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Abstract. Pelvic organ prolapse (POP) occurs when changes to the pelvic organ support structures cause descent or herniation of the pelvic organs into the vagina. Clinical evaluation of POP is a series of manual measurements known as the pelvic organ prolapse quantification (POP-Q) score. However, it fails to identify the mechanism causing POP and relies on the skills of the practitioner. We report on a modified vaginal speculum incorporating a double-helix fiber-Bragg grating structure for distributed pressure measurements along the length of the vagina and include preliminary data in an ovine model of prolapse. Vaginal pressure profiles were recorded at 10 Hz as the speculum was dilated incrementally up to 20 mm. At 10-mm dilation, nulliparous sheep showed higher mean pressures (102 ± 46 mmHg) than parous sheep (39 ± 23 mmHg) ($P = 0.02$), attributable largely to the proximal (cervical) end of the vagina. In addition to overall pressure variations, we observed a difference in the distribution of pressure that related to POP-Q measurements adapted for the ovine anatomy, showing increased tissue laxity in the upper anterior vagina for parous ewes. We demonstrate the utility of the fiber-optic instrumented speculum for rapid distributed measurement of vaginal support. © *2016 Society of Photo-Optical Instrumentation Engineers (SPIE)* [DOI: 10.1117/1.JBO.21.12.127008]

Keywords: fiber-optic sensors; prolapsed; pelvic support; fiber-Bragg gratings; vaginal pressure profile.

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1 Introduction

The three main contributors to the support for the pelvic organs, bladder, bowel, and uterus include the suspensory ligaments of the uterus at the cervical level, the endopelvic fascia of the vaginal wall, and the levator ani skeletal muscles of the pelvic floor.[1,2] Childbirth injuries damage these support structures, which overstretch or tear, resulting in weakening of the vaginal wall and allowing descent or herniation of the pelvic organs into the vagina.[3] The clinical consequences of pelvic organ prolapse (POP) are difficulty in voiding and evacuating stool, compromised sexual function, urinary and fecal incontinence, or a general feeling of discomfort due to a bulge in the vagina. The condition has been described as a "hidden epidemic"[2] due to the large number of (76%) of women experiencing POP symptoms at some stage of life,[4,5] and it accounts for 20% of women awaiting gynecologic surgery in the UK.[6] There is an estimated 19% lifetime risk of surgical requirement for POP.[7] Primary factors that strongly influence the appearance of POP are childbearing,[4,5,8] age, and high body mass index.[4,5] Strong correlations between the incidence of POP and pregnancies, assisted deliveries including vacuum and particularly forceps,[8] birth weight, the number of vaginal deliveries,[9] and older age at first delivery have also been reported.[4,5]

A commonly used method for the evaluation of POP and integrity of the pelvic floor is the pelvic organ prolapse quantification (POP-Q) scoring system, developed as a six defined point anatomical measurement system with three additional general measurements to enhance both clinical and academic quantification of POP. The system was introduced to standardize terminology and measurement and uses the hymen as the point of reference to quantify the mobility and dimensions of specific internal and external anatomic locations during a pelvic examination.[10,11] POP-Q evaluation provides an objective site-specific system approach to communicate POP severity between practitioners, but it fails to identify the underlying cause of the problem and lacks the ability to provide data that can be used to develop understanding of the mechanism of POP. The system is arguably difficult to learn and overall adoption is not universal.

The need to measure and quantify the strength and structural integrity of the vaginal wall and its surrounding structures is exemplified by the number of investigators performing measurements of intravaginal pressure,[12,13] vaginal/levator ani closure force,[14] and developing devices to measure vaginal tissue mechanical properties.[15,16] Constantinou et al.[17] developed a probe for making such measurements whereby two leaf-spring cantilevers were attached to a rod and inserted in the vagina. As the rod was withdrawn from the vagina, diametrically opposed cantilevers containing force transducers generated deflection measurements to describe the mechanical properties of the anterior and posterior vaginal walls. This technique measured vaginal closure force during voluntary and cough-induced pelvic floor muscle contractions but only addressed two points of the vagina at a time. Guaderrama et al.[18] used a water perfused

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catheter and a rapid pullback method to determine the vaginal pressure profile at rest and during levator ani contraction, determining the variable pressures present along the walls of the vagina. A single-point vaginal pressure measurement device developed by Arora et al.[12] uses a wireless device for the measurement of intravaginal pressure during physical activity. A speculum device with rigid, dilatable blades, developed by Ashton-Miller et al.,[14] uses a strain gauge on each blade in an effort to determine contraction force of the levator ani muscle, a key support structure maintaining the integrity of the pelvic floor. Like many of the devices described to date, this instrument suffered from an inability to discern the difference between the contraction force of the physical structure (levator ani) from the force imparted on the device by intra-abdominal pressure (IAP), which fluctuates with tidal breathing and varies dramatically during events such as a cough, Valsalva, or voluntary pelvic floor activation. This device has been revised to separate IAP from levator ani contractile force and the reaction force of the symphysis pubis, but pressure distribution through the whole vagina is not measured.[19]

Magnetic resonance imaging (MRI) has been used effectively for several dynamic studies.[20,21] However, access to MRI scanners is expensive and limited, particularly in remote areas. Furthermore, MRI images take over a second to acquire.[21] MRI does not yet provide the temporal resolution to investigate the most rapid, dynamic events such as a cough or sneeze.

While the above techniques all provide invaluable information on the integrity of the vaginal wall, there is a need for a rapid, accurate, and quantifiable test that can provide distributed dynamic pressure measurement along the full vaginal length. Such measurements would accurately determine the precise location of the damaged vaginal tissue in both symptomatic and preclinical POP.

Optical fiber sensors have become increasingly attractive in biomedical sensing since they are flexible, can be multiplexed to create multiple discrete sensing locations, and are electromagnetically inert. The advent of fiber-Bragg gratings (FBGs) has enabled the development of distributed pressure, temperature, and strain measurements. FBGs are localized sensors inscribed into the core of an optical fiber that are extremely sensitive to strain due to its effect on the optical path length through the grating. The characteristic (unstrained) Bragg wavelength (λ_B) of FBGs written at discrete points along a fiber may be varied, allowing gratings to be wavelength encoded, which in turn permits distributed sensing using wavelength division multiplexing techniques.[22]

One complication that often confounds the use of FBGs as strain gauges is their pronounced sensitivity to changes in temperature. Wang et al.[23] introduced an a thermal FBG pressure sensor design that effectively removed thermal artefact by using a pair of FBG-inscribed fibers wound together in a double helix, so the thermal effects were substantially removed. This technique has been subsequently employed to make distributed pressure measurements under bandages used in compression therapy.[24]

We have adapted this FBG-based distributed measurement technique to make an instrumented vaginal speculum with sensors located every 10 mm along both the upper and lower blades. This allows distributed pressure measurements to be made in the vagina to identify changes in support and possible defects in pelvic supporting tissue created by pregnancy and childbirth. The device has been validated in an ovine model comprising nulliparous and multiparous ewes and compared in parallel with a modified clinical POP-Q assessment to identify vaginal wall weakness (similar to POP-Q in women).

2 Methods

A standard stainless steel duckbill bivalve speculum was modified so that the upper and lower blades remained parallel during dilation. The speculum could be locked at any dilation between 0 and 20 mm. At zero dilation, the separation of the upper and lower sensor regions is ~15 mm.

2.1 Sensor Arrays

Fiber-optic pressure sensing arrays with seven sensing elements spaced 10 mm apart were fabricated as described by Wang et al.[23] (Fig. 1) and bonded to both the upper (seven sensors) and lower blades (seven sensors) of the modified speculum (Fig. 2).
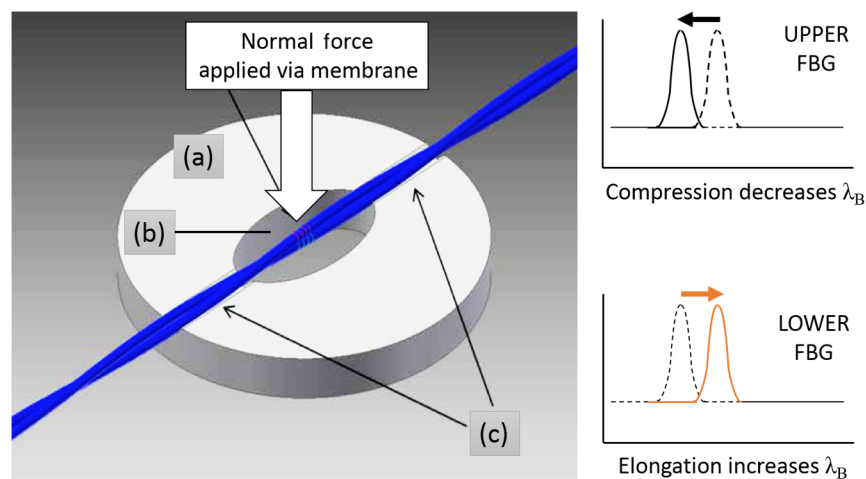

Fig. 1 A schematic adapted with permission from Ref. 23 showing the helically paired-FBG orientation. Each sensor is comprised of (a) metallic annular support, (b) FBG pair oriented above and below each other, and (c) glue bonds. A force applied normally to the plane of the solid substrate causes compression of the top fiber and elongation of the bottom fiber.
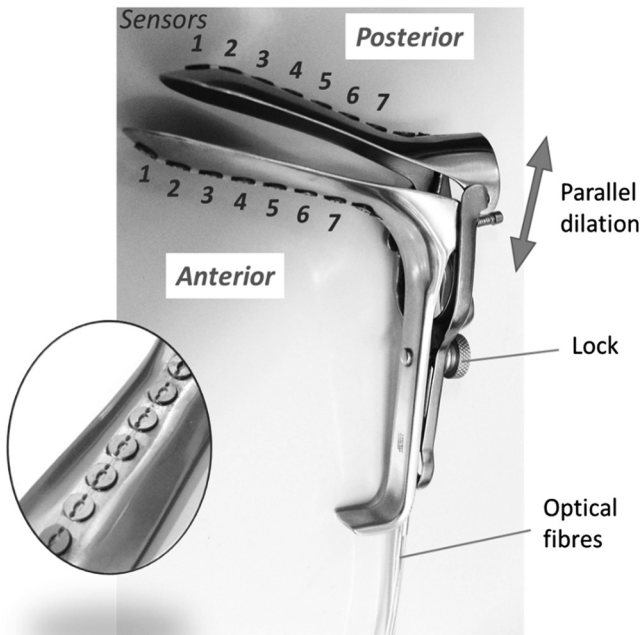
Fig. 2 Modified speculum showing sensors arranged along upper (posterior) and lower (anterior) blades (detail inset).

Fig. 3 Change in Bragg wavelength per mmHg applied pressure for each sensor on upper and lower speculum blades.

Fig. 4 The difference in wavelength between top and bottom fibers in response to the application of calibrated loads at three temperatures. Differences in Bragg wavelengths are shown on the primary axis. Equivalent pressures for a typical calibration value of 0.0025 nm mmHg^{-1} are shown on the secondary axis for reference.

In brief, draw tower grating (DTG) optical fibers with FBGs were written at 10 mm spacing along their length with 2 nm spectral separation between each grating (FBGS Technologies GmbH, Germany). Fiber pairs were then wound together in a double helix pattern with a pitch equal to the spatial separation of the grating pairs. The fibers were then bonded to an annular metallic substrate on each side of the FBG pair with the FBGs positioned above and below each other in the plane normal to the substrate (see Fig. 1). Deflection of the fibers due to a force applied normal to the substrate causes relative compression in the top fiber (reducing the Bragg wavelength of the FBG) compared with elongation in the bottom fiber (increasing the Bragg wavelength). The applied force is, therefore, proportional to the differential change in wavelength of the FBG pair. Changes in temperature affect both FBGs equally, making the force measurement independent of temperature. Each blade of the speculum was covered with a separate latex sleeve to provide a membrane protect the fibers and to deflect the underlying FBG in response to applied force. The fiber arrays were connected to a four-channel optical interrogator (FBG-scan 804D, FBGS, Belgium) allowing the Bragg wavelengths of all FBGs to be monitored in real time.

The device was calibrated by applying a known pressure to each sensor using a pneumatically inflated bladder. In practice, this type of sensor measures a contact force that relates to the compliance of the vaginal wall. However, since the obstetrics and gynecology community is more familiar with pressure measurement, the sensors arrays were calibrated in pressure units of mmHg applied via the pneumatic cuff and mmHg were used for all subsequent analyses. Figure 3 shows the sensitivity of each individual sensor as a change in Bragg wavelength per unit of applied pressure.

The temperature insensitivity of the double-helix sensor configuration was verified by applying calibrated loads to the sensor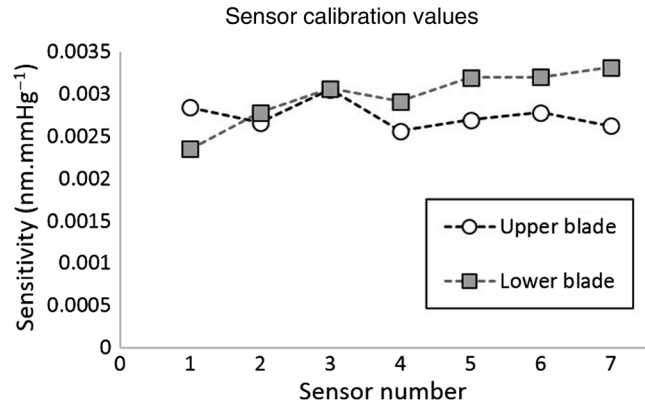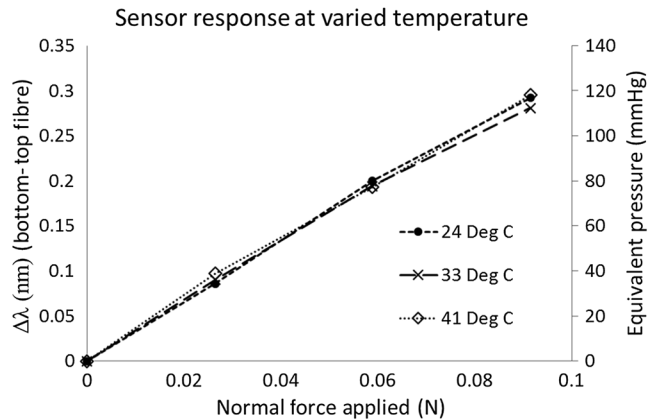s as the temperature of the speculum was varied between 24°C and 41°C. Figure 4 shows the response of a typical sensor at three different temperatures. The measured force inferred from the differential change in Bragg wavelength remained unchanged as the temperature increased.

2.2 Distributed Pressure Measurements in Ovine Vagina

The experimental procedures were approved by the Monash Medical Centre Animal Ethics Committee A (MMCA/2013/38). Sheep were housed in paddocks of the Monash University Animal Service facilities in compliance with the National Health and Medical Research guidelines for the care and use of laboratory animals. This study examined 15 Border Leicester Merino ewes of which 3 were nulliparous (age 2 years) and 15 were parous, having delivered between 1 and 7 lambs in 1 to 4 pregnancies. The parous ewes ranged in age from 3 to 5 years, and the last lambs were born 6 months prior to this study.

Conscious sheep were constrained in a standard commercial v-drive, and a modified POP-Q assessment was performed on each conscious animal by experienced gynecologists (A.R., N.Y.). The measurements were modified to suit the ovine pelvic anatomy as shown in Fig. 5. In these measurements, tissue laxity
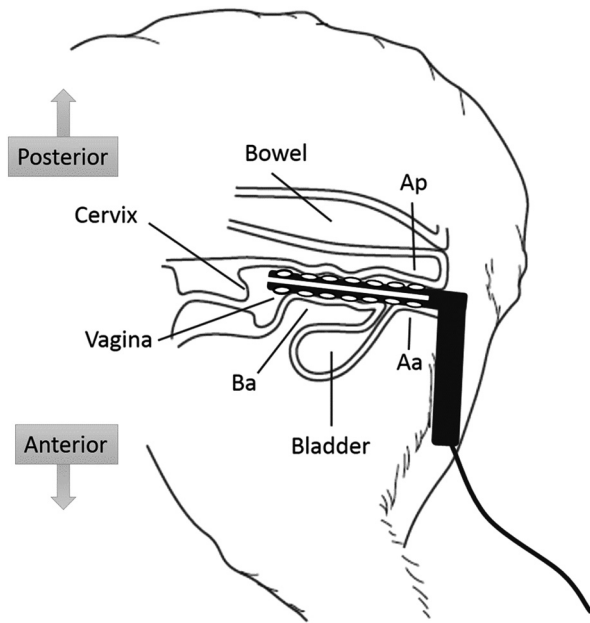
Fig. 5 Positioning of the fiber-optic speculum in relation to the ovine pelvic anatomy and the locations of the associated sites for POP-Q measurements (Aa, Ba, Ap). The upper speculum blade is positioned along the posterior vaginal wall incorporating Ap (distal posterior), with the lower blade positioned along the anterior wall incorporating Ba (proximal anterior vagina) and Aa (distal anterior vagina) regions.

was determined by using manual traction with forceps on the tissue in three regions of the vagina (Aa, Ba, Ap) (Fig. 3), using the urethra as a reference point for Ba (proximal anterior) and the point at which the inner mucous membrane of the vagina joins the skin in the distal vagina for Aa (distal anterior) and Ap (distal posterior). Immediately after vaginal wall displacement measurements were taken, the fiber-optic speculum was used to measure the force exerted by the vaginal walls. The speculum was inserted until the hilt of the blades contacted the perineal body in an orientation such that the upper and lower blades were in contact with the posterior and anterior vaginal wall, respectively (Fig. 5). Since pressure increased on each of the sensors on insertion, any sensors that remained exposed outside the vagina were readily identified.

Pressure was recorded at 10 Hz using custom software developed in LabVIEW (National Instruments, Texas). Pressure profiles along both anterior (lower blade) and posterior (upper blade) vaginal walls were recorded for the undilated speculum after which the blades were dilated at 5-mm increments up to a maximum of 20 mm unless significant discomfort was observed. The speculum blades were then returned to the undilated state in the same 5-mm increments (relaxation). The pressure profiles were recorded as static measurements at each stage during both dilation and relaxation to allow direct comparison between subjects. Events such as struggling, urination, sneezing, stamping gestures, and defecation were noted, and measurements were taken when the ewe was as passive as possible.

2.3 Statistical Analysis

Data are presented as mean $\pm$ standard error of the mean (SEM). The cohort was divided into groups of nulliparous and parous ewes, and the overall pressure as well as the discrete

pressure on each individual sensor was compared by Student's t-tests. $P < 0.05$ was considered statistically significant.

3 Results

The 10-Hz data acquisition was adequate to obtain pseudocontinuous measurements of pressure fluctuations from all sensor locations. Measured pressures ranged from 0 to 300 mmHg. Data were recorded when the ewes were in a passive state, and dynamic variations associated with activity of the animals within the V-drive, which were clearly visible in the pressure recordings, were ignored.

Figure 6 shows the mean (of anterior and posterior combined) pressure at 10 mm dilation recorded during the dilation and relaxation cycles for the seven sensor locations along the vagina, with sensor 1 located toward the cervix. Since it was not possible to reach the full 20 mm dilation in all animals, data recorded at 10 mm dilation were used for the analysis. In general, recorded pressures were higher during increasing dilation compared to the same measurement taken on relaxation, which was assumed to be due to the animal acclimatizing to the device. For nulliparous sheep, the overall pressure at 10-mm separation during dilation was 17.5% higher than at 10-mm separation during relaxation ($P < 0.01$ by sensor-paired Student's t-test) (Fig. 6). For the parous group, the mean pressure was 38% higher in the preversus postmaximal dilation measurements ($P < 0.01$). It was decided to use the measurements taken during relaxation of the speculum as these appeared less affected by movement of the animal. The mean pressure across all sensors was 102 ± 46 mmHg for nulliparous ewes compared with a mean pressure of 39 ± 23 mmHg for parous ewes ($P < 0.05$). The difference between nulliparous and multiparous pressure readings was largest in the proximal vagina region, closest to the cervix, between sensors 1 and 3, with another point of higher pressure measured at sensor 5.

Analysis of the pressure along each blade of the speculum identified some significant differences in the distribution of pressure between nulliparous and parous ewes (Fig. 7). Pressures were higher on the upper blade [posterior wall, Fig. 7(a)] for nulliparous ewes at each end for sensors 1 to 2 and for sensor 5 ($P < 0.01$). The pressure distribution on the lower blade showed no difference between groups in the distal vagina. Much higher pressures were measured for the anterior
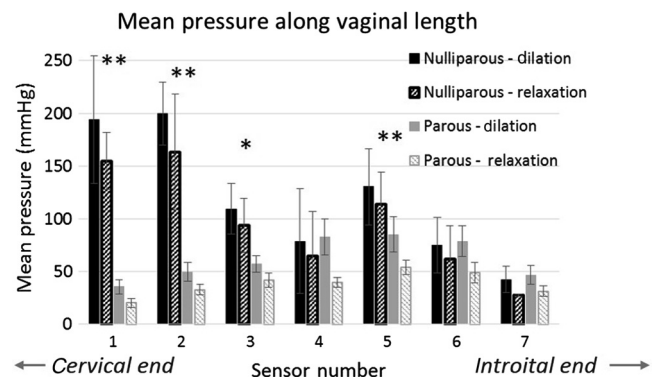

Fig. 6 Mean pressures $\pm$ SEM for sensor locations 1 to 7 upon initial dilation to 10 mm and at 10-mm dilation after maximal stretch (20 mm). A difference in pressure distribution for nulliparous versus parous sheep in absolute values before and after maximal dilation was observed. Differences in pressure between nulliparous and parous ewes are indicated (**$P < 0.001$; *$P < 0.05$).
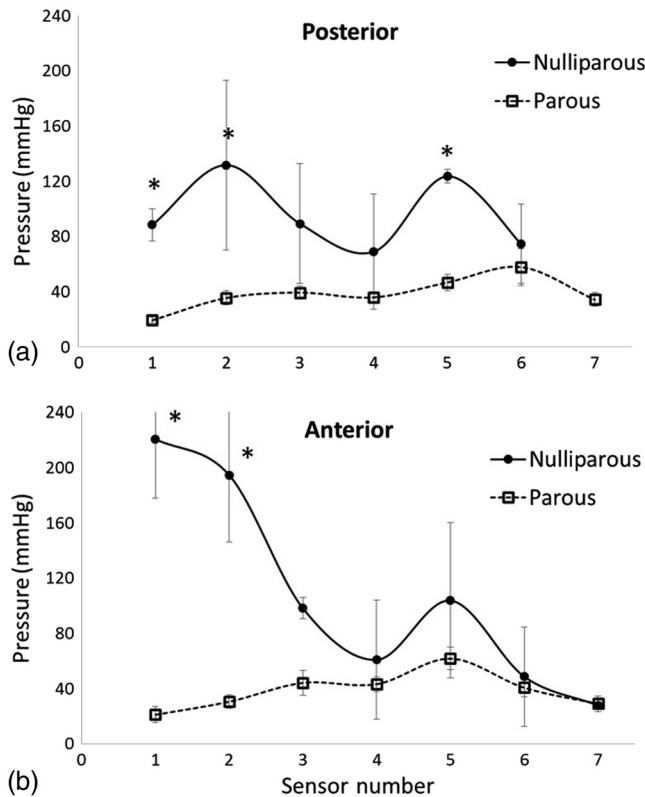
(a)

(b)

Fig. 7 Distribution of pressure on (a) posterior and (b) anterior blades at 10 mm dilation for nulliparous ($n = 3$) and parous ($n = 12$) ewes. Data are mean $\pm$ SEM *$P < 0.01$ (nulliparous versus parous).

Fig. 8 Pressure distribution (mean $\pm$ SEM) along the anterior vaginal wall for parous ewes exhibiting vaginal displacement at the Ba position (> -2) as measured in the modified POP-Q assessment (dotted line) and parous ewes with no displacement at the Ba location (-3) (solid line). The mean pressure across all sensors for each of these groups was nominally equal at 39 mmHg, indicated by the horizontal dashed line to highlight the variation in the relative distribution of pressure for the two groups. The horizontal bars and asterisk highlight pressure regions at sensors 1 to 3 and 5 to 7 where pressure differs significantly between the two groups of ewes (Ba displaced, $n = 5$; no Ba displacement, $n = 5$; *$P < 0.05$).

wall of the proximal vagina in the nulliparous group compared with those measured for the parous group. For sensors 1 and 2 in the proximal anterior vagina, the pressures were significantly different (200 ± 60 mmHg for the nulliparous ewes compared with 40 ± 20 mmHg for the parous group, $P < 0.001$) [Fig. 7(b)]. Poor sensor contact at the introitus prevented reliable measurements from being recorded at sensor 7 on the posterior blade for nulliparous ewes.

Within the group of parous ewes, POP-Q measurements identified a subgroup where excessive displacement was observed in the Ba (proximal anterior vagina) position due to increased tissue laxity. To test whether this vaginal wall laxity is detected as a change in pressure measurement for the respective sensors on the speculum, the parous ewe pressure data were divided into two groups based on displacement values in the Ba region of the proximal anterior vagina (-3 no displacement versus values > -2 for Ba displacement group). Figure 8 shows the mean pressure distribution on the anterior vaginal wall for parous ewes only. For those ewes with Ba displacement, the region from sensors 1 to 3, which corresponds to the Ba region, showed lower mean pressure (22.8 ± 4.4 mmHg) than the same sensors in those ewes without Ba displacement (44 ± 12 mmHg), $P < 0.05$. Conversely in the distal vagina region (sensors 5 to 7), the group that exhibited Ba displacement showed higher pressure (57 ± 8 mmHg) than the group that did not show Ba displacement (32 ± 11 mmHg).

4 Discussion

A modified optical fiber-speculum has been successfully used to discern general variations in pressure applied by the vaginal
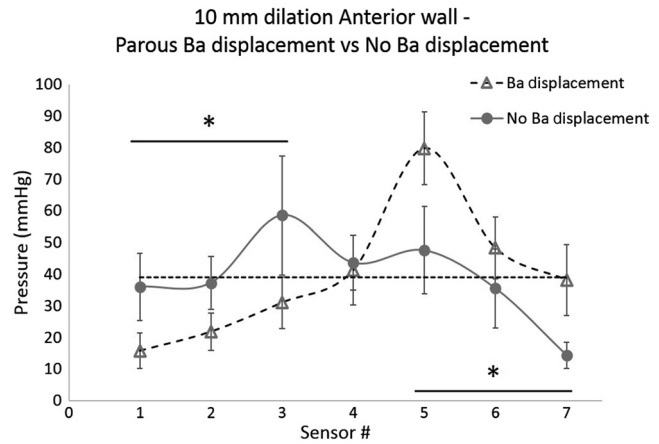
wall, as well as resolving the spatial variation in this pressure. A key finding in this first assessment of our device in the ovine model is that the distribution of pressure, as well as the mean pressure, is significantly different between nulliparous and parous ewes. Our data demonstrate lower support in parous ewes, suggesting a weakening of the vaginal wall that may be derived from injury associated with birth.[25] Furthermore, the pressure sensor device discriminated between parous ewes with normal and abnormal vaginal displacement measurements based on modified POP-Q measurements. The identification of a region (equivalent to Ba of the POP-Q in humans) of less support in the proximal region of the anterior vaginal wall of parous ewes may be linked to irreversible traumatic changes associated with pregnancy and parturition. Guaderrama et al.[18] provide some insight into the variability of pressure distribution along the length of the human vagina as well as around its circumference by making dynamic measurements from a quadrant water-perfused catheter. As the catheter was drawn along the length of the vagina, it showed a distinct region of high pressure through the mid to distal vagina of around 35 to 40 mmHg in nulliparous women. Their findings highlight the need for distributed pressure measurement but cannot be directly compared with ours due to the obvious differences in size of the instruments and pelvic anatomy. We have not found any similar data in the published literature that allow us to relate our distributed pressure results to others in the ovine model.

We have observed that the use of rigid, movable blades enabled the distribution of vaginal wall pressure to be measured. While the mean pressure across all sensors on the anterior wall is nominally the same for parous ewes both with and without vaginal tissue displacement in the Ba region, we observed differences in the distribution of this pressure at the specific sensor sites that correlated with the location of the Ba measurements that differed between these two groups (Fig. 8).

This colocation of differences in the modified POP-Q and pressure profile measurements suggests that the instrumented

speculum may provide an alternative means of identifying and localizing prolapse or provide a viable means of screening for elevated risk of prolapse in parous women.

5 Limitations of the Study

Our ability to draw physiological conclusions based on these data is limited by the small number of ewes available with known birth histories for the investigation and the large variance of the data. Contributing factors to the large variance in our measurements, in addition to the standard physiological variations, were the posture of the sheep in the v-drive and their level of agitation and activity. Discomfort of the ewes and nervous clenching on the speculum may also have confounded the data. Integration of pressure readings over a slightly longer period or repeated dilation and relaxation of the speculum during measurement may reduce the artefact attributable to animal movement.

Relation of these data recorded in this ovine model to human physiology is limited due to the clear differences between human and ovine anatomy and orientation (as reflected by the modifications made to the POP-Q examination to suit the ovine anatomy). Sheep are prostrate quadrupeds with gravity acting on the pelvic structure in an anterior direction, which will clearly have a large impact on results despite the closely matched vaginal dimensions of the two species. For example, the weight of the bladder on a poorly supported anterior vaginal wall causes prolapse of the bladder into the vagina (cystocoele) in humans,[19] whereas in the ovine model gravity draws the bladder away from the proximal anterior vagina. However, these preliminary results clearly demonstrate the utility of the fiber-optic speculum as a device for detecting variations in vaginal pressure along the entire vaginal length on both anterior and posterior walls.

6 Conclusions

These preliminary data verified the ability for an instrumented speculum containing arrays of sensors along the upper and lower blades to measure variations in pressure along the length of the ovine vagina and demonstrated its ability to discern differences in the overall magnitude and distribution of pressure due to physiological variation. We have verified the ability of the modified optical fiber-speculum device to discern differences in vaginal pressure in the ovine model. Our measurements demonstrated a general decrease in the elasticity or support of the vagina with parity, and there was some agreement between a relevant modified POP-Q measurement and the speculum data. Further work is required to more vigorously validate the utility of our speculum device and to gain a better understanding of how the information it provides relating to the distribution of support in the vagina should be interpreted and related to the appearance of POP.

In summary, we have demonstrated a high-resolution vaginal pressure measurement device that will provide quantified, spatially resolved, and dynamic pelvic support information that is likely to be of great benefit in dynamic assessment as it is developed for use in the conscious human patient where dynamic stimuli can be requested.

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