

A feasibility study of three-dimensional ultrasound imaging of the vagina under distension

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Abstract

Background: The distension properties of the vagina are critical to its function including support of surrounding organs, childbirth, and intercourse. It could be altered by many pathophysiological processes like pregnancy, radiotherapy, and reconstruction surgery. However, there are no clinically available diagnostic tools capable of quantifying the distension properties of the vagina.

Purpose: A proof-of-concept study was designed to assess the feasibility of a novel three-dimensional (3D) ultrasound imaging technique that allows quantitative evaluation of the vagina under distension.

Methods: Patients with symptomatic pelvic organ prolapse (POP) were recruited for the study. An ultrathin, oversized bag was inserted into the vagina and filled with water using a modified urodynamics system. The instilled water volume and intravaginal pressure were continuously recorded. At maximum vaginal capacity, 3D transintroital ultrasound of the distended vagina and surrounding pelvic structures was performed. Exams were performed in duplicate for each patient, two hours apart (round A and round B). Following the development of a 3D surface model of the distended vagina from each scan, several measurements were obtained, including cross-sectional area, anteroposterior (AP) length and lateral width in the plane of minimum hiatal dimensions (PMHD), AP and lateral diameter at the pubic symphysis (PS) level, maximum and minimum diameter, and maximum vertical length. To assess repeatability between measurements in two rounds, the coefficient of variation (CV) and the intraclass correlation coefficient (ICC) were calculated for each measurement. Correlations between physical measurements including the pelvic organ prolapse quantification (POP-Q) system and vaginal diameter measurements, and obtained metrics were also assessed.

Results: Sixteen patients with POP (average age 69 years) completed both rounds of imaging. There was sufficient echogenicity on 3D transintroital ultrasound of the distended vaginal wall to establish boundaries for 3D surface models of the vagina. Overall, all metrics had good or excellent reliability ($ICC = 0.77\text{--}0.93$, $p < 0.05$; $CV = 3\%\text{--}18\%$) except maximum diameter, which demonstrated only moderate reliability ($ICC = 0.67$, $p = 0.092$). Strong correlations were found between physical exam measurements including D point of POP-Q, introitus diameter and lateral diameter at apex, and maximum vaginal capacity, maximum vertical length, lateral diameter at PS, minimum diameter, and distended PMHD measurements. The results demonstrated that this system could generate 3D models of the shape of the distended vagina and provide multiple metrics that could be reliably calculated from automated analyses of the models.

Conclusions: A novel system for evaluation of the distension properties of the vagina was developed and preliminary evaluation was performed. This system may represent a technique for evaluation of the biomechanical and structural properties of the vagina.

KEYWORDS

biomechanics, pelvic organ prolapse, ultrasound

1 | INTRODUCTION

The vagina is an elastic and muscular canal, whose ability to distend is critical to its function, including facilitating arousal, intercourse, support of surrounding organs, and enabling childbirth.^{1–5} The size, shape, and elasticity of the vagina can vary between patients and change through a patient's lifetime due to factors such as aging, hormonal changes, or childbirth. It can also be affected by iatrogenic causes, such as radiotherapy, which leads to vaginal stenosis in 50%–80% of cases within 3 years of treatment and would seriously alter the distension properties of the vagina resulting in severe dyspareunia.^{6–8} Additionally, the development of vaginal stenosis or fibrosis is a major complication of reconstructive surgery for the development of a neovagina in patients with vaginal agenesis or those undergoing gender-affirming surgery.^{9,10} On the other hand, a large body of research has demonstrated that during pregnancy, the pelvic tissues undergo notable remodeling resulting in increased elasticity of the vagina and pelvic floor muscles.^{11–13} These maternal adaptations are thought to serve a vital role in protecting the mother from the future development of pelvic floor disorders (PFDs).^{14,15} Additionally, structural changes and mechanical dysfunction of the vagina and surrounding anatomy are associated with PFDs such as pelvic organ prolapse (POP), defined as the descent of one or more of the vaginal compartments past the level of the hymen.¹⁶ This is likely often thought to be due to decreased support at the distal vagina and enlarged urogenital hiatus. PFDs affect up to 25% of the female population in the United States alone.¹⁷

Despite the many pathophysiological processes that can alter the distension properties of the vagina and the fundamental role that these properties play in vaginal function, there are no clinically available diagnostic tools capable of measuring them. Current methods to assess vaginal properties are physical assessments, including the POP quantification (POP-Q) system and the Oxford pelvic floor strength scale, which provide fast and inexpensive measures of the vagina.^{18–20} POP-Q consists of nine measurements, six of which provide the distance of various parts of the vaginal wall with respect to the hymenal plane. The other three include measurements of the genital hiatus, perineal body, and total vaginal length. However, they do not capture the

distension properties of the vagina and are limited in their quantification of forces and pressure distributions required to derive biomechanical properties.

To better understand the biomechanical properties of the vagina, several instruments have been studied, which quantify isolated in vivo mechanical properties of the tissues in the vagina, load-force generated by the pelvic floor muscles during contraction, and the force/pressure distribution along the length of the vagina at rest and during pelvic floor contraction.^{21–26} However, these devices are unable to capture the distension properties of the vagina and are limited to singular anatomic planes. Shear wave elastography (SWE), which provides biomechanical properties of individual tissues, cannot provide an evaluation of the global properties of the vagina, or geometric information about the potential capacity of the vagina or its function. Moreover, as the pelvic floor is a complex structure that contains muscles, fascia, and ligaments, there is a lack of consensus on what constitutes normal stiffness values for the pelvic floor, which makes it difficult to interpret SWE results and apply them in a clinical setting.^{27,28} Three-dimensional (3D) transperineal ultrasound (TPUS) has been used for pelvic floor and POP characterization. The area of the levator ani on the plane of minimal hiatal dimensions (PMHD) in 3D TPUS is correlated with prolapse.²⁹ The combination of distension and ultrasound imaging, and magnetic resonance imaging have demonstrated a complex vaginal distended shape and associated pressure and volume that cannot be observed in an undistended state.^{30,31} However, such techniques have not been applied to characterizing the entire vagina, including both distal and proximal portions, where important support structures exist.

There is an unmet clinical need for a tool that can reliably measure the distension properties of the vagina. Such a tool may have immediate application in monitoring this important function following pelvic radiotherapy or neovaginal reconstructive surgery. Early identification of pathologic fibrotic changes, which result in functional changes in compliance or stiffness of the vagina, is critical given the difficulty in treating higher grades of fibrotic disease.^{32,33} Similarly, a tool that can quantify the distension properties of the vagina may be used to study changes in this property across pregnancy to identify patients at high risk for maternal obstetric trauma, or evaluation of patients before and

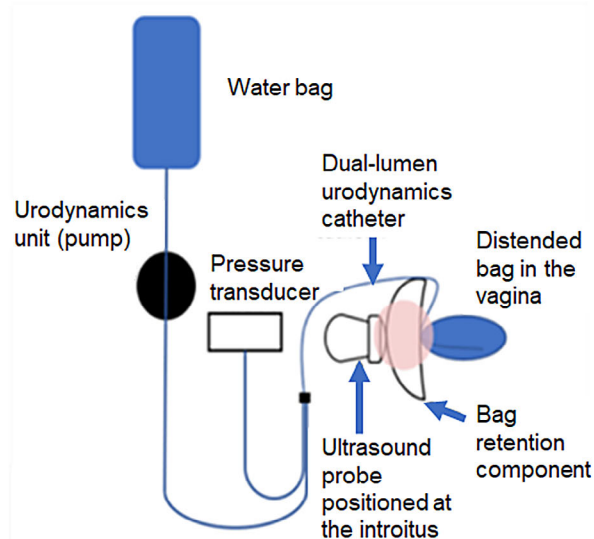
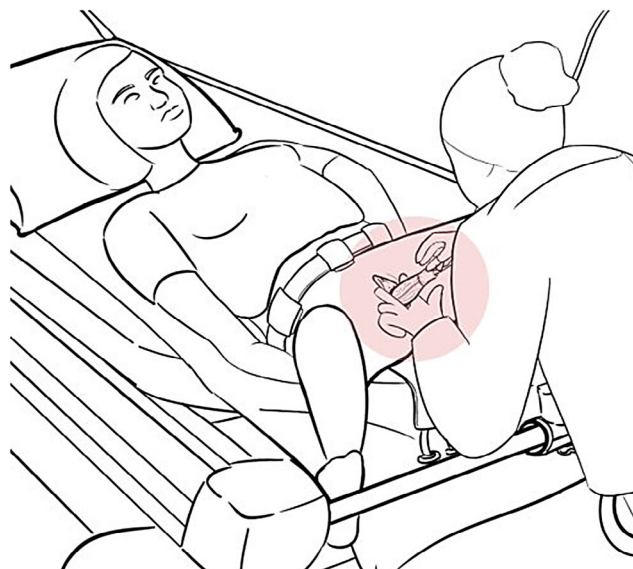


FIGURE 1 A schematic of the measurement system and procedure. Water was pumped through a dual-lumen catheter into an ultrathin polyurethane bag inserted in the vagina. A pressure transducer measured the pressure within the bag. Ultrasound images were acquired through the retention device. The bag was inserted while the participants were in dorsal recumbent position.

after surgery for pelvic floor disorders.^{26,34} To address the unmet clinical need, we developed a novel system that integrates 3D transintroital ultrasound imaging with a modified uroynamics system. This imaging system allows 3D ultrasound imaging of the distended vagina in its entirety. The objective of the proof-of-concept study was to evaluate the feasibility of this technique by assessing its ability to capture vaginal shape, volume, and pressure under distension with water.

2 | MATERIALS AND METHODS

This study was reviewed and approved by the Mount Sinai Hospital Research Ethics Board (#20-0113-A). Written informed consent was obtained from all participants prior to enrollment in the study.

The imaging system (Figure 1) consisted of an ultrasound scanner (GE Healthcare Voluson E10, MA, USA) with a 3D probe (RAB6-D, GE Healthcare, MA, USA) and a commercially available urodynamic system (UDS) (GOBY EQ, Laborie Medical Technologies Corp, NH, USA). A custom ultrathin, oversized, polyurethane bag was developed to distend the vagina. The bag was fitted with a dual-lumen water-filled uroynamics catheter (Laborie Medical Technologies Corp, NH, USA) for water infusion and pressure measurement. Preliminary development efforts (not published) revealed a propensity of the bag to fall out of the vagina during the distension process. Therefore, a proprietary retention device was designed that allowed the bag to remain in the vagina while being distended. It was expected that bag retention issues were more likely to occur in

symptomatic POP patients as the decreased pelvic support level and enlargement of the urogenital hiatus make it harder for these patients to retain objects within the vagina including tampons.³⁵

The system was first evaluated in four healthy volunteers. This served as an initial test to determine the need for any changes with respect to the design of the system or testing protocol. Given our preliminary experience with expulsion of the bag during distension prior to this study, further assessments were performed in a POP patient population as a means of stress-testing the system.³⁶

Based on previous literature investigating the reproducibility of pelvic floor ultrasound measurements,^{37,38} we recruited a total of 22 patients for this study, which accounts for a participation drop rate of 15% (three patients). The exclusion criteria were as follows: age under 18, a history of pelvic radiation or surgery for PFDs, inability to perform Valsalva or pelvic muscle contractions, restricted mobility that limits ambulation, neurologic lesions, and/or history of pessary-related complications.

2.1 | Exam protocol

Demographic patient information at the initial visit from the database of the clinical, including prolapse stage, body mass index (BMI), age, and parity were collected. Patients were asked to remove their pessaries and void immediately prior to ultrasound examination.

First, all patients underwent additional physical exam assessment of the vagina to estimate the introital diameter, anteroposterior (AP) length and lateral width near

the apex. All of these measurements are estimated by hand, with the vagina, at least marginally, stretched by abducting the second and third digits.³⁹ Second, baseline 3D TPUS examination was performed. The baseline TPUS images were used to assess the dimensions of the PMHD.

Next, a tissue preconditioning phase was performed. Preconditioning is a well-established procedure critical for the mechanical characterization of biological tissue due to history-dependent tissue responses to applied loads.^{40–43} Preconditioning acts to reduce the effects of these history-dependent properties by redistributing fluid, and by breaking transient hydrogen bonds formed while tissue is not loaded.⁴⁴ In this application, it was performed in order to achieve a steady and repeatable mechanical response from the tissues.⁴⁵ With the patient in a dorsal recumbent position, the custom bag was inserted into the vagina, the bag retention device was placed over the vulva, and the bag was filled with water via the attached catheter at a constant flow rate of 140 mL/min. Patients were instructed to avoid speaking or moving during the filling process to reduce pressure artifacts introduced by unintentional increases in intra-abdominal pressure. The bag was filled until the patient indicated a sensation of vaginal fullness such that the patient felt additional filling could not be performed with adequate comfort, at which point, the filling was stopped. This stage was annotated as the point of “first sensation,” based on a similar precedent implemented during urodynamic bladder testing.⁴⁶ This volume was maintained for 20–30 s to allow for tissue relaxation and for the patient to acclimate to the sensation. Next, only if the patient reported the feeling of fullness had reduced, the filling procedure was resumed until the patient again felt a sensation of vaginal fullness. At this point, the filling was stopped, and the volume was maintained for 20–30 s to allow for further tissue relaxation. This was documented as the point of maximum vaginal capacity. The water was then removed from the bag. This marked the end of the preconditioning phase. A preconditioning phase was implemented to a similar strain magnitude and at a similar strain rate as would be seen during the data collection phase due to the observation of differences in strain response of tissue preconditioned at lower strain values in biological tissue.^{40,47,48} Holding the tissue at a consistent strain for a short period of time during preconditioning was performed to mimic the data collection protocol, in which the distension volume was held constant for a minimum of 30 s while an ultrasound image was acquired.⁴⁹

Next, the data collection phase was performed. The filling procedure was repeated for a second fill, and when the patient's maximum vaginal capacity was reached following this fill a 3D transintroital ultrasound image was acquired. The image orientation and position were optimized to capture the entire bag distended

inside the vagina, and the posterior half of the pubic symphysis (PS) at a minimum. Subsequently, all water was removed from the bag. The water volume and pressure inside the bag were continuously recorded throughout the filling procedure. Note that the filling process was performed twice: once for the preconditioning phase (not part of data acquisition) and second for the data acquisition phase. This entire procedure of preconditioning fill followed by a data collection fill (the second fill) is referred to as a “round” of imaging of the distended vagina.

The entire procedure (i.e., preconditioning fill and the second fill) was repeated for each patient, with a 2-h period of free mobility between rounds (i.e., Rounds A and B). A two-hour window was set between rounds where the patient was allowed full mobility. The effects of preconditioning on material properties can persist up to 24 h in some tissue.⁴⁷ Both data collection rounds were scheduled within 1 day to maximize patient retention, which would not provide sufficient time for the effects of preconditioning to wear off. Therefore, preconditioning was performed to reduce the effects of history-dependent loading on material properties.

2.2 | Image processing

Figure 2 illustrates the image processing details. The acquired images were subject to manual segmentation utilizing 3D Slicer⁵⁰ by an expert with over 2 years of experience analyzing 3D TPUS volumes. The PMHD²⁹ in the baseline TPUS images, captured at a resting state, and also in the distended vagina transintroital images, were identified and segmented, tracing the inferior pubic ramus and levator ani muscle. Subsequent metrics were quantified from the PMHD segmentations including the area, AP length, and lateral width of the PMHD (Figure 2a).

The bag in 3D ultrasound images of the vagina at maximal capacity, was also manually segmented. The contour of the distended bag was traced in 3D Slicer and filled in manually in each slice in the sagittal plane to create a 3D model. The bag was first segmented in each image slice and a 3D surface model of the distended vagina was created. The PS and levator plate were also segmented as anatomical landmarks. A reference line was drawn horizontally in the midsagittal plane at the level of the PS. The following distended bag metrics (Figure 2b) were obtained in the 3D segmented volume: maximum and minimum diameter of the whole bag, maximum vertical length, the AP and lateral diameter of the bag at the level of the reference line (i.e., the PS) in the axial plane. These measurements were automatically generated from the segmented 3D volumes using a Python algorithm developed in-house.

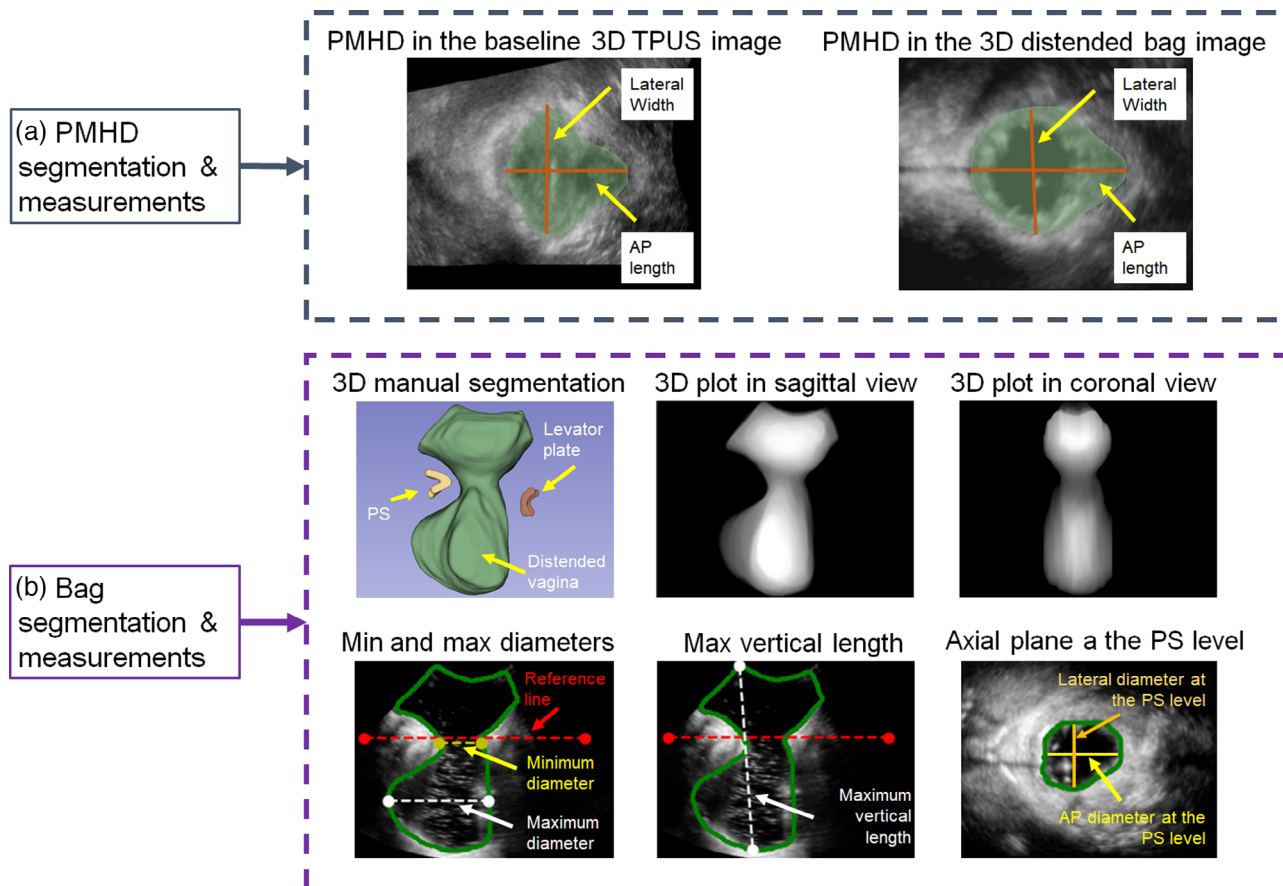


FIGURE 2 Ultrasound image segmentation and automatic measurements metric calculation. (a) PMHD area, AP length and lateral width of the vagina at the maximum distension. (b) 3D volume of distended bag and automatic extraction of ultrasound metrics in the distended vagina. Please note the measurements were done in 3D, using the 3D segmented volume, and are only shown in the sagittal view here for presentation. Also, the portion of the image and the 3D segmentation that is above the perineal body is water in the bag retention device.

2.3 | Data analysis

All the obtained metrics were described using descriptive statistics, including the means with standard deviation (SD) and median with interquartile range (IQR). The coefficient of variation (CV) between rounds A and B were calculated to understand the relative variability among the different metrics, with a generally accepted cut-off at 20%.⁵¹ The intraclass correlation coefficient (ICC) was used to evaluate reliability of each metric. The guidelines provided by Koo et al.⁵² were used as criteria for poor ($ICC < 0.5$), moderate ($0.5 < ICC < 0.75$), good ($0.75 < ICC < 0.90$), and excellent reliability ($ICC > 0.90$). The 95% confidence intervals (CIs) for the ICC values were calculated according to the methods described by Bartlett.⁵³ To assess the system's validity against physical exam assessments, the correlational analyses were performed between semi-quantitative physical exam metrics (POP-Q, introital diameter, vaginal AP length and lateral diameter at apex), and distension metrics (maximum instilled volume, maximum intravaginal pressure, distended PMHD area, AP length and lateral width,

maximum and minimum diameter, and maximum vertical length) obtained from round B to ensure we measured the tissue properties in the most repeatable condition possible, as previously described in the preconditioning step. A correlation coefficient (r) > 0.6 was used as threshold for determining strong correlation.⁵⁴ Moreover, cursory analysis of pressure-volume data during filling was performed to identify potential artifacts and assess the general shape of the pressure-volume curves.

3 | RESULTS

For initial testing, four healthy volunteers were recruited. Descriptive statistics for distension metrics among the volunteers are listed in Table 1. Overall, the bag was retained in all volunteers throughout distension, and the volunteers found the exam protocol to be acceptable with minimal discomfort. Therefore, the protocol remained unchanged for the system evaluation in patients. Following the completion of tests with healthy volunteers, the system was further "stress-tested" in patients with POP. Twenty-two patients were enrolled

TABLE 1 Obtained metrics of healthy volunteers.

Obtained metrics	Healthy volunteer ID				Mean (SD)
	HV01	HV02	HV03	HV04	
Max vaginal capacity (mL)	323	436	365	414	385 (44)
Max intravaginal pressure (cmH ₂ O)	39	67	57	80	61 (15)
AP diameter at PS level (mm)	34	82	78	51	61 (20)
Lateral diameter at PS level (mm)	33	57	39	49	44 (9)
Maximum diameter (mm)	76	107	130	93	102 (20)
Minimum diameter (mm)	24	50	29	35	35 (10)
Maximum vertical length (mm)	142	146	147	181	154 (16)
Distended PMHD Area (cm ²)	19	32	18	23	23 (6)
Distended PMHD AP length (mm)	57	79	62	61	65 (8)
Distended PMHD Lateral width (mm)	53	55	44	54	52 (4)
Baseline PMHD Area (cm ²)	7	16	11	13	12 (3)
Baseline PMHD AP length (mm)	36	58	49	52	49 (8)
Baseline PMHD Lateral width (mm)	30	34	44	39	37 (5)

TABLE 2 Demographic and clinical characteristics of study patients.

Variables	Patients (N = 16)
Age (y), mean (SD)	69 (8)
BMI mean (SD)	24 (4)
Parity, Median (Q1–Q3)	2 (2–2.5)
POP-Q stage, n (%)	
Stage 2	10, 63%
Stage 3	4, 25%
Stage 4	2, 13%

and completed both rounds of imaging. Despite working well in healthy volunteers, the retention device was unable to retain the bag in the first four patients with POP. Therefore, minor modifications were made including replacing some softer parts with more rigid components. Subsequently, the system was tested in the remaining 18 patients. The bag was successfully retained in all of these patients throughout the exam protocol. Of the 18 patients, two were excluded from analysis due to improper bag placement in one patient and an incomplete dataset due to operator error in another patient. Therefore, a total of 16 patients were included in the analysis.

The patient population was clinically homogeneous with $n = 15$ (94%) having POP-Q stage 2 or 3 prolapse, and $n = 12$ (75%) having anterior-predominant prolapse (Table 2). The POP stage was calculated based on the baseline POP-Q measurements.⁵⁵ However, there

was one patient who did not have POPQ collected, so the POP stage provided by the clinician was used in this study. There was sufficient echogenicity of the distended vaginal wall to establish boundaries for 3D surface models of the vagina in all patients. Representative images of the vagina at maximum capacity are shown in Figure 3.

Descriptive statistics for bag measurements and corresponding ICC are presented in Tables 3 and 4, respectively. The average PMHD measurements on distended bag images were larger than those in baseline 3D TPUS images, indicating a pelvic floor shape change under applied force and pressure. The average maximum vaginal capacity ($\pm$ SD) was 485 ($\pm$ 104) mL, and this metric demonstrated excellent repeatability (ICC = 0.90). Overall, all metrics had good or excellent reliability except maximum diameter, which demonstrated only moderate reliability (ICC = 0.67). Among all measurements, maximum vertical length had the least variation (CV = 3%) and the maximum intravaginal pressure showed the highest variation between exams (CV = 18%), suggesting large variation in the pressure at which filling was no longer tolerated by patients.

The results of the correlational analyses are provided in Table 5. Strong correlations were found between physical exam measurements that stretch/distend the vagina (i.e., introitus diameter and lateral diameter at apex) and maximum vaginal capacity, maximum vertical length, lateral diameter at PS, minimum diameter, distended PMHD area and lateral width. However, there was relatively poor correlation between distension metrics and POP-Q, with the exception of point D (the topmost point of the posterior vaginal wall), which significantly correlated with the lateral diameter at PS, minimum diameter, maximum instilled volume and the distended PMHD lateral width.

In the pressure-volume curves (Figure 4), the initial filling phase was characterized by a toe region, followed by a linear region until the point of “first sensation” at which the pump was stopped. During the gap in filling, the curves generally exhibited a steady drop in pressure over time. After the 20 s relaxation period, the pressure continued to linearly increase upon restarting the filling.

All healthy volunteers’ and patients’ ultrasound images collected in rounds A and B are provided as in Figure S1 and S2, respectively. The pressure-volume curves for all patients are provided as in Figure S3.

4 | DISCUSSION

In this study, the feasibility of a novel system for imaging the vagina under distension was evaluated in healthy volunteers and POP patients. It was demonstrated that this system could generate 3D volumetric models of the shape of the distended vagina, and provide multiple metrics (including diameters, areas, and volumes) that

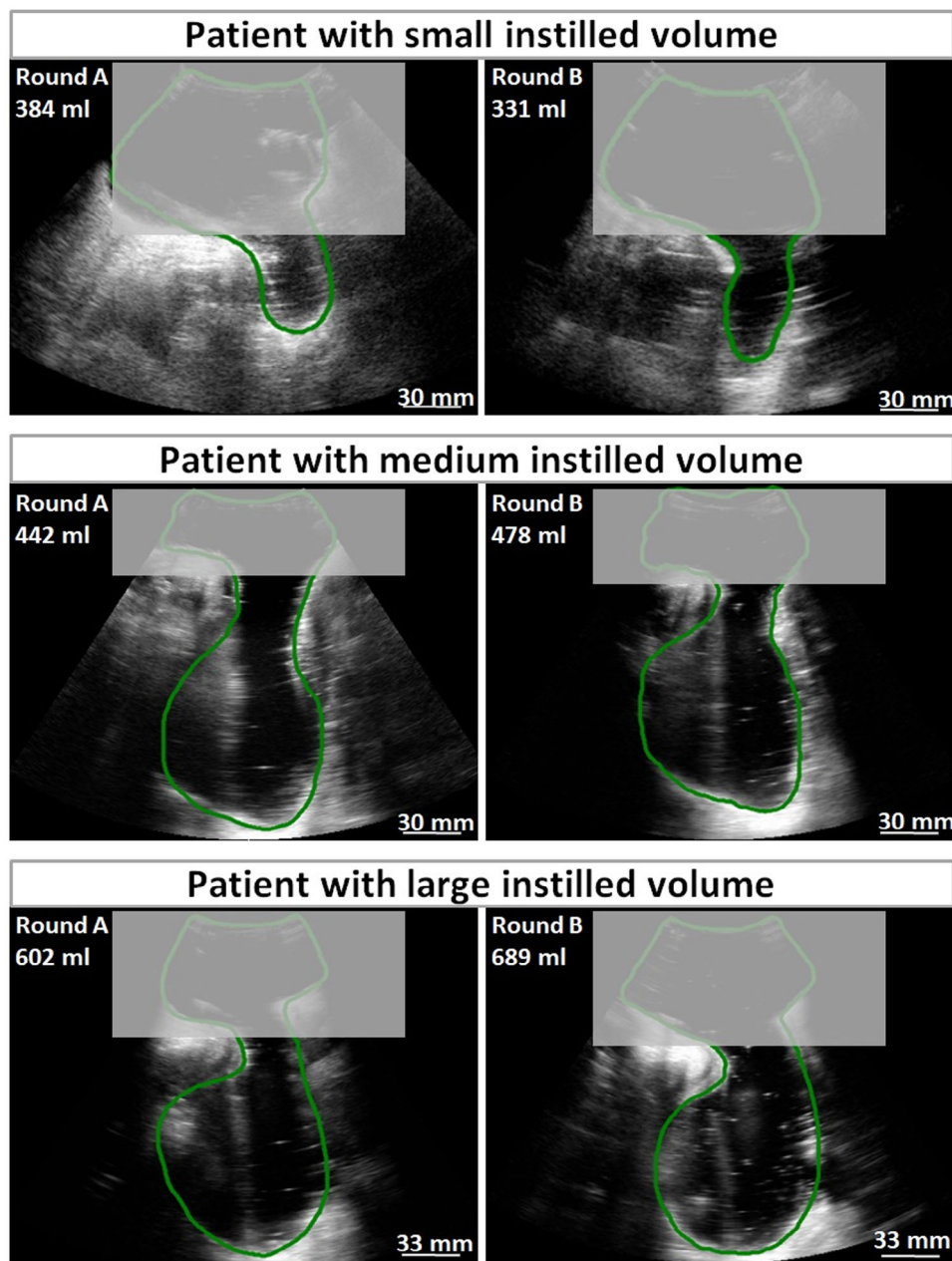


FIGURE 3 Contours of three representative patients in round A and B: a patient with small, medium and large instilled volume. The corresponding instilled volume is indicated for each image. The gray boxes in the images indicate the region of the water retention device.

could be reliably calculated from automated analyses of these models and generate pressure-volume curves that revealed characteristics specific to the biomechanical properties of soft tissues. Overall, these data demonstrate the feasibility of using this system for evaluating the distension properties of the vagina, which may provide valuable clinical insight and early detection of various pathophysiological processes. Monitoring the distended properties of the vagina over time opens up novel diagnostic options for patients who suffer with conditions that impact distension, including those that may pertain to obstetrical changes and vaginal patency following radiation therapy and reconstruction surgery,

which could result in earlier intervention and improved therapy for symptom management.

The repeatability of the measurements acquired using the measurement system within a short time frame, and thus with functionally similar properties, indicated excellent overall repeatability of the system. All obtained metrics demonstrated good or excellent repeatability as measured by ICC scores (Table 4). The largest variation was observed in maximum intravaginal pressure, which was expected due to the subjective nature of the patient-based feedback for the distension endpoint. As distension to a maximal point only happens during extreme conditions, such as childbirth,

TABLE 3 Descriptive distension metrics among patients.

Metrics	Round	Mean (SD)	Median (Q1–Q3)	Average across all measurements (SD)
Max vaginal capacity (mL)	A	471 (82)	473 (394–517)	485 (104)
	B	501 (119)	489 (420–569)	
Max intravaginal pressure (cmH ₂ O)	A	50 (18)	49 (33–65)	49 (18)
	B	48 (18)	45 (36–57)	
AP diameter at PS level (mm)	A	38 (8)	39 (31–41)	39 (8)
	B	40 (8)	43 (30–45)	
Lateral diameter at PS level (mm)	A	38 (7)	38 (35–40)	37 (9)
	B	37 (10)	34 (32–42)	
Maximum diameter (mm)	A	96 (9)	94 (89–101)	98 (11)
	B	100 (13)	97 (88–112)	
Minimum diameter (mm)	A	33 (5)	34 (29–37)	34 (7)
	B	35 (8)	35 (28–41)	
Maximum vertical length (mm)	A	167 (16)	171 (159–176)	169 (16)
	B	172 (15)	173 (167–183)	
Distended PMHD Area (cm ²)	A	25 (4)	25 (23–28)	25 (6)
	B	26 (6)	28 (21–29)	
Distended PMHD AP length (mm)	A	64 (5)	63 (62–67)	65 (7)
	B	66 (9)	68 (59–72)	
Distended PMHD Lateral Width (mm)	A	53 (6)	55 (54–58)	56 (7)
	B	56 (9)	57 (52–62)	
Baseline PMHD Area (cm ²)	A	16 (4)	15 (14–16)	16 (4)
	B	16 (4)	15 (14–16)	
Baseline PMHD AP length (mm)	A	55 (7)	55 (49–57)	56 (8)
	B	57 (8)	55 (53–61)	
Baseline PMHD Lateral Diameter (mm)	A	44 (8)	45 (38–52)	43 (7)
	B	43 (6)	41 (40–46)	

it was difficult to standardize the sensation of true maximal distension. This made the process of instructing patients to provide an end-point sensation difficult and likely contributed to the variability in the maximum intravaginal pressure measurements. Moreover, the measurement variability in the maximum diameter of the vagina between two rounds of examinations had moderate repeatability and 95% CI cover zero, without statistical significance. This was likely due to the subjective measure of maximum capacity and segmentation error as parts of the bag borders, at larger depth, were challenging to identify due to acoustic shadowing caused by the PS.

Strong correlations were observed between the metrics obtained from the distended vagina and physical exam measurements of distension, which may be indicators of the clinical applicability of the measurement system. The strongest correlations were observed between the maximum vaginal capacity and both introital diameter and lateral diameter of the vagina at the apex (Table 5), which indicated that the manometry

system distended the vagina similarly to currently accepted gold-standard clinical evaluations. The maximum vaginal capacity, AP diameter, lateral diameter, and bag length correlated with clinical measurements of the vagina including vaginal lateral width at the apex and introitus diameter. This finding suggests that this technique may help differentiate anatomical characteristics even within a relatively homogenous patient population (i.e., mostly stage II prolapse in our study). Conversely, poor correlations were observed between POP-Q measures and the measurement system-acquired measures as expected. POP-Q measures are obtained at an undistended state of the vagina and during Valsalva (except for total vaginal length, which is measured at a resting state). As a result, pelvic organs are pushed down and toward the introitus for the POP-Q assessment. However, the presented measurement system obtains metrics of the distended vagina where the pelvic organs are pushed away from the introitus due to water infusion in the vagina. While POP-Q metrics can characterize prolapse and determine the position of pelvic

TABLE 4 Repeatability analyses with intraclass correlation and coefficient of variation.

Metrics	ICC (95% CI, <i>p</i> value)	CV between two rounds
Max vaginal capacity (mL)	0.90 (0.52, 0.92, <i>p</i> < 0.001)	8%
Max intravaginal pressure (cmH ₂ O)	0.82 (0.25, 0.86, <i>p</i> = 0.002)	18%
Ap diameter at PS level (mm)	0.89 (0.48, 0.91, <i>p</i> < 0.001)	9%
Lateral diameter at PS level (mm)	0.87 (0.41, 0.90, <i>p</i> < 0.001)	12%
Maximum diameter (mm)	0.67 (−0.17, 0.70, <i>p</i> = 0.092)	7%
Minimum diameter (mm)	0.84 (0.30, 0.87, <i>p</i> < 0.001)	10%
Maximum vertical length (mm)	0.93 (0.65, 0.95, <i>p</i> < 0.001)	3%
Distended PMHD Area (cm ²)	0.85 (0.32, 0.88, <i>p</i> < 0.001)	10%
Distended PMHD AP length (mm)	0.77 (0.09, 0.81, <i>p</i> = 0.011)	6%
Distended PMHD Lateral width (mm)	0.85 (0.35, 0.88, <i>p</i> < 0.001)	5%

TABLE 5 Correlational analyses between physical exam measurements and distension metrics.

Distended bag metrics	POP-Q measures										Physical exam diameters		
	C	Aa	Ba	D	Ap	Bp	gh	pb	tvI	POP stage	Introital diameter	Apex lateral diameter	Apex AP diameter
Max instilled volume (ml)	0.41	0.2	0.47	0.61*	0.33	0.55*	0.46	0.05	0.07	0.38	0.71*	0.72*	0.18
Max pressure (cmH ₂ O)	0.03	0.17	0.01	0.09	0.18	0.23	0.14	0.1	0.28	0.18	0.25	0.21	0.51
AP diameter at PS level (mm)	0.37	0.16	0.43	0.53	0.18	0.47	0.31	0.08	0.1	0.38	0.46	0.34	0.19
Lateral diameter at PS level (mm)	0.41	0.38	0.57*	0.70*	0.44	0.56*	0.5	0.16	0.1	0.48	0.64*	0.61*	0.02
Maximum diameter (mm)	0.18	0.33	0.38	0.22	0.49	0.44	0.24	0.29	0.08	0.46	0.11	0.1	0.54
Minimum diameter (mm)	0.51	0.23	0.51	0.62*	0.26	0.55*	0.25	0.01	0.02	0.48	0.64*	0.57*	0.31
Maximum vertical length (mm)	0.2	0.17	0.24	0.45	0.22	0.24	0.55*	0.02	0.03	0.19	0.58*	0.61*	0.17
Distended PMHD Area (cm ²)	0.47	0.09	0.36	0.53	0.26	0.47	0.33	0.18	0.06	0.17	0.60*	0.58*	0.33
Distended PMHD AP length (mm)	0.46	0.09	0.31	0.48	0.12	0.36	0.23	0.06	0.03	0.07	0.55*	0.51	0.39
Distended PMHD Lateral width (mm)	0.48	0.23	0.41	0.60*	0.31	0.46	0.41	0.16	0.04	0.27	0.62*	0.67*	0.28

Note: All data presented as *r* values between physical exam measures (columns) and distension metrics (rows).

*Bold font indicates *p* < 0.05.

POP-Q measures:

C: the most distal edge of the cervix or leading edge of the vaginal cuff. This location identifies if the cervix is descending.

Aa: the point at the midline of the anterior vaginal wall.

Ba: the point that refers to the most distal portion of the remaining upper anterior side of the vaginal wall.

D: the point at the posterior fornix in patients with a cervix.

Ap: the point at the midline of the posterior vaginal wall 3 cm proximal to the hymen.

Bp: the point at the most distal portion of any part of the posterior vaginal wall.

gh: the distance from the midline of the external urethral meatus to the midline of the posterior hymenal ring.

pb: the distance from the posterior margin of the genital hiatus to midanal opening.

tvI: the greatest depth of the vagina when C and D are completely reduced.

organs with respect to the hymenal plane, they fall short in capturing distended properties of the vagina, which may limit the capacity for clinicians to address problems related to distension, including obstetric monitoring and changes in vaginal properties following radiation therapy. While characterizing the vaginal properties at a non-distended state is essential to understanding disease states, it is also important to characterize the properties at its other functional, distended states.

Many other techniques have been developed to quantify properties of the vagina.^{21–23,26} However, none of the existing methods are able to characterize the vagina at all functional states of distension cohesively. In a

previous study,³⁰ to gain insight into the structural and biomechanical properties of the distal vagina, the distal vagina was distended, reaching a maximum volume and pressure of 70 mL and 73 cmH₂O, respectively. In this study, the average maximum instilled volume and pressure were 485 mL and 49 cmH₂O, respectively. This volume was considerably higher and the pressure lower than the values reported by Jung et al.³⁰ Such differences could be explained by the fact that the method presented here distended the entire vagina, while in Jung et al.'s study,³⁰ only the distal vagina was distended. Furthermore, participants in this study had POP and a mean age of 69 years, while the participants in the

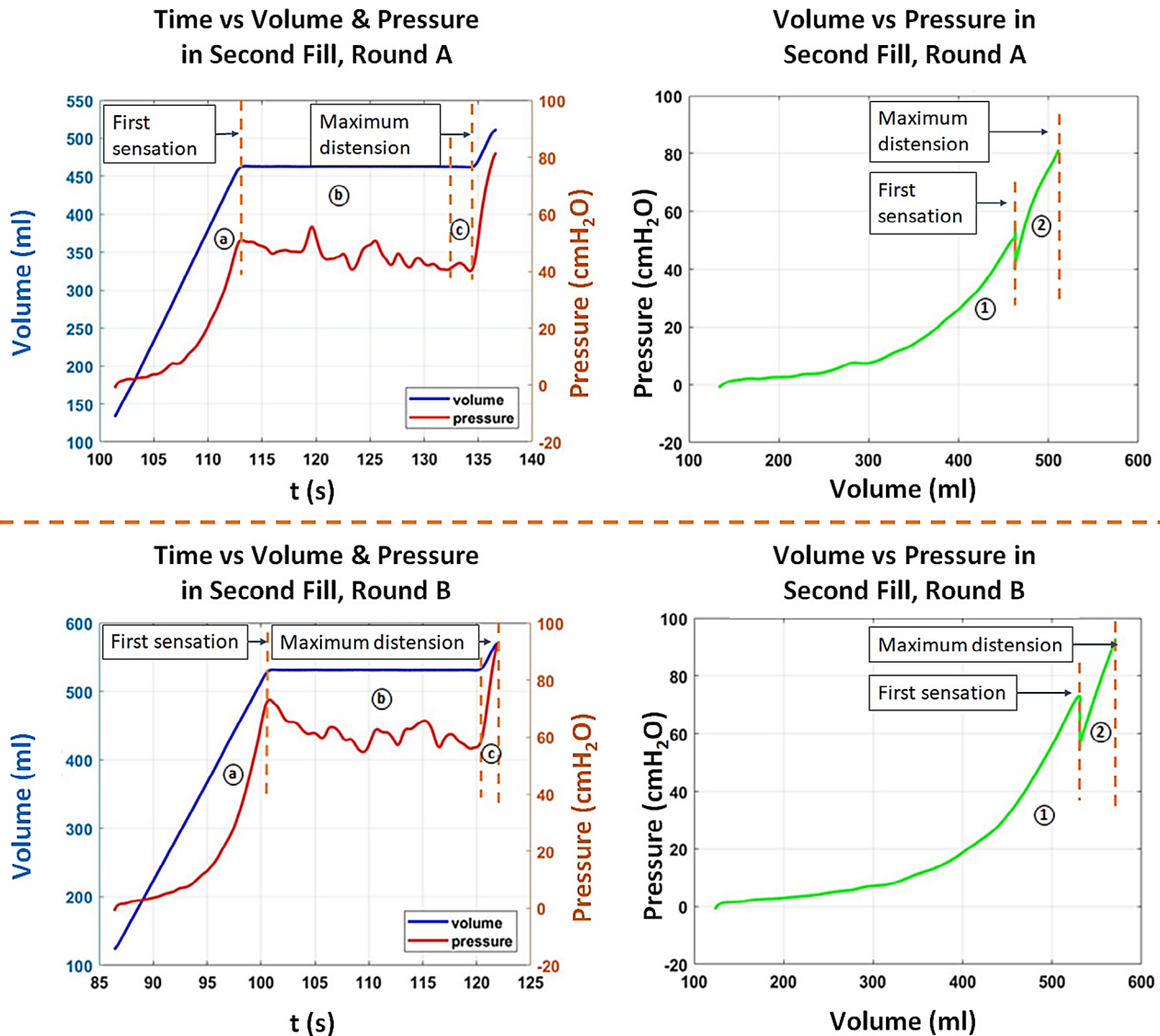


FIGURE 4 Representative plots of pressure versus volume, and volume and pressure versus time for the second fill in round A and B. (a) Filling from the start to the patient's first sensation; (b) muscle relaxation period; (c) start of the filling until the maximum vaginal capacity volume is reached. (1) Initial filling; (2) filling restart.

other study were nulliparous women with a mean age of 24 years. Moreover, in our study, we accounted for tissue relaxation effects and integrated a preconditioning step prior to performing the imaging protocol.

One of the strengths of this study was that the system was assessed in patients with POP, which represents a "worst case" patient population due to variations in anatomy and larger genital hiatus that make bag retention challenging. However, the findings in this study need to be interpreted in the context of several limitations. First, while a sample size of 16 was sufficient for the purposes of the proof-of-concept study, the results of the repeatability analysis should be interpreted as preliminary due to the relatively small sample size and only one repeated exam. Second, patient recruitment was not stratified based on the prolapse stage. Most

patients in this study had stage II prolapse. Differentiation of prolapse stages or types was not investigated with this preliminary data. Third, this study did not include a control group to determine the sensitivity of the measurement system and the expected differences in the measurements between the control group and patient population. Fourth, the maximum vaginal capacity was determined based on the patient's sensation of pressure, which is a subjective measure and likely introduced measurement variability in the repeated rounds. Fifth, the 3D surface models were generated from manual segmentations, the accuracy of which was affected by the bag wall visibility. The bag was designed to be oversized so that the shape of the distended vagina captured by the ultrasound was not affected by the shape of the bag. However, the excess bag material would

occasionally bunch in the vagina and cause image artifacts, such as blurry boundaries of the bag. If the bag was not inserted deep in the vagina, bag bunching at the distal vagina would hinder acoustic transmission and adequate bag visualization for segmentation. As a result of this, one dataset was excluded from the analysis. Sixth, the inter-and intra-operator variability of manual segmentations was not assessed in this study.

In future studies, efforts will be directed toward establishing an objective criterion to identify the threshold value for the maximum capacity of the vagina. Furthermore, the issue of subjective determination of the distension endpoint will be tackled in upcoming iterations through the implementation of a standardized pressure or volume distension point that can be applied uniformly across all subjects. Furthermore, future investigations will involve inter-and intra-operator variability of manual segmentations, and a control group to determine the ranges of each metric within a controlled cohort and assess the sensitivity of this system in detecting differences in vaginal properties between a control and patient population. Applications of this novel distension measurement system span from characterization of the vagina in patients with PFDs, to repair and reconstructive surgery, to obstetric monitoring. For example, characterization of the in-vivo biomechanical properties of the tissues could help determine the most optimal surgical procedure for POP repair.²¹ Moreover, in preparation for vaginal delivery, this technique may be useful in monitoring structural changes of the vagina and surrounding tissues during pregnancy, where the properties of the vagina must change drastically during gestation to facilitate vaginal delivery. Devices have been developed for vaginal delivery preconditioning by expanding the vagina or stretching the pelvic floor tissue.^{56,57} However, currently, no tool exists for analyzing the vaginal distension properties or quantifying these changes through gestation. By distending the vagina, the proposed technique can provide biomechanical and structural data that may be particularly relevant for better understanding the impact of vaginal delivery on the pelvic structures. In addition, prior studies have found that the vaginal dimensions might be factors to predict pessary treatment success.^{58,59} The measurements are currently performed via physical assessment. The proposed system provides a quantitative method to obtain such structural measurements of the distended vagina, which may increase the accuracy of pessary prediction models and may be used to design patient-matched devices for pelvic floor therapy, such as personalized dilators or pessaries.

5 | CONCLUSION

We demonstrated a novel measurement system for evaluation of the distension properties of the vagina.

The system's reliability and measurement correlations with physical assessment were evaluated in a preliminary study involving POP patients. The described system exhibits potential for offering a quantitative approach to assess the biomechanical and structural characteristics of the vaginal anatomy, thereby it might potentially enhance the detection of pathophysiological processes of diverse nature.

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CONFLICT OF INTEREST STATEMENT

Shufei Zhang, Alexandra M. Blokker, Ahmed Eltahawi, and Golafsoun Ameri are full-time employees at Cosm Medical. Ali Borazjani, Christopher X. Hong, and Colleen D. McDermott are advisor/consultant for Cosm Medical. Colleen D. McDermott is also a medical advisor for Szio Inc. and a speaker for Pfizer; neither of these two companies were involved with any facet of this study.

DATA AVAILABILITY STATEMENT

Data is not available for sharing.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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