Journal of Biomechanics 48 (2015) 1575–1579

Contents lists available at ScienceDirect

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com

In vivo estimation of perineal body properties using ultrasound quasistatic elastography in nulliparous women

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ARTICLE INFO

Article history:
Accepted 28 February 2015

Keywords:
Perineal body
Ultrasound elastography
Elastic modulus

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.

1. Introduction

The perineal body lies interposed subcutaneously between the vagina and the anal canal. It is most consistently recognizedanatomically (Oh and Kark, 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 (Fig. 1A). While the composition of the perineal body has been described as ‘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 in which a baby's head must stretch enough to be able to pass through (Fig. 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 and 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 during ordinary B-mode scanning (Ophir et al., 1991). Computerized analysis of changes in the

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http://dx.doi.org/10.1016/j.jbiomech.2015.02.056
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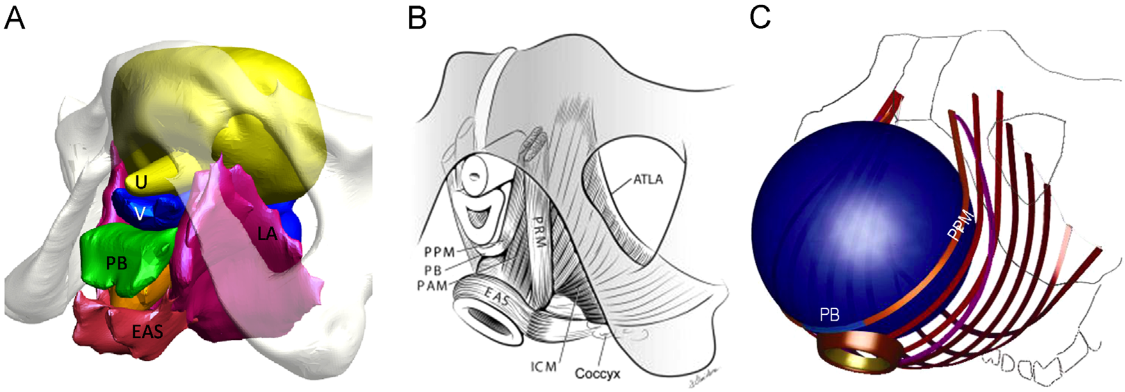

Fig. 1. (a) 3D pelvic floor anatomy reconstrcuted from a healthy, 45-year-old women's MRI in three-quarter, left, anterolateral view. Note the spatial relationship between perineal body (PB) and overall envelop of levator ani muscle (LA). U: Urethra; V: Vagina; EAS: the external anal sphincter, modified from Luo et al. (2011) (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 et al. (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).

speckle distance is then performed. The strain distribution within a region of interest (ROI) is often illustrated by a color map, where large 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 of 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.

2. Methods

2.1. The development of the synthetic reference standoff pad

A custom-made polyvinyl chloride plastisol (PVCP) standoff pad (Fig. 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. Fig. 2B shows the typical compression test stress and strain curve, with the estimated elastic compression modulus of 35 kPa. Fig. 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.

2.2. 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 an 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 (Fig. 3A and 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 5 s. 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.

2.3. 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 (Fig. 3C) and then average strain in the ROI for perineal body (based on anatomy, roughly triangularly shaped with the height around 1.5 cm) and standoff pad was calculated from strain distribution maps(Fig. 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.

2.4. 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.