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In Vivo Estimation of Perineal Body Properties Using Ultrasound Quasistatic Elastography in Nulliparous Women

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Abstract

Objective—The perineal body must undergo a remarkable transformation during pregnancy to accommodate an estimated stretch ratio of over 3.3 in order to permit vaginal delivery of the fetal head. Yet measurements of perineal body elastic properties are lacking *in vivo*, whether in the pregnant or non-pregnant state. The objective of this study, therefore, was to develop a method for measuring perineal body elastic modulus and to test its feasibility in young nulliparous women.

Methods—An UltraSONIX RP500 ultrasound system was equipped with elastography software. Approximately 1 Hz free-hand sinusoidal compression loading of the perineum was used to measure the relative stiffness of the perineal body compared to that of a custom reference standoff pad with a modulus of 36.7 kPa. Measurements were made in 20 healthy nulliparous women. Four subjects were invited back for second and third visits to evaluate within- and between-visit repeatability using the coefficient of variation.

Results—The mean± SD elastic compression modulus of the perineal body was 28.9 ± 4.7 kPa. Within- and between-visit repeatability averaged 3.4% and 8.3%, respectively.

Conclusion—Ultrasound elastography using a standoff pad reference provides a valid method for evaluating the elastic modulus of the perineal body in living women.

Keywords

Perineal Body; Ultrasound Elastography; Elastic modulus

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Conflict of Interest Statement
This is no conflict of interest regarding to the research in this article.

Introduction

The perineal body lies interposed subcutaneously between the vagina and the anal cannal. It is most consistently recognizable anatomically (Oh 1973) and on MR images (Larson et al. 2010) in the midsagittal plane as a pyramidal structure made up of three regions: superficial, mid and deep. The left and right puboperineal muscles, originating ~1 cm on either side of the pubic symphysis from the posterior aspect of the pubic bone, each insert into the left and right lateral margins, respectively, of the perineal body mid region (Figure 1A). While the composition of the perineal body has been described has 'fibromuscular' (Soga et al. 2007) most text books consider it passive connective tissue. During the second stage of vaginal birth, the left and right puboperineal muscles, with the perineal body interposed, are arranged in series to form a "U-shaped" sling which a baby's head must stretch enough to be able to pass through (Figure 1B) Ashton-Miller and DeLancey 2009). For example, this sling is subject to a remarkable stretch ratio, ~3.3, during the late second stage of labor (Lien et al. 2004, Jing et al. 2012) raising the risk of stretch-related trauma. In regard to that risk, it has been hypothesized that the perineal body may act as a "fusible link" during late second stage (Ashton-Miller & DeLancey 2009) in that the more it can stretch, the less the adjacent puboperineal muscles have to stretch. This then reduces the risk for perineal body injury as well as the more common injury near the origin of the puboperineal muscles at the pubic bone during difficult deliveries (Kearney et al. 2006).

Despite the importance of the perineal body and the remarkable change in mechanical properties it must undergo during vaginal birth, there is a dearth of *in vivo* measurements of perineal body tissue mechanical properties, even in the non-pregnant state. Two non-invasive methods of imaging the perineal body include MR and ultrasound. Since the latter is relatively inexpensive and already available in every labor and delivery unit, it was practical to use in the present study. Quasistatic ultrasound elastography is a test method based on compressing the tissue of interest under the ultrasound transducer strain distribution within a region of interest (ROI) is often illustrated by a color map, where large during ordinary B-mode scanning (Ophir et al, 1991). Computerized analysis of changes in the speckle distance are then performed. The strain, low stiffness (soft tissue) is indicated in red and small strain, high stiffness (hard tissue) in blue. The strain ratio between two ROIs can further be calculated. The stiffness of a target soft tissue can then be expressed as an elastic modulus (N/m^2) given that strain ratio if the elastic modulus of one ROI is known a priori.

Elastography of perineal body is complicated by the absence of a natural reference material in that anatomical area; this is in contradistinction to the breast where adipose tissue can serve as a reliable reference material (Gong et al, 2011). For this reason it has not been possible to make a quantitative comparison of the stiffness of perineal body at different stages of pregnancy or between women at any one of those stages.

The objective of this study, therefore, was to demonstrate the feasibility of estimating perineal body tissue properties *in vivo* by using a quantitative ultrasound elastrography and an artificial reference material.In this paper we report preliminary findings in 20 nulliparous women and test the hypothesis that perineal body elastic modulus in nullipara is similar to that of published striated muscle.

Methods

The Development of the Synthetic Reference Standoff Pad

A custom-made polyvinyl chloride plastisol (PVCP) standoff pad (Figure 2A) was developed. A mixture of liquid plastic and plastic softener, in a ratio of 2 : 1 (www.pouryourownworms.com), was heated to 400 °F and then poured into a custom mold to create a standoff pad with the sleeve that is pulled over the distal aspect of an ultrasound probe. Small micro glass beads were added to the mixture to add micro reflectors within the standoff pad. The standoff pad surface parallel to the transducer was cast with a layer of sandpaper at the bottom of the mold to produce a rough surface that reduces reflection artifacts (Huang et al, 2007). Samples made from the same mixture were cast and placed in a materials testing machine to measure the elastic modulus at a strain rate of 20%/s in standard compression tests. Figure 2B shows the typical compression test stress and strain curve, with the estimated elastic compression modulus of 35 kPa. Figure 2C demonstrates that after the first week of curing, the pad's modulus had stabilized with little additional change over the next month. The elastic compression modulus of standoff pad compression samples was found to average 36.7 kPa and this value was used as a common reference in estimating the perineal body modulus from the measured strain ratio.

Ultrasound Elastography Imaging Technique

Twenty health nulliparous women were recruited as controls in ongoing Institutional Review Board approved study of fetal head descent and term pregnancy's effect on perineal tissue properties. They had no connective tissue and neurologic disorder, no genital anomalies and were without prior urogynecologic surgery. Their perineal bodies were first visually inspected and then evaluated by a single operator who is an experienced midwife (LKL) and knowledgeable about perineal body anatomy. The data were collected using UltraSONIX RP500 ultrasound system (Analogic Ultrasound, Peabody, Massachusetts) with an L14-5/38 linear transducer having a central frequency of 10 MHz running elastography software (Ophir et al, 1991, Zahiri-Azar and Salcudean, 2006) Each testing visit included three trials. Subjects were in supine position with sole of the feet together flat on the bed and knees apart as far as they felt comfortable to expose the perineum. The distance between the knees were kept same between trials. During each trial, the ultrasound transducer was held perpendicular to the skin surface of perineal body region (Figure 3: A, B) and was pressed into the perineum by free-hand manipulation using a sinusoidal compression force applied at ~1 Hz using a metronome. Visual feedback on the screen guided the operator to target the maximum strain deformation in the standoff pad at around 10% between minimum and maximum compression. B-mode images and strain distribution color maps from elastography were recorded at 20 Hz for about 5s. A quality bar provided by the manufacturer indicated whether two consecutive image frames contained the same anatomical structures and whether the strain values were within a plausible range. Trials exhibiting obvious out-of-plane slippage motions, imaging artifacts and/or poor quality indicators were excluded from further analysis.

Data Analysis Methods

An off-line Matlab program (version 2013a, MathWorks. Inc) was written for the data analysis. First, the anatomical regions were identified and tracked in B mode images (Figure 3C) and then average strain in the ROI for perineal body (based on anatomy, roughly triangularly shaped with the height around 1.5cm) and standoff pad were calculated from strain distribution maps(Figure 3D). The frames in which maximum strains in the standoff pad were achieved with satisfactory quality indicators were selected from the ~5 s cineloop to calculate each strain ratio between perineal body and standoff pad. The mean strain ratio was used to estimate the elastic modulus for each subject given the known standoff pad elastic modulus (36.7 kPa). A histogram of elastic moduli was plotted to examine the nature of the distribution in the healthy nulliparous perineal body.

Method Validation and Repeatability

A PVCP phantom was made in a cylinder shape using the similar technique as the standoff pad, but with a 3 to 2 plastic-to-softener ratio. Samples of the phantom material were cast and tested using a standard compression test machine, and an average elastic compressive modulus of 23.6 ± 2.2 kPa was found. The phantom was then evaluated using the ultrasound elastography method with the standoff pad.

A subset of four women was invited for the second and third testing visits. The repeatability of the testing method was evaluated as coefficient of variation (ratio of standard deviation over mean) for within- and between visits.

Results

The mean (± SD) age of the 20 nullipara was 22.7± 2.4 years and the mean BMI was 22.6 ± 3.2 kg/m^2 . Among these twenty women, there are 30% Caucasian, 50% black, 20% Asian and 20% identified themselves as others. The estimated elastic moduli among healthy nulliparous women were normally distributed with a mean of 28.0 kPa and a standard deviation of 4.7 kPa (Normality Kolmogorov-Smirnov Test p = 0.200), ranges from 19.1 to 38.6 kPa (Figure 4).

The estimation of phantom property using ultrasound elastography with standoff pad is 26.4 ± 1.2 kPa, which is 11.8% overestimation compared to the results from the standard compression test. For the subset of four women, the coefficient of variation (S.D./mean) for within-visit variation was 3.4% ± 2.9% and 8.3% ± 5.6% for between-visit variations.

Discussion

The results suggest that it is possible to estimate the compressive elastic modulus of the perineal body tissue in vivo using ultrasound elastography and a known synthetic reference material. The distribution of the perineal body modulus in healthy nullipara appears normally distributed and in a similar range to that reported for striated muscle using elastography techniques (Wells and Liang , 2011). We also demonstrated that the measurement technique has similar repeatability within- and between-visits to that reported for elastography used in evaluating uterine cervix stiffness (Swiatkowska-Freund et al

2014). The present technique slightly overestimated the compressive modulus (11.8%) compared to the standard compression test.

There has been increasing interest in using elastography to both evaluate the stiffness of the uterine cervix in order to supplement cervical length assessment when evaluating woman at risk of preterm delivery, and for planning for the induction of labor (for example, Fruscalzo et al. 2012, Molina et al. 2012, Hernandez-Andrade et al. 2012). The technique with the probe reference ‘cap’ has shown promise before in clinic applications (for example, Hee et al. 2013 and 2014). The present study used a similar technique to measure the modulus of the perineal body, an important anatomical structure that is widely discussed in the gynecology and obstetrics literature but rarely studied. Hungr N et al (2012) developed an PVC male perineum phantom with the mechanical property in the range of prostatic tissues and there are increasing elastography studies of male perineum (for example, Mohareri et al 2014) focusing on the prostate cancer detection. Better quantification of perineal body properties in women should enhance our understanding of the function of this structure during child birth. Specifically, the quantification of perineal body modulus will make it possible to determine how perineal body modulus is related to puboperineal muscle injury, the single largest risk factor in causing pelvic organ prolapse (DeLancey et al. 2007); this carries a life-time risk of surgery of 12.6% (Wu et al. 2014). Ideally, we would want to evaluate the perineal body modulus while it is undergo large strain when baby head is crowning (Jing et al 2012), but this is difficult in practice due to technical challenges and a highly stressful environment in the delivery room at that time. In this study we estimated compressive modulus of perineal body, which is a measurement similar to the way a clinician manual palpates the body, as an important first step toward the objective quantification of the perineal body modulus. Future experiments or computational simulation could be used to study how the compressive modulus of perineal body relates to its tensile modulus as it undergoes large strain.

A general limitation of the free hand quasistatic elastography method used in this study is that both the compression force and its rate of application can be highly operator dependent. The best results are achieved when the examiner compresses and decompresses the tissue uniformly in the axial direction with a constant maximum speed that induces the proper strain rate (Zahiri-Azar and Salcudean, 2006). Lateral or out-of-plane motions can result in decorrelation, which reduces signal-to-noise ratio and introduce measurement error. In this study, there was only a single operator with knowledge of the highly variable nature of the anatomy and with adequate training to generate consistent measurements prior to data collection. The trials that resulted in visible out-of-plane motions were excluded from analysis. To minimize the variation of compression force, we provide the operator with visual feedback of standoff pad thickness on the display screen and trained the operator to apply a force which generated a maximum strain of 10% in the standoff pad. We also provided the operator with a metronome to help her generate the proper compression rate by calling for a 1 Hz sinusoidal compression force waveform over time. The target compression loading rate matched that used to test the synthetic standoff pad in the materials testing machine. Another general limitation of elastography is that the method assumed no tissue constraints during the deformation. This assumption is valid for the standoff pad, but because of a limited understanding of the complex anatomy of the perineal body region and its connection with surrounding tissue, it is not clear at present how the surrounding tissue would affect the deformation of the perineal body when it is compressed by the probe. Detailed anatomical and histological studies are needed that are combined with biomechanical modeling to better understand structure-function relationships. In addition, as most biological tissues do not behave like a linear elastic material, it should be emphasized that the calculation of the tissue stiffness is only an estimation of the elastic modulus.

Recently, researchers have begun using shearwave elastography to evaluate cervical tissue stiffness (for example, Hernandez-Andrade, 2014; Palmeri et al 2013) because of its advantage that the generation of the mechanical impulse is operator independent and the stiffness measurement is an absolute measurement. However, morphological factors can influence shear-wave propagation such as complex tissue composition and boundary condition. Whether shearwave elastography could safely be used to image perineal body tissue during the second stage is an open question given the proximity of the fetal brain during delivery. However, the safety of compression ultrasonography is unquestioned because the mechanical loading of the perineal body is similar to the modest load applied by health providers during manual palpation.

In conclusion, quasistatic elastography with a reference standoff pad is a promising quantitative method evaluating the elastic modulus of the perineal body. Our preliminary data, despite their limitations, provide a first order *in vivo* estimation of the nulliparous perineal body modulus. These results provide a baseline for future studies aimed at address relevant clinical questions such as how much late stage pregnancy affects perineal body modulus and whether, for example, it is affected by perineal massage .

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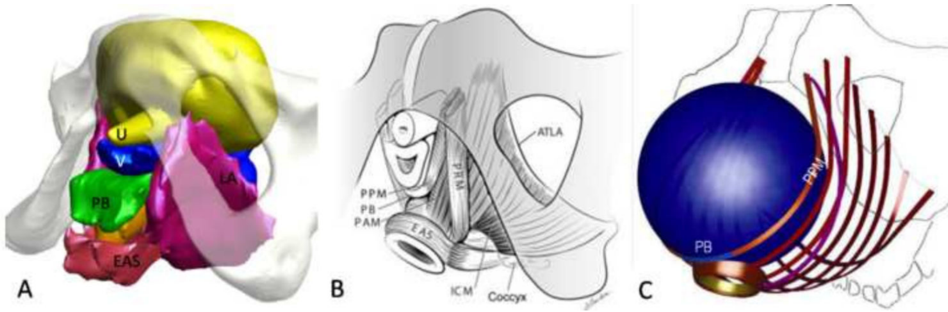

Figure 1.
(a) 3D pelvic floor anatomy reconstrcuted from a healthy, 45-year-old women's MRI in three-quarter, left, anterolateral view. Note the spatial relationship between perineal body (PB) and overall envelop of levator ani muscle (LA). U:Urethra; V: Vagina; EAS: the external anal sphincter (b) Schematic view of the components of levator ani muscles and perineal body (PB) from below shows the perineal body uniting the two ends of the puboperineal muscle (PPM). ATLA: arcus tendineus levator ani; PAM: the puboanal muscle; ICM: the iliococcygeal muscle; PRM: the puborectal muscle. Note that the vulvar structures and perineal membrane have been removed and the urethra and vagina have been transected just above the hymenal ring. Modified from Kearney (2004); (c) a three-quarter, left, anterolateral view of a model fetal head (dark blue) “crowning”, and the simulated stretch of the puboperineal muscle (PPR, the single red color band). Note that muscle band inserts onto the lighter blue band representing part of the perineal body (PB), with which it is in series. Modified from Lien et al. (2004)

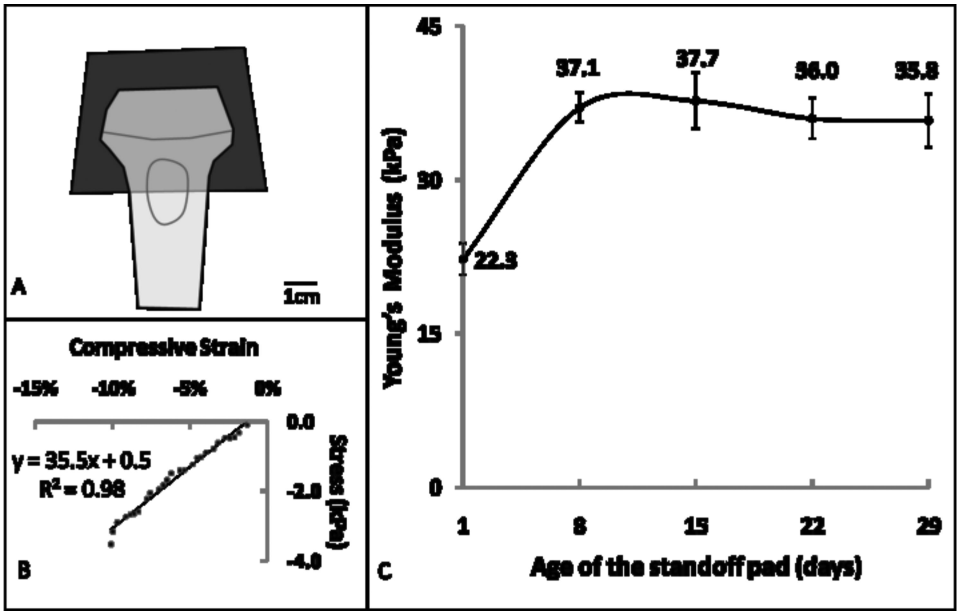

Figure 2.

(A) The standoff pad shown slipped into place over the distal part of the ultrasound transducer. (B) A sample compression test result for the standoff pad material. (C) The measured change in the standoff pad's Young's modulus over a month. The error bars show the standard deviations for the material samples.

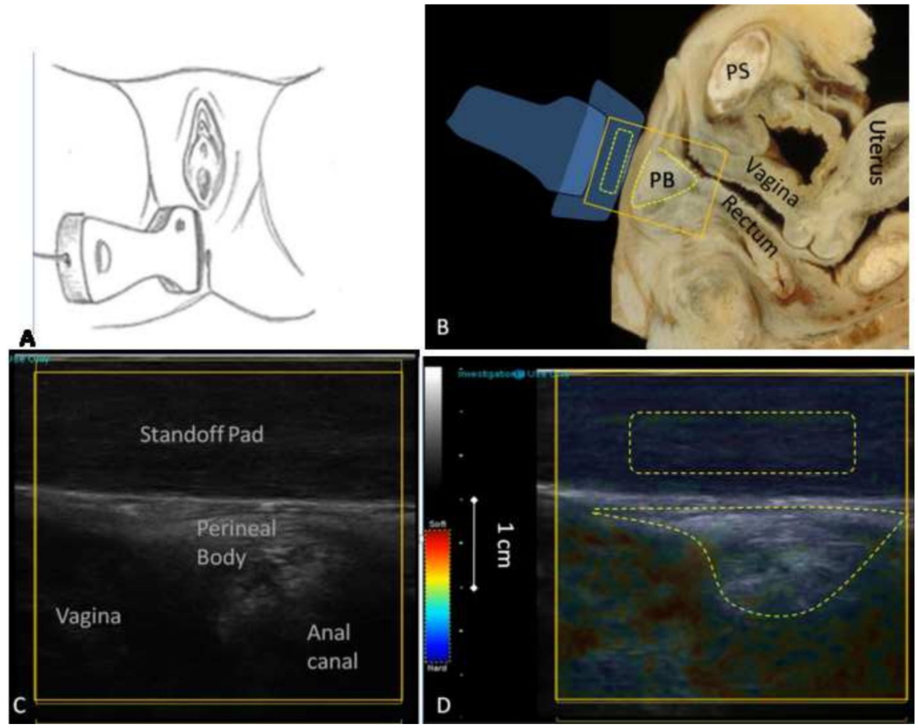

Figure 3.
(A) Caudal view of the transducer position on the perineal body and the scan angle. (B) The approximate anatomical regions of interest (dashed) for the standoff pad and the perineal body are shown within the dashed lines. (C) Anatomical relationships on the B mode images. (D) Sample strain ratio (SR) measurement comparing standoff pad and perineal body strains using elastography images.

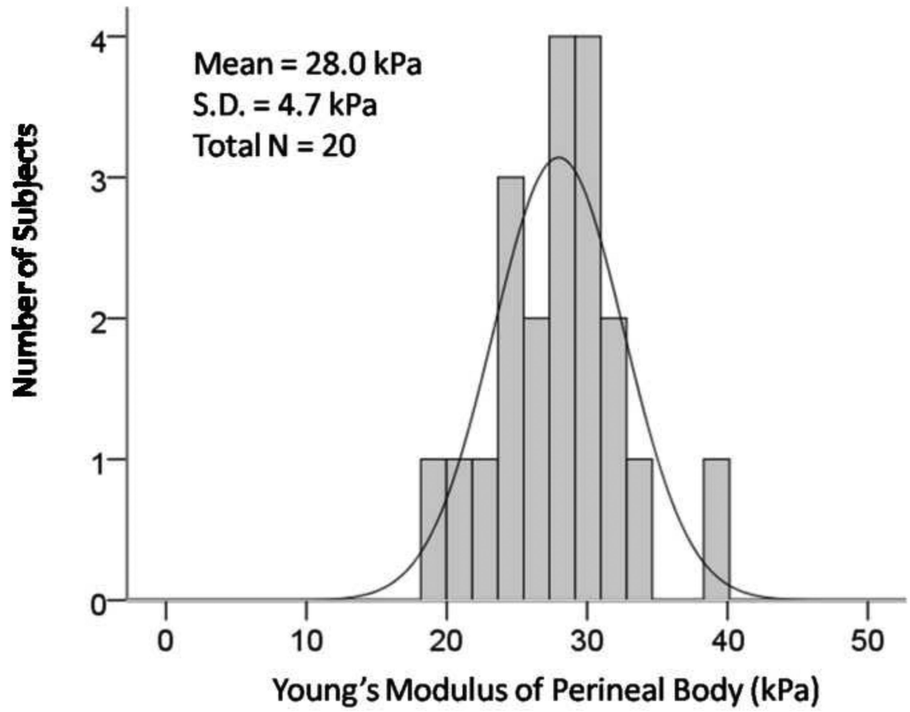

Figure 4.
Distribution of measured perineal body compression moduli of 20 nulliparous women