



In vivo assessment of the levator ani muscles using shear wave elastography: a feasibility study in women

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Abstract

Introduction and hypothesis We hypothesized that shear wave elastography (SWE) technology might be useful for assessing the elastic properties of the pelvic floor in women. Our primary objective was to evaluate the feasibility of assessing the levator ani muscles using SWE in women. Our secondary aim was to investigate the changes in their elastic properties from rest to Valsalva maneuver.

Methods During this prospective feasibility study in nonpregnant female volunteers, we collected data on participant age, body mass index (BMI), parity, and time since the delivery. The levator ani muscles of each participant were assessed using SWE technology at rest and during a Valsalva maneuver by measuring the shear modulus (in kilopascals). We then assessed the changes in the shear modulus at rest and during the Valsalva maneuver using a Wilcoxon test.

Results Twelve parous women participated in this study. The mean time since the last delivery was 14 months, the mean age was 31 years, and mean BMI was 28 kg.m^{-2} . All the assessments performed at rest were successfully completed, but we encountered two failures during the Valsalva maneuver. The mean shear modulus increased by a factor of more than 2 from rest to the Valsalva maneuver for both the right (16.0 vs 35.4 kPa) and left side (17.1 vs 37.6 kPa).

Conclusions An assessment of the elastic properties of the levator ani muscles is feasible for nonpregnant women. The reproducibility of the technique and its application in pregnant women and women with pelvic floor disorders must be investigated.

Keywords Biomechanics · Levator ani muscle · Elastography · Shear wave · Pelvic floor · Women

Introduction

Pelvic floor disorders (PFDs), including pelvic organ prolapse and urinary and anal incontinence, are common conditions that can strongly affect women's health [1, 2]. Despite a lack

of data on the pathophysiology of these disorders, vaginal delivery is a well-known risk factor for pelvic floor damage. To date, the role of the intrinsic biomechanical properties of pelvic tissues (pelvic floor elasticity, stiffness, distension) in pelvic floor damage and PFD occurrence remains poorly

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investigated [3–6]. Furthermore, both the preventive and predictive strategies for pelvic floor damage at childbirth and PFD occurrence remain disappointing [7–11].

This potential impact of the intrinsic characteristics of the pelvic floor on PFD occurrence is supported by several publications reporting an association between joint mobility and PFD [5, 12–14]. These studies' results suggest that women with particular intrinsic biomechanical characteristics may have tissues with specific properties, leading to excessive mobility that could be established as excessive joint mobility for a peripheral joint and PFD for the pelvic floor. However, these biomechanical characteristics of the pelvic floor are not considered in either the risk prediction of PFD or the prediction of PFD treatment effectiveness (surgery and or physiotherapy). It is possible that taking these characteristics into account will improve our predictive and preventive strategies and lead to an individualized assessment.

The anatomical structure that is most involved in supporting the pelvic organs includes the levator ani muscles, which can be damaged during childbirth [15]. The levator hiatus is represented by the space between the two levator ani muscles (left and right) and constitutes the widest hernial opening in the human body. Damage to the levator ani muscles (avulsion, over-distension, etc.) may have an impact on the size and distension of the levator hiatus. It has been reported that the size of the levator hiatus is associated with the risk of PFD and especially with pelvic organ prolapse [16]. This observation suggests that taking the biomechanical characteristics of the levator ani muscle into account might be useful for predicting PFD occurrence and treatment effectiveness.

The main risk factor described for PFD occurrence is vaginal delivery, which is hypothesized to induce perineal trauma and, in particular, levator ani muscle trauma. Indeed, an over-distended levator ani muscle and/or a muscle with an avulsion may lead to an oversized levator hiatus, leading to PFD. If we can predict which women are at a high risk of levator ani muscle damage, we may be able to predict which women are at risk of PFD after childbirth. This risk prediction should consider both the effect of the delivery and the effect of the pregnancy itself on the intrinsic characteristics of the pelvic floor.

During pregnancy, there is an increase in both pelvic floor distension and in peripheral ligamentous laxity [5, 17]. The maximal pelvic floor distension occurs during childbirth, when the pelvic floor muscles can be stretched to up to three times their initial length [15]. In a recent study, we reported an association between increased ligamentous laxity and levator hiatus distension in a cohort of pregnant women [6]. In that study, the pregnant women with the greatest peripheral ligamentous laxity (assessed at the second metacarpo-phalangeal joint using a specific extensometer) were those with the greatest levator hiatus distension (assessed using 4D perineal ultrasound) [6].

We hypothesized that the newest functional imaging technologies may be useful for assessing *in vivo* the biomechanical characteristics of the pelvic floor.

Shear wave elastography (SWE) technology (Supersonic Imagine, Aix en Provence, France) is an innovative technology used to perform quantitative *in vivo* biomechanical assessments of tissues during an ultrasound examination [18–20]. The procedure consists of applying a mechanical perturbation to induce the propagation of a shear wave into the tissue of interest by using a specific ultrasound probe [18, 19]. The shear wave is an acoustic wave that propagates in the transverse plane into the tissue, where it induces the mechanical perturbation [21]. The device can measure the wave's propagation speed because of its ultrafast ultrasound acquisition. This propagation speed correlates with the stiffness of the tissue: the stiffer the tissue, the faster the wave's propagation speed [18, 19]. This technology has already been used to assess the elastic properties of superficial muscles, especially in the sports domain [18, 19]. It has also been used in pregnant women to assess the elastic properties of the cervix and the myometrium [22, 23]. The shear wave signal is close to the acoustic signal used for conventional ultrasound and is a compression wave that propagates in a longitudinal plane into the tissue [21]. The potential risks and use restrictions for SWE are not different from those for classic ultrasound.

The main endpoint of this study was to evaluate the feasibility of an *in vivo* assessment of the properties of the levator ani muscle using SWE technology in a cohort of nonpregnant women. The secondary endpoint was to evaluate the capacity of the device to evaluate objective changes in the elastic properties of the muscles by comparing measurements at rest, when the muscle is in a neutral position, and during the Valsalva maneuver, when the muscle is in a stretched position.

Materials and methods

This prospective longitudinal study was conducted at our University Department of Obstetrics and Gynecology from 17 November 2016, to 12 December 2016.

Eligible participants were volunteer nonpregnant women who had participated in a previous study, assessing the association between ligamentous laxity and levator hiatus distension during pregnancy [6]. Exclusion criteria were previous PFD and/or a personal history of joint disease.

There was one clinic visit for each participant during which we assessed the levator ani muscles using SWE technology.

We collected the following anthropometric data and socio-demographic data: age, body mass index (BMI), and time since the last delivery.

At the time of inclusion, the women underwent an ultrasound assessment of the levator ani muscle using SWE performed using an Aixplorer V11 ® device (Supersonic

Imagine, France). The Aixplorer scanner allows the user to perform both classical two-dimensional B-mode ultrasound acquisition and SWE during the same assessment and with the same material. The assessments were performed after voiding with the woman in the lithotomy position at rest, and then at maximal strain during the Valsalva maneuver. We asked participants to perform two initial Valsalva maneuvers with biofeedback instruction to prevent levator co-activation from serving a confounding factor in our analysis [24].

We first located the levator ani muscle, at its pubic insertion, using the classic two-dimensional ultrasound mode with an SL 15–4 linear probe (4–15 MHz) of 5 cm in length [25]. This method was previously used to assess levator ani avulsion and led to an 87% agreement between observers [25]. The probe was first placed in the sagittal plane on the perineum. We then applied an inclination of 10° to identify the pubic insertion of the levator ani [25]. Once the levator ani muscle was correctly identified, we performed the SWE assessment. The assessment at rest, consisted of a static assessment with one picture. The limits of the levator ani muscles were outlined by hand, and the Young modulus (in kilopascals) was obtained within these limits (Figs. 1, 2). The Young modulus characterizes the stiffness of a tissue and is reported to be the relation between a stress and a strain in an isotropic tissue (a tissue whose mechanical properties are similar in all directions). The shear modulus represents the stiffness of a tissue in an anisotropic tissue, such as muscle. However, the calculation for the Young modulus using the device assumes that the

tissue is isotropic (a tissue in which mechanical properties are similar in all directions). Because this assumption is not true for the muscle, the Young modulus was divided by a factor of 3 to obtain the shear modulus (in kilopascals) [19, 26]. A previous study showed that the shear modulus is strongly and linearly related to the Young modulus measured using traditional methods of material testing [19, 26]. This observation clearly demonstrates the relevance of shear modulus measurements obtained using ultrasound SWE for the study of muscle biomechanics [19, 26]. For the assessment during the Valsalva maneuver, we performed a dynamic acquisition from the rest position to 5 s of maximal strain during the Valsalva. For this dynamic acquisition, we outlined by hand the limits of the levator ani muscle in each picture, and the Young modulus and then the shear modulus were reported for each picture, as described for the assessment at rest. The highest shear modulus obtained during the acquisition was reported as the shear modulus of the levator ani muscle during the Valsalva maneuver. We performed a dynamic acquisition during the Valsalva maneuver with interval measures during the process to systematically record the highest shear modulus that a static measure, not exactly at the maximal Valsalva, might have missed.

The procedure was performed for both the right and left sides, and the shear modulus was reported at rest and during the Valsalva maneuver for the two sides.

We reported the population characteristics for age, BMI, and time since the last delivery in terms of the mean and standard deviation (SD), and we reported the number of successfully completed procedures and the number of failed

Fig. 1 Levator ani muscle assessment at rest using shear wave elastography technology

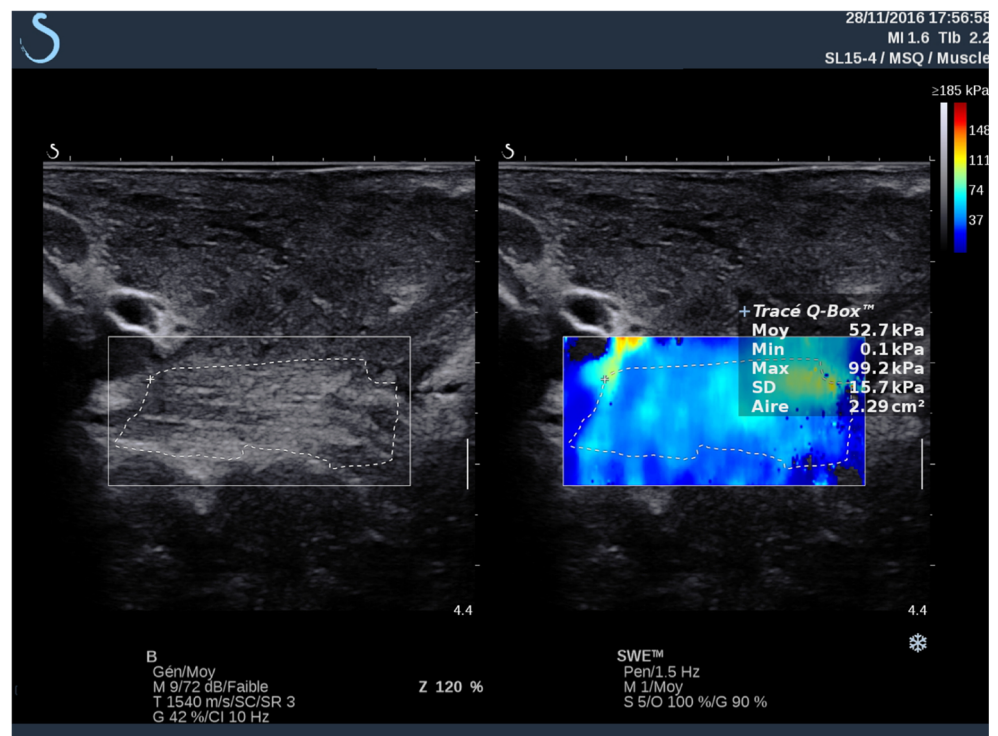
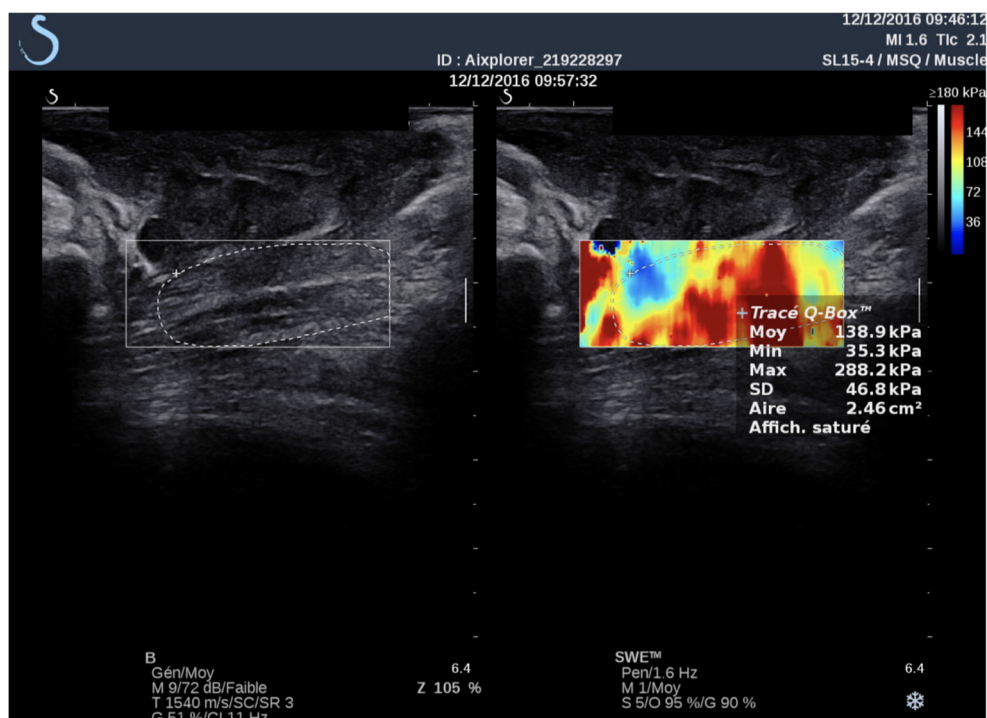


Fig. 2 Levator ani muscle assessment during Valsalva maneuver using shear wave elastography technology



procedures. We then reported the mean and SD for the shear modulus at rest and during the Valsalva maneuver for both right and left levator ani muscles (as means and SD) to check the feasibility of the technique for the two sides.

We assessed changes in levator ani shear modulus from rest to the Valsalva maneuver using a Wilcoxon test.

Because the main endpoint was to describe the feasibility of the technique and not its reliability, a power calculation was not performed. Furthermore, there are no previously published data that would have allowed such a calculation.

For all analyses, the statistical significance threshold (α) used was 5%.

Analyses were performed using the Stata software (version V14IC; Stata Corporation, College Station, TX, USA).

Our local ethics committee (protocol no: 2014-A01467–40, Comité de Protection des Personnes Ouest-III) and the National Drug Safety Agency (protocol no: 141380B-22, Agence Nationale de Sécurité du Médicament et des produits de santé) reviewed and approved the protocol. Written, freely given informed consent was obtained from each study participant before inclusion in the study and the realization of any investigations.

Results

A total of 12 women were included in this study. They were all parous women. All 12 had a history of almost one delivery, with 10 vaginally delivered and 2 delivered by cesarean

section. The characteristics of the study population are reported in Table 1.

All assessments performed at rest were successfully completed. We reported two assessment failures during the Valsalva maneuver, which corresponded to the two women with the highest BMI (37.7 and 42.2 kg.m⁻²).

The mean shear modulus assessed at rest and during the Valsalva maneuver for both the right and left levator ani muscles is reported in Table 2. The mean shear modulus increased by a factor of more than 2 from rest to the Valsalva maneuver. There were no significant differences in any measurements between the left and the right sides.

Comment

Main findings

In nonpregnant women, it is possible to assess the elastic properties of the levator ani muscles in vivo using SWE at

Table 1 Characteristics of the participants

	Mean (SD)
Age, in years	31 (2.6)
Body mass index, in kg/m ²	28 (7.4)
Parity	1.9 (0.7)
Delay since the last delivery, in months	14 (2)

SD standard deviation

Table 2 Elastic properties of levator ani muscles at rest and at the Valsalva maneuver

	Mean shear modulus at rest, in kPa (SD)	Mean shear modulus at Valsalva, in kPa (SD)	<i>p</i> *
Right side	16 (6.9)	35.4 (13.9)	< 0.005
Left side	17.1 (7.6)	37.6 (13.1)	< 0.005

*Wilcoxon test

rest and during the Valsalva maneuver. The mean shear modulus and, therefore, the stiffness of the levator ani muscle increased by a factor of more than 2 from rest to the Valsalva maneuver.

Strengths and limitations

The first limitation of this study is that it deals with parous women, who potentially have existing pelvic floor damage. Thus, the shear modulus that we reported for the levator ani muscle may not be representative of the elastic properties of the levator ani muscle in nulliparous women, because a damaged levator ani muscle probably exhibits different biomechanical behavior than an undamaged one [27]. Nevertheless, this limitation did not bias our analysis because our main objective was to assess the feasibility of the procedure and not to describe the elastic properties of the levator ani muscle.

In addition, there are no previously published data concerning the reliability of the SWE technique for this specific use in pelvic floor assessment. Nevertheless, considering the easy access to the pelvic floor when using ultrasound, the feasibility of SWE measurement for this muscle reported in the present study, and the good reliability reported for other muscles, such as the abdominal muscles, gastrocnemius muscle, and biceps brachii, we are confident that a future study will demonstrate the good reliability of this method for pelvic floor muscles [28, 29].

Another limitation of this study is the small number of women included, which is inherent to the pilot feasibility design of the study. Our results must be considered proof of concept of the feasibility of the procedure. This feasibility would have to be confirmed and its reproducibility investigated before any application in clinical practice.

Interpretation

To our knowledge, this is the first study to report the use of SWE technology to assess the elastic properties of the pelvic floor in vivo in women. Only one author has described an in vivo assessment of the elastic properties of the levator ani muscles. Kruger et al. used an elastometer for measuring levator ani muscle stiffness at rest in pregnant and nonpregnant

women [30, 31]. The device used in the study consisted of a vaginal speculum coupled with force sensors, which enabled a force/displacement curve to be obtained to calculate the stiffness of the levator ani muscle with good reproducibility [30, 31]. In their work, Kruger et al. reported that the stiffness of the levator ani muscle is more significant in postpartum versus antenatal assessment (436 N/m ± 198 N/m vs 325 N/m ± 14 N/m) [30, 31]. This procedure is interesting, but has several limitations. First, because the device is placed into the vagina and measures the displacement of the speculum, the result may be influenced by the elastic properties of the vaginal wall. Thus, the stiffness that is measured may reflect the global stiffness, including at least the vaginal wall and the levator ani muscle. Second, the authors did not perform the assessment in cases of vaginal infection or when the fetal head was too low. This could highlight some possible difficulties for its wider use in pregnant women [30, 31]. Third, there may be a problem of acceptability for pregnant women to undergo an intrusive vaginal examination. Nevertheless, the global technique used by Kruger et al. remains quite interesting because it provides an assessment of the whole perineum including the vagina, the levator ani muscles, and the fascia. This is a different approach than ours, as we aimed to specifically investigate the elastic properties of the levator ani muscle. The two procedures may be complementary because SWE allows an individual assessment of the pelvic floor tissues and Kruger et al.'s device provides an assessment of the whole pelvic floor; thus, the potential interactions between these different structures can be addressed.

Chen et al. attempted to assess the elastic properties of the perineal body using elastography in nonpregnant women [32]. To our knowledge, this was the first description of the use of elastography to assess the pelvic floor. The author reported that the mean compression modulus of the perineal body was 28.9 kPa [32]. The first limitation of this technique is that it requires the interposition of a custom reference standoff pad made of liquid plastic and plastic softener [32]. The elastic properties of this structure are known, and this technique allows the elastic properties of the target tissue to be measured compared with this reference pad [32]. This type of measure, which uses an interface between the probe and the tissue, may be less efficient than a direct assessment of the tissue without any interference. The use of SWE avoids the use of a standoff pad when performing a direct quantitative assessment of the pelvic floor. This technique remains quite interesting because, as noted for Kruger et al.'s device, it provides a global assessment of the region of interest, including muscles, ligaments, and fascia [32]. This technique may be complementary to our technique, which enables a direct assessment of one structure.

Silva et al. published a work in which the elastic properties of the pubovisceral muscle were elegantly calculated using an inverse finite element [33]. They reported the material constants of the pubovisceral muscle for continent women that

lead to shear modulus values of 78 ± 44 kPa (using shear modulus = $2 \cdot C1$ for the neo-Hookean model), 80 ± 48 kPa (using shear modulus = $2 \cdot (C1 + C2)$ for the Mooney–Rivlin model) and 62 ± 46 kPa (using shear modulus = $2 \cdot C1$ for the Yeoh model). These values are in the same range, but are notably higher than the values reported in the present study (17 ± 7 kPa). Nevertheless, the number of volunteers in both studies was low, and the studies used very different methods; thus, the comparison should be considered carefully. Furthermore, comparing the results of these studies may be difficult because the study populations are quite different (continent and noncontinent women in the study by Silva et al. versus parous women in our study). The assessments were also done in different positions (dorsal decubitus for MRI acquisition in the study by Silva et al. versus the lithotomy position in our study). Finally, the technique used in the study of Silva et al., inverse finite element, is quite different than our technique, which involves a direct assessment with an instant measure of the shear modulus [33]. This is probably the reason for the differences observed in these two studies.

We reported a 100% success rate using SWE for the assessment at rest, but we reported two failures of the assessment during the Valsalva maneuver. As previously stated, these failures occurred in the women with the highest BMI. These difficulties were due to the loss of visibility of the levator ani muscle during the Valsalva maneuver, as the muscle became too deep to be clearly located using our 15–4 linear probe. In women with a very high BMI, these difficulties are more apparent owing to the thickness of the soft parts of the pelvic floor. To fulfill the objective of assessing elasticity during the Valsalva maneuver in all women, it would be necessary to use different probes that allow deeper assessments.

The results of this study are encouraging, but need to be confirmed in a larger population and include a reliability assessment. Furthermore, the association between the elastic properties of the pelvic floor in women, as assessed using SWE, and the clinical and ultrasound pelvic floor distension measures should be evaluated. Indeed, if there is no association between elastic properties and pelvic floor distension, it would question the relevance of these measures.

Future studies should investigate the feasibility of assessing other components of the pelvic floor complex, such as ligaments and the vaginal wall. Indeed, the biomechanical behavior on muscles depends on their elastic properties and their attachments (ligaments). There are reports in the literature that assess peripheral ligaments using SWE [21]. However, the measurements are more challenging for thin and stiff structures such as tendons and ligaments [19]. Therefore, the feasibility, validity, and reliability of this technique need to be demonstrated for pelvic floor ligaments and the vaginal wall.

In our experience, the stiffness of the levator ani muscle significantly increased from rest to the Valsalva maneuver, which means that the stretched levator ani muscle is stiffer

than it is at rest. This observation is in agreement with clinical observations made during childbirth: during the period between the onset of pushing and fetal head delivery (the period of maximal distension of the perineum) the pelvic floor is stiffer than it is at the beginning of the second stage of labor. It has been reported that the tissues with the least stiffness may easily reach their plasticity threshold, which is the threshold beyond which irreversible damage to the intrinsic material's structure occurs [34]. Plasticity is a material intrinsic characteristic and means that a material remains deformed after being stressed. Elasticity characterizes the ability of a material to recover its initial state after being stressed by an external force [34]. A plastic deformation consists of an irreversible deformation due to permanent changes in the intrinsic structure of a material. Conversely, an elastic deformation constitutes a reversible process caused by an external force, with a return to the initial state once this force is no longer applied [34]. Thus, it would be very helpful to be able to measure the stiffness of the stretched levator ani muscle before attempting to predict the risk of pelvic floor damage, such as levator ani avulsion during childbirth, that is implicated in PFD occurrence. To predict pelvic floor traumas, other biomechanical factors can be included in a hypothetical predictive model. One factor is the maximal strength that the tissue can support before rupture. This threshold is impossible to measure in individual patients. One alternative approach would be to perform measurements of muscle volume, which should be related to the maximal strength that it can support. Thus, the combination of both volume and the elastic modulus of the pelvic floor could provide good predictive measures of the risk of damage. These studies may provide information about the intrinsic characteristics of the pelvic floor and especially its rupture threshold. In addition, the potential for an individual material to reach its plasticity or rupture threshold depends on its mechanical characteristics, but also on the stress applied to the material. A predictive model for pelvic floor trauma could also include data on the stress applied: fetal head circumference, fetal weight, instrumental delivery, etc. Excessive stress, such as that caused by a large fetal head circumference, could lead to excessive muscular distension beyond the physiological range; if the muscle reaches its plasticity threshold, plastic deformation could occur. The mechanical properties of the ligaments and tendons should be assessed and probably included in such a predictive model because the ability of muscle to distend is also related to the flexibility of its attachments, which play the role of a “shock absorber.”

Other studies have reported the use of SWE in pregnant women without any fetal complications [22, 23]. It would be interesting to ascertain if the elastic properties of the pelvic floor muscle assessed using SWE during pregnancy are predictive of the risk of pelvic floor damage at childbirth and the risk of PFD after childbirth. Every woman undergoes ultrasound during pregnancy, and the possibility of performing an

assessment of the elastic properties of the pelvic floor during the same visit with the same device would likely be considered acceptable by most women.

Conclusion

It is feasible to assess the elastic properties of the levator ani muscle in vivo using SWE in a cohort of nonpregnant women. This is the first report of such an in vivo assessment of the elastic properties of the levator ani muscles using a non-invasive technology similar to ultrasound. The next step is to assess the reliability of the procedure (intra- and inter- observer concordance) in addition to the concordance between the elastic properties and clinical distension of the pelvic floor, before considering its use in our clinical practice. Future studies will determine whether this technique can provide data to support individual risk prediction of PFD and thereby enable us to better individualize treatment decisions (e.g., type of physiotherapy, type of surgery).

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Compliance with ethical standards

Conflicts of interest None.

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