A Low-Cost, Easily Deployable Vesicovaginal Fistula Occluding Device for Providing Interim Continence

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Madhurima Das[1]
Department of Mechanical Engineering,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: rimadas@mit.edu

Katie S. Hahm[1]
Department of Mechanical Engineering,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: khahm@mit.edu

Ava A. LaRocca[1]
Department of Mechanical Engineering,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: alarocca@mit.edu

Cecilia Alessandra Luna
Department of Mechanical Engineering,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: aleluna@alum.mit.edu

Keegan Mendez
Health Sciences and Technology,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: kmendez@mit.edu

Rachel Hoffman
Department of Mechanical Engineering,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: rachelmh@mit.edu

Connor A. Verheyen
Health Sciences and Technology,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: connorv@mit.edu

Tesia G. Kim
Gynecology and Reproductive Biology,
Beth Israel Deaconess Medical Center,
Boston, MA 02215
e-mail: tkim5@bidmc.harvard.edu

Bridgette W. Wamakima
Obstetrics and Gynecology,
Beth Israel Deaconess Medical Center,
Boston, MA 02215
e-mail: bwamakim@bidmc.harvard.edu

Ellen T. Roche
Professor
Fellow ASME
Department of Mechanical Engineering,
Massachusetts Institute of Technology,
Cambridge, MA 02139
e-mail: etr@mit.edu

Vesicovaginal fistulas (VVFs), abnormal openings between the vagina and bladder, disrupt the lives of over 3 million people worldwide due to resulting incontinence and infections. VVFs are commonly treated with surgery after the fistula has had time to heal over several months. In low-resource areas, immediate incontinence often leads to ostracization from the community and can be devastating for the patient. To address this problem, we have designed a three-tiered silicone plug consisting of a bladder-dwelling disk, a midfistula disk, and a vagina-dwelling cross-shaped tapered plug, all supported on a central stem. The system is designed to occlude the fistula and enable full continence until the patient is able to access surgery. This proof-of-concept device withstands typical expulsion forces from the bladder and does not leak under typical bladder filling or urination pressures. The maximum device expulsion force is 3.69 N and it is watertight up to 9.8 kPa. It is designed to be easily deployed by trained community members. [DOI: 10.1115/1.4053603]

1 Introduction

1.1 Motivation. Vesicovaginal fistulas (VVFs) are abnormal connections between the vagina and bladder that result in continuous leakage of urine. This leads to complications such as recurrent infections and patient discomfort [1].

It is estimated that over 3 million people worldwide experience the difficulties of a VVF, with many living in developing regions of the world [2]. In this setting, 90–95% of VVFs are formed by pressure-induced tissue necrosis as a result of protracted labor when access to obstetric care is limited [1,3]. The standard of care is an invasive surgery, and while it is often effective for patients, there is often a waiting time following fistula formation of a few weeks to months while the fistula tissue epithelializes [4]. In the meantime, patients live with significant social stigma and ostracization, while simultaneously recovering from a traumatic delivery. They manage their incontinence with whatever materials they have on hand, but because sanitary napkins and adult diapers may not be easily accessible, their symptoms include a constant unpleasant odor and urine leakage [5,6]. The Global Burden of Disease Study classifies untreated VVFs as having an impact on patients' quality of life that can be worse than tuberculosis and similar to amputation of both arms [7]. These people face stigmatization and isolation from their communities, resulting in a high emotional toll [1]. This situation is exacerbated by the lack of access to surgery, as surgeons are not always permanently present and may have to fly in to perform the surgeries. As such, many patients go without treatment for extended periods of time.

The primary goal of this work is to make the fistula watertight and prevent incontinence immediately after the fistula forms. We address an unmet need to develop a minimally invasive, nonsurgical device and procedure to immediately enable full continence for patients with VVFs as they wait for surgical correction. Due to the lack of immediate access to medical professionals, it must be deployable by community members in low-resource areas. Figure 1 shows our proposed solution—a three-tiered silicone plug that fills the fistula until the patient is able to access surgery—and a potential insertion strategy is discussed in the Supplemental Material on the ASME Digital Collection.

[1]Madhurima Das, Katie S. Hahm, and Ava A. LaRocca contributed equally to this work.

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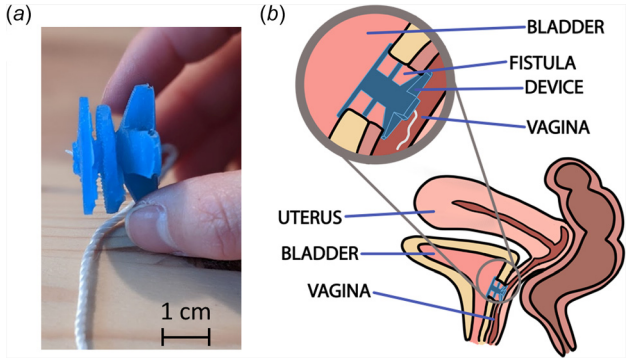

Fig. 1 (*a*) Three-tier silicone device for occluding VVFs and (*b*) the device shown in the anatomical context of the vesicovaginal fistula

1.2 Functional Requirements. The design of this device is driven by the needs and constraints of low-resource environments and is subject to the following functional requirements (FRs):

FR1: The device must achieve temporary full continence for fistulas that are 2 cm in diameter for this demonstration.
FR2: The device should not exacerbate tissue damage or erosion.
FR3: The device should last at least 2 months until the patient is able to receive surgery [4].
FR4: The device must be low-cost, under $10.
FR5: The device must be minimally invasive and deployed transvaginally without general or local anesthesia.
FR6: The device must be simple to insert by a trained community member who does not have formal medical training.
FR7: Fabrication in a range of sizes should be possible.

1.3 Background. Vesicovaginal fistulas may present in a wide range of sizes, severities, and complexities [8]. Generally, they may vary in size from a pinhole to several centimeters in diameter. Over 90% of fistula cases in developing countries are caused by obstructed labor, which leads to larger fistulas [1]. We will focus on fistulas of 2.0±0.2 cm diameter that are type 1.b.i in the Goh classification [8]. This indicates that the fistula is high up in the vaginal canal (type 1), has a medium diameter between 1.5 and 3 cm (class b), and has no or mild fibrosis (class i) [8]. VVFs penetrate bladder wall tissue, which is of the order of 7.9 mm thick [1], and the vaginal wall tissue, which is significantly thinner at around 2.3 mm [9]. The elasticity of the bladder ranges from 147 kPa to 527 kPa depending on the bladder fill volume [10]. The vaginal wall is significantly more compliant, with reported Young's modulus measurements in the range of 5–15 kPa [11,12]. For our testing, we focused on the bladder wall properties due to its significantly greater thickness and stiffness to ensure the device is not expelled from the fistula.

Another design consideration is fluid exposure. The device is continuously exposed to urine and vaginal discharge. Urine contains minerals that can lead to calcification [13], resulting in additional design constraints. Additionally, a recently formed fistula is an open wound; therefore, infection is a potential concern. A successful seal mechanism of the device may reduce the risk of infection. The device must seal against the pressure inside the bladder. At rest, intravesical pressure does not exceed 20 cmH_2O (2.0 kPa), though during urination, pressure can reach 60 cmH_2O (5.9 kPa) [14].

Regardless of access, patients must wait for at least 6 weeks for fistula tissue to epithelialize in order to receive surgery [4]. During this time, the patient can suffer from incontinence and ostracization. To mitigate this, a device should be deployed once a fistula has been detected, soon after the patient has given birth, and should remain effective until surgery is available.

1.4 Prior Art. There are several existing patents with a mechanical approach to fistula closure in other parts of the body [15,16]. Most patents rely on either patching the fistula or pinching surrounding tissue together [15,16]. One patent relies on a foldable patch that is inserted through a syringe-shaped applicator [15]. The applicator insertion mechanism is small enough to pass through the fistula and deploy the patch folded inside, which is then maintained in place with a tensioned string [15]. Another device used in gastrointestinal procedures uses metal clips to pinch gastrointestinal tissues together [16]. This device is not appropriate for VVF treatments as the sharp metal clips may cause pain and discomfort for patients, as well as additional tissue tearing. These devices do not fit the constraints for low-cost solutions for VVFs and require advanced medical training to deploy.

Biomaterial treatments, such as Coseal [17] and Vasalgel [18], have been shown to promote tissue closure and wound healing and come in a wide variety of properties that could be tailored to fistula repair. While hydrogels have the ability to effectively adhere to tissue and stop liquid flow, they are not ideal for this purpose as they are expensive, difficult to deploy, and often have short shelf lives [19,20]. Thus, our final device design is developed taking these shortcomings into consideration.

In this paper, we present the design of a VVF occluder, shown in Fig. 1, as follows: first, we describe the design, materials, and fabrication; next, we perform structural analysis on this design; then, we test its performance; and finally, we discuss our results, limitations, and future work.

2 Design and Methods

2.1 Device Design. The VVF occluder is a three-tier silicone plug with a bladder-dwelling disk, a midfistula disk, and a vagina-dwelling cross-shaped cone. Each component is supported on a central stem. A tether embedded in the core remains in the vagina to allow retrieval if necessary. The design is shown in Fig. 2. The bladder-dwelling disk covers the fistula opening to achieve watertightness while also providing a flange normal to the fluid pressure to resist dislodging when the bladder is full. The middle disk stabilizes the plug within the fistula to keep the cap centered over the fistula opening. The taper on the vaginal side is intended to accommodate small fluctuations in the fistula size or wall thickness and prevents the device from slipping into the bladder. The

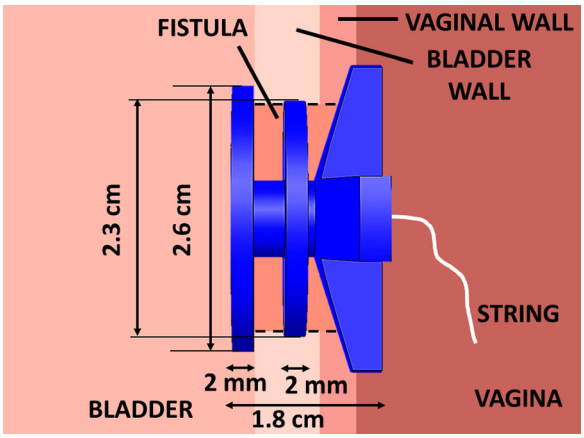

Fig. 2 The device design and its measurements. The intended positioning between the vaginal and bladder walls is shown. The bladder has a higher pressure than the vagina; the first disk and tapered cross create a seal while the middle disk stabilizes the device.

tapered plug and middle disk also help center and self-align the plug within the fistula in case of small misalignment. The tapered plug is cast as a cross shape and the disks are molded with grooves for ease of collapsing to fit through the fistula during insertion. We envision care providers having a set of devices of different prefabricated sizes, with the care provider selecting the appropriate device after manual sizing, similar to the procedure for evaluating cervical dilation during labor [21] or pessary fitting/implantation [22]. Manual sizing is standard practice in the developed and developing world and is anticipated to be a skill already possessed by or easily taught to those who would be deploying our device.

2.2 Device Materials and Fabrication. This device will be composed of medical grade silicone, similar to the material for a menstrual cup [23]. Additionally, the silicone could be coated in a microbial biosurfactant, R89 biosurfactant (R89BS) to keep the device clean and free of bacterial growth [24]. The main considerations for material selection involve modulus of elasticity, risk of biotoxicity, and risk of infection. The selected medical grade silicone is matched to the modulus of elasticity of the bladder tissue to minimize tissue damage (satisfies FR 2) and to ensure a watertight seal that does not disrupt regular tissue function. Furthermore, medical grade silicone is able to remain in the body for extended periods of time with low risk of infection (satisfies FR 3). For example, silicone pessaries (intravaginal stabilizing devices) can remain inserted for up to 3 months, which would align appropriately with the amount of time patients must wait to see surgeons [22]. Comfort for the wearer was another key consideration for material selection. Similar devices such as pessaries and other silicone-based intravaginal devices (such as menstrual cups and the Nuvaring birth control method) have been shown to be comfortable to the wearer [25]. Silicone is also the sheath material of some Foley catheters, which can remain in the bladder for several weeks [26]. Finally, the toxicity of medical grade silicone is not currently a concern as predicate devices demonstrate that silicone is well-accepted within the bladder and vagina [26,27].

We fabricated the device by molding the disks and core separately using Moldstar 31-T from Reynolds Advanced Materials in Brighton, MA (Smooth-On) and then assembling using Sil-poxy. The final device will be fabricated in one piece via injection molding with a medical grade silicone (e.g., NuSil), which would allow for low-cost, large-scale production in a variety of sizes. From a material analysis of this device, the estimated cost is $6.67 per unit (satisfies FR 4) [28–31].

2.3 Fistula Phantoms. A synthetic phantom was used to simulate fistulas for testing. For this test, the phantom approximated the fistula geometry with a thickness of 1 cm [9,32] and a 2-cm diameter circular hole cut out. To mimic tissue properties, we chose the silicone Ecoflex 00-30 (Smooth-On) given its modulus that was similar to bladder wall tissue [10]. To simulate the natural biological fluid environment present at the fistula site, we spread fluid on the phantom wall.

2.4 Test Setups. Three tests were performed, as described below—the first two used the demonstration fistula phantoms described in Sec. 2.3, while the third test was performed in a more anatomically accurate model. The first test was used to test the force required to fully expel the device from the fistula and was used as a preliminary screening to optimize device dimensions and features. The second phantom test and the anatomical model test were used to validate the performance of the design by showing that the device resisted leakage for all physiological bladder pressures and standard bladder curvature.

2.4.1 Pull-Out Force Test Setup. To test pull-out force, we made a fixture to stabilize the fistula phantom within the tensile grips of an Instron 5944 single-column universal materials tester

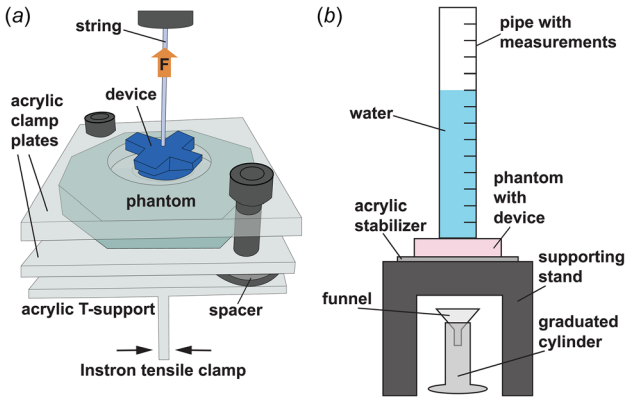

Fig. 3 (*a*) Schematic of the fixture used to stabilize the phantom in the Instron for pull-out force testing and (*b*) experimental setup for testing different bladder pressures

(Fig. 3(*a*)). The fixture pieces were laser cut from 0.3 to 0.8 cm thick acrylic sheets. The clamp plates were 8 cm square with a 4 cm diameter centered hole to clamp the phantom. The T-support pieces were joined with epoxy and a tab-and-slot joint. The bottom clamp plate was separated from the T-support platform with three washers for a spacing of approximately 0.5 cm. Two M8 bolts were thread through opposite corners of the stack-up and were secured with hand-tightened nuts. The top clamp of the Instron held the threaded region of an upside-down bolt, to which the device strings were tied. All tests were performed using a 50-N load cell, following a typical displacement-driven tensile test program.

2.4.2 Pressure Test Setup. To test for leakage due to bladder pressure, we placed the fistula phantom with the device preinserted over an acrylic stabilizer and a support stand. A hole was cut in the support to accommodate the conical end of the device and allow any leakage to drain into the funnel and graduated cylinder under the fistula. A clear polyvinyl chloride pipe with 5.2 cm diameter and 122 cm length was placed on top of the phantom. Water was poured slowly into the pipe at 10 cm height increments. At each increment, the leakage from the fistula for 1 min was recorded. Figure 3(*b*) shows a schematic for this test setup.

2.4.3 Anatomical Model Pressure Test Setup. To better demonstrate the device's ability to resist bladder pressure, we built a model that mimics the typical testing setup used with a Laborie urodynamics system. This pressure testing setup was designed and conducted by obstetrics and gynecology clinicians who are familiar with running the urodynamics test in live patients. The model was built within a to-scale pelvic model to provide geometry constraints. A thin, flexible bag was used as a pressure vessel (the bladder). The catheter of the urodynamics device was inserted through an opening in the bag, and the opening was sealed around the catheter to prevent leakage. The catheter both measures the pressure within the bag and is used to introduce fluid. A slit was made in the bag to represent the fistula. To mimic the thickness of the fistula tissue, we used another compliant silicone phantom, and the silicone sheet was distorted within the pelvic model to match the actual curvature of a bladder. The device was then inserted into the curved silicone, and a second bag was connected to the vaginal side of the fistula to collect any leakage. Colored water and clear plastics were used to make it easy to visually track leakage. A diagram of this setup is shown in Fig. 4.

To run the test, both bags were initially emptied. The urodynamics device was connected to a computer, and the standard urodynamics fill test was performed to introduce fluids and increase the pressure in the simulated bladder. Fluid was introduced gradually up to 500 mL, a typical maximum bladder capacity [33]. The fluid-filled bag was squeezed to mimic the high pressures of a

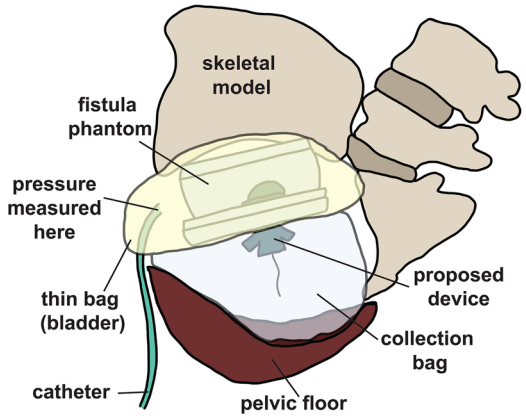

Fig. 4 A diagram of the urodynamic testing experimental setup. The silicone fistula phantom was placed inside the bladder model. A catheter was used to measure the bladder pressure while continuously filling the bladder. The collection bag under the bladder was monitored for leakage.

typical urodynamics test, where the patient coughs to cause a spike in the bladder pressure. The pressure was recorded as the obstetrics and gynecology clinicians watched for leakage.

3 Structural Analysis

3.1 Expulsion Force Analysis. For a first-order approximation of bladder pressure, we modeled the pressure that would cause device expulsion as a point force. Using the relation between force and pressure in Eq. (1), we found the force equivalent ($F_{\text{equivalent}}$) to the maximum bladder pressure ($P_{\text{bladder,max}}$) of 60 cmH_2O/5.9 kPa [14] was 1.85 N (Eq. 2), where A_{fistula} is the area of the fistula (radius approximated as 1 cm). We used this value in Sec. 4.1 as the minimum pull-out force the device must withstand.

$$F_{\text{equivalent}} = P_{\text{bladder,max}} \times A_{\text{fistula}} \tag{1}$$

$$F_{\text{equivalent}} = 60\,\text{cm}\,\text{H}_2\text{O} \times \pi \times (1\,\text{cm})^2 = 1.85\,N \tag{2}$$

3.2 Buckling Analysis. We performed structural analysis to ensure that the middle disk does not buckle and potentially misalign the device. The uniform pressure on the surface of the disk from the stretching of the bladder wall (P_{bladder}) should be less than the critical buckling pressure for a disk (P_{critical}). In Eqs. (3) and (4), R is the radius of the disk and ϵ is the strain of the bladder tissue. The modulus of elasticity of the bladder (E_b) is 125 kPa [14] and of the disk (E) is 729 kPa [34]. We used the expression for critical buckling pressure of a disk [35] to calculate this inequality as follows:

$$P_{\text{bladder}} \leq P_{\text{critical}} \tag{3}$$

$$E_b \epsilon \leq \frac{3\text{EI}}{R^3} \tag{4}$$

The middle disk size was then designed such that it is larger than the fistula but still holds true to this inequality. The middle disk radius is 2.2 cm and the thickness is 2 mm.

4 Results

4.1 Pull-Out Force Testing. Pull-out force testing was performed as described in Sec. 2.4.1 on an Instron 5944 using a standard tensile program. To test the VVF occluder device, it was loaded into the fistula phantom and mounted in the fixture. The string of the device was tied to the head of the bolt clamped in the upper jaws of the Instron.

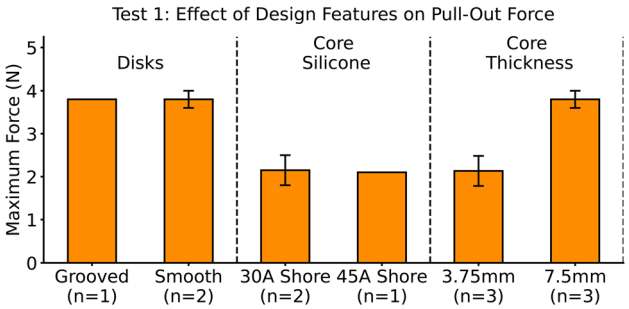

Fig. 5 Comparison of the effect of various design features on pull-out force. Error bars represent the range of values for conditions with greater than one replicate.

First, we used this test to determine how varying device design features affect pull out force. This test was then repeated on the final design to ensure repeatability. The design features that were varied were type of disks (grooved or smooth), core silicone stiffness (30 A or 45 A [36]), and core diameter (3.75 mm or 7.5 mm). When controlling for core thickness, neither disk type nor silicone type had an effect on pull-out force as shown in Fig. 5. Core thickness was the only feature that had an effect on pull-out force—by increasing the core diameter, the pull-out force was increased by 78% from an average of 2.1 N–3.8 N as shown in Fig. 5. We then tested five devices in the final design with a thin core and 6 devices in the final design with a thick core. Each device was tested three times and averaged. The thick core enabled the device to exceed the pull-out force threshold set in Sec. 3.1, with a pull-out force of 3.69 ± 0.42 N, which is analogous to a bladder pressure of 120 cmH_2O (11.8 kPa) as shown in Fig. 6.

4.2 Watertightness and Pressure Testing. As indicated by the functional requirements, the watertightness of the device is of utmost importance. Preliminary testing is described in Sec. 2.4.2 and the testing setup is shown in Fig. 3(*b*). The device successfully withstood pressures up to 100 cmH_2O, or 9.8 kPa, with no leakage. This indicates that, when correctly sized, the device does not allow for any leakage while the bladder is at rest (up to 2.0 kPa), or during urination (up to 5.9 kPa), satisfying FR 1 [14].

We performed similar testing in a more complex anatomical model as described in Sec. 2.4.3. Due to the compliance of the bag used as a bladder analogue, simply filling the bag to the maximum bladder capacity of 500 mL did not achieve the high pressures that the water column test achieved (Fig. 7). However, when the cough was mimicked by squeezing the bag, the spikes of

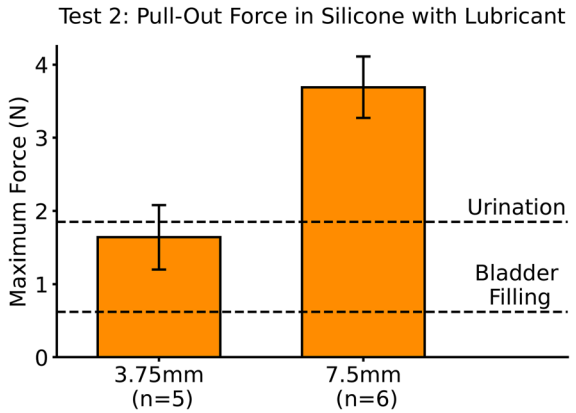

Fig. 6 Comparison of the pull-out force of thin- and thick-cored devices in the lubricated silicone fistula phantom. The threshold forces corresponding to bladder filling and urination pressures are indicated.

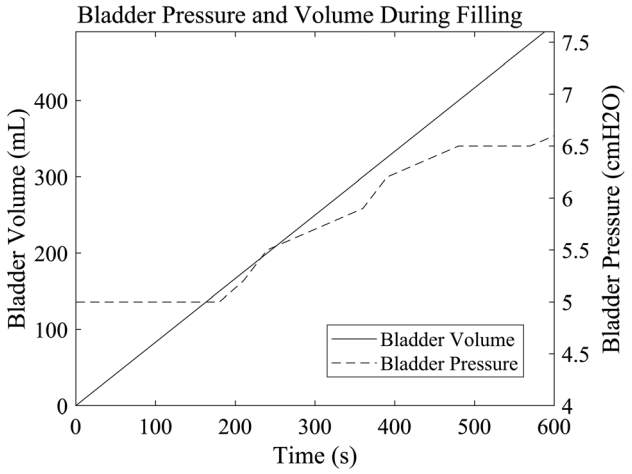

Fig. 7 Plot monitoring the urodynamics setup over time. Liquid was introduced to the simulated bladder at a steady-rate, and internal pressure was recorded. No leakage was detected throughout the bladder filling process.

pressure that are observed during a typical urodynamics test were also observed, and the peak pressure was comparable to the high vesical pressures observed physiologically (Fig. 8). The device did not leak throughout the entire filling process and cyclic pressurization pulses, confirming its ability to perform in a more geometrically complex setup and under more physiologically accurate bladder filling conditions.

5 Discussion

5.1 Discussion of Results. The testing informed the final design choices for the device. The requirement to maintain pull-out stability led to the choice of the thicker core. The pull-out force testing results shown in Fig. 5 contrast the optimal design for potential ease of insertion, which would benefit from a low-profile device with increased flexibility. The grooved disk feature did not impact pull-out force so we preserved this feature. The grooves and cross-shaped tapered plug design allow the device to collapse into an insertion tool.

The results from the pressure testing validated that the device can withstand the physiological range of bladder pressures in both a simplified test setup and in an anatomical model. The results also validated the assumption made in the pull-out force testing that maximum force is analogous to the maximum bladder pressure the device can resist. From the maximum pull-out force of 3.69 N, we would expect leakage to begin around 120 cmH_2O, which is consistent with the results discussed in Sec. 4.2.

5.2 Comments on Sizing and Insertion. The current standard of practice for midwives measuring cervical dilation is to use their fingers to estimate the size of the opening [21]. We encourage the use of the same approach for sizing fistulae in order to choose the correct device to insert. The relative simplicity and enduring reliance on this practice imply that manual sizing could easily and effectively be translated to our device.

Deployment of this device is similar to that of pessaries, tampons, and intra-uterine devices that are inserted through the vagina. The device is designed to be folded up into a smaller diameter for a more comfortable insertion since it needs to fit through a smaller opening before unfurling the bladder-dwelling disk into the correct position. The attached safety string can also be gently pulled to ensure the bladder-dwelling disk of the device is flush against the bladder wall, creating a fluid tight seal and avoiding excess device material in the bladder. Tampons [37] and intrauterine devices (IUDs) [38] are both inserted in a similar way, by being expelled from a small-diameter tube and self-unfurling/self-aligning into their final shape and position. For IUD insertion, the provider first measures the depth of the uterus and then adjusts the insertion tool to the appropriate length so that the IUD is positioned correctly and does not perforate the uterus. Supplemental Material on the ASME Digital Collection explains in detail how we adapted a tampon applicator to serve as a proof-of-concept for inserting our device.

5.3 Risk Analysis. In order to understand potential health risks that may arise for our device, the risks produced by similarly invasive implants such as pessaries and menstrual cups were analyzed and used as reference [39]. Table 1 shows the assessment of various risks with use of this device.

The most severe risk is the device dislodging into the bladder, as recovery would require trained medical intervention and potential surgery, which is inaccessible in the regions we are targeting. It took significant axial force (as described in Sec. 4.1) to dislodge the device from the fistula phantoms during benchtop testing. Since the only forces in the fistula are mostly radial, the likelihood of the device dislodging into the bladder is slim. In addition, the pressure in the bladder is larger than the pressure in the vagina, which makes dislodging into the bladder less likely. Further preclinical trials (described below) would inform any necessary design revisions to minimize the chance of this risk occurring.

Other risks assessed include infections, ulcerations, and dislodgement. Pessaries were chosen as a primary reference for these because of the similarity of material used, the types of body tissues and fluids the devices interact with, and the longevity of the device placement within the body. Our device mimicked the material of pessaries given the minimal effects in changing the vaginal microbiome [40,41] and the flexibility and smooth surfaces to avoid erosion while also applying pressure to the lower urinary tract to help prevent incontinence. In addition, given that our target patient population is younger than patients typically using pessaries (postmenopausal with atrophic vaginal mucosa), erosions and ulcerations would not be as common [42]. In regards to infection, the patient is already at risk of infection as the bladder is directly exposed to the vaginal microbiome. Our assumption is that the device would not only act as a barrier for involuntary leakage of urine into the vagina but also potentially block bacteria ascending from the vagina.

To assist in removal and address the risk of dislodgement, the device's safety string was modeled after the IUD. To remove an IUD, the strings are grasped and the device is easily removed. When IUD strings are not visualized, a series of techniques can be applied [43]. Common items such as a cotton swab, pap smear brush, or tweezers can be used to catch the string and subsequently remove the device. If a piece of the device was retained in the bladder, the patient may need a cystoscopy to retrieve the fragment. Cystoscopy is frequently performed without anesthesia and has been shown to be utilized in resource poor settings [44,45].

5.4 Limitations. There are limitations to the proposed approach that require further testing and design work on the device. Before the device can be tested in actual patients, the testing described in this paper should be replicated in ex vivo bladder tissue samples and the device should be subjected to cyclic fatigue testing. Additionally, there are some results that can only be determined through a preclinical animal study before the device is tested in humans. While the effect of movement on device dislodgement could theoretically be tested partially in vitro, the device performance should be tested in vivo to withstand normal body motion to ensure that the device remains secure despite natural movements. In vivo preclinical models will also be critical for characterizing biological responses such as inflammation, foreign body response, calcification on the bladder side, and endothelialization.

Dislodgment force and water pressure testing showed that a correctly sized device is successfully able to withstand typical

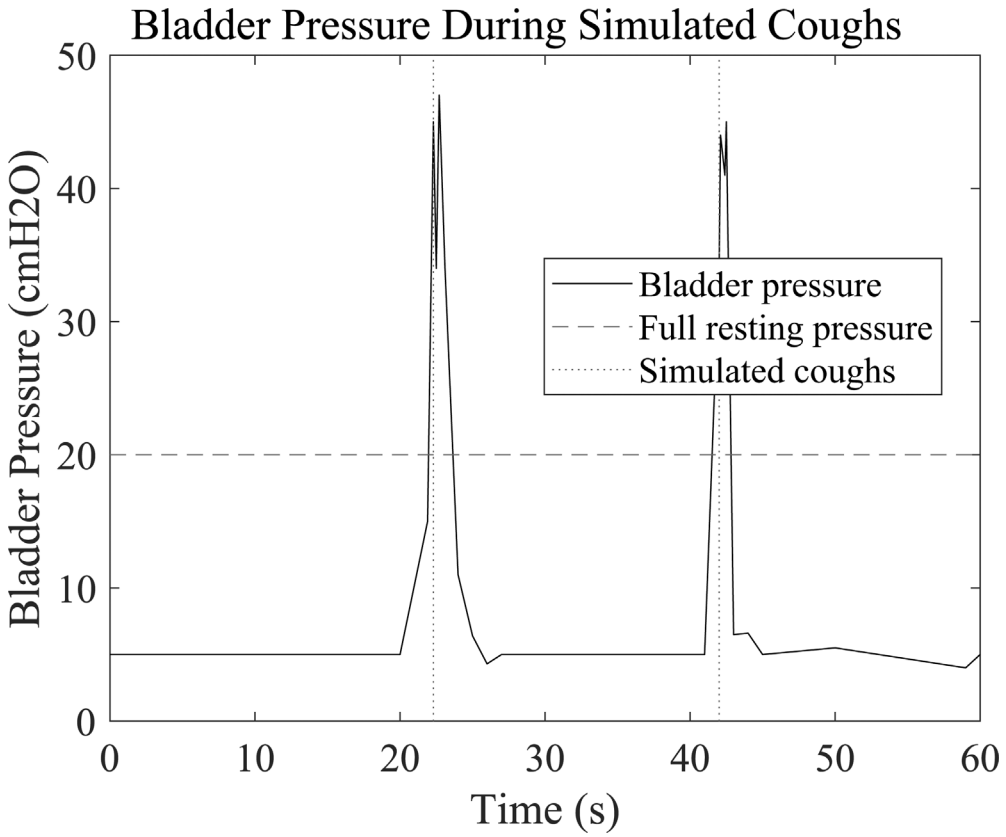

Fig. 8 Bladder pressure during two simulated coughs. The dotted lines show the cyclic pressurization pulses, and the dashed line shows the physiological bladder resting pressure when it is full. No leakage was detected throughout the experiment both at resting pressure and through simulated coughs.

Table 1 Risk analysis

Risk	Grade [39]	Frequency
Device dislodges into bladder	3	Low
Ulceration pain	1	Low
Material allergy	1	Low
Bleeding	1	Medium
Vaginal discharge	1 and 2	Medium
Increased pelvic pressure, pain, or obstruction of elimination (urine or feces)	2	Low
Erosion	2	High
Vaginitis	2	Low

bladder pressures without leakage and displacing or dislodging. However, benchtop testing has not addressed several key concerns. First, we have not established a finalized procedure for sizing. Additionally, we do not have data for fistulae of irregular shapes for this proof of concept. Similarly, we have included a potential mechanism for insertion in the Supplemental Material on the ASME Digital Collection but have not developed a tool for testing in an anatomical model. Finally, we do not have data showing how the device reacts to daily movement and whether or not this increases the likelihood of dislodgement of the device into the bladder.

6 Conclusions and Future Work

The final design balances ease of insertion with stability within the fistula. This device is an improvement on prior art because it is self-aligning, less invasive, and is less likely to be harmful to surrounding tissue. It is designed to be easily deployed by a trained community member who is not a medical practitioner. It has significant potential for scaling to fit a range of fistula sizes, and can be inserted similarly to other devices used in this region of the body. The device has been shown to withstand typical pressures during both bladder filling and urination while remaining watertight. Additionally, the device is low cost and can be manufactured at high volumes. By stymying incontinence as a bridge to surgery, this device has the potential to prevent societal ostracization and improve the quality of life of patients in low-resource areas.

Our preliminary testing suggests a few ways to augment the current design for future improvement. The device was designed to fit a limited range of fistula sizes, but due to the modular fabrication of the current design, it could easily be adapted to a range of sizes. To stabilize the device against extreme movements, the patient could insert a tampon to stabilize the device and to absorb any stray leakage during high intensity activities. Finally, the design could be revisited to make the device removable to allow for replacement or cleaning in the event of a further delayed surgery.

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