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Vaginal tactile imaging: A review

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ABSTRACT

Vaginal Tactile Imaging is a novel technology that creates a visual map of the female pelvic floor based on its biomechanical properties. The vaginal tactile imager is a medical device built on this technology to assist clinicians in diagnosis and prognosis of pelvic floor conditions and treatment from detailed characterization of vaginal tissue elasticity, pelvic support and function. This information is presented in the form of tactile images, a format in which pressure mapping is combined with spatial dimensions. The dynamic pressure patterns are combined using two opposing areas along the vaginal walls during Valsalva maneuver, voluntary and reflex muscle contraction, and involuntary relaxation. Based on these measurements, the biomechanical integrity score of the pelvic floor was developed and introduced to facilitate clinical interpretation of the complex data. This article begins with a brief overview of the tactile imaging for a broad spectrum of applications, clinical research findings and their respective impact. Then the article focuses on the evolution of the technology and its progressive development for the female pelvic floor disorders characterization and diagnostics, including evaluation of surgical intervention. Finally, future possibilities for tactile imaging are discussed, including applications in obstetrics and a fusion with ultrasound imaging.

Keywords: Vaginal tactile imaging; biomechanical mapping; biomechanical integrity score; tissue elasticity; pelvic support; pelvic muscles; pelvic organ prolapse; urinary incontinence

INTRODUCTION

Pelvic organ prolapse (POP) is a highly prevalent condition affecting 40-50% of women during their lifetimes.[1-3] Urinary incontinence (UI) affects up to 48% of women.[4,5] Both POP and UI are more common in women than in men, and their prevalence is increased with age.[3-6] POP is often associated with concomitant pelvic floor disorders, UI and fecal incontinence, pelvic pain, voiding, and sexual dysfunctions.[7] These conditions cause significant morbidity beyond the physical and the quality-of-life impacts.[8,9]

The true etiology of POP and UI and variations observed among individuals are not entirely understood. These disorders are thought to share common pathogeneses, weakening (elasticity changes) of the connective support tissues and pelvic floor muscle dysfunction.[10-22] The lifetime surgery risk for either UI or POP in women is about 20%.[23,24] A POP surgical failure rate

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of 61.5% for uterosacral ligament suspension and 70.3% for sacrospinous ligament fixation groups in a representative study was reported.[25] The estimated annual cost of POP surgeries and UI care in the U.S. is about $24 billion.[26,27]

With the global population getting older the pelvic floor diseased conditions will increase in prevalence.[3,28] It is projected that by 2050, 43.8 million women, or nearly 33% of the adult U.S. female population, would be affected by at least one troublesome pelvic floor disorder.[6,29] Additionally, due to the Coronavirus disease-2019 pandemic a large number of the population has been unable to attend routine appointments increasing the likelihood of undiagnosed pelvic floor conditions.

The current clinical practice for assessment of POP and UI is generally limited to the evaluation of surface anatomy by manual palpation. In severe or complicated cases, ultrasound, magnetic resonance imaging (MRI), and X-ray imaging may be used for additional evaluation. Bladder and rectum function tests, such as urodynamics, manometry, or defecography might also be employed.[7,30-34]

Conventional ultrasound is available for the imaging of pelvic floor organs. Perineal or translabial, transvaginal, and abdominal ultrasounds are increasingly used for assessing POP and UI.[35-38] Ultrasound, as a part of the diagnostic workup, enables morphological and dynamic assessment of the lower urinary tract. In the last decade, transrectal ultrasound gained ground for assessing the female urogenital organs.[39]

Despite criticisms that MRI is an expensive modality, cost-analysis studies are demonstrating utility for MRI in surgical decision-making trees for patients at risk for POP repair failure. Novel measures such as anterior pelvic area and levator volumes are proposed.[40] Diffusion-weighted imaging, dynamic contrast-enhanced MRI, and susceptibility-weighted imaging were developed for evaluation of endometriosis, local staging of cervical and endometrial cancers, and assessment of nodal and peritoneal metastases.[41] Dynamic MRI is used for the assessment of fecal incontinence.[42,43]

Biofeedback with vaginal pressure measurements (air balloon or 1-2 pressure sensors) has been widely utilized in the treatment of pelvic floor dysfunctions, mainly by promoting patient learning about muscle contraction.[44,45] Urodynamics records pressure measurements in the bladder, urethra, vagina, and rectum with catheters. Despite technical and procedural advances in urodynamics, the role of urodynamics in women with UI remains controversial.[46-49]

None of the above-listed techniques produce biomechanical mapping (stress-strain and functional) of the female pelvic floor structures with accurate anatomical identification.

Elastography, or elasticity imaging, involves the application of a stress to soft tissue and measurement of the resulting tissue mechanical response. There are several methods available to apply stress to a tissue and to measure the resulting response. The stress can be generated from an external source such as a compression probe, an external vibrator, acoustic radiation force, or physiological sources of motion (cardiac motion and fluid flow). The most common measurement methods of tissue response (strain) include ultrasound, MRI, and mechanical/tactile imaging.[50,51] The strain ultrasound is not capable of soft tissue characterization on an absolute scale without stress data. Shear wave elastography seems too complicated for intravaginal application due to the heterogeneity of the tissues.[52-55] The MRI elastography is a complex technology with a relatively high cost and low resolution.[56-58] A mechanical imaging (MI) reconstructs form and elasticity distribution of an organ or object based on pressure patterns of the object surface and expected anatomy and pathology of the object.[59] A tactile imaging probe translates stress data from the surface of deformed soft tissue into a 2D tactile image, assessing tissue biomechanical parameters.[60,61] It also provides high-definition pressure response patterns at Valsalva maneuver, voluntary and reflex pelvic muscle contractions.[14] Tactile imaging is a relatively simple and inexpensive technique.[62] With the increasing need for diagnostics and no practical method for biomechanical assessment of the female pelvic floor, tactile imaging may have a profound impact on women's healthcare.

Definitions

MI is a modality of medical diagnostics based on reconstruction of tissue structure and viscoelastic properties using mechanical sensors. The essence of MI is the solution to an inverse problem using the data of stress patterns on the surface of tissue compressed by a pressure sensor array. A key feature of MI is "knowledge-based imaging". To produce a 3D image, the computer uses both the measured parameters of an individual examined object and a general database on anatomy and pathology of the object.[59]

Tactile imaging is a medical imaging modality that translates the sense of touch into a digital image. The tactile image is a function of $p(x, y, z)$, where p is the pressure on the soft tissue surface under applied deformation and x, y, and z are the coordinates where p was measured. The tactile image is a pressure map on which the direction of tissue deformation is specified.[63]

Functional tactile imaging translates muscle activity into dynamic pressure pattern $p(x, y, t)$ for an area of interest, where t is time and x, y are coordinates where the pressure P was measured. It may include: (1) Muscle voluntary contraction, (2) involuntary reflex contraction, (3) involuntary relaxation, and (4) specific maneuvers.[61]

Biomechanical mapping = Tactile imaging + Functional tactile imaging.[64]

A tactile imaging probe has a pressure sensor array mounted on its face that acts similarly to human fingers during a clinical examination, deforming the soft tissue and detecting the resulting changes in the pressure pattern on the surface. The sensor head is moved against or over the surface of the tissue to be studied, and the pressure response is measured at multiple locations along the tissue. The results are used to generate images that show pressure distribution over the area of the tissue under study. The tactile image *p (x, y, z)* reveals tissue or organ anatomy and elasticity distribution.[61]

History

Throughout the years several mechanical and tactile imaging systems have been developed for prostate, breast, muscle, and other soft tissues. The prostate mechanical imager (PMI) was designed to assist in diagnosis of prostate pathologies. The PMI system works through use of a transrectal probe with two pressure sensing arrays to acquire data from rectal wall and anus, and a 3D orientation sensor. The device aims to provide a more accurate and sensitive method for detection of prostate abnormalities as opposed to digital rectal examination (DRE).[65] Figure 1 presents mechanical images of the prostate. The left panel presents 2D cross-sectional mechanical images for the 3D prostate image presented on the right panel. These images clearly demonstrate the prostate abnormality with a nodule in the left lobe and prostate asymmetry. In the clinical study of 168 patients the PMI was able to create full 3D mechanical images of the prostate in 84% of patients while demonstrating a higher sensitivity than DRE for the biopsy detected nodules.[66]

In the application of MI technology for breast, the breast mechanical imager (BMI) was designed to image breast tissue and assist in the diagnosis of benign versus cancerous lesions.[67] The BMI had 2D pressure array with 192 pressure sensors. An examination procedure and algorithms to provide assessment of breast lesion features such as hardness related parameters, mobility, and shape have been developed. Figure 2 presents an example of the MI of a breast lesion. A statistical Bayesian classifier was constructed to distinguish between benign and malignant lesions by utilizing all the listed features as the input. Clinical results for 179 cases collected at four different clinical sites, established a reliable image formation of breast tissue abnormalities and calculation of lesion features. The tactile imaging demonstrated increased hardness and strain hardening as well as decreased mobility and longer boundary length in comparison with benign lesions for the histologically confirmed malignant breast lesions. Statistical analysis of differentiation capability for 147 benign and 32 malignant lesions revealed an average sensitivity of 91% and specificity of 87%. The area under the receiver operating characteristic curve characterizing benign and malignant lesion discrimination is 86% with the confidence interval ranging from 80 to 91%, with a significance level of

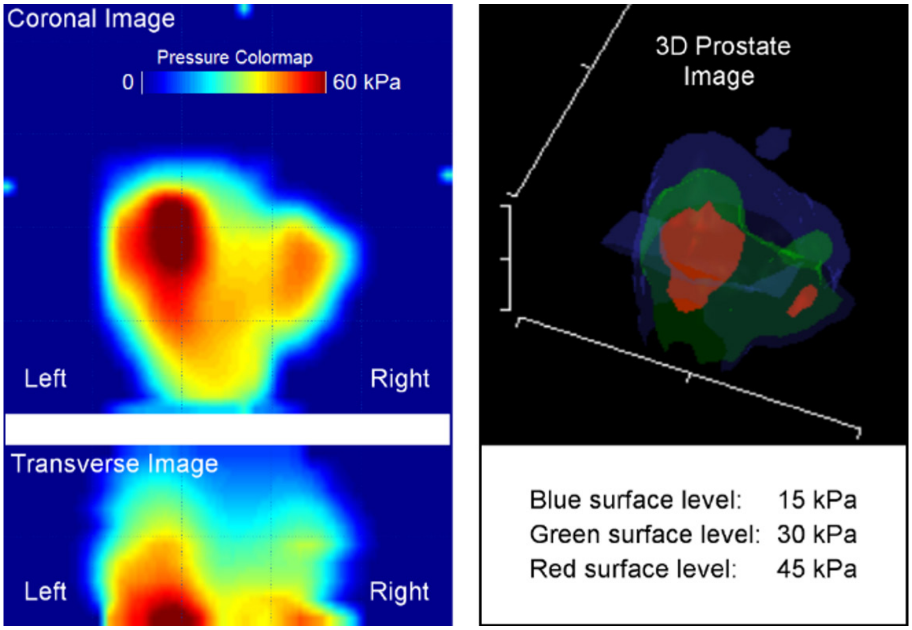

Figure 1. Prostate mechanical imaging for a 62 y.o. patient. Left panel - 2D orthogonal cross-sections of prostate, coronal (upper left) and transversal (lower left) tactile images; right panel - 3D reconstruction of the prostate with three iso-surfaces of pressure (see text)

p=0.0001.[68] We hypothesized that the BMI has the potential to be used as a cost-effective device for cancer diagnostics that could reduce the benign biopsy rate, serve as an adjunct to mammography and to be utilized as a screening device for breast cancer detection.

For validation of the MI devices, the tissue elastometer was designed to measure stress-strain relationship for soft tissue and to calculate its Young's modulus in the range of 10-400 kPa. In the testing of the excised tissue samples the repeatability of elasticity measurements was demonstrated in the range of 8-14%.[69]

Quantification of the mechanical properties of muscle is of a significant clinical interest. Local changes in the mechanical properties of muscle are often associated with clinical symptoms. In particular, myofascial trigger points (MTrPs) are a very common, yet poorly understood and overlooked cause of non-articular musculoskeletal pain. MTrPs are localized, stiff, hyperirritable tender nodules, palpated in taut bands of skeletal muscle. Objective validated measures of the mechanical properties of MTrPs could potentially be a clinical outcome measure. Ultrasound shear wave elastography and tactile imaging as complementary objective methods to assess the mechanical properties of MTrPs were explored on 50 subjects (27 healthy controls and 23 with symptomatic chronic neck pain and active MTrPs). The upper trapezius muscles in these subjects were imaged using shear wave elastography using an external vibration source to measure shear wave speed and dispersion in tissue, and tactile imaging using an array of pressure sensors creating a 3D reconstruction of mechanical structures in tissue. It was found that symptomatic muscle tissue in subjects with neck pain is mechanically more heterogeneous and stiffer compared to normal muscle in control subjects.[70]

Changes in the elasticity of the vaginal walls, connective support tissues, and muscles are thought to be significant factors in the development of POP. It poses two questions specific to the biomechanical properties of pelvic support tissues: how does tissue elasticity affect the development of POP and how can functional elasticity be maintained through reconstructive surgery? A first prototype of vaginal tactile imaging probe for visualization and assessment of elastic properties of pelvic floor tissues was comprised of 120 sensors array for 2D pressure response pattern and a tilt sensor (Figure 3). We assumed that the slope of a peak pressure value related to specified zone inside a tactile image versus total applied force to the probe head

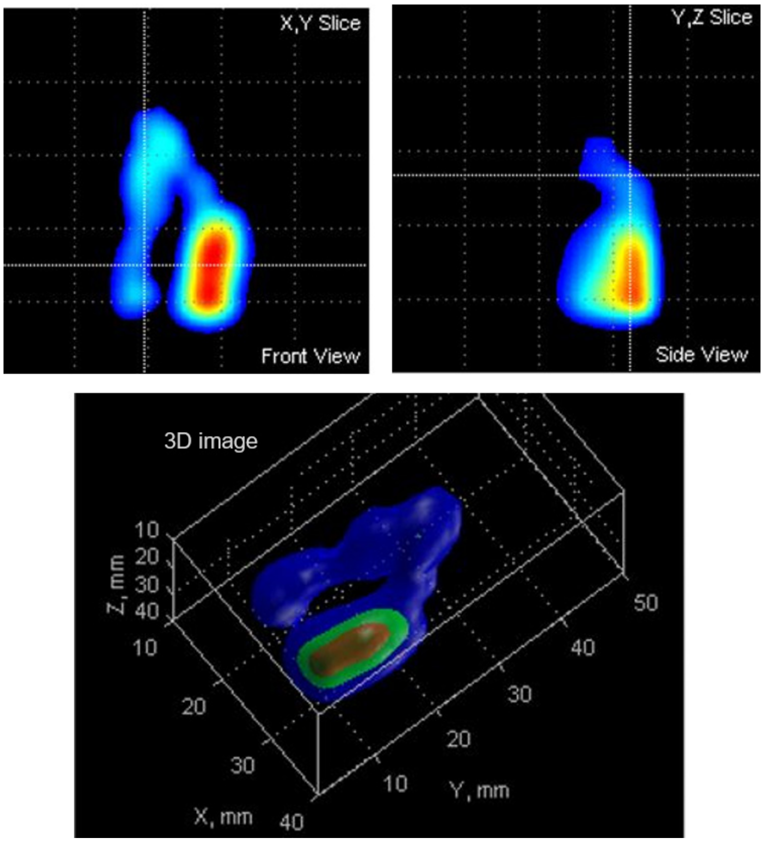

Figure 2. Mechanical imaging of breast lesion for a 45 y.o. patient. Upper panels - 2D orthogonal cross-sections of the lesion, coronal (left) and sagittal (right) mechanical images; lower panel - 3D mechanical image of the lesion

(scanhead) characterizes relative elasticity of a hard inclusion placed inside soft tissue against which the scanhead has been pressed. The probe was used in a pilot clinical study with 13 patients and demonstrated that vaginal walls increased rigidity due to implanted mesh grafts following reconstructive pelvic surgery and showed potential for prolapse characterization.[60]

The purpose of the next study was to assess the clinical suitability of 3D vaginal tactile imaging and tissue elasticity quantification under normal and prolapse conditions. The updated tactile imaging device included a vaginal probe with a 6D (three coordinates and 3 angles) electro-magnetic motion tracking system. The pressure sensor array comprised 128 capacitive pressure sensors.[20] Three orthogonal projections of the 3D vaginal pressure integrated response (tactile image) with probe location are observed by the operator in real time. The examination procedure with the vaginal probe included multiple compressions of the vaginal walls and composition of a circumferential 3D vaginal tactile image.[61] Figure 4 presents examples of examination results for normal and prolapse conditions. Specifically, Figure 4A shows transverse and sagittal cross-sections of the 3D vaginal tactile image for a 63 y.o. patient with normal pelvic floor anatomy on manual palpation during physical examination. Figure 4B shows transverse and sagittal planes of 3D vaginal tactile image received with VTI for a 77 y.o. patient with Stage III prolapse in the anterior and upper half of the posterior compartment that recurred less than a year from a vaginal hysterectomy and anterior repair. Study with 31 subjects demonstrated significant differences in anterior and posterior vaginal tissue elasticity with POP development stage ($p<0.0001$). The most affected locations were the mid and apical aspects of the anterior vaginal walls, where elasticity is decreasing up to 340% from normal to POP stage III. The lesser affected was the mid-posterior part where elasticity decreased up to 220%, the apical side walls of the vagina (decrease of approximately 100%), and the mid side walls of the vagina where we did not detect statistically significant tissue elasticity decrease. That means the horizontal (anterior, posterior) support structures weaken the most under POP conditions. This approach also allowed anatomical characterization of POP development. Specifically, we found that the anterior/posterior spacing increases for the apical part of vagina from 18±6 mm under normal conditions to 32±12 mm under POP stage III. The comfort level of VTI examination was found very close to manual palpation by 77% of patients.[61]

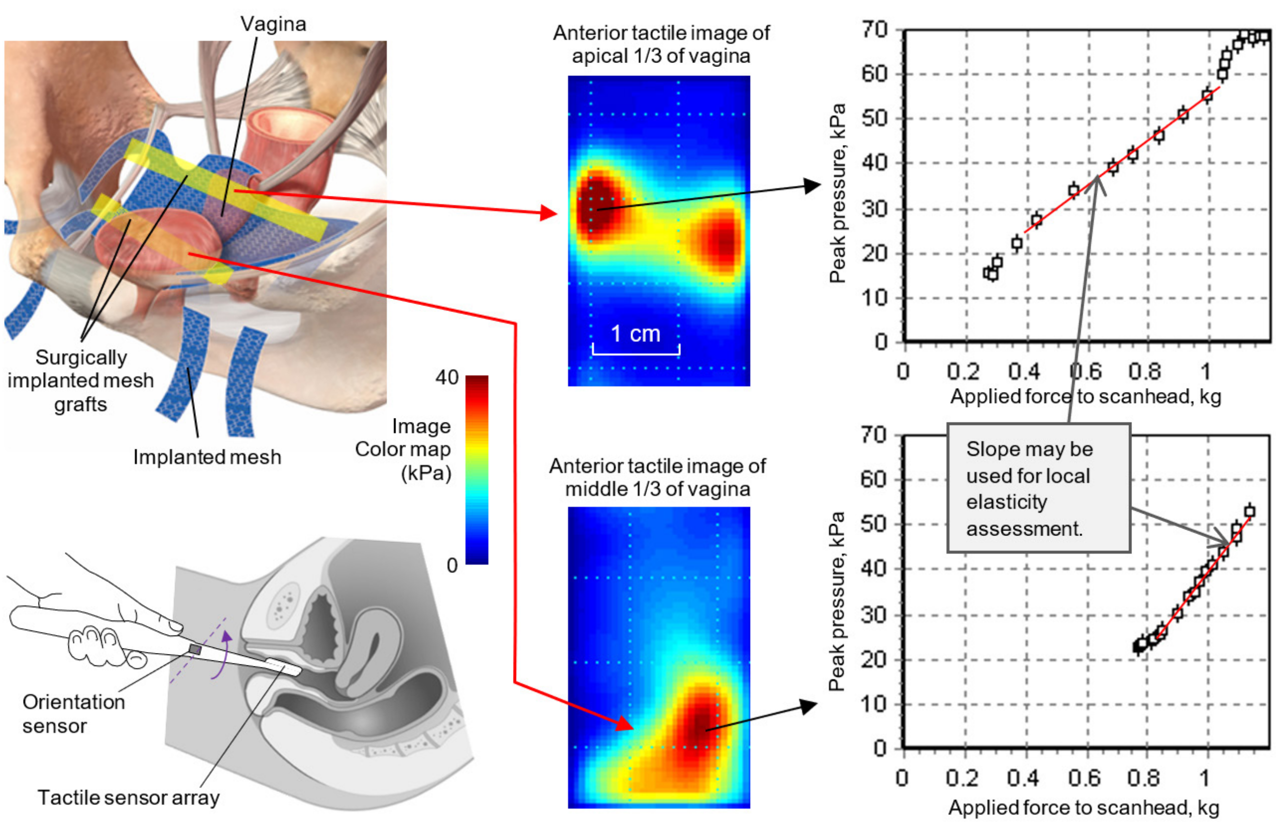

Figure 3. Tactile imaging of anterior and posterior vaginal walls. The diagrams on the left showcase the mesh graft implementation and below that shows a patient examination with the vaginal tactile imaging probe. This approach provides visualization and quantitative elasticity evaluation (see right graphs) at pelvic locations where these mesh grafts were placed (see two tactile images in the middle of the figure) [adapted from (60) with permission]

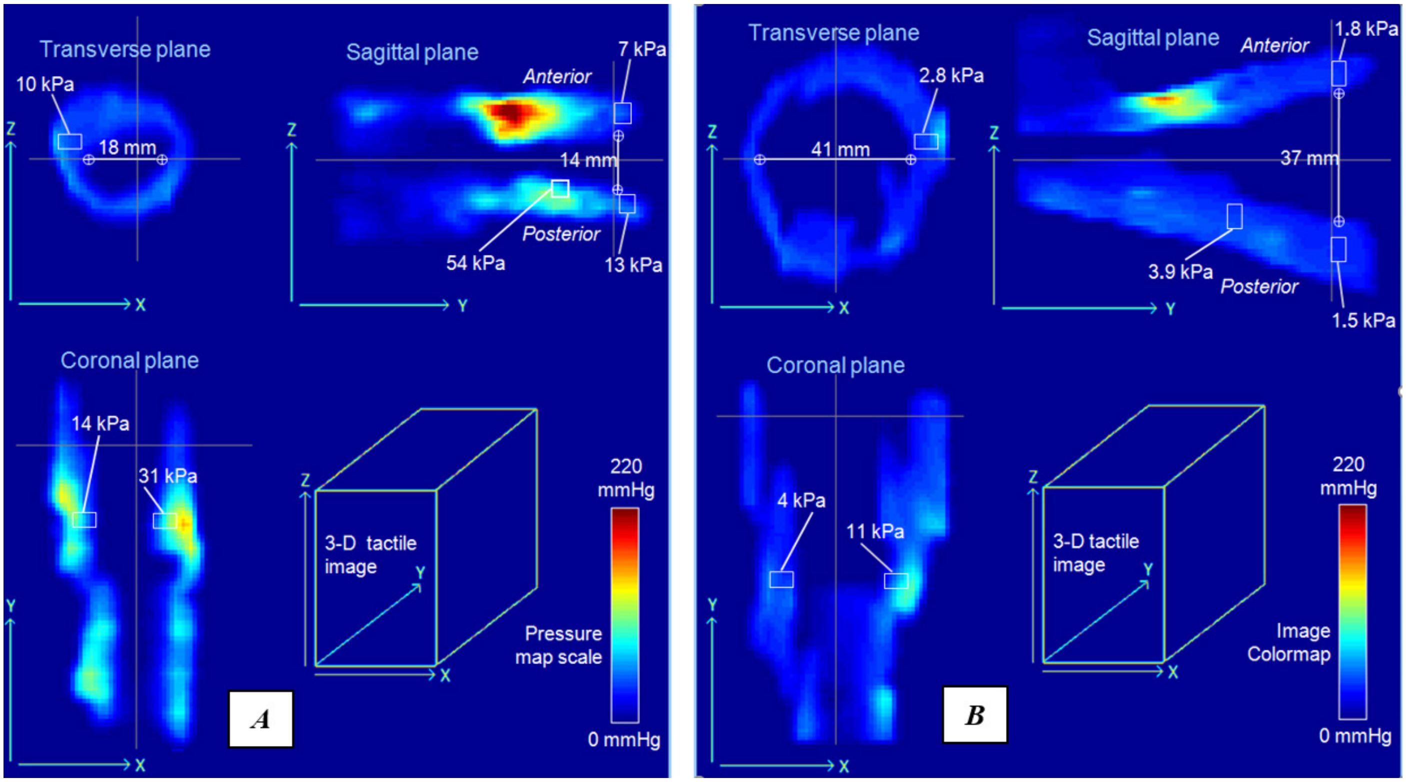

Figure 4. Cross-sections of 3D vaginal tactile images received with the vaginal tactile imaging device equipped with six-degrees-of-freedom motion tracking of the probe. The Y-axis represents distance along the vagina. Tactile images on the left are a patient with normal pelvic floor conditions (A) and tactile images on the right are of Stage III prolapse (B). Young's modulus (kPa) for vaginal tissue was calculated for areas specified by a rectangle [adapted from (61) with permission]

Vaginal Tactile Imager (VTI)

The VTI comprises a vaginal probe with 96 pressure (tactile) sensors, an orientation sensor, temperature sensors, micro-heating elements, and an electronic board (see Figure 5A). The pressure sensors provide pressure patterns (25 frames per second) from contact with the vaginal walls during the examination. The 3D accelerometer is used to measure the rotation and elevational angles of the probe. Probe positional information is combined with the pressure patterns from the tactile sensors to accurately track the location of the probe in the female pelvic floor during the examination. The temperature control system (micro-heating elements and temperature sensors) preheats the probe body including the tactile sensors to a temperature of 36 °C before the examination begins. The temperature stability of the probe increases accuracy of the tactile sensors and improves patient comfort. During the patient examination procedure, data are sampled from the probe sensors and displayed on the VTI computer display in real time. The calibration chamber is used to calibrate the tactile sensors in the vaginal probe by applying air pressures in the range from 0 to 40 kPa. The tactile sensors are calibrated every time before the patient examination relative to two independent highly accurate air pressure transducers. A lubricating jelly is used for patient comfort and to provide reproducible boundary/contact conditions with deformed vaginal tissue.

The pressure sensors sensitivity, defined as an average noise level, was found of about 50 Pa with dynamic response 40 ms and a measuring range up to 100 kPa. The spatial resolution of 1.0 mm along the VTI probe is achieved by a real-time pressure and positioning data processing.

Intra- and inter-observer agreements were evaluated in the subset of 12 subjects that have been enrolled into a larger observational case-controlled study (NCT02294383 at ClinicalTrials.gov).[71] Two measurements of the full set of VTI parameters (markers) were obtained by two observers. Agreements within and between observers for VTI parameters were analyzed using 95% prediction intervals, Bland-Altman plot with 95% limits of agreement, and the intraclass correlation coefficient (ICC).[72,73] All twelve subjects were successfully scanned with the VTI four times; two scans were completed by each of two operators. Mean patient age was 39.0 years (range 26 to 60), pelvic floor conditions were from normal (10 subjects) to Stage I/II POP (one subject with Stage 1 and one subject with Stage II prolapse), and mean parity of 1.2 (range 0 to 2). The data set with 1920 VTI measurement

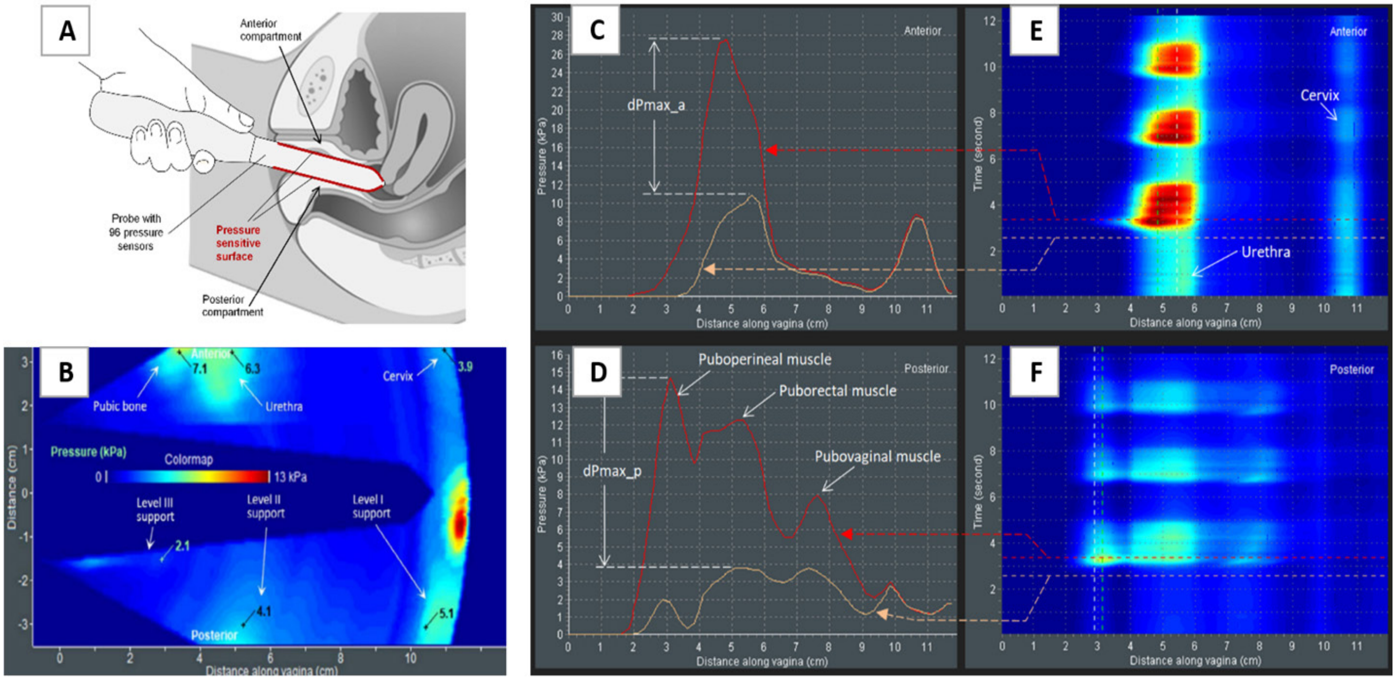

Figure 5. The vaginal tactile imaging probe with orientation sensor positioning during pelvic examination (A). Tactile imaging of anterior and posterior compartment at probe elevation relative to the hymen (B). Anterior (C) and posterior (D) pressure distribution along the vagina at pelvic muscle contraction. Dynamic pressure patterns along anterior (E) and posterior (F) compartments during pelvic muscle contraction

records (12 subjects x 10 parameters x 4 locations x 4 VTI scans) was analyzed. Intra-observer ICC was found in the range from 0.80 (Test 8: Reflex contraction at cough) to 0.92 (Test 3: Probe rotation) with average value of 0.87. Inter-observer ICCs were found in the range from 0.73 (Test 2: Probe elevation and Test 8: Reflex pelvic muscle contraction at cough) to 0.92 (Test 3: Probe rotation) with average value of 0.82. Intra-observer ICC was found in the range from 0.80 (Test 8: Reflex pelvic muscle contraction at cough) to 0.92 (Test 3: Probe rotation) with average value of 0.87 for all 10 parameters. Intra-observer limits of agreement were in the range from ±11.3% (Test 1: Probe insertion) to ±19.0% (Test 8: Reflex pelvic muscle contraction) with average value of ±15.1%. Inter-observer limits of agreement were in the range from ±12.0% (Test 5: Voluntary pelvic muscle contraction) to ±26.7% (Test 2: Probe elevation) with average value of ±18.4%. Based on these results the conclusion was made that there is reasonable intra- and inter-observer reproducibility for VTI measurements, though improved inter-observer reproducibility can be reached by operator training and consistency in VTI examination technique.[71]

The VTI examination procedure consists of eight tests: 1) Probe insertion, 2) elevation, 3) rotation, and 4) Valsalva maneuver, 5) voluntary muscle contraction, 6) voluntary muscle contraction (left versus right side), 7) involuntary relaxation, and 8) reflex muscle contraction (cough). Tests 1-5 and 7-8 provide data for anterior/posterior compartments; test 6 provides data for left/right sides. The probe's maneuvers in tests 1-3 accumulate multiple pressure patterns from the tissue surface to compose an integrated tactile image corresponding to each test for the investigated area using the image composition algorithms.[61] Tests 1 and 3 provide data for assessment of the vaginal tissue elasticity, test 2 provide parameters to characterize the pelvic support strength. Test 4-8 provide the dynamic pressure patterns for functional characterization. The VTI examination with all tests 1-8 completed takes 3-5 minutes. Figure 5 illustrates the probe positioning and examples of an acquired tactile images for the selected tests. Figure 5B shows acquired tactile images for anterior and posterior vaginal compartments for test 2 (probe elevation). The vaginal probe elevation acquires pressure feedback from the pelvic floor structures at about 15-40 mm depth under significant tissue deformation (up to 45 mm) for the anterior and posterior vaginal compartments. The VTI probe include an orientation sensor to measure an elevation angle, such that the pressure feedback acquired by pressure sensor arrays from the contact with the vaginal walls can be mapped along the elevation angle. The up and down elevation of the vaginal probe is usually completed relative to the hymen. In the anterior compartment, from left to right, tactile responses from the pelvic bone (pubic symphysis), the urethra, and the cervix may be observed. In the posterior compartment, from left to right, tactile responses from Level III support, Level II support, and Level I support may be seen. Level III support includes perineum and puborectal muscle, Level II support includes puboanal and pubovaginal muscles, and Level I support includes iliococcygeal muscle, levator plate, cardinal and uterosacral ligaments.[17] Figure 5C illustrates the test 5 approach for VTI capturing parameters at voluntary muscles contractions. Three contractive peaks are observed in the posterior compartment which are described as originating from puboperineal, puborectal, and pubovaginal muscles. The contractive changes for these 3 posterior peaks have different value and separated along the vagina for the subject.

Comfort level: Based on the recorded feedback, subjects found on average the VTI procedure more or at least as comfortable as manual palpation. Specifically, 54% classified the VTI examination as more comfortable, 36% as the same, and 10% as less comfortable than manual palpation.[63]

Indications for use: The VTI was cleared by the FDA for the following indication "The VTI obtains a high-resolution mapping of pressures and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures and store the corresponding data. It also provides visualization, analysis tools and information. The real time data as well the analysis information can then be viewed with an intention of assisting in the diagnosis and evaluation. The device is intended for use by physicians, surgeons and medically trained personnel".[74]

It is important to note that the VTI is not a diagnostic device; it is not intended to be used to diagnose any specific diseased conditions, such as POP or UI, on the binary basis as present versus absent. It is an imaging device and the image interpretation has to be completed by a clinician taking into account knowledge of general and functional pelvic anatomy, and their clinical experience and skills. The Integral Theory developed by Petros[22] may be used for identification of the pelvic floor structures contributing into the tactile images and dynamic pressure patterns acquired with the VTI.

VTI Clinical Applications

The VTI was uniquely designed to collect measurements for biomechanical characterization of the female pelvic floor. It is capable of quantifying muscle function, support strength, and tissue elasticity. This gives the device value in determining the inciting event for pelvic floor disease conditions. It was shown that with the VTI, a Biomechanical paradigm could achieve a baseline to assist in diagnosing POP conditions or estimate the risk factor for future POP.[14,61,75] Through this paradigm the pelvic floor conditions can be characterized by 52 VTI parameters derived from eight different tests (as previously described). This large body of measurements could be used to evaluate individual variations as well as identify specific potential markers that characterize tissue properties and muscle function in patients' diseased conditions that are accompanied by changes in mechanical properties and, often, physiologic manifestations. For a female patient that presents with complaints of increasing vaginal pressure, discomfort, backache, and bulging exacerbated by lifting and straining, the physician can perform transvaginal biomechanical mapping with the VTI probe to define the pelvic defects and to use this information to determine the best course of treatment. The procedure images are visualized in real time on a display to provide feedback to an operator, then used to produce an examination report in a form of a computer file and hard-copy record, so that the physician can review and interpret the results, dictate a report, and discuss the results with the patient. Clinical disorders that can benefit from the VTI to help optimize and monitor treatment include POP, stress UI, tissue atrophy, and others where the pelvic diseased conditions are accompanied by significant changes (100-500%) of pelvic tissue biomechanical properties and functions. The proposed approach also may help further differentiate the types of pelvic floor conditions, their underlying severity, and understand how to tailor treatments for the individual patient in the most effective manner.

Factors that expand on the biomechanical paradigm of the female pelvic floor include patient age, weight, height, and parity. The quantifiable impact of these factors was studied with the VTI.[76] Of the 52 VTI parameters, 12 had statistically significant correlation in patient age and 9 parameters were correlated with parity number. No parameter was found to have direct correlation with patient weight. Therefore, VTI measurements confirm generally observed correlation in age and parity with an increased risk of deteriorated biomechanical pelvic conditions. Future studies will be able to build on this information and give an increasingly more comprehensive understanding of the biomechanical condition that can be expected for a healthy patient.

A recent VTI study was designed to estimate the efficacy of different pelvic floor surgical procedures. Patients were recruited and examined prior to surgery and then four to six months after surgery. Seventy-eight cases with a total of 255 surgical procedures were included in reported data analysis.[77] The list of surgical procedures included sacral colpopexies, sacrospinous ligament suspensions, uterosacral ligament suspensions, illiococcygeal suspension, anterior and posterior colporrhaphies, enterocele repairs, perineorrhaphies, total and supracervical hysterectomies, and midurethral sling. Results of the study demonstrated VTI documented biomechanical changes varied by procedure. The VTI parameters strongly correlated weak pelvic floor pre-surgery with positive POP surgery outcome of improved biomechanical properties. However, the data indicated that strong biomechanical pre-operative pelvic conditions may lead to negative changes after the surgery. Authors concluded that (1) POP surgery, in general, improves the biomechanical conditions and integrity of the weak pelvic floor, (2) the proposed biomechanical parameters can predict changes resulting from POP surgery.[77] This provides a promise of using the VTI to reduce the POP failure rates by preventing or delaying a surgery that would be ineffective for the individual. Additional studies and analysis could have the potential to inform surgeons on what procedure would work best on a case-by-case basis.

Another study was focused on hysterectomy patients and found a quantifiable change in key biomechanical properties of the tissues before and six months after surgery. Results showed mean tissue elasticity improvement due to the anatomical changes after hysterectomy, and mean urethral mobility decrease.[78]

In women with cervical cancer, treatment with radiation may cause changes in vaginal biomechanical properties, anatomy, and function. A study aimed to objectively assess effects of radiation therapy on vaginal elasticity, wall mobility, and contraction strength measured using the VTI, and to evaluate associations of these changes with sexual function. A total of 25 subjects with locally advanced cervical cancer were included in the final data analysis. Following radiation therapy, the mean scores for vaginal elasticity and vaginal tightening were significantly lower than at pre-treatment. Accompanied by the significant decreases in pelvic muscle mobility and pelvic muscle contraction strength. The conclusion was made that women with locally advanced cervical cancer who have been treated with radiation therapy exhibit persistent vaginal biomechanical changes that compromise sexual activity and result in considerable distress.[79] There are many other medical procedures that could get better efficacy and risk analysis with quantifiable biomechanical data from the VTI.

Recently, many clinics have been offering vaginal treatments using carbon dioxide lasers or radiofrequency devices. These are new procedures with relatively low efficacy data. The VTI is able to test the claims of these energy-based rejuvenation therapies. Three independent studies have been performed and found increases in both tissue elasticity and pelvic muscle strength.[80-82] All of these studies followed patients for under a year so it is hard to say what the long-term effects of vaginal rejuvenation would be. The overall population for these studies is still very low. Additional work would need to be done to fully validate such procedures.

The benefits of biomechanical data have been shown in multiple clinical studies but it became clear that 52 VTI parameters expressed in raw units might be difficult for interpretation in routine clinical practice. Ideally, for VTI measurements to be clinically useful, they should be presented in terms that are readily understandable by patients and clinicians as well as to be independent of the particular measurement device. that is why the biomechanical integrity score (BI-score) was introduced as a single parameter in the units of standard deviation to characterize the biomechanical status of the female pelvic floor.[83] The BI-score is built from five components derived from the VTI data: (1) Tissue elasticity, (2) pelvic support, (3) pelvic muscle contraction, (4) involuntary muscle relaxation, and (5) pelvic muscle mobility. The BI-score as well as all its five components were normalized using data from a clinical population with normal pelvic floor conditions. The BI-score for an individual is the deviation from the healthy population's average. Figure 6 shows the BI-score graph as it appears to the clinician. The graph is presented similarly to T-score for bone density, measured in units of standard deviation relative to the patient's age. To validate this approach, 253 subjects with normal and POP conditions were included in the multi-site observational, case-control study; 125 subjects had normal pelvic floor conditions and 128 subjects had POP stage II or higher. The p-value for the BI-score in POP population versus normal population was 4.3×10^{-31}. A reference BI-score curve against age for normal pelvic floor conditions was defined. Three colored backgrounds (normal, transition and diseased zones) have been suggested to be used in the presentation of the patient VTI examination results as shown in Figure 6. The POP diagnostic accuracy of the BI-score, calculated as an area under a receiver operating characteristics curve for the analyzed sample, was found as 89.7%.[84] The dependence of the BI-score on age for normal pelvic conditions is described as a second order curve (see blue line in Figure 6); its ± standard deviations are depicted by the dashed curves. It is clear that an age-adjusted BI-score can also be calculated relatively to the normal similar to the Z-score in the bone densitometry. As with bone density measurement, it is important to monitor patient progress with or without treatment. For this reason, it would be important to define the minimal clinically important difference in BI-score. The future research directions also may address (1) BI-score use for monitoring of a pelvic floor treatment outcome, (2) obtaining periodic BI-scores before a woman has symptoms, (3) recommendation for specific treatment based on the five components, (4) predictive capabilities of the BI-score for symptoms. The BI-score is currently validated for POP, but

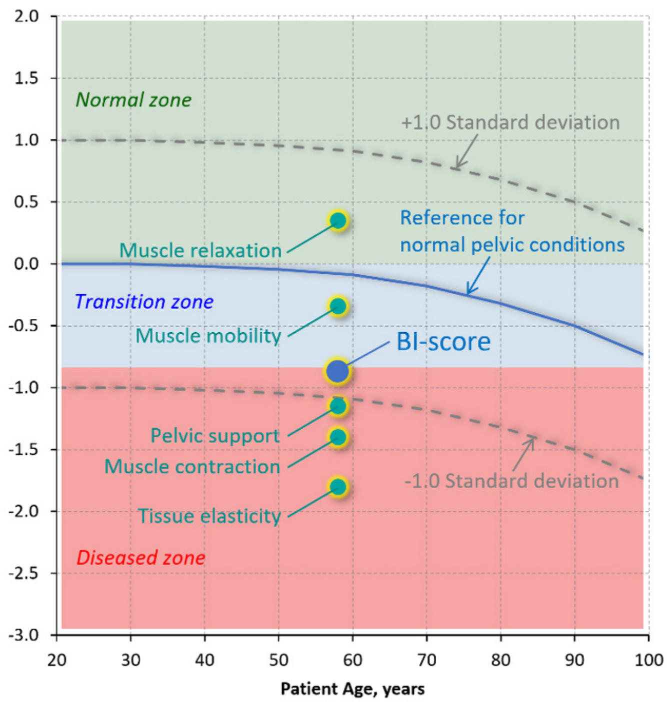

Figure 6. Biomechanical integrity score (BI-score) and its five components for a 58 y.o. patient acquired with the vaginal tactile imager (adapted from (83)]

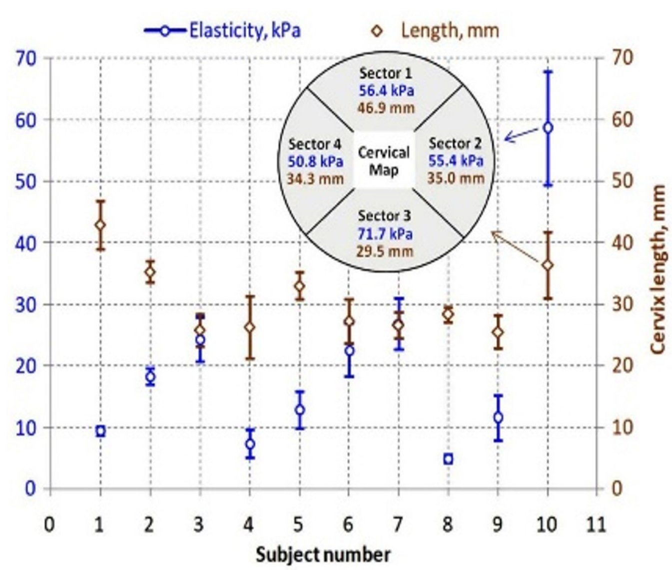

Figure 7. Cervical elasticity and length for 10 pregnant women measured with Cervix monitor and graphed by case. The circular cervical map shows averages values for the studied population in respective sector of the Cervix [adapted from (85)]

it can also be used for characterization of other pelvic diseased conditions which change the biomechanical components. This approach can be used in diagnosing and monitoring pelvic conditions as well as in selecting and evaluating treatment.

Future Directions

One of the greatest complications in infant and maternal health is a spontaneous preterm delivery. There are interventions that can reduce the harm of preterm birth however there is still no diagnostic tool to accurately forecast a preterm delivery. The Cervix monitor is a device that combines tactile and ultrasound technology to evaluate cervical depth and elasticity which may detect cervical conditions leading to spontaneous preterm delivery. The Cervix monitor probe has a single ultrasound transducer designed for cervical depth measurement. The probe then compresses the cervix, this compression creates a change in the ultrasound signal which is used to quantify cervical strain and tactile sensors to find an applied pressure to the cervical surface. With all that information the device can generate Young's modulus and depth for the patient's cervix. A pilot clinical study was designed to compare 10 non-pregnant women with 10 women 22-29 weeks pregnant.[85] It found that pregnancy decreased cervical elastic modulus from 54±17 kPa to 19.7±15.4 kPa. Additionally, pregnancy was correlated with a decrease in cervical length from 42±13 mm to 30.7±6.6 mm. The data in Figure 7 shows length and elasticity numbers for the 10 pregnant women in the study. It should be noted that soft tissue can vary drastically between individuals, however if the device tracks a single patient throughout pregnancy cervical effacement could be accurately measured and risk of preterm delivery may be identified and combined with the other important obstetrical markers. Extended clinical study with a larger sample size is on the way.

Another device designed to predict maternal birth trauma is the antepartum tactile monitor (ATM). A highly specialized probe with a double curve sensor array designed to simulate the shape of fetal head during delivery (see upper panel in Figure 8), sets ATM apart from the VTI in addition to other differences in technological as well as in clinical aspects. The ATM vaginal probe uses a six degrees-of-freedom electromagnetic motion tracking sensor to generate accurate positions and orientations in space of all 168 tactile sensors to form tactile images. Using the probes geometry and the tactile imaging information, the computer performs finite element modeling (FEM) to calculate Young's modulus of the tissues. Examination procedure was designed with the probe being inserted and contacting the critical locations along the birth canal to receive stress-strain data for structures behind the vaginal walls and estimate the critical measurements between opposite sides of the vagina. The probe is pressed and slides along the posterior vaginal wall until reaching the vaginal introitus. Then the probe is rotated and the same procedure is done on the anterior vaginal wall.

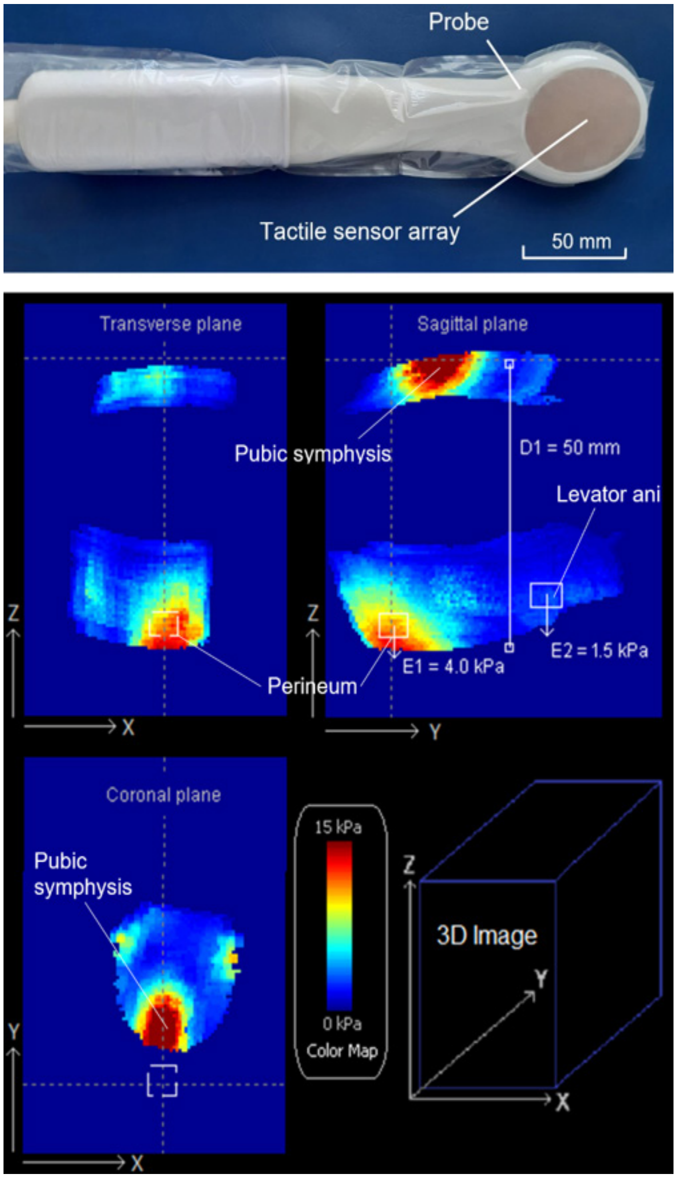

Figure 8. Top image shows the antepartum tactile monitor (ATM) probe, below is a screenshot from the ATM software interface showing tactile images in three orthogonal cross-sections with Y-axis representing distance along the vagina [adapted from (86)]

This procedure forms tactile images of the perineum, levator ani, and pubic symphysis (see Figure 8). In a study of the ATM, 20 nulliparous women were successfully examined with real-time observation of the probe location, applied load to the vaginal walls, and 3D tactile image composition. Authors concluded that tactile imaging reproducibly characterized perineal elasticity and pubic bone-perineal critical distance.[87] The ATM requires further technological development and clinical validation.

Tactile (stress) and ultrasound (anatomy, strain) image fusion may furnish new insights into soft tissue characterization. A study was completed to explore imaging performance and clinical value of

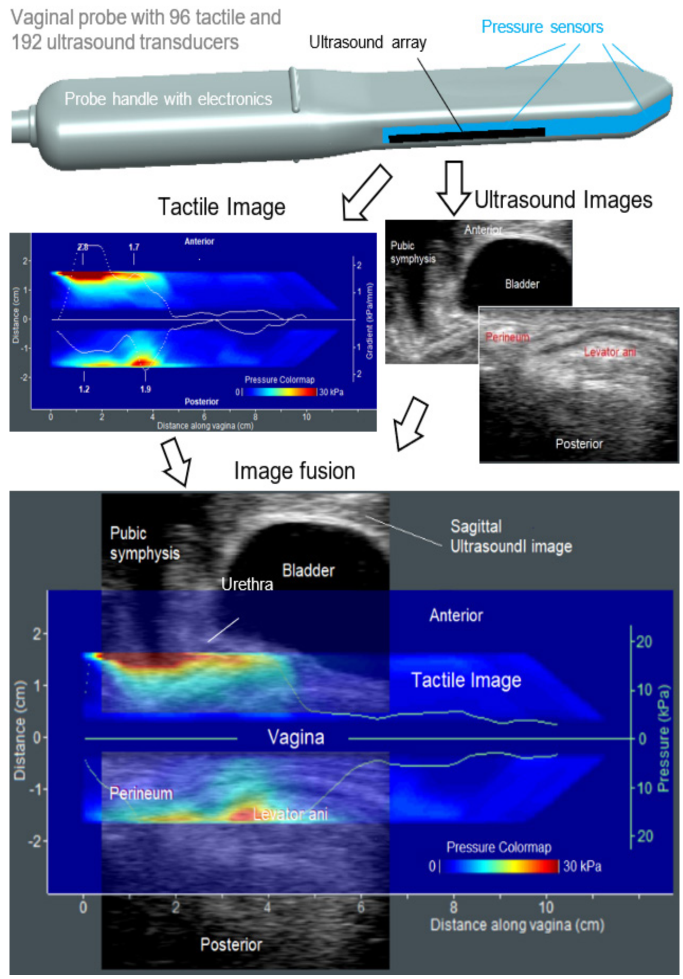

Figure 9. Tactile and ultrasound image fusion for test 1 (probe insertion) allows identification of pelvic anatomical landmarks and elasticity assessment for critical structures; 34 y.o. women with normal pelvic conditions [adapted from (88)]

vaginal tactile and ultrasound image fusion for characterization of the female pelvic floor. A novel probe with 96 tactile and 192 ultrasound transducers was designed. Intravaginal tactile and ultrasound images were acquired for vaginal wall deformations at probe insertion, elevation, rotation, Valsalva maneuver, voluntary contractions, involuntary relaxation, and reflex pelvic muscle contractions. Biomechanical mapping included tactile/ultrasound imaging and functional imaging. Twenty women were successfully studied with the probe. Tactile and ultrasound images for tissues deformation as well as functional images were recorded. Tactile (stress) and ultrasound (strain) images create stress-strain maps for the tissues of interest in absolute scale. Functional images allowed identification of active pelvic structures and their biomechanical characterization (anatomical measurements, contractive mobility and strength). Fusion of the modalities provides recognition and characterization of levator ani muscles (pubococcygeal, puborectal, iliococcygeal), perineum, urethral, and anorectal complexes critical in prolapse and/or incontinence development. Figure 9 presents an example of tactile ultrasound image fusion for yest 1 (probe insertion); identifying specific pelvic structures contributing to the tactile image composition (pubic symphysis, urethra in anterior and perineum, levator ani in posterior compartments). The pressure gradient distributions (kPa/mm) for vaginal wall deformation is orthogonal to vaginal canal direction (up and down) revealing elasticity distribution along the vagina. It has been concluded that vaginal tactile and ultrasound image fusion provides unique data for biomechanical characterization of the female pelvic floor.[88]

Further, the fusion of tactile and ultrasound techniques in one probe has fundamental importance, because these technologies are complementary to each other: Tactile images provide stress data and ultrasound images provide strain data as well as anatomy for the same tissue during its deformation. This approach might be used for the detection and characterization of endometriosis, adenomyosis, uterine fibroids and ovarian cancer; as well as breast cancer. Vaginal tactile ultrasound imaging may provide characterization of levator ani muscles (pubovaginal, puboanal, puborectal, iliococcygeal), perineum, urethra, and key ligaments (cardinal and uterosacral) critical in POP/UI development. Imaging of the anatomical and mechanical defects within the pelvic floor, provides anatomical and functional information necessary for a custom pessary design. The biomechanical data can be applied for computer simulation of surgical procedures and treatment effectiveness. Bringing novel biomechanical characterization for critical soft tissues/structures may provide extended scientific knowledge and improve clinical practice.

CONCLUSION

Obstetrics and gynecology are integral parts to the healthcare system and the continuation of a thriving population. While it is evident that diagnostics are progressing at a rapid pace it seems urogynecologists are relying on manual palpation and speculums for characterization and monitoring of the diseased conditions which effect millions of women. The new biomechanical paradigm for tissue/structure characterization may improve diagnostic accuracy of complex pelvic floor disorders and selection rate of optimal treatment. Biomechanical mapping of the female pelvic floor before surgery and probability assessment for success of specific surgical procedures and their combinations to recover healthy biomechanical status of the pelvic floor may change clinical practice.

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REFERENCES

1. Weintraub AY, Glinter H, Marcus-Braun N. Narrative review of the epidemiology, diagnosis and pathophysiology of pelvic organ prolapse. Int Braz J Urol 2020; 46: 5-14.
2. Iglesia CB, Smithling KR. Pelvic Organ Prolapse. Am Fam Physician 2017; 96: 179-85.
3. Jelovsek JE, Maher C, Barber MD. Pelvic organ prolapse. Lancet 2007; 369: 1027-38.
4. Al-Mukhtar Othman J, Åkervall S, Milsom I, Gyhagen M. Urinary incontinence in nulliparous women aged 25-64 years: a national survey. Am J Obstet Gynecol 2017; 216: 149.e1-149.e11.
5. Markland AD, Richter HE, Fwu CW, Eggers P, Kusek JW. Prevalence and trends of urinary incontinence in adults in the United States, 2001 to 2008. J Urol 2011; 186: 589-93.

6. Wu JM, Vaughan CP, Goode PS, et al. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. Obstet Gynecol 2014; 123: 141-8.
7. The American College of Obstetricians (ACOG) and Gynecologists and the American Urogynecologic Society (AUGS). Pelvic Organ Prolapse. Practice Bulletin Number 185. Female Pelvic Medicine & Reconstructive Surgery 2017; 23: 353-64.
8. Johnston SL. Pelvic floor dysfunction in midlife women. Climacteric 2019; 22: 270-6.
9. Lukacz ES, Santiago-Lastra Y, Albo ME, Brubaker L. Urinary Incontinence in Women: A Review. JAMA 2017; 318: 1592-604.
10. Kieserman-Shmokler C, Swenson CW, Chen L, Desmond LM, Ashton-Miller JA, DeLancey JO. From molecular to macro: the key role of the apical ligaments in uterovaginal support. Am J Obstet Gynecol 2020; 222: 427-36.
11. Gong R, Xia Z. Collagen changes in pelvic support tissues in women with pelvic organ prolapse. Eur J Obstet Gynecol Reprod Biol 2019; 234: 185-9.
12. Cohn JA, Smith AL. Management of Occult Urinary Incontinence with Prolapse Surgery. Curr Urol Rep 2019; 20: 23.
13. Hervé F, Abrams P, Bower W, et al. Is our current understanding and management of nocturia allowing improved care? International Consultation on Incontinence-Research Society 2018. Neurourol Urodyn 2019; 38(Suppl 5): S127-33.
14. Egorov V, Shobeiri AS, Takacs P, Hoyte L, Lucente V, van Raalte H. Biomechanical mapping of the female pelvic floor: prolapse versus normal conditions. Open J Obstetrics and Gynecol 2018; 8: 900-25.
15. Fuselier A, Hanberry J, Margaret Lovin J, Gomelsky A. Obesity and Stress Urinary Incontinence: Impact on Pathophysiology and Treatment. Curr Urol Rep 2018; 19: 10.
16. Cardenas-Trowers O, Meyer I, Markland AD, Richter HE, Addis I. A Review of Phytoestrogens and Their Association With Pelvic Floor Conditions. Female Pelvic Med Reconstr Surg 2018; 24: 193-202.
17. DeLancey JO. Pelvic floor anatomy and pathology. In: Biomechanics of the Female Pelvic Floor, Eds. Hoyte L, Damaser MS, Elsevier, 2016: 13-51.
18. Jallad K, Gurland B. Multidisciplinary Approach to the Treatment of Concomitant Rectal and Vaginal Prolapse. Clin Colon Rectal Surg 2016; 29: 101-5.
19. Cox L, Rovner ES. Lower urinary tract symptoms in women: epidemiology, diagnosis, and management. Curr Opin Urol 2016; 26: 328-33.
20. Egorov V, van Raalte H, Lucente V. Quantifying vaginal tissue elasticity under normal and prolapse conditions by tactile imaging. Int Urogynecol J 2012; 23: 459-66.
21. Shobeiri SA. 2D/3D Endovaginal and Endoanal Instrumentation and Techniques. In: Practical Pelvic Floor Ultrasonography: A Multi-compartmental Approach to 2D/3D/4D Ultrasonography of Pelvic Floor. Springer-Verlag New York, 2014: 19-44.
22. Petros PEP. The Female Pelvic Floor: Function, Dysfunction and Management According to the Integral Theory. 3rd Ed. Springer-Verlag: Berlin, 2010: 1-330.
23. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse sughjrgery. Obstet Gynecol 2014; 123: 1201-6.
24. Smith FJ, Holman CDJ, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. Obstet Gynecol 2010; 116: 1096-100.
25. Jelovsek JE, Barber MD, Brubaker L, at al. NICHD Pelvic Floor Disorders Network. Effect of Uterosacral Ligament Suspension vs Sacrospinous Ligament Fixation With or Without Perioperative Behavioral Therapy for Pelvic Organ Vaginal Prolapse on Surgical Outcomes and Prolapse Symptoms at 5 Years in the OPTIMAL Randomized Clinical Trial. JAMA 2018; 319: 1554-65.
26. Subak LL, Waetjen LE, van den Eeden S, Thom DH, Vittinghoff E, Brown JS. Cost of pelvic organ prolapse surgery in the United States. Obstet Gynecol 2001; 98: 646-51.
27. Morrison A, Levy R. Fraction of nursing home admissions attributable to urinary incontinence. Value Health 2006; 9: 272-4.
28. Nygaard I, Barber MD, Burgio KL, et al. Pelvic Floor Disorders Network. Prevalence of Symptomatic Pelvic Floor Disorders in US Women. JAMA 2008; 300: 1311-6.
29. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in U.S. Women: 2010 to 2050. Obstet Gynecol 2009: 114: 1278-83.
30. The American College of Obstetricians (ACOG) and Gynecologists and the American Urogynecologic Society (AUGS). Urinary Incontinence in Women. Practice Bulletin Number 155. Obstet Gynecol 2015; 126: e66-e81.
31. The American College of Obstetricians (ACOG) and Gynecologists and the American Urogynecologic Society (AUGS). Pelvic Organ Prolapse. Interim update. Female Pelvic Medicine & Reconstructive Surgery 2019; 25: 397-408.
32. Silva AC, Maglinte DD. Pelvic floor disorders: what's the best test? Abdom Imaging 2013; 38: 1391-408.
33. Swamy N, Bajaj G, Olliphant SS, et al. Pelvic floor imaging with MR defecography: correlation with gynecologic pelvic organ prolapse quantification. Abdom Radiol (NY) 2021; 46: 1381-89.
34. Taylor SA, Halligan S. Evacuation proctography and dynamic cystoproctography. In: Imaging Pelvic Floor Disorders. Eds.: Stoker J, Taylor SA, DeLancey JOL. Springer-Verlag, Berlin, 2008; 61-73.
35. Bahrami S, Khatri G, Sheridan AD, et al. Pelvic floor ultrasound: when, why, and how? Abdom Radiol (NY) 2021; 46: 1395-413.
36. Shobeiri SA (Editor). Practical Pelvic Floor Ultrasonography: A Multicompartmental Approach to 2D/3D/4D Ultrasonography of Pelvic Floor. Springer-Verlag New York, 2017: 1-368.
37. Dietz HP. Ultrasound in the assessment of pelvic organ prolapse. Best Pract Res Clin Obstet Gynaecol 2019; 54: 12-30.

38. Stone DE, Quiroz LH. Ultrasound Imaging of the Pelvic Floor. Obstet Gynecol Clin North Am 2016; 43: 141-53.

39. Minagawa T, Ogawa T, Ishizuka O, Nishizawa O. Impact of dynamic transrectal ultrasonography on pelvic organ prolapse. J Urol 2015; 193: 670-6.

40. Fitzgerald J, Richter LA. The Role of MRI in the Diagnosis of Pelvic Floor Disorders. Curr Urol Rep 2020; 21: 26.

41. Sakala MD, Shampain KL, Wasnik AP. Advances in MR Imaging of the Female Pelvis. Magn Reson Imaging Clin N Am 2020; 28: 415-31.

42. Alapati S, Jambhekar K. Dynamic Magnetic Resonance Imaging of the Pelvic Floor. Semin Ultrasound CT MR 2017; 38: 188-99.

43. Salvador JC, Coutinho MP, Venâncio JM, Viamonte B. Dynamic magnetic resonance imaging of the female pelvic floor-a pictorial review. Insights Imaging 2019; 10: 4.

44. Burns PA, Marecki MA, Dittmar SS, Bullough B. Kegel's exercises with biofeedback therapy for treatment of stress incontinence. Nurse Pract 1985; 10: 28, 33-4, 46.

45. Fitz FF, Resende AP, Stüpp L, Sartori MG, Girão MJ, Castro RA. Biofeedback for the treatment of female pelvic floor muscle dysfunction: a systematic review and meta-analysis. Int Urogynecol J 2012; 23: 1495-516.

46. Finazzi-Agro E, Gammie A, Kessler TM, et al. Urodynamics Useless in Female Stress Urinary Incontinence? Time for Some Sense-A European Expert Consensus. Eur Urol Focus 2020; 6: 137-45.

47. Clements MB, Zillioux JM, William Pike C, Rapp DE. Has the use of preoperative urodynamics for stress urinary incontinence surgery changed following the VALUE study? Neurourol Urodyn 2020; 39: 1824-30.

48. Yared JE, Gormley EA. The Role of Urodynamics in Elderly Patients. Clin Geriatr Med 2015; 31: 567-79.

49. Dillon BE, Zimmern PE. When are urodynamics indicated in patients with stress urinary incontinence? Curr Urol Rep 2012; 13: 379-84.

50. Sarvazyan A, Hall TJ, Urban MW, Fatemi M, Aglyamov SR, Garra BS. An overview of elastography-an emerging branch of medical imaging. Curr Med Imaging Rev 2011; 7: 255-82.

51. Wells PNT, Liang HD. Medical ultrasound: imaging of soft tissue strain and elasticity. J R Soc Interface 2011; 8: 1521-49.

52. Sarvazyan A, Rudenko OV, Swanson SD, Fowlkes JB, Emelianov SY. Shear wave elasticity imaging: a new ultrasonic technology of medical diagnostics. Ultrasound Med Biol 1998; 24: 1419-35.

53. Inoue Y, Kokudo N. Elastography for hepato-biliary-pancreatic surgery. Surg Today 2014; 44: 1793-800.

54. da Silva NPB, Hornung M, Beyer LP, et al. Intraoperative Shear Wave Elastography vs. Contrast-Enhanced Ultrasound for the Characterization and Differentiation of Focal Liver Lesions to Optimize Liver Tumor Surgery. Ultraschall Med 2019; 40: 205-11.

55. Rostaminia G, Awad C, Chang C, Sikdar S, Wei Q, Shobeiri SA. Shear Wave Elastography to Assess Perineal Body Stiffness During Labor. Female Pelvic Med Reconstr Surg 2019; 25: 443-7.

56. Low G, Kruse SA, Lomas DJ. General review of magnetic resonance elastography. World J Radiol 2016; 8: 59-72.

57. Hughes JD1, Fattahi N, Van Gompel J, Arani A, Meyer F, Lanzino G, Link MJ, Ehman R, Huston J. Higher-Resolution Magnetic Resonance Elastography in Meningiomas to Determine Intratumoral Consistency. Neurosurgery 2015; 77: 653-8; discussion 658-9.

58. Garra BS. Elastography: history, principles, and technique comparison. Abdom Imaging 2015; 40: 680-97.

59. Sarvazyan A. Mechanical imaging: a new technology for medical diagnostics. Int J Med Inform 1998; 49: 195-216.

60. Egorov V, van Raalte H, Sarvazyan A. Vaginal Tactile Imaging. IEEE Trans Biomed Eng 2010; 57: 1736-44.

61. Egorov V, van Raalte H, Lucente V, Sarvazyan A. Biomechanical characterization of the pelvic floor using tactile imaging. In: Biomechanics of the Female Pelvic Floor, Eds. Hoyte L, Damaser MS, Elsevier 2016: 317-48.

62. Sarvazyan A, Egorov V, Son JS, Kaufghfman CS. Cost-effective screening for breast cancer worldwide: current state and future directions. Breast Cancer (Auckl) 2008; 1: 91-9.

63. van Raalte H. Egorov V. Tactile imaging markers to characterize female pelvic floor conditions. Open J Obstet Gynecol 2015; 5: 505-15.

64. Egorov V, Lucente V, Shobeiri AS, Takacs P, Hoyte L, van Raalte H. Biomechanical mapping of the female pelvic floor: uterine prolapse versus normal conditions. EC Gynaecol 2018; 7: 431-46.

65. Egorov V, Ayrapetyan S, Sarvazyan AP. Prostate mechanical imaging: 3-D image composition and feature calculations. IEEE Trans Med Imaging 2006; 25: 1329-40.

66. Weiss RE, Egorov V, Ayrapetyan S, Sarvazyan N, Sarvazyan A. Prostate mechanical imaging: a new method for prostate assessment. Urology 2008; 71: 425-9.

67. Egorov V, Sarvazyan AP. Mechanical imaging of the breast. IEEE Trans Med Imaging 2008; 27: 1275-87.

68. Egorov V, Kearney T, Pollak SB, et al. Differentiation of benign and malignant breast lesions by mechanical imaging. Breast Cancer Res Treat 2009; 118: 67-80.

69. Egorov V, Tsyuryupa S, Kanilo S, Kogit M, Sarvazyan A. Soft tissue elastometer. Med Eng Phys 2008; 30: 206-212.

70. Turo D, Otto P, Egorov V, Sarvazyan A, Gerber LH, Sikdar S. Elastography and tactile imaging for mechanical characterization of superficial muscles. J Acoust Soc Am 2012; 132: 1983.

71. van Raalte H, Lucente V, Sonia E, et al. Intra- and inter-observer reproducibility of vaginal tactile imaging. Female Pelvic Med Reconstr Surg 2016; 22(Suppl 5): S130-1.

72. Bartlett JW, Frost C. Reliability, repeatability and reproducibility: Analysis of measurement errors in continuous variables. Ultrasound Obstet Gynecol 2008; 31: 466-75.

73. Bland JM, Altman DG. Applying the right statistics: Analyses of measurement studies. Ultrasound Obstet Gynecol 2003; 22: 85-93.

74. Vaginal Tactile Imager, FDA Approval K142355, May 28, 2015. Accessed on-line on May 5, 2022. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142355.pdf

75. Lucente V, van Raalte H, Murphy M, Egorov V. Biomechanical paradigm and interpretation of female pelvic floor conditions before a treatment. Int J Womens Health 2017; 9: 521-50.

76. Egorov V, Lucente V, VAN Raalte H, et al. Biomechanical mapping of the female pelvic floor: changes with age, parity and weight. Pelviperineology 2019; 38: 3-11.

77. Egorov V, Takacs P, Shobeiri SA, et al. Predictive value of biomechanical mapping for pelvic organ prolapse surgery. Female Pelvic Med Reconstr Surg 2021; 27: e28-e38.

78. Lauterbach R, Gruenwald I, Matanes E, Matar K, Weiner Z, Lowenstein L. The impact of vaginal hysterectomy and uterosacral ligament suspension on vaginal elasticity and sexual function. Eur J Obstet Gynecol Reprod Biol 2021; 258: 29-32.

79. Matanes E, Linder R, Lauterbach R, et al. The impact of radiation therapy on vaginal biomechanical properties. Eur J Obstet Gynecol Reprod Biol 2021; 264: 36-40.

80. Lauterbach R, Gutzeit O, Matanes E, et al. Vaginal Fractional Carbon Dioxide Laser Treatment and Changes in Vaginal Biomechanical Parameters. Lasers Surg Med 2021; 53: 1146-51.

81. Bensmail H. Evolutions in diagnosis and treatment of vaginal laxity. EC Gynaecology 2018; 7: 321-7.

82. van Raalte H, Bhatia N, Egorov V. Is it all just smoke and mirrors?: vaginal laser therapy and its assessment by tactile imaging. International Urogynecocolgy Journal 2016; 27(Suppl1): S120-1.

83. Egorov V, van Raalte H, Takacs P, Shobeiri SA, Lucente V, Hoyte L. Biomechanical integrity score of the female pelvic floor. Int Urogynecol J 2022; 33: 1617-31.

84. Hajian-Tilaki K. Receiver operating characteristic (ROC) curve analysis for medical diagnostic test evaluation. Caspian J Intern Med 2013; 4: 627-35.

85. Egorov V, Rosen T, van Raalte H, Kurtenoks V. Cervical Characterization with Tactile-Ultrasound Probe. Open J Obstet Gynecol 2020: 10: 85-99.

86. Rusavy Z, Kalis V, Aglyamov S, Egorov V. Feasibility and safety of antepartum tactile imaging. Int Urogynecol J 2021; 32: 1785-91.

87. Brandt JS, Rosen T, van Raalte H, Kurtenos V, Egorov V. Characterization of perineum elasticity and pubic bone-perineal critical distance with a novel tactile probe: results of an intraobserver reproducibility study. Open J Obstet Gynecol 2020; 10: 493-503.

88. Egorov V, van Raalte H, Shobeiri S. Tactile and ultrasound image fusion for functional assessment of the female pelvic floor. Open J Obstet 2021; 11: 674-88.