Presentation Number: 188

3-D IMAGING AND QUANTIFICATION OF VAGINAL TISSUE ELASTICITY UNDER NORMAL AND PROLAPSE CONDITIONS

H. VAN RAALTE[1], V. LUCENTE[2], V. EGOROV[3];
[1]Princeton Urogynecology, Princeton, NJ, [2]The Inst. for Female Pelvic Med., Allentown, PA, [3]Artann Lab., Trenton, NJ.

Consent obtained from patients: Yes
Level of support: Not Applicable
Work supported by industry: No

Objective:
The objective of this study is to assess the clinical suitability of a new approach for 3-D imaging and quantification of vaginal tissue elasticity under normal and prolapse conditions.

Background:
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. To date, there is no standardized, non-invasive, reproducible tool to accurately assess the circumferential elastic properties of the vagina. In prior studies, we clinically tested the Vaginal Tactile Imager (VTI) which allows for tissue imaging at specified locations in vagina and assessment of tissue elasticity by means of introduced elasticity index [1]. VTI is based on principles similar to those of manual palpation. It is capable of visualizing tissue mechanical structure by measuring surface stress patterns under tissue deformation using a pressure sensor array [2].

Methods:
Thirty one women were enrolled in the study (clinical trials identifier NCT01111916). The study subjects included 18 women with normal pelvic support and 13 women with pelvic organ prolapse (Stage I-III). Average age was 60±17 (range 28–90). The transvaginal probe comprised of 128 pressure sensors and a 3-D motion tracking sensor covered by disposable sheath used with ultrasound lubricant. The images were obtained and recorded in an office setting at the time of routine vaginal examination. Three orthogonal projections of 3-D vaginal tactile image with VTI probe location are observed by operator in real time. The Pelvic Organ Prolapse Quantification (POP-Q) system for prolapse classification. Tissue elasticity (Young's modulus) was calculated from spatial gradients in resulting 3-D tactile image. Each VTI examination took 3–5 min.

Results:
All 31 women were successfully examined with the VTI device. 3-D images of the vagina were recorded and stored. We found substantial differences in anatomy and tissue elasticity between normal and prolapse conditions. Average values for tissue elasticity for anterior and posterior compartments for normal conditions were 7.2±4.9 kPa and 6.6±4.0 kPa respectively. For Stage III prolapse the average values for tissue elasticity for anterior and posterior compartments were 1.6±0.9 kPa and 1.7± 1.1 kPa respectively. Figure 1 and Figure 2 present examples of examination results for normal and prolapse conditions. The patients were asked to assess comfort level of the VTI examination relative to manual palpation: 77% said that VTI procedure is the same, 20% less comfortable, and 3% more comfortable. No adverse events were reported.

Conclusions:
Our findings suggest that VTI is suitable for 3-D imaging of the vagina and provides quantitative assessment of vaginal tissue elasticity. VTI offers insight into individual variations in biomechanical properties of vaginal tissues to further our understanding of prolapse and optimize surgical repairs.

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References:
1. IEEE Trans. Biomed. Eng. 2010; 57(7):1736–44.
2. Int. J. Med. Inf. 1998; 49: 195–216.

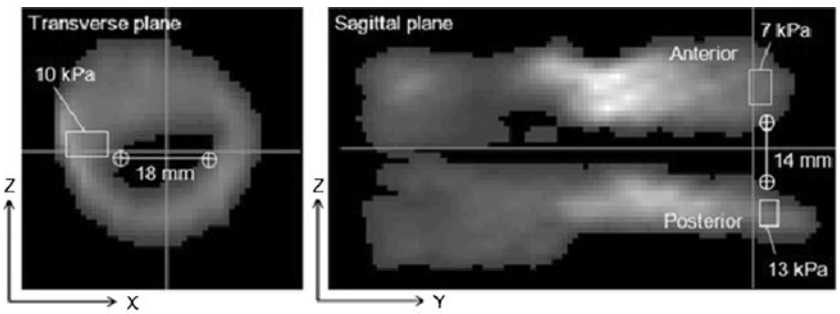

Figure 1. Transverse and sagittal cross-sections of 3-D vaginal tactile image received with VTI for a patient (63 y.o.) with normal pelvic floor conditions as was detected by manual palpation during physical examination. Young's modulus was calculated for areas specified by the rectangular markings.

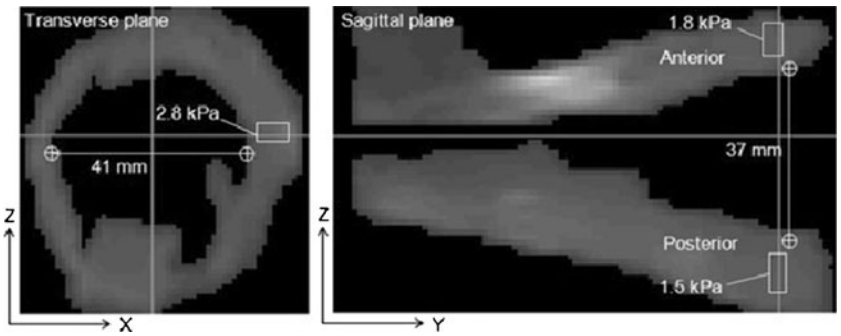

Figure 2. Transverse and sagittal cross-sections of 3-D vaginal tactile image obtained with VTI for a patient (77 y.o.) with Stage III prolapse in anterior and upper half of the posterior compartment that recurred less than one year from a vaginal hysterectomy and traditional anterior repair.

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WHAT HAVE WE LEARNED FROM BASIC SCIENCE FOR MESH COMPLICATION IN PELVIC FLOOR RECONSTRUCTIVE SURGERY? FROM INFECTION TO POLYPROPYLENE DEGRADATION?

V. LETOUZEY[1], A. CORNILLE[1], P. MOURTIALON[1], X. GARRIC[1], J. LAVIGNE[2], R. DE TAYRAC[1];
[1]CRBA, Montpellier, France, [2]ESPRI INSERM 26, Nimes, France.

Consent obtained from patients: Not Applicable
Level of support: Not Applicable
Work supported by industry: No

Objective:
To explore the pathogenesis of prosthetic complications, our study aims to determine the stages between infection and erosion. Using a model of mesh infection we experimentally tested Clave's conclusion [1] regarding a correlation between infection and polypropylene "degradation".

Background:
Pelvic organ prolapse surgery uses prosthetic reinforcements to reduce recurrence. Specific complications occur in at least 5% of cases (prosthetic vaginal erosions). The assumptions are many and the infection is rarely found. However, the prostheses explanted from patients have an electron microscopic appearance of varnish which may correspond to a bacterial biofilm or to a degradation of polypropylene. A subclinical mesh infection, acquired during the initial implantation, may result in wound separation with subsequent mesh exposure.
In a recent study we observed a significant correlation between infection and shrinkage [2].

Methods:
Ex vivo explanted meshes for the surgical treatment of symptomatic vaginal erosion, has been observed by scanning electron microscopy (SEM).
In vivo, we implanted mesh in a rat model of incisional hernia and abdominal infected with E. coli during repair surgery. Polypropylene meshes were implanted in the incisional abdominal hernia model in Wistar rats and inoculated with 10^6 CFU of Escherichia coli, as described previously [2]. After 30 days the meshes were explantated and washed with DMSO (dimethyl sulfoxide) and ultrasonic shock, then examined by Environmental Scanning Electron Microscope (ESEM).
In vitro, polypropylene mesh was placed in wells containing culture medium with or without bacteria (E. coli).
At the same time, polypropylene meshes were inoculated in vitro with the same isolate of Escherichia coli, then explanted after 2–15 days and washed with the same process.
We studied the clinical, bacteriological and ESEM prosthetic characteristics.

Results:
(Figure 1)
In these studies we also observed signs of superficial degradation and transverse cracks on explanted mesh from patients (A&B), in vitro and in vivo infected meshes, but this appeared to concern only the biofilm, with no effect on the implant thread itself.
This film is not found in control groups not infected.
After cleaning meshes, analysis revealed that the underlying polymer is intact.
Scanning electron microscopy of low weight, macroporous, monofilament knitted polypropylene mesh extracted after 30 days with infection by *E. Coli* in an incisional abdominal hernia model in Wistar rats. The explanted infected mesh shows transverse cracks (C). After washing with DMSO (D) and ultrasonic shock (E), it appears marked modifications in mesh surface corresponding to the biofilm (C), and after biofilm removal, no polymer degradation was seen any more (E).
Environmental Scanning Electron Microscopy of in vitro infection of low weight polypropylene macroporous knitted mesh extracted from a bacterial culture medium infected by *E. Coli* after 2 (F), 5 (G) and 15 days (H). Figure 1.F shows the beginning of biofilm formation. Figure 1.G shows cracks in the biofilm at mesh interstices. Figure 1. H shows transverse cracks in the biofilm. Figure 1 I shows non-degraded polymer thread after washing out the biofilm.

Conclusions:
The prosthetic infection, thus forming a bacterial biofilm acts as a coating and would be associated with prosthetic erosions, without changing the underlying polymer.
This study allows us to reproduce experimentally the microscopic appearance of meshes clinically complicated and requiring surgical intervention.