Published in final edited form as:

Biomed Microdevices. 2009 December ; 11(6): 1213–1221. doi:10.1007/s10544-009-9339-z.

Development of a Novel Intra-vaginal Transducer with Improved Dynamic Response

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Abstract

Limitations of standard clinical pressure transducers have hampered our ability to provide reliable measurements of intra-abdominal pressure (IAP) during physical activities. To overcome these limitations, a novel intravaginal transducer (IVT) capable of accurate, reliable, and continuous IAP measurements during normal activity was developed. The design was validated through comparison with standard clinical pressure transducers in both bench top and clinical tests. The IVT demonstrated an improved dynamic response when compared to a standard rectal balloon catheter. Additionally, the radially symmetric design allows for accurate measurement within non-fluid-filled tissue cavities and simple placement within the vaginal canal. This is an advantage over sensor-tipped transducers which are only reliable in fluid-filled compartments. The IVT design presented here is preliminary to a wireless version that will allow for IAP measurement during activities outside the clinic.

Keywords

pressure transducer; pressure sensor; intra-abdominal pressure; vaginal transducer; frequency response; dynamic response; physical activity

1. Introduction

Modern techniques for continuously monitoring physiologic pressure typically utilize electromechanical sensors to convert pressure into an electrical signal which may be processed, displayed, and stored. Micromachined, piezoresistive silicon pressure sensors have become the clinical standard for continuous pressure measurements. These sensors are accurate, inexpensive and can be packaged into different types of transducer housings. Various single use medical devices have been developed implementing this sensor technology, including devices for continuously monitoring blood pressure (ANSI/AAMI, 1994/(R)2006), amniotic fluid pressure (Murray, 1997), intracranial pressure (Stefini and

Rasulo, 2008), bladder pressure (Culligan et al., 2001) and gastrointestinal pressure (Fang et al., 2004).

Most continuous pressure monitoring devices that are used in the clinic can be classified as either sensor-tipped catheters or fluid-coupled transducers. Sensor-tipped catheters are designed so the sensor may be placed directly at the source of physiologic pressure by mounting it to the distal terminus of a catheter. These devices measure dynamic pressures more accurately than fluid-coupled devices, due to their more direct form of measurement (Stoker, 2004). However, the accuracy of sensor-tipped catheters is incumbent on the placement and orientation of the sensor tip within the physiologic environment. Because the sensor is placed at the tip of the catheter and is typically oriented facing away from the catheter's midline, it becomes highly direction-dependent when placed in contact with tissue because it measures the normal force of the tissue interacting with the transducer (Holt et al., 1990; Lose et al., 2002).

In contrast to sensor-tipped catheters, fluid-coupled systems locate the sensor externally to the patient and couple the sensor to the physiologic source via a fluid-filled catheter line. The fluid-filled tube conveying the pressure signal can have an effect on the measurement accuracy and fidelity as the signal traverses the tubing from the source to the sensor (Hunziker, 1987; Hundley et al., 2006). Dampening and resonance effects in these systems depend on factors such as the length, diameter and stiffness of the tubing. In addition, the presence of air bubbles anywhere within the system further alters the transducer response (Hunziker, 1987; Hundley et al., 2006). Systems which are not critically damped can lead to erroneous measurement data in clinical environments and a misunderstanding of the generation and propagation of physiologic pressures. Fluid-coupled systems have evolved to include open-ended catheter and balloon-catheter systems. Open-ended catheters must couple the sensor to a physiologic compartment that is liquid or gas filled environment. Balloon catheters in contrast transmit pressure by the displacement of partially filled balloons and can be used in non-fluid filled environments such as the vagina or rectum.

Several types of fully implantable transducers based on microelectromechanical systems (MEMS) have been developed for monitoring physiologic pressure. These systems utilize telemetry to communicate pressure information from within the body to an externally located receiver. Commercial systems are available from several manufacturers for both research and clinical applications. Wireless systems, in which both nodes (implanted sensor and receiver) have internal power, provide high data bandwidth and ranges of 0.2 – 10m (reference X1, reference X2). These systems require batteries which must be charged or replaced and necessitate larger packages. Smaller implantable systems based on active telemetry have been developed where the primary node powers the secondary node via electromagnetic coupling (ref X3, ref x4). These systems do not require batteries and therefore have a longer lifetime and smaller size. Other systems based on passive telemetry systems use coupled inductors where the secondary node passively loads the primary node. The primary node oscillation changes as a function of pressure and alters the frequency spectrum of the transmitted signal (ref X5). Passive telemetry systems for biomedical pressure measurement have been approved by the FDA for endovascular monitoring (ref X6, ref X7). To date these fully implantable MEMs systems have only been designed to work in fluid filled environments and are not suitable for measurements in body cavities such as the vagina and rectum.

The limitations of current physiologic pressure transducers have restricted our understanding of and ability to acquire reliable intra-abdominal pressure (IAP) measurements in urogynecological studies. In the urodynamics clinic, both fluid-coupled and sensor-tipped transducers are commonly placed within the bladder (Kron et al., 1984; Cheatham and

Safcsak, 1998; Iberti et al., 1987), rectum (Barbalias, 1983; Obeid et al., 1995) or upper vagina (Obeid et al., 1995; McCarthy, 1982) to obtain surrogate IAP measurements. However, different transducer types do not produce identical responses during routine urodynamic studies (Hundley et al., 2006; Zehnder et al., 2008). This disparity is likely due to the limitations and inherent differences of each transducer system. Most sensor-tipped IAP measurements record pressures measured within the rectum or the vagina. However, these cavities are not closed-system, liquid or gas filled compartments and can therefore lead to erroneous readings when the sensor-tip is pressed up against the tissue wall. Occasionally, sensor-tipped catheters are placed in the bladder. These must be positioned properly without contacting the tissue wall and must be inserted through the urethra. This technique is not popular for longer term measurements of IAP because catheter placement is uncomfortable and adds a small risk of urinary tract infection (Malbrain, 2004). Balloon catheter fluid-coupled systems used in the rectum and vagina can be more favorable for static IAP measurement, but their poor dynamic response often leads to imprecise measurements during physical activity.

In addition to limiting the quality of the information that can be derived in the urodynamics laboratory, current transducers also preclude our ability to accurately measure IAP during physical exertion in real-world settings (such as occupational exertion or exercise). Elevated IAP during physical activity has been implicated in the pathogenesis of pelvic organ prolapse, urinary incontinence, and abdominal hernias, but there is discrepancy among clinicians and researchers as to which activities truly increase IAP to an undesirable level (Weir et al., 2006). This ambiguity is partly due to the inability of current transducers to accurately measure IAP during physical activity. Further, these transducers have not been designed for use outside the clinical laboratory setting. With an appropriate instrument to measure IAP, physicians will be able to gain a better understanding of the role that physical activity plays in post-operative healing, as well as in the development and recurrence of conditions like pelvic floor disorders. We hypothesized that a liquid filled, balloon-type device that contained an integral sensor could be placed in the upper vagina to measure IAP continuously, accurately and reliably during physical activity. To test this hypothesis, we developed a novel intravaginal transducer (IVT) and validated its performance with bench and clinical testing. Here we report the design, in-vitro testing and clinical evaluation of the IVT in a configuration that connects via a cable tether to a data acquisition instrument. The device design and system architecture will be further developed into a wireless transducer that will allow for accurate intra-abdominal pressure measurements during routine daily activities outside of the clinic.

2. Materials and Methods

The design strategy for the IVT was to place a microsensor and associated electronic components within a compliant, fluid-filled structure to be placed in the upper vagina for pressure monitoring. Pressures or forces applied against the compliant wall of the fluid-filled capsule would result in an increased intracapsular fluid pressure and be measured by the internal sensor. User comfort and device performance guided the overall design requirements. Components, subassemblies and finished prototypes were evaluated at different stages of the project in order to ensure the design requirements and specifications were met. The design and construction methods are outlined below.

2.1 Capsule Design

The external geometry of the transducer was designed as a bullet-shaped capsule due to its familiar profile (tampon-like), rounded terminus and reported comfort. The shape also provided for comfortable insertion in the patient and a simple molding process. The final size and dimensions were 1.2 centimeters in diameter and 3 centimeters in length with a

hemispherical distal terminus. A consistent method for in-house molding of thin-walled, bullet-shaped capsules was developed using relatively simple aluminum molds, a vacuum chamber and a laboratory oven. Capsules were molded from silicone elastomer (Vi-Sil, 50 Shore A) and cured at 120 °C for 15 minutes.

2.2 Microsensor Package Design and Assembly

A piezoresistive pressure sensor die (gauge-type microsensor - P562, Novasensor - GE) was prepared by attaching 50 μm diameter, gold plated copper, polyurethane insulated bonding wire (Phelps-Dodge) using a Westbond 7400 manual wirebonder with wedge bond tooling (CF-104-1/16-437-003-003-MP-E, Deweyl Tool Co.). Wire bonds were reinforced with a small amount of acrylic-based, uv-cure adhesive (3321 Loctite). The microsensor was attached to a custom-made, 0.75 mm thick FR-4 printed circuit board using uv-cure adhesive (3321, Loctite) on one corner of the microsensor and uv-cure silicone (17007, Loctite) around the remaining perimeter (Fig. 1). The acrylic-based adhesive ensured the sensor was fixed to the PCB, while the compliant uv-cure silicone provided a flexible seal. Microsensor wires were soldered to their mating pads on the circuit board and the assembly was mounted at the base of a machined aluminum ring (11 mm OD $\times$ 9 mm ID $\times$ 4 mm) using uv-cure adhesive. The space in the aluminum ring above the electronic assembly was filled with silicone gel (Vi-Sil) to protect the electronic components and to transmit pressure to the microsensor. The silicone gel was cured at room temperature for 36 hours.

2.3 Final Transducer Assembly

The underside of the circuit board was prepared by attaching a 40 cm long vent tube (0.6 mm OD $\times$ 0.4 mm ID - Pebax 6333SA, Medical Extrusion Technologies, Inc.) to a hole drilled directly beneath the mounted microsensor using uv-cure adhesive (3321, Loctite). The sensor operates in differential mode with the hole and attached tube serving as an atmospheric reference or “vent” that connects one side of the microsensor diaphragm to atmospheric pressure. To complete the subassembly, four pieces of insulated copper magnet wire (40 cm long, 0.007 gauge - 0.4 mm diameter, Small Parts, Inc.) were soldered to the requisite pads on the underside of the printed circuit board. The vent tube and wires were then assembled into the tether assembly; a long, slender, cable-like structure for electrical insulation, atmospheric venting and retrieving the transducer assembly. The wires and vent tube of the sensor subassembly were threaded through a piece of silicone tubing (3 mm OD $\times$ 2 mm ID $\times$ 30 cm - Med-ex, Small Parts, Inc.) that served as an insulator for the wiring as well the outer casing of the tether. The distal end of the silicone tube was arranged so it was adjacent to the bottom of the circuit board. The proximal end of the silicone tube was accessed with a blunt needle and filled with newly mixed, vacuum degassed silicone elastomer (Vi-Sil, 50A) with a 5 ml plastic syringe. The assembly was placed into the bottom of the thin-walled capsule base and fixed into place by molding a thick silicone section (Vi-Sil, 50 Shore A) that captured the electronic circuit board and ring, attached and sealed the compliant capsule and integrated the silicone tether. The entire assembly was cured in the oven for 20 minutes at 80 °C. After curing, the vent tube was exposed to atmospheric pressure by pulling it through a side hole at the proximal end of the tether. A male circular connector (A22000 – male 5 pin mini, Omnetics, Inc) was soldered to the wires and attached to the tether using a final silicone molding process. An extension cable was also prepared to provide sufficient length for connections to the data acquisition system within the clinic. A female circular connector (A22001 – female 5 pin mini, Omnetics, Inc.) was soldered to an Ethernet cable, and a silicone tube was cut and used as a sheath over the electrical connections. A cross-sectional view of the completed sensor design (absent the silicone tether tubing and vent) is shown in Fig. 2.

The capsule was filled with 2.5 mL of deionized water by inserting a 22 gauge taper tip needle (OK International, TT22-1-1/4PK) through the outer diameter of the silicone base until the tip was within the air filled capsule space. A 5ml syringe attached to the needle was used to introduce the water and the air was vented by inserting a second needle without a syringe through the base.

2.4 Critical Function Prototype Testing

Overpressure and compression tests were conducted on capsules with various wall thicknesses to determine potential failure modes and to optimize the capsule wall thickness. Capsules of three different wall thicknesses (0.635 mm, 0.890 mm and 1.27 mm) were fabricated, sealed with silicone and filled with 2.5 mL of water for testing. To test compression load capacity, the capsules were compressed in a materials test instrument (Instron) up to 1000 N (224 lbs) or failure.

A test was conducted to evaluate the ability of the silicone gel to transmit pressure to the microsensor. Sensors were mounted to the base of aluminum housings and covered with gel layers of varying thicknesses: 2 mm, 4.1 mm and 6.3 mm. A calibrated pressure generator (Tescom ER 3000) with a NIST calibrated reference transducer (Pressure Systems – KPSI, 0–6 psig p/n 30-142-1006) was used to pressurize the gel. Microsensor response was observed using a multichannel data acquisition instrument (34970A, Agilent Technologies) to determine if there was a loss in sensitivity as gel thickness increased.

2.5 Prototype Bench Testing

A pressure chamber was built to test the output sensitivity, linearity and frequency response of the IVT (Fig. 3). The chamber consisted of an acrylic tube (2 3/4" OD × 21/2" ID × 6", US Plastics) sealed water-tight to a square acrylic base (15 cm × 15 cm × 1 cm) using uv-cure adhesive. A multi-function pressure waveform generator (WGA-200, Millar Instruments) was connected to an electromagnetic pressure converter (Millar Instruments) mounted air-tight to the top of the compartment. The pressure waveform was manipulated by means of a function generator (33220A, Agilent Technologies). Two luer-type stopcocks were mounted at the top of the pressure chamber to provide a means of filling the chamber with water as well as provide fixed pressures to the chamber from the pressure generator (Tescom ER 3000) via silicone tubing (1/87Prime; ID × 1/4" OD, Small Parts, Inc.). The newly designed IVT and a conventional rectal transducer (CAT411, Laborie Medical Technologies) were inserted into the water chamber through two large holes which were then sealed with silicone (Vi-Sil, 50 Shore A). The responses of the intravaginal and rectal transducers were compared to a designated reference transducer. The reference transducer was a modified conventional continuous blood pressure transducer (Intran, Utah Medical). The transducer was prepared by removing a small portion of the fluid pathway that covers the pressure aperture, thereby exposing the gel-filled aperture directly to the water in the chamber. This modification allowed the transducer to capture pressures applied directly to the sensor diaphragm. This is the same principle that guides the design of sensor-tipped transducers, which are considered the gold-standard for accuracy during dynamic pressure measurements. The reference transducer was inserted through a hole in the pressure chamber and sealed with silicone (Vi-Sil, 50 Shore A). The chamber was filled with degassed water until the water line reached just below the stopcock openings.

The linearity of the IVT was tested by stepping the pressure up to 387 cm H₂O (5.5 psi) in increments of 35 cm H₂O. The response curve was used to calculate the transducer's sensitivity and offset. Next, the frequency responses of the IVT and rectal transducer were characterized and compared against the response of the reference transducer. An offset pressure of 87 cm H₂O (1.2 psi) was applied to the chamber via the pressure generator in

order to obtain pressure measurements within a clinically relevant range. Then, using the pressure waveform generator, swept sine wave tests and impulse (square wave) response tests were performed to analyze the dynamic response of the transducers according to industry guidelines (ANSI/AAMI, BP22:1994/(R)2006). Transducer outputs were acquired and stored using a breakout box (SCC-68, National Instruments), a DAQ card (PCI-6221, National Instruments), and a custom LabView 8.0 program. Pressure measurements were sampled at 1000 Hz and averaged with a 10-sample moving window.

2.6 Final Prototype Clinical Evaluation

After obtaining University of Utah IRB approval and informed consent from each participant, we evaluated prototype devices in 8 volunteers undergoing standard urodynamic testing. A single-use prototype intravaginal sensor and standard rectal balloon catheter were placed in each of the study participants by a member of the clinical research team. Each of the women performed routine urodynamics tasks such as coughing and Valsalva maneuvers. For this research a series of squats, lifts, and jumps were added to the protocol. All tasks were performed with a bladder volume of 200 mL. Measurements were sampled at 15 Hz for the rectal transducer using standard clinical cystometry software (Laborie Medical Technologies). The IVT output was sampled at 20 Hz using a data acquisition unit (34970A, Agilent Technologies). The response of each transducer was plotted and compared. Peak pressure values measured from both transducers during significant physical activity were recorded and plotted against each other. Pressure change rate was also calculated to determine the change rate's effect on measurement agreement.

3 Results

3.1 Critical Function Prototypes

During the compression test, eight of nine devices supported compressive forces up to 1000 N (224 lb) in the materials test instrument. The remaining capsule leaked and burst when compressed to approximately 250 N (56 lb). The capsule that failed (0.890 mm thick wall) was found to contain small defects caused by air bubbles formed in the silicone wall during the molding process. Because all of the unflawed capsules tested were capable of withstanding forces much greater than physiological forces, the thinnest wall capsule (0.635 mm) was selected for the final design to optimize sensitivity.

Results of the microsensor/gel sensitivity tests showed that the microsensor sensitivity decreased by less than 1% when placed under less than 4.1 mm of gel. In the final design, the microsensor was placed under a 3 mm thick gel layer.

3.2 Prototype Bench Testing

The intravaginal sensor demonstrated a linear response ($R^2 = 0.9996$) from 0 to 387 cm H₂O and a sensitivity of 1.61E-5 mV/V/cm H₂O (Fig. 4). The dynamic response of each transducer is illustrated by the results from the impulse response test shown in Fig. 5. The fluid-coupled rectal balloon catheter exhibited a response typical of an underdamped second-order system. An overshoot of 107% was measured from the balloon catheter's response to an impulse pressure input. The natural frequency, F_n , of the rectal transducer was calculated to be 17.6 Hz and the damping coefficient, D , was calculated to be 0.01 representing a highly underdamped system. These performance characteristics were verified by the results from the swept sine wave test shown in Fig. 6. The flat bandwidth (15% tolerance) of the balloon catheter was determined to be 5 Hz from the swept sine wave results. Flat bandwidth is defined to be the range of frequencies, beginning with 0 Hz, over which accurate measurements may be obtained. Natural frequencies and damping

coefficients for the IVT and reference transducer were incalculable, demonstrating no measurable overshoot during the swept sine wave or impulse response tests.

3.3 Final Prototype Clinical Evaluation

During clinical testing, measurements from the prototype intravaginal pressure sensor correlated with a conventional urodynamics balloon catheter placed in the rectum throughout most physical activities such as lifting 10 lbs. (Fig. 7). However, during a few select activities (i.e. jumps), the sensor response was very different (Fig. 8). Closer examination revealed that the transducers' responses were similar during physical activities inducing gradual IAP changes ($dP/dt < 150 \text{ cm H}_2\text{O/sec}$, $r^2 = 0.961$), but the transducers responded very differently during physical activities which caused abrupt IAP changes (Fig. 9). During activities which caused abrupt IAP changes ($dP/dt > 450 \text{ cm H}_2\text{O/sec}$), the rectal balloon catheter measurements significantly overshoot the vaginal transducer's measurements at both the peaks and the troughs.

Physicians familiar with sizes and shapes of other vaginal devices evaluated the external dimensions and geometry and concluded that the design should be comfortable and properly retained within the vagina during physical activity. All women who used the device verified that the IVT was more comfortable than the rectal and bladder catheter transducers.

4. Discussion

We have developed and validated the performance of a novel IVT for use in urogynecological studies to continuously monitor IAP during physical activity. Our design has overcome many of the limitations displayed by fluid-coupled and sensor-tipped transducers that are currently used in the clinic. The results of our frequency response testing demonstrate that the IVT has superior dynamic response compared to a standard fluid-coupled rectal balloon catheter and the IVT does not require the use of a fluid filled catheter line which is known to cause system resonance and noise. Furthermore, the IVT design is radially symmetric which allows pressure measurement independent of direction within a non-fluid-filled tissue compartment, thus minimizing the need for the precise placement required by sensor-tipped transducers. By combining vaginal placement, comfortable design, integral sensor and non-critical placement, the IVT provides a foundation for a wireless device that can be used outside the clinic to obtain continuous pressure measurements during daily activities.

The improved dynamic response of our IVT compared to a conventional fluid-coupled balloon catheter transducer is evident from the results of the impulse response and swept sine wave tests. The recordings from the vaginal device showed no measureable overshoot or resonance effects and were nearly identical to the response of the reference transducer. The balloon catheter provided accurate measurements when gradual pressure changes (i.e. low dP/dt) were introduced into the chamber, but displayed resonance effects during abrupt pressure changes (i.e. high dP/dt). The response of the balloon catheter is typical of fluid-coupled transducers, which are inherently underdamped ($D < 1$) due to tubing compliance, fluid inertia, and viscous effects (Stoker, 2004). The fluid-coupled transducer bandwidth may be increased by shortening the catheter line, but such modifications can limit patient mobility. We have designed our device such that the microsensor is located within a fluid filled capsule at the physiologic source. This eliminates the need for a fluid-filled catheter line and minimizes resonance effects.

Results from our pilot clinical trial confirmed the improved dynamic response of our intravaginal sensor compared to the rectal transducer during certain physical activities that promoted rapid changes in IAP. Our clinical trial was limited in that we were unable to

compare the response of our transducer to absolute IAP. True IAP measurements are obtained only by breaching the peritoneal cavity, which for our studies was unreasonable. Our approach was to compare the IVT's response to a current standard clinical IAP transducer, the rectal balloon catheter. During physical activities involving gradual pressure changes, the IVT was comparable to the rectal transducer. However, during activities involving abrupt pressure changes such as forceful coughing and jumping, the rectal balloon catheter measured a significant overshoot compared to the intravaginal device (Fig. 9). The results from benchtop frequency response tests lead us to believe that the IVT provided more accurate measurements than the fluid-filled transducer during these rapid increases in IAP, and will therefore provide more accurate and reliable IAP measurement when used by women undergoing a broad range of real-world activities.

Vaginally located transducers are preferred over bladder or rectal locations because vaginal access is considered safe, comfortable and less invasive (Oddsson et al., 2005; Donnelly et al., 2004). The vagina however is not fluid filled and despite their accuracy in fluid filled environments, sensor-tipped catheters have been shown to be imprecise when tested in non-fluid filled cavities (Anderson et al., 1983). Our device places the microsensor at the physiologic site of interest as does the sensor-tipped catheter, however the IVT's unique packaging design allows for accurate and precise measurements within a non-fluid-filled tissue compartment such as the vagina. In comparison to sensor-tipped catheters, these advantages can promote enhanced accuracy, longer duration of measurements and more personal mobility.

To maintain device functionality and ensure patient safety, the IVT was designed to be fully encapsulated in a silicone capsule. The silicone capsule consists of a compliant wall, transducer base and tether. The silicone capsule seals the packaged electronics and fluid inside the device, protecting the electronics from body fluids and maintaining a dielectric barrier. Additionally, the capsule was designed to maintain structural integrity under physiologic loadings without compromising device performance. Compression tests demonstrated that fluid-filled capsules were able to withstand forces many times greater than seen within the upper vagina (Guaderrama et al., 2005). These compression tests caused devices with air bubbles and other inconsistencies in the silicone wall to fail. As a result, we modified our fabrication and inspection techniques to eliminate these defective components from subsequent transducers. Response testing confirmed the capsule wall maintained sensor sensitivity.

To measure IAP during real-world physical activity, we have to consider the transducer system noise and artifacts caused by bodily motion and disturbance of the fluid-filled tubing lines. The effects of physical movement on sensor-tipped transducers, fluid-coupled transducers, and the IVT were not analyzed quantitatively in the present study. However, several irregular pressure changes were seen in balloon catheter measurements, but not in IVT measurements, while patients were moving. Bouncing and jerking of the transducer fluid-line is nearly unavoidable during physical activity and it's known that disturbances to the catheter line of fluid-coupled transducers can cause signal noise and artifact. While fluid-coupled devices provide a safe and effective means for continuously monitoring pressure in many clinical applications, it appears to represent a significant limitation for IAP measurement during physical activity. Physical activity can also cause sensor-tipped catheters to shift or move. Since the accuracy of sensor-tipped catheters is heavily dependent on direction placement location, unavoidable shifting during activity may lead to inaccurate measurements (Holt et al., 1990). Our transducer design does not have a fluid-filled line that can be disturbed, nor does it require perfect placement. Therefore, we consider the design of our IVT with the microsensor placed at the pressure source to be better suited for continuous measurement during patient ambulation and daily physical activity.

One current limitation of our device is that it requires a cabled connection to a data acquisition unit. Although we believe its design allows for greater patient mobility than other transducers within the urodynamics laboratory, a wireless version would allow unrestricted patient ambulation outside the clinic. Our primary goal in this study was to validate the performance of our transducer as a wired version; our future work will involve the further development of the device into a wireless implant. Another limitation was the duration of the test; no long term drift tests were conducted. The goal of the study was to compare the newly developed device to the current standard used in the urogynecology clinic. During routine urogynecologic measurements, the sensors are used for short durations and therefore we did not include long term drift tests or investigations for ionic contamination of the sensor and circuit. Future work where these devices are used for ambulatory monitoring will include long term stability tests.

In summary, our studies demonstrate that our newly-developed IVT, when compared to a rectal balloon catheter, provides a more accurate tool for researchers and clinicians to understand IAP during various physical activities. Designed with this intended use in mind, it affords a better solution than sensor-tipped and fluid-coupled transducers that are currently used for IAP measurements in urogynecological studies and may ultimately provide clinicians with a revised understanding of IAP during real world physical activities.

5. Conclusion

Our newly developed IVT is capable of accurately and reliably measuring pressures in the laboratory when compared to standard physiologic pressure transducers. The new transducer is superior to the standard fluid-filled transducer in its ability to measure rapid pressure changes as demonstrated in our bench and clinical testing. Because the new implant uses a microsensor located at the physiologic source, it provides a superior dynamic response in comparison to the standard fluid-filled transducer and is more suitable for pressure measurement during physical activity. In addition, our IVT design overcomes limitations associated with the use of sensor-tipped systems for real-world IAP measurements. Based on the design of this newly developed transducer, we are developing a wireless version to facilitate real-world IAP measurements. The ability to measure real-world IAP will provide valuable information concerning pelvic floor loadings during daily activities and will help piece together a more comprehensive understanding that will improve patient outcomes.

Abbreviations

IAP	intra-abdominal pressure
IVT	intravaginal transducer

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Fig. 1.
Photograph of piezoresistive microsensor mounted to a custom-made printed circuit board

Fig. 2.

Photograph displaying a cross-section of the intravaginal transducer. The picture shows an instrumentation amplifier (AD8220, Analog Devices) and a surface mount gain resistor (Panasonic) soldered to the circuit board. These components were absent from transducers tested in the current study

Fig. 3.

Dynamic response test setup. The three transducers were placed within the pressure chamber. (from left to right: reference transducer, rectal balloon catheter, and IVT)

Fig. 4.
Calibration curve for the intravaginal transducer

Fig. 5.
Response of three transducers during an impulse response test

Fig. 6.
Swept sine wave frequency plot for three transducers

Fig. 7.
IAP measurements while subject lifts 10 lbs

Fig. 8.
IAP measurements while subject jumps 5 times

Fig. 9.

Intravaginal transducer response compared to rectal balloon catheter response during physical exertion. This data is taken from eight volunteers. The solid line represents perfect agreement between the two transducer systems. Low dP/dt is defined as less than 150 cm H₂O/sec; high dP/dt is defined as greater than 450 cm H₂O/sec. These measurements are referenced to the balloon catheter