White Paper

Biomechanical Mapping in Pelvic Organ Prolapse Management

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1. Executive Summary

Biomechanical mapping of the female pelvic floor is a new methodology for characterization of pelvic diseased conditions which caused by changes in tissue elasticity, pelvic support and function.

Vaginal Tactile Imager (VTI) provides a comprehensive set of biomechanical parameters to aid in diagnosis and evaluation of vaginal and pelvic floor conditions. It allows characterization of tissue elasticity, pelvic support and function in patients with pelvic organ prolapse (POP). The VTI has FDA approval and CPT Code. The VTI can be used for POP treatment planning and monitoring.

This approach has been validated in 6 completed clinical trials. Another 14 clinical trials with the VTI are under way. Recent study with 255 surgical procedures performed at 5 clinical sites has demonstrated that biomechanical changes resulting from POP surgery can be predicted with the VTI.

2. Introduction

A Recent survey by the American Urogynecologic Society identified the research questions with the highest priority pertaining to pathophysiology and treatment of pelvic organ prolapse (POP) [1]. According to the survey, mechanistic research on pelvic supportive structures, clinical trials to optimize outcomes after POP surgery and evidence-based quality measures for POP outcomes are among the main focus areas. These research questions are relevant due to the overall recurrence rate of 20% in vaginal prolapse surgery [2]. The surgical failure rate is as high as 61.5% in the uterosacral ligament suspension group and 70.3% in the sacrospinous ligament fixation group in the representative randomized clinical study with the 5-year outcomes [3].

Many female pelvic floor disorders, including POP, are manifested by concurring changes in the mechanical properties of pelvic organs. Therefore, the biomechanical mapping of response to applied pressure or load within the pelvic floor and muscle contractive patterns opens new possibilities in the biomechanical assessment and monitoring of the female pelvic floor conditions.

3. Biomechanical Mapping

3.1. Definitions

Tactile Imaging is a medical imaging modality translating 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 soft tissue surface under applied deformation and *x,y,z* are coordinates where pressure *P* was measured. The tactile image is a pressure map on which the direction of tissue deformation must be specified.

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 pressure P was measured. It may include: muscle voluntary contraction, involuntary reflex contraction, involuntary relaxation, specific maneuvers.

Biomechanical Mapping = Tactile Imaging + Functional Tactile Imaging

The biomechanical mapping allows a comprehensive set of parameters to characterize tissue elasticity, pelvic support and function.

3.2. Technological solution and patents

A Vaginal Tactile Imager (VTI), model 2S (Advanced Tactile Imaging, New Jersey), was developed and clinically validated for the biomechanical mapping of the pelvic floor [4-6]. The VTI probe is equipped with a pressure sensor array which measures the dynamic pressure response to applied deformation, integrates and visualizes in real time the biomechanical map of the examined area.

The VTI probe, as shown in **Figure 1**, is equipped with 96 pressure (tactile) sensors spaced at 2.5 mm consecutively on both sides of the probe, an orientation sensor, and temperature controllers to provide the probe temperature close to a human body. During the clinical procedure, the VTI probe allows acquisition of the pressure response patterns during tissue/structure deformations from vaginal walls along the entire vagina to visualize vaginal and pelvic floor support structures, and to record pelvic floor muscle contraction patterns. The VTI software provides data visualization, analysis, information and reporting tools. The acquired data can then be used for quantitative biomechanical assessment of the vaginal and pelvic floor conditions.

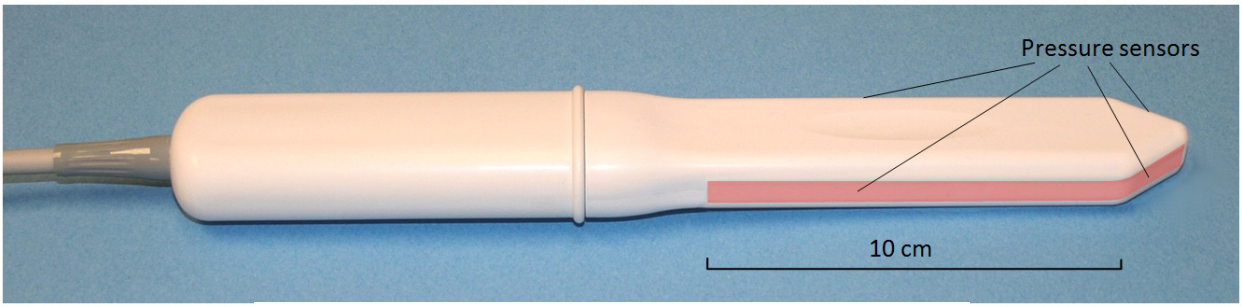

Figure 1. *Vaginal Probe. Pressure sensors are aligned on the outer surfaces of the probe (highlighted in the image).*

The VTI examination procedure consists of eight Tests (see **Table 1**). Tests 1–5 and 7–8 provide data for anterior/posterior compartments; test 6 provides data for left/right sides [9, 11]. This VTI probe allows 3–15 mm tissue deformation at the probe insertion (Test 1), 20–45 mm tissue deformation at the probe elevation (Test 2), 5–7 mm deformation at the probe rotation (Test 3) and recording of dynamic responses at pelvic muscle contractions (Tests 4–8) [7-13]. The probe maneuvers in Tests 1–3 are used to accumulate multiple pressure patterns from the tissue surface and create an integrated tactile image for the investigated area employing the image composition algorithms [6].

Table 1.*VTI examination includes 8 procedure tests.*

Test No.	Procedure	Output
Test 1	Probe insertion	Tactile image for vaginal anterior and posterior compartments along the entire vagina (resistance, force, work, tissue elasticity)
Test 2	Probe elevation	Tactile image for anterior and posterior compartments which related to pelvic floor support structures (pressure value sand pressure gradients for specified/critical locations)
Test 3	Probe rotation	Tactile images for left and right sides along the entire vagina (force and pressure values for specified positions/locations)
Test 4	Valsalva maneuver	Dynamic pressure response from opposite sites (anterior *vs* posterior) along the entire vagina (changes in force and pressure; pressure peak displacements).
Test 5	Voluntary muscle contraction	Dynamic pressure response from opposite sites (anterior *vs* posterior) along the entire vagina (changes in force and pressure; maximum pressure values).
Test 6	Voluntary muscle contraction (sides)	Dynamic pressure response from opposite sides (left *vs* right) along the entire vagina (changes in force and pressure; maximum pressure values).
Test 7	Involuntary relaxation	Dynamic pressure response from opposite sites (anterior *vs* posterior) along the entire vagina (changes in pressure).
Test 8	Reflex muscle contraction (cough)	Dynamic pressure response from opposite sites (anterior *vs* posterior) along the entire vagina (changes in force and pressure; pressure peak displacements).

Patents: 9,861,316; 8,840,571; 8,419,659; 8,187,208; 8,142,368; 8,069,735; 8,052,622 and counting.

3.3. FDA Indications for Use

Device Trade/Proprietary Name: Vaginal Tactile Imager
Device Class: Class II
Product Code: HIR
Regulation Number: 884.1425
510(k) Number: K142355

Indications for Use: The Vaginal Tactile Imager 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.

3.4. Parameters and their interpretation

Overall, VTI software automatically calculates 52 biomechanical parameters for specified locations in the pelvic floor. Every parameter is placed in the scale from normal to diseased conditions. Twelve (12) of them characterize tissue elasticity, 12 for pelvic support and 28 for pelvic functional assessment [11, 12]. The anatomical assignment of the targeting/contributing pelvic structures into the specified parameters is based on the functional anatomy of the pelvis [9, 14–18].

3.5. Inter- and intra-observer measurement reproducibility

The VTI reproducibility was studied with 1920 VTI measurements (12 subjects x 10 parameters x 4 locations x 4 VTI examinations). Specifically, intra-observer Intraclass Correlation Coefficients (ICC) were found in the range from 0.80 for Test 8 to 0.92 for Test 3 with average value of 0.87 for all 10 parameters. Inter-observer ICCs were found in the range from 0.73 for Test 2 and Test 8 to 0.92 for Test 3 with average value of 0.82. Furthermore, Intra-observer 95% limits of agreement were in the range from ±11.3% for Test 1 to ±19.0%% for Test 8 with the average value of ±15.1%. Inter-observer 95% limits of agreement were in the range from ±12.0% for Test 5 to ±26.7% for Test 2 with the average value of ±18.4% [8]. These correspond to moderate VTI intra- and inter-observer reproducibility. The anticipated average error in VTI parameters was 14% for intra-observer and 18% for inter-observer measurements.

4. Improved Characterization of Pelvic Organ Prolapse

The VTI study on 96 subjects with normal and POP conditions (42 subjects had normal pelvic floor conditions and 54 subjects had POP) demonstrated that 33 of 52 VTI parameters statistically sensitive ($p<0.05$; *t*-test) to the POP development. Among these 33 parameters, 11 parameters show changes (decrease) in tissue elasticity, 8 parameters show deteriorations in pelvic support and 14 parameters show weakness in muscle functions for POP versus normal conditions [11]. It means that biomechanical mapping of the female pelvic floor with the VTI provides a unique set of parameters characterizing POP versus normal conditions. These objectively measurable biomechanical transformations of pelvic tissues, support structures, and functions under POP may be used in future research and practical applications.

Figures 2-10 illustrate normal and POP conditions in clinical cases with VTI findings.

The VTI characterization of uterine prolapse is reported in Ref. [13].

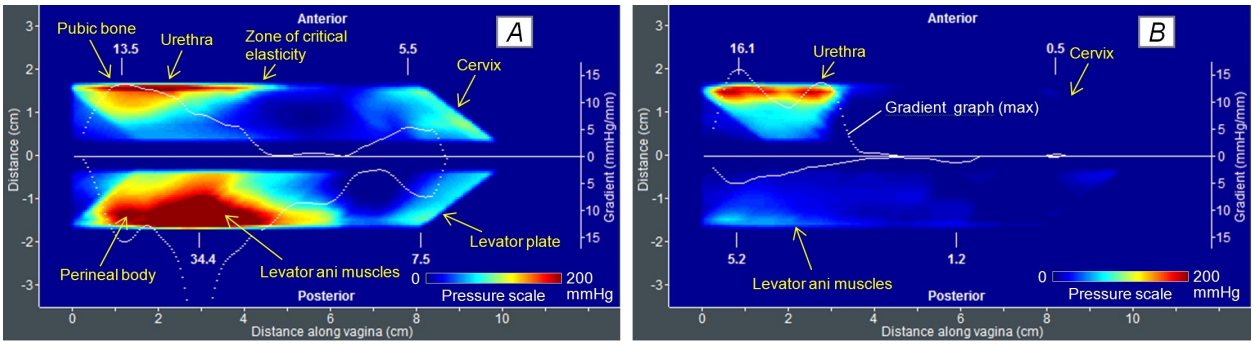

Figure 2. *Test 1 (VTI probe insertion) results for two patients with stiff (A) and much softer vaginal tissue (B). White lines show spatial pressure gradients for anterior and posterior compartments.*

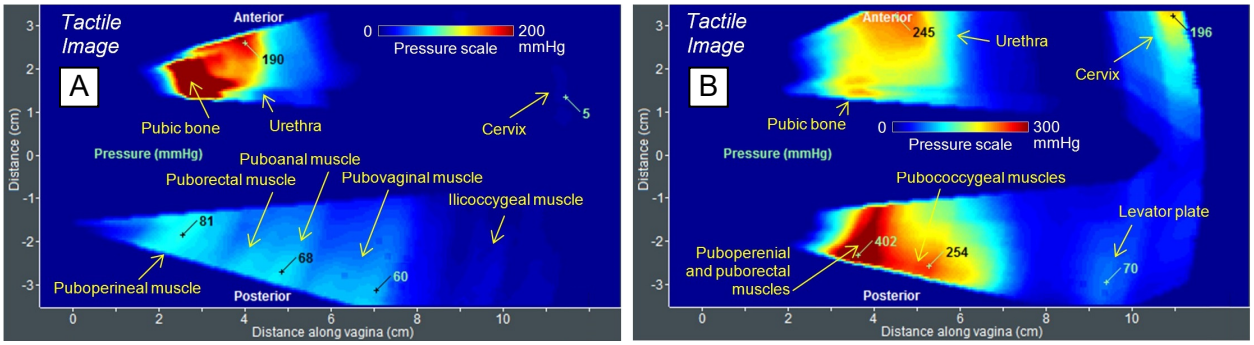

Figure 3. *Test 2 (VTI probe elevation) results for two patients with weak (A) and strong pelvic floor support (B).*

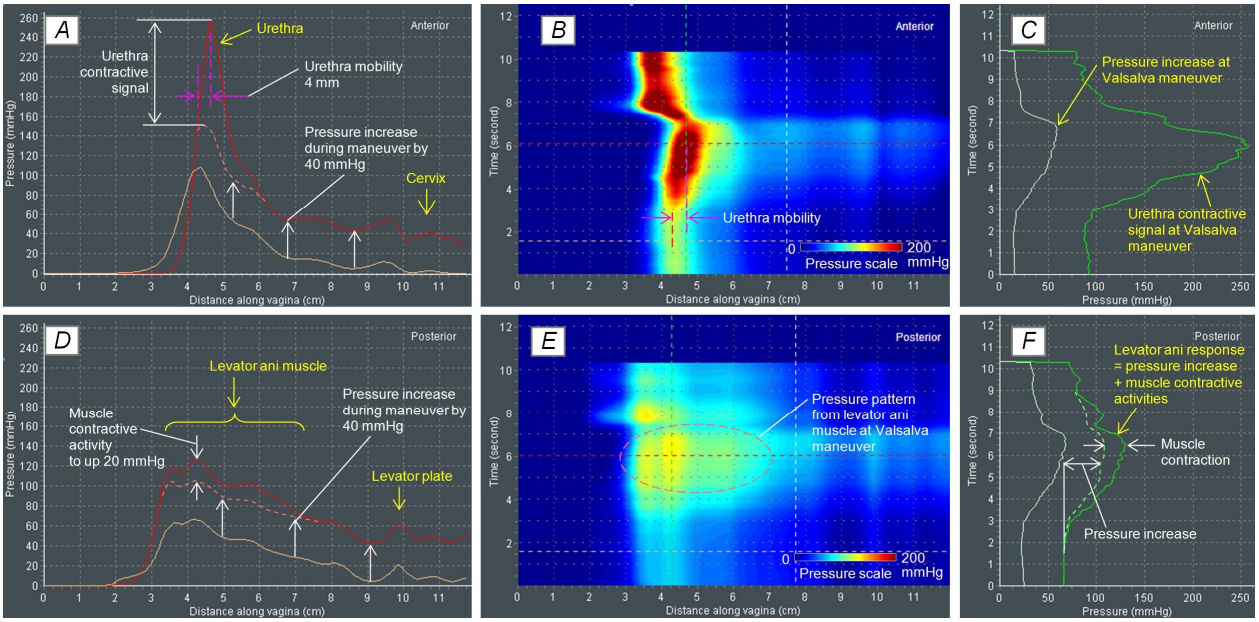

Figure 4. *Test 4 (Valsalva maneuver) results for a 51 y.o. patient with normal pelvic support. A, D – anterioir and posterior pressure patterns at Valsalva maneuver (red lines) and at rest (light brown lines); B, E – anterior and posterior dynamic pressure pattern along the vagina; C, F – pressure dynamic at specific locations (see dotted lines in B, E).*

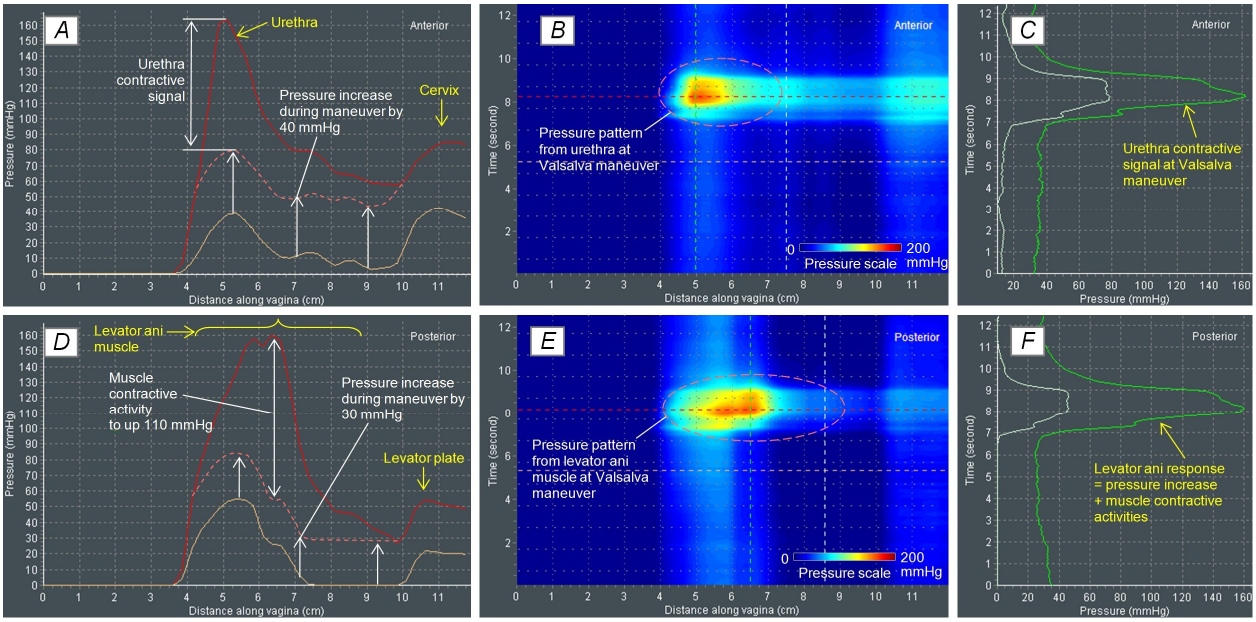

Figure 4. *Test 4 (Valsalva maneuver) results for a 52 y.o. patient with normal pelvic floor support. A, D – anterior and posterior pressure patterns at Valsalva maneuver (red lines) and at rest (light brown lines); B, E – anterior and posterior dynamic pressure pattern along the vagina; C, F – pressure dynamic at specific locations (see dotted lines in B, E).*

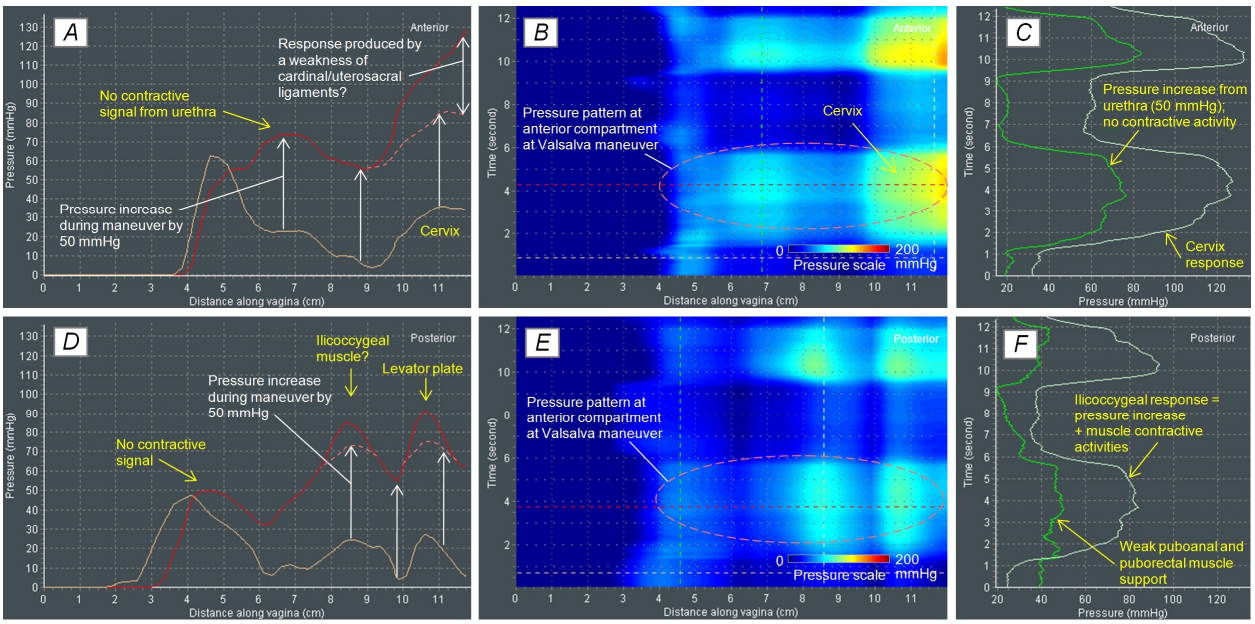

Figure 5. *Test 4 (Valsalva maneuver) results for a 66 y.o. patient with Stage IV prolapse. A, D – anterior and posterior pressure patterns at Valsalva maneuver (red lines) and at rest (light brown lines); B, E – anterior and posterior dynamic pressure pattern along the vagina; C, F – pressure dynamic at specific locations (see dotted lines in B, E).*

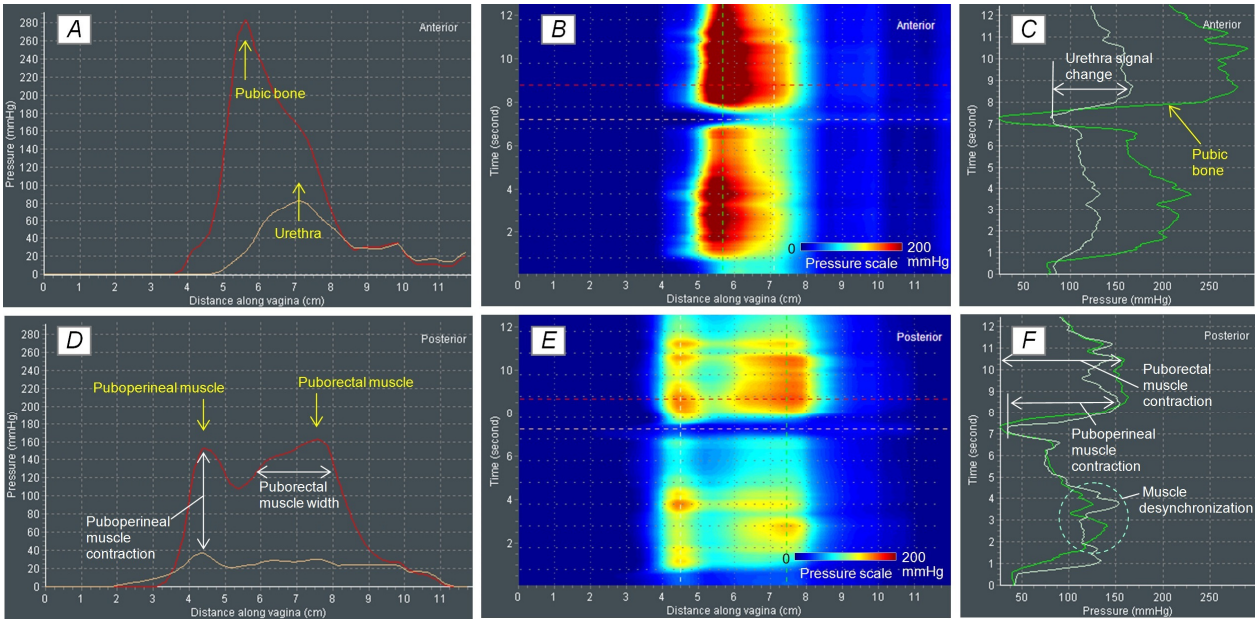

Figure 6. *Test 5 (voluntary muscle contraction) results for a 35 y.o. patient with normal pelvic floor support. A, D – anterior and posterior pressure patterns at muscle contraction (red lines) and at rest (light brown lines); B, E – dynamic pressure pattern along the vagina; C, F – muscle contraction dynamic at specific locations (see dotted lines in B, E).*

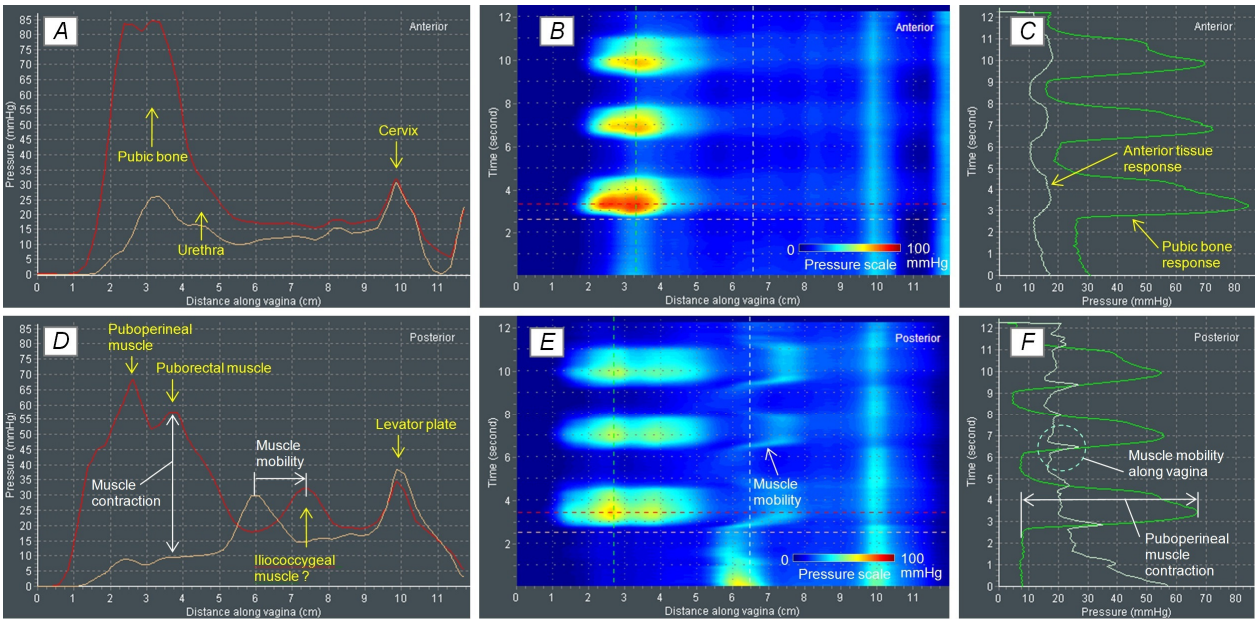

Figure 7. *Test 5 (voluntary muscle contraction) results for an 80 y.o. patient with Stage II prolapse. A, D – anterior and posterior pressure patterns at muscle contraction (red lines) and at rest (light brown lines); B, E – dynamic pressure pattern along the vagina; C, F – muscle contraction dynamic at specific locations (see dotted lines in B, E).*

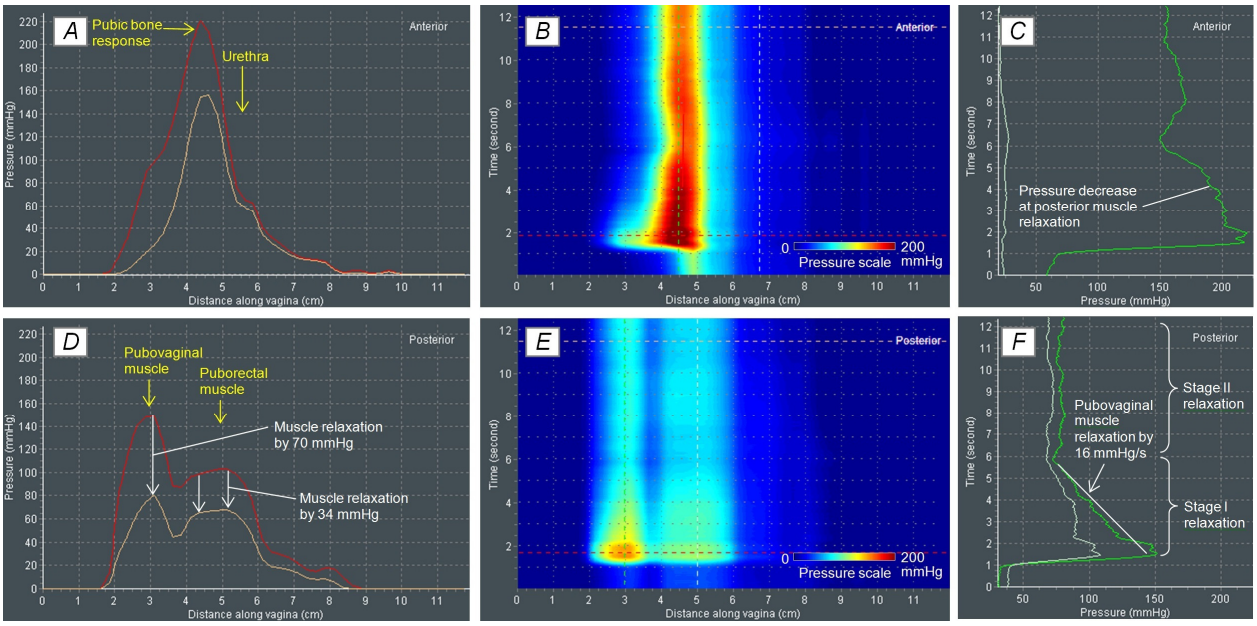

Figure 8. *Test 8 (involuntary muscle relaxation) results for a 71 y.o. patient with Stage II prolapse. A, D – anterior and posterior pressure patterns at muscle relaxation (from red to light brown lines); B, E – anterior and posterior dynamic pressure pattern along the vagina; C, F – muscle relaxation dynamic at specific locations (see dotted lines in B, E).*

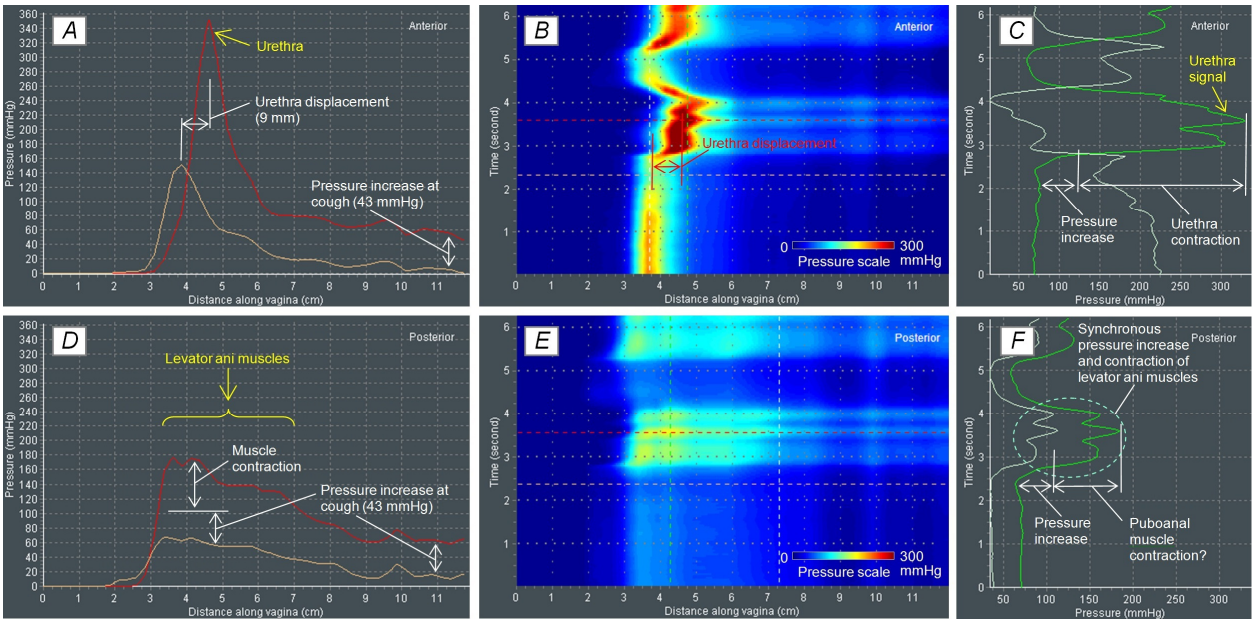

Figure 9. *Test 8 (involuntary muscle contraction) results for a 51 y.o. patient with normal pelvic floor support. A, D – pressure patterns at muscle contraction (red lines) and at rest (light brown lines); B, E – anterior and posterior dynamic pressure pattern along the vagina; C, F – muscle contraction dynamic at specific locations (see dotted lines in B, E).*

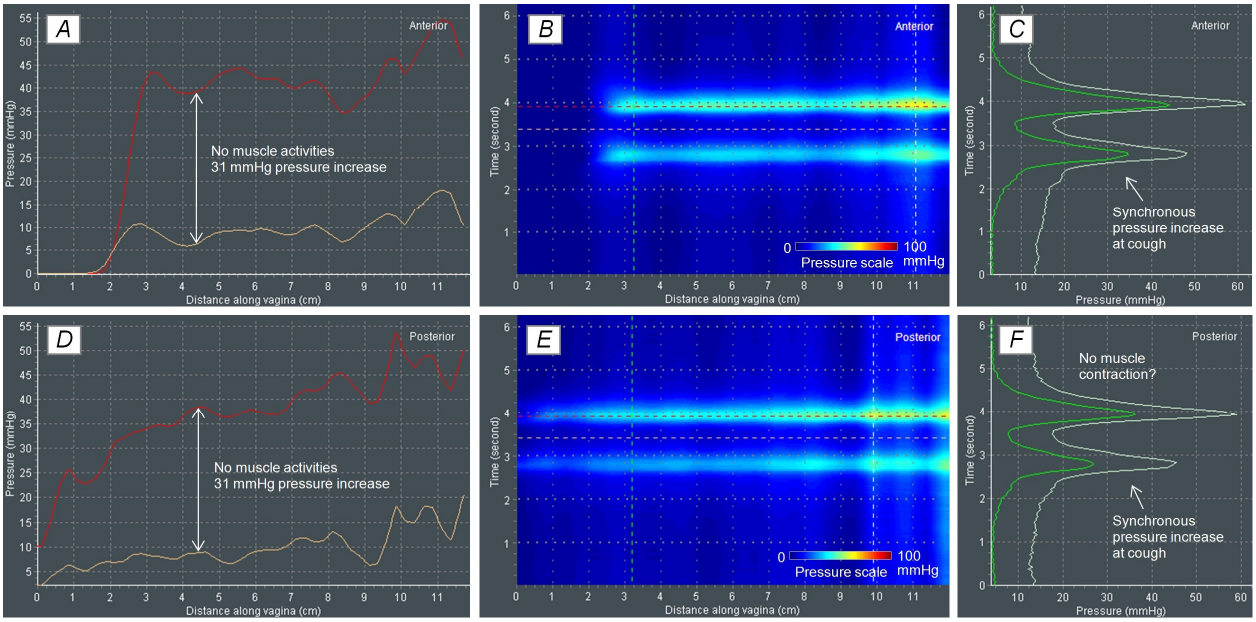

Figure 10. *Test 8 (involuntary muscle contraction) results for a 64 y.o. patient with Stage IV prolapse. A, D – pressure patterns at muscle contraction (red lines) and at rest (light brown lines); B, E – right and left sides dynamic pressure pattern along the vagina; C, F – muscle contraction dynamic at specific locations (see dotted lines in B, E).*

5. Treatment Planning and Monitoring

5.1. Non-surgical treatment monitoring

A pilot clinical study with 12 subjects to explore tissue atrophy changes after applied vaginal laser treatment demonstrated significant improvements of vaginal tissue elasticity and pelvic floor support in 8 of 12 patients. The pelvic muscle strength for voluntary muscle contractions increased in 10 of 12 patients from 63% to 233%. It was concluded that VTI allows monitoring biomechanical transformation of tissues after the vaginal laser treatment [19].

Another clinical study concluded that VTI allows monitoring of biomechanical transformation of tissues after the radiofrequency treatment. Dynamic Quadripolar Radiofrequency treatment was used in that study [20].

5.2. Pre-operative assessment of prolapse conditions (case report)

We report here on 68-year-old patient who complained of increasing vaginal pressure, discomfort, backache and bulging exacerbated by lifting and straining. The pelvic floor conditions were categorized as POP Stage III in anterior and POP Stage II in posterior compartments; no uterine prolapsed and no prior pelvic surgery. The patient had stress urinary incontinence. The VTI examination procedure according to CPT Code 0487T (biomechanical mapping, transvaginal, with report) included 8 tests as listed in Table 1. The VTI test results are present in **Figures 11 - 15**. The VTI Tests 1 provides data related to the vaginal tissue elasticity (**Figure 11**). Test 2 provides identified parameters (pressure responses to tissue deflection) related to the pelvic support structure (**Figure 12**). Tests 4, 5 and 8 provide comprehensive information about the pelvic functions such as muscles contraction strength and muscle mobility (**Figures 13-15**). The following surgical procedures were completed on this patient to correct the pelvic deficiency: sacral colpopexy; abdominal enterocele repair and sling insertion [21].

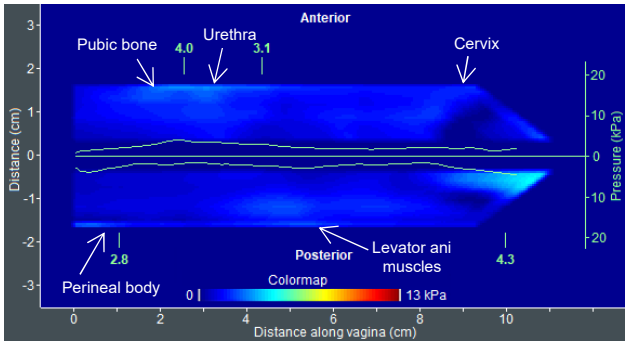

Figure 11. *A tactile image acquired during the VTI probe insertion (Test 1) with anatomical landmarks and maximum pressure graphs (green lines, kPa) along anterior and posterior compartments.*

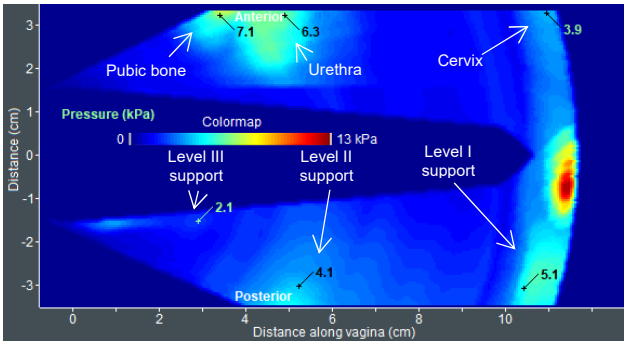

Figure 12. *A tactile image acquired during the VTI probe elevation (Test 2) with anatomical landmarks and pressure values at specified locations.*

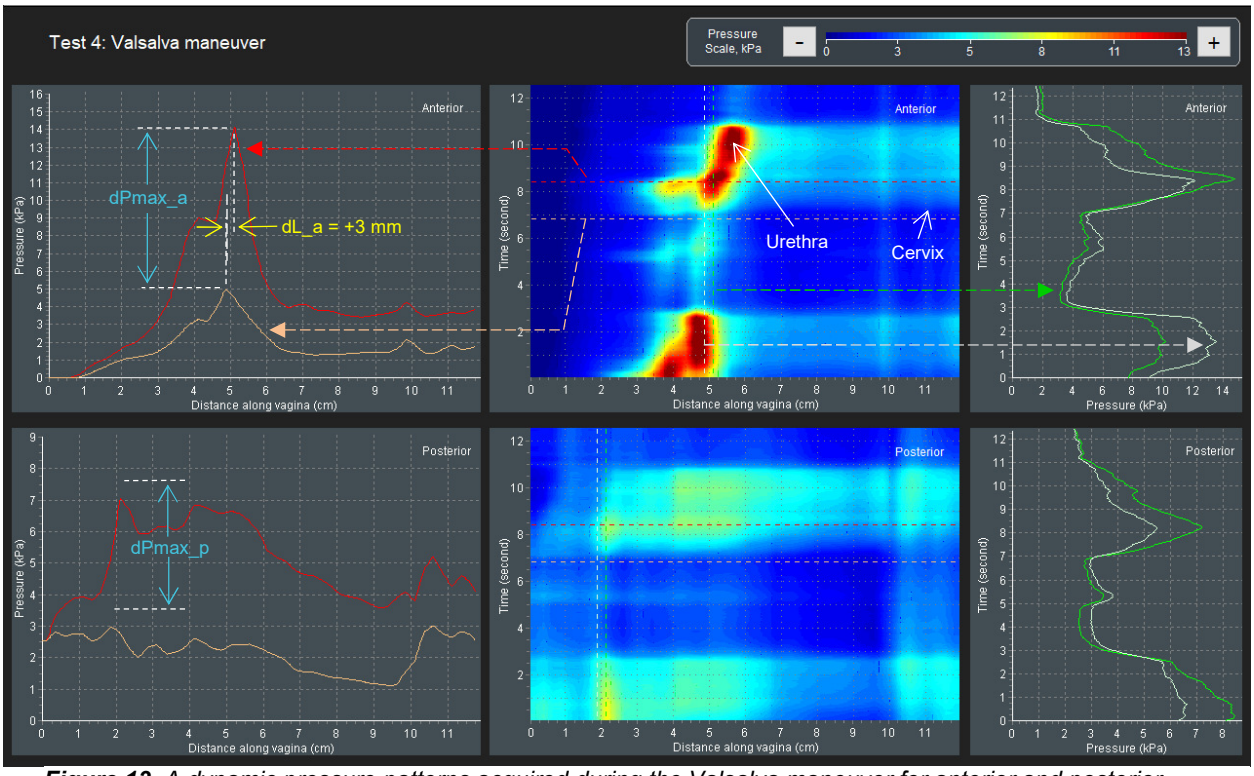

Figure 13. *A dynamic pressure patterns acquired during the Valsalva maneuver for anterior and posterior compartments (Test 4).*

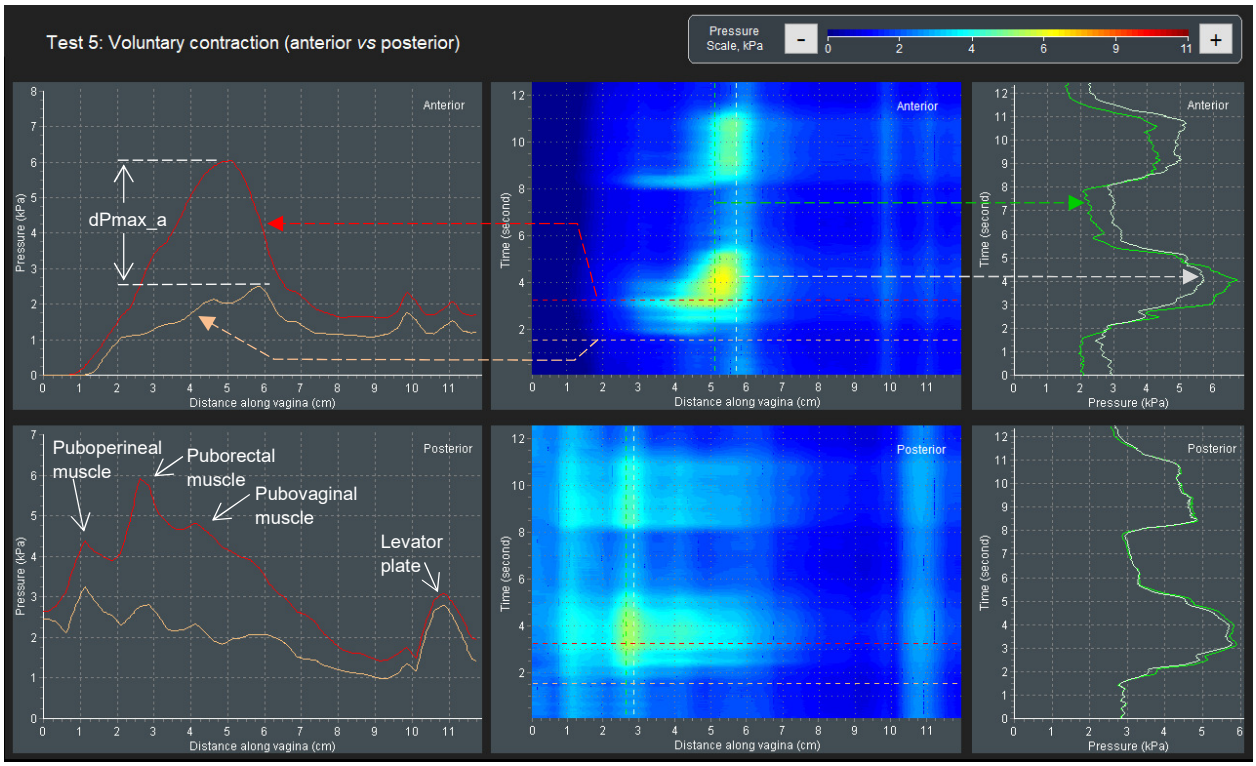

Figure 14. *A dynamic pressure patterns acquired during the voluntary muscle contraction for anterior and posterior compartments (Test 5).*

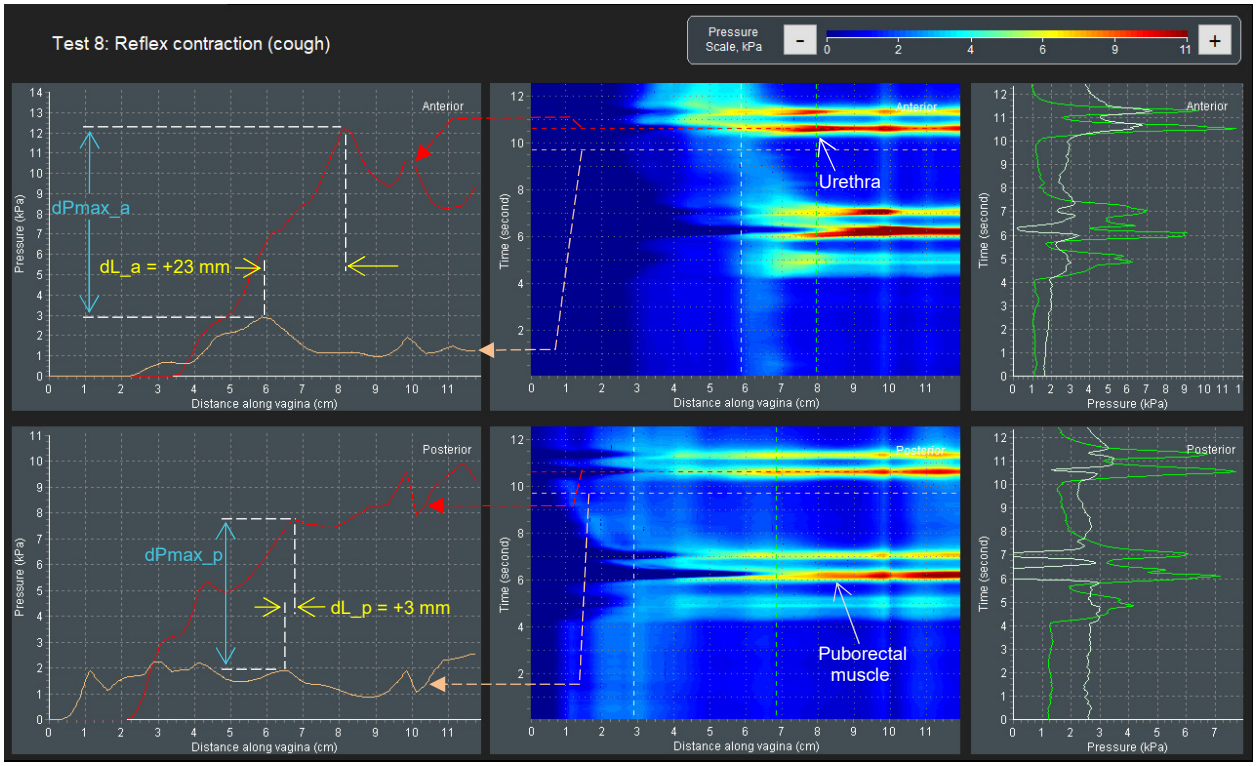

Figure 15. *A dynamic pressure patterns acquired during the reflex contraction (cough) for anterior and posterior compartments (Test 8).*

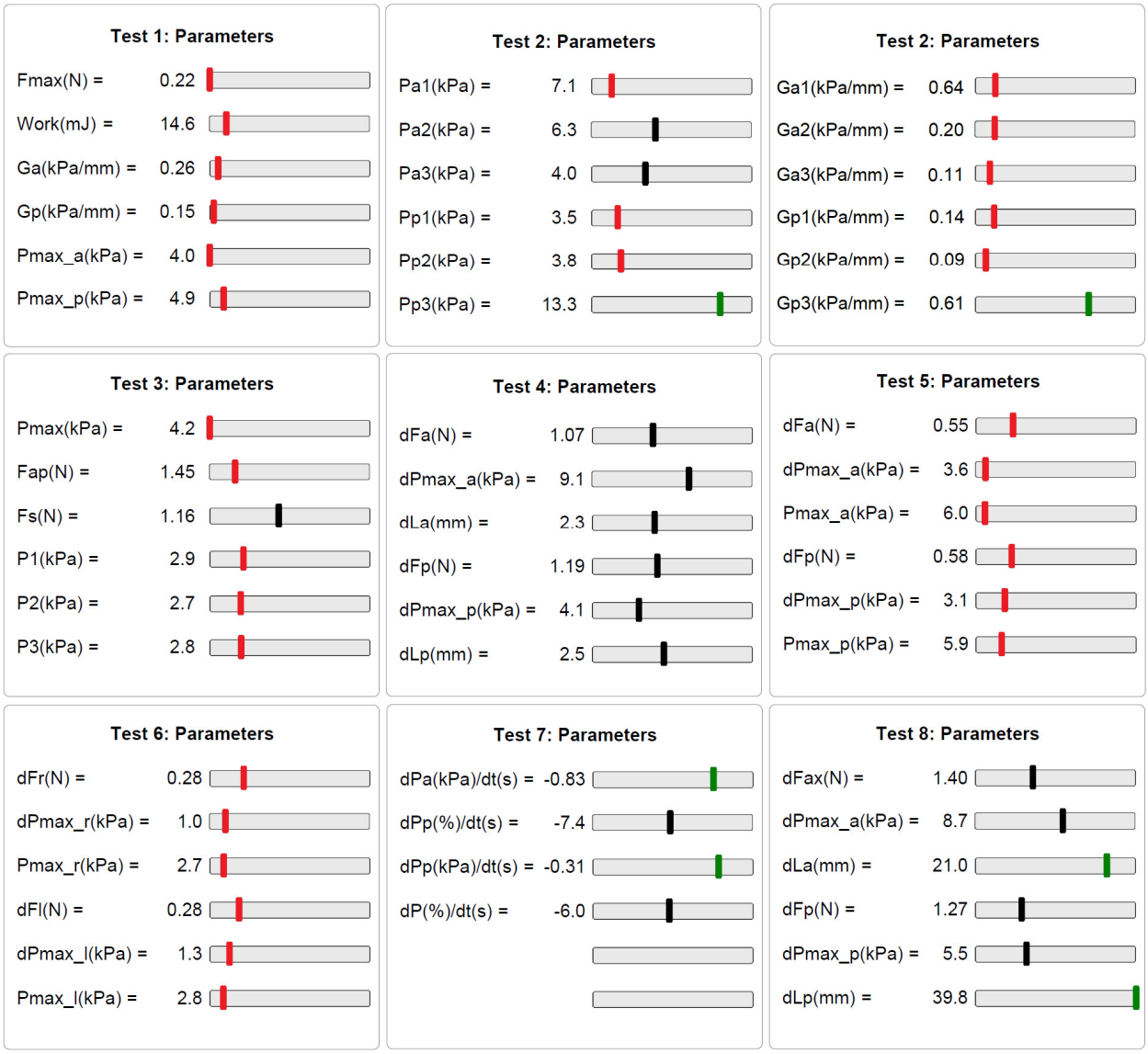

Figure 16. *A set of 52 biomechanical parameters was provided by VTI in the preoperative examination of this* 68-year-old *patient.*

Red *color bar means this parameter value is placed in lower 25% of scale from diseased to normal conditions;*

Black *color bar means this parameter value is placed between 25% and 75% of scale; and*

Green *color bar means this parameters is placed in upper 25% (from 75% to 100%) of scale from diseased to normal conditions.*

Parameter explanation and interpretation can be found in Ref. [11].

5.3. Predictive value of biomechanical mapping for pelvic organ prolapse surgery

POP surgery aims to restore the anatomy, biomechanical integrity, and functions of the female pelvic floor [22, 23]. The clinical study was designed to explore biomechanical changes in pelvic floor after POP surgery. A biomechanical mapping of the pelvic floor was performed before and after the surgery. 78 subjects with 255 surgical procedures were analyzed across the five participating clinical sites. The biomechanical data for 52 parameters were acquired by the VTI. The two-sample *t*-test ($p<0.05$) was employed to test the null hypothesis that pre-surgery data in Group 1 (positive parameter change after surgery) and pre-surgery data in Group 2 (negative parameter change after surgery) belonged to the same distribution. All 52 *t*-tests for Group 1 versus Group 2 had *p*-value in the range form $4.0*10^{-10}$ to $4.3*10^{-2}$ associating all of the 52 parameter changes after surgery with the pre-surgical conditions. The *p*-value of before and after surgery correlation ranged from $3.7*10^{-18}$ to $1.6*10^{-2}$ for 50 of 52 tests with Pearson correlation coefficient ranging from -0.79 to -0.27. Thus, vaginal tactile imaging parameters strongly correlated weak pelvic floor pre-surgery with the positive POP surgery outcome of improved biomechanical properties [24]. **Figure 17 and 18** show two examples of how after surgery change depends on presurgery value of the same VTI parameter.

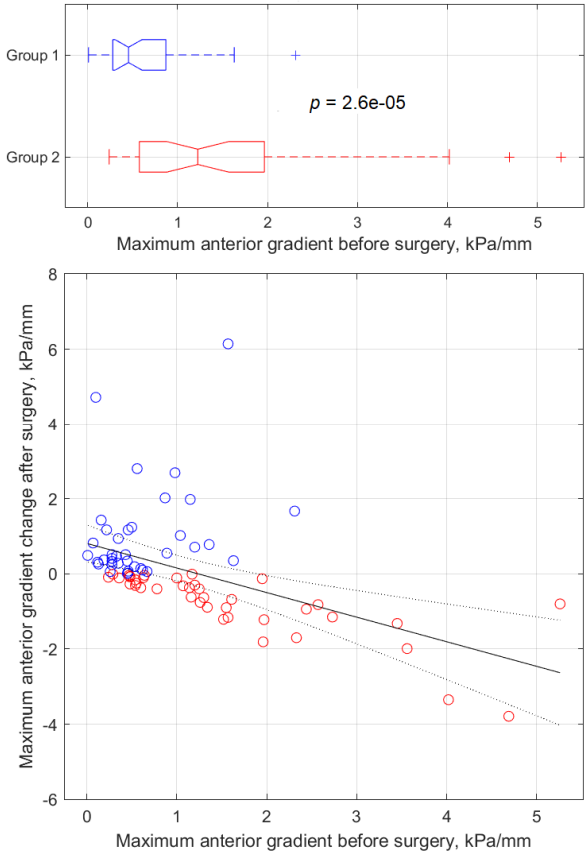

Figure 17. *Anterior elasticity change after surgery versus its pre-surgery value.*

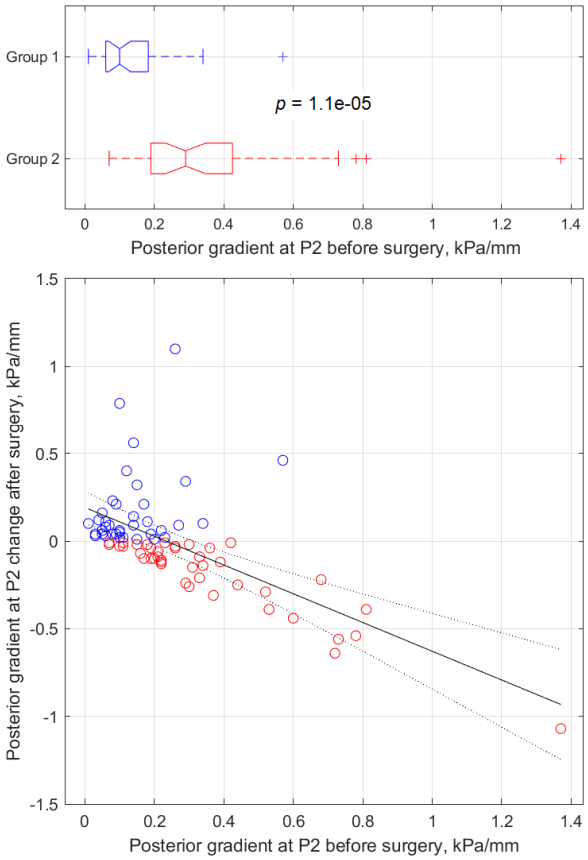

Figure 18. *Posterior Level II pelvic support change after surgery versus its pre-surgery value.*

This allows the conclusion that:

- POP surgery, in general, improves the biomechanical conditions and integrity of the weak pelvic floor
- Pre-surgical biomechanical parameters can predict changes resulting from POP surgery

6. CPT Coding and Reimbursement

The American Medical Association (AMA) established a new Category III Reimbursement Code for the examination procedure with the VTI: 0487T "Biomechanical mapping, transvaginal with report".

AMA Description of Procedure (0487T): Physician performs biomechanical mapping using a vaginal probe. Multiple (up to 8) sub-procedures are completed to collect comprehensive biomechanical data for characterization of the vaginal and pelvic floor conditions. The procedure images are visualized in real time on a display to provide feedback to an operator and mapped 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. The measurements include pressure response distribution along the anterior and posterior compartments of the vagina at probe insertion; pressure response pattern of pelvic floor support structures and ligaments at probe elevation; circumferential pressure mapping of the vaginal walls to assess irregularities along the entire vagina due to implants, hypertonic muscles or scar tissue; pattern of involuntary muscle contractions along the entire vagina while performing the Valsalva maneuver; pattern of voluntary muscle contractions for anterior vs posterior and for left vs right sides; pattern for involuntary muscle contraction (cough) and involuntary relaxation by assessing the muscles resting tone and contraction strength distributions of the anterior and posterior compartments. The physician then interprets the results, dictates a report and discusses the results with the patient.

The payment for the claim is not guaranteed and is at the discretion of each individual insurance company. Moreover, there is no set payment amount approved by the AMA. If coverage is denied, it is recommended that providers submit supplementary information to justify the claims and the necessity of the procedure. ATI can assist with the informational materials for the justification. The company has developed Payment Rationale for the suggested billing at 4.70 RVU that could be provided upon request. There is also a possibility of the "patient-pay" model. Further, ATI offers purchase and lease options of the device that could help mitigate the reimbursement risk.

The Company provides the device delivery, training, technical support with 24 months warranty.

7. Acknowledgements

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