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# **3D TACTILE IMAGING IN EARLY PROLAPSE DETECTION**

#### Hypothesis / aims of study

Changes in the elasticity of vaginal walls, connective support tissues and muscles are thought to be significant factors in the development of pelvic organ prolapse. The objective of this study is to estimate the ranges of normality for tissue elasticity of vagina and pelvic floor support structures, and to explore the possibilities of 3D tactile imaging in early prolapse detection.

#### Study design, materials and methods

In the period between December 2011 and December 2012, 136 women were enrolled in the observational case controlled study with transvaginal tactile imaging and underwent examination with the Vaginal Tactile Imager (VTI). The study subjects included 36 women with normal pelvic support, 11 women with stage I, 43 women with stage II, and 46 women with stage III prolapse. The average age was 56±22 years, from 21 to 90 years old. The VTI includes a transvaginal probe, a motion tracking system, a data acquisition electronic unit, and a computer with a touch screen monitor. The transvaginal probe is comprised of two pressure sensor arrays, a temperature sensor, a micro-heater, and a motion tracking sensor. The first array contains 104 pressure sensors and is installed on the probe surface to contact the vaginal wall. The second array contains 12 pressure sensors and is mounted in the probe tip to contact the uterus during the examination procedure. The VTI examination was performed on patients in the standard position for a routine gynecologic exam with an empty bladder and rectum. The full VTI examination requires 3 to 5 minutes to complete. Three orthogonal projections of the 3-D vaginal pressure map with the VTI probe location are observed by the operator in real time. The VTI clinical operators were trained on pelvic floor models prior to the VTI clinical application to standardize imaging techniques. The examination procedure includes multiple compressions of the vaginal walls and allows a circumferential 3-D tactile image or pressure map of the vagina to be composed. The tissue elasticity, Young's modulus, was calculated from the spatial gradients in the resulting 3-D tactile images. We use a non-linear tissue deformation model that was validated with silicone samples with a known elasticity distribution. The VTI provides reproducible elasticity measurements with a resolution better than 10% and accuracy within 20% for the expected tissue elasticity range from 2 to 40 kPa.

#### **Results**

All 136 enrolled women were successfully examined with the VTI. 3-D images of the vagina and the surrounding structures were recorded and stored. We established the elasticity distribution and its variation for normal pelvic floor conditions. We found substantial differences in the anatomy and tissue elasticity between normal and prolapse conditions. Specifically, we observed changes from 150% to 300% in the vaginal tissue elasticity for stage II and III prolapse compared to normal conditions. The range of normality (normal pelvic support) for the tissue elasticity (Young's modulus, kPa) of the apical anterior is [5.3; 27]; the apical posterior is [4.4; 23]; the mid anterior is [6.7; 32]; the mid posterior is [8.0; 39]; and the mid lateral vaginal walls is [7.5; 31]. Our preliminary results show that stage I prolapse cases have about 50% overlap with the ranges of the tissue elasticity for the normal conditions. We estimated an average value of the tissue elasticity for the anterior and posterior under prolapse stage II and III conditions to be  $2.9 \pm 1.8$  kPa; these cases have only about 5% overlap with the normal conditions.

#### Interpretation of results

These results are in agreement with our earlier findings [1, 2]. The VTI enables the quantification of the vaginal tissue elasticity and the strong differentiation between normal and stage II and III prolapse conditions. The overlap in tissue elasticity between normal and stage I prolapse conditions means that a) in some cases under stage I prolapse the tissue elasticity is the same as in normal conditions, or b) the normal case, as defined by the POPQ system, with lower values of Young's modulus, is already in the range for stage I prolapse. In other words, the left side of the normality range with the decreased tissue elasticity may enable the detection of pre-prolapse conditions that require attention to delay the observable prolapse development. The pressure pattern on the surface of the vaginal wall under applied load reveals not only the elasticity conditions of the vaginal wall itself, but also the elasticity distribution of the underlaying structures. The greater the applied pressure, the deeper the structures surrounding the vagina may be visualized. The softer the tissues, the deeper the structures may be visualized by tactile imaging because these softer tissues may be deformed more. The elasticity values calculated at the mid lateral vaginal walls may be related to the conditions of the underlying puborectalis, levator ani, and obturator internus muscles; the mid posterior elasticity to the rectovaginal fascia and perineal body; the apical posterior elasticity to the uterosacral ligaments; and the anterior elasticity to vesical and pubocervical fascia. The pressure patterns on the surface of the vaginal walls together with the tissue displacement under the applied deformations can be considered as a documentation of the current elasticity state of the vagina and the pelvic floor support structures that are elements of biomechanical system providing a critically important set of physiological processes.

#### Concluding message

Our findings suggest that the normality ranges for the tissue elasticity of the vagina and the pelvic floor support structures evaluated by the VTI may be used as the markers for characterizing pelvic floor conditions. It seems possible, at least in 50% of the cases, to use VTI for the detection of early pre-prolapse conditions not observed by the POPQ approach.

### **References**

- 1. IEEE Trans. Biomed. Eng. 2010; 57(7):1736-44;
- 2. Int. Urogynecology J. 2012; 23(4):459-66.

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