE

This certifies attendance at the **Expert Scientific Meeting 2016 (ESM 2016)** in Lisbon, Portugal, July 27-30, 2016.

Following podium presentation was presented during the ESM conference: "*Multidimensional Loads Distribution along the Vaginal Cavity in Pompoir Practitioners*".
The above paper won the 2016 art in science® Award.

Yours sincerely,

i. A. Daniela Jírova-Enzmann
ESM 2016 organizing committee

OLIMPÍADA
inovação
2013

CERTIFICADO

2° LUGAR – PROVA DE CONCEITO

A Universidade de São Paulo – USP certifica para os devidos fins que o Projeto n° 163:

"Construção de ferramenta de avaliação da distribuição multivetorial de cargas do assoalho pélvico feminino"

tendo como participantes:

Amanda Amorim

Anice Passaro

Isabel de Camargo Neves Sacco

Licia Pazzoto Cacciari

foi classificado em **2° lugar na Olimpíada USP de Inovação 2013**, contribuindo para a disseminação da cultura de inovação e empreendedorismo no meio acadêmico e social.

realização: USP inovação apoio: PRÓ-REITORIA DE PESQUISA FINEP AGÊNCIA BRASILEIRA DA INOVAÇÃO Ministério da Ciência, Tecnologia e Inovação GOVERNO FEDERAL BRASIL PAÍS RICO É PAÍS SEM POBREZA

Prof. Dr. Vanderlei Salvador Bagnato
Coordenador da Agência USP de Inovação

ESM 2014 Award
Most Promising Proposal (MPP)

Presented to:

Licia Cacciari

Force Generation in the Woman Pelvic Floor – Is it possible to scan its coordination capacity?

Maria R Pasquale

Maria Pasquale, ESM 2014 Organizing Committe