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

Madhurima Das[1 2], **Katie S. Hahm**[1 2], **Ava A. LaRocca**[1 2], **Cecilia Alessandra Luna**[2], **Keegan Mendez**[2], **Rachel Hoffman**[2], **Connor A. Verheyen**[2], **Tesia G. Kim, M.D.**[3], **Bridgette W. Wamakima, M.D.**[3], **Ellen T. Roche**[2]

Vesicovaginal fistulas (VVFs), abnormal openings between the vagina and bladder, disrupt the lives of millions of 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, the immediate incontinence often leads to ostracization from the community, and can be devastating for the patient. To occlude the fistula and enable full continence until the patient is able to access surgery, we have designed a three-tiered silicone plug consisting of a bladder-dwelling disc, a mid-fistula disc, and a vagina-dwelling cross-shaped tapered plug, all supported on a central stem.

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 100 cmH2O or 9.8 kPa. It is designed to be easily deployed by trained community members without medical qualifications.

Keywords: fistula, vesicovaginal, incontinence, implant, low-resource, occluder

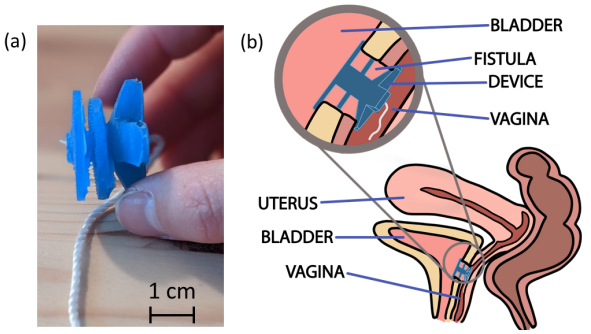

Fig. 1: (a) Three-tier silicone device for occluding VVFs. (b) The device shown in the anatomical context of the vesicovaginal fistula

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 [3] [1]. 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 also recovering from a traumatic delivery. They manage their incontinence with whatever materials they have on hand, but because sanitary napkins and adult diapers are not easily accessible, their symptoms include a constant unpleasant odor and puddles of urine forming wherever they stand [5] [6]. The Global Burden of Disease Study classifies untreated VVFs as having a more negative impact than tuberculosis and a similar impact as 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. Therefore many patients go without treatment for extended periods of time.

The primary goal is to make the fistula watertight and prevent incontinence immediately after the fistula forms. There is a need to develop a minimally invasive, non-surgical device and procedure to immediately enable full continence for patients with VVFs before they have access to surgery. Due to the lack of immediate access to medical professionals, it must be deployable by community members in low-resource areas. Fig. 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 Information.

[1]Authors contributed equally to this work.

[2]Department of Mechanical Engineering in the Massachusetts Institute of Technology, Cambridge, MA 02139, USA. Email: {rimadas, khahm, alarocca, aleluna, kmendez, rachelmh, connorv, etr}@mit.edu

[3]Beth Israel Deaconess Medical Center, Boston, MA 02215, USA.

1.2 Functional Requirements

The design of this device is driven by the needs and constraints of low-resource environments and is determined by the following functional requirements:

1. The device must achieve temporary full continence for fistulas that are 2 cm in diameter for this demonstration.
2. The device will not exacerbate tissue damage or erosion.
3. The device will last at least 2 months until the patient is able to receive surgery [4].
4. The device must be low-cost, under $10.
5. The device must be minimally invasive and deployed transvaginally without general or local anesthesia.
6. The device must be simple to insert by a trained community member who does not have formal medical training.

Although we developed the device for one specified fistula size, the design can be fabricated in other sizes.

1.3 Background

VVFs 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 third world 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 1.5-3 cm (Class b), and has no or mild fibrosis (Class i) [8]. VVFs penetrate bladder wall tissue, which is approximately 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 5-15kPa [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 vagina.

Another anatomical consideration is fluid exposure. The device would be continuously exposed to urine and vaginal discharge. The urine contains minerals that can lead to calcification [13], resulting in additional constraints within the design of the device. Additionally, a recently-formed fistula is an open wound, therefore infection is a potential concern. The experience of the clinical authors suggests that the vagina has an active and diverse microbiome that creates a hostile environment for common infectious bacteria [14]. Given a successful seal mechanism of the device, clinical authors agree that the wound could likely heal without fear of infection. The device must seal against the pressure inside the bladder. At rest, intrabladder pressure does not exceed 20 cmH2O (2.0 kPa), though during urination, pressure can reach 60 cmH2O (5.9 kPa) [15].

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 [16] [17]. Most patents rely on either patching the fistula or pinching surrounding tissue together [16] [17]. One patent relies on a foldable patch that is inserted through a syringe shaped applicator [16]. 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 [16]. Another device used in gastrointestinal (GI) procedures uses metal clips to pinch GI tissues together [17]. 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 [18] and Vasalgel [19], 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 [20] [21]. 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 disc, a mid-fistula disc, and a vagina-dwelling cross-shaped cone. Each component is supported on a central stem. A string embedded in the core remains in the vagina to allow retrieval if necessary. The design is shown in Fig. 2. The bladder-dwelling disc covers the fistula opening to achieve water-tightness while also providing a lip normal to the fluid pressure to resist dislodging when the bladder is full. The middle disc 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 tapered plug and middle disc 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 discs 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 select-

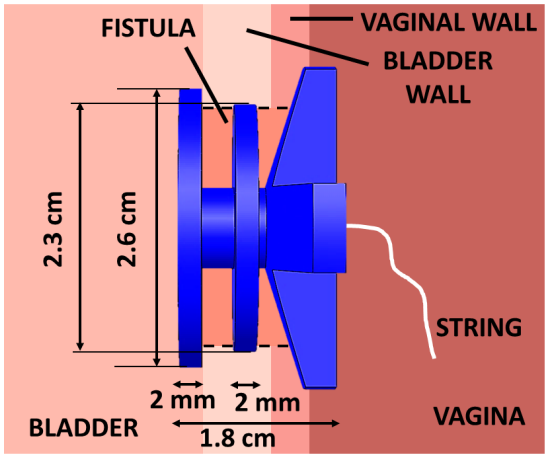

Fig. 2: The device design and its measurements. The intended positioning between the vaginal and bladder walls is shown. The bladder has a higher pressure than the vagina; the first disc and tapered cross create a seal while the middle disc stabilizes the device.

ing the appropriate device after manual sizing, similar to the practice for pessary fitting/implantation [22].

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 will 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 water-tight 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 prosthetics) 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 a concern as ample testing demonstrates that silicone is well-accepted within the bladder and vagina [26] [27].

We fabricated the device by molding the discs and core separately using Moldstar 31-T (Smooth-On) and then assembling using Sil-poxy. The final device will be fabricated in one piece via injection molding, 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] [29] [30] [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 [32] [9] and a 2 cm diameter circular hole cut out. To mimic tissue properties, we chose the silicone Ecoflex 00-30 (Smooth-On) due to it having a similar modulus to bladder wall tissue [33]. To simulate the natural biological fluids that would be present at the fistula site, we spread oil of a similar viscosity on the phantom wall.

2.4 Test Setups

Three tests were performed. The first two were performed with the demonstration fistula phantoms described above, 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)). The fixture pieces were laser cut from 0.3-0.8 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 stackup 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 with the device pre-inserted 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 placed under the fistula. A clear PVC 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 one minute was recorded. A schematic for this test setup is shown in Fig. 3(b).

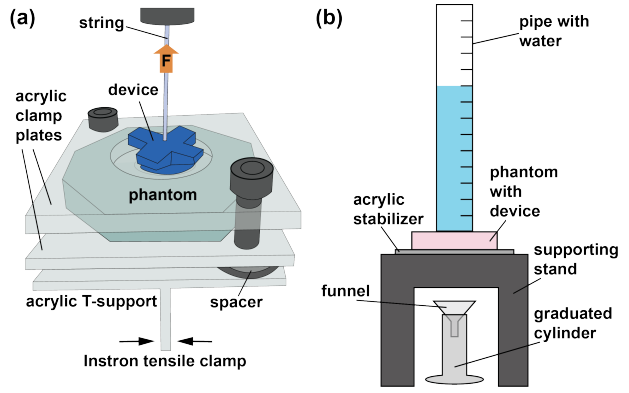

Fig. 3: (a) Schematic of the fixture used to stabilize the phantom in the Instron for pull-out force testing. (b) Experimental set up for testing different bladder pressures.

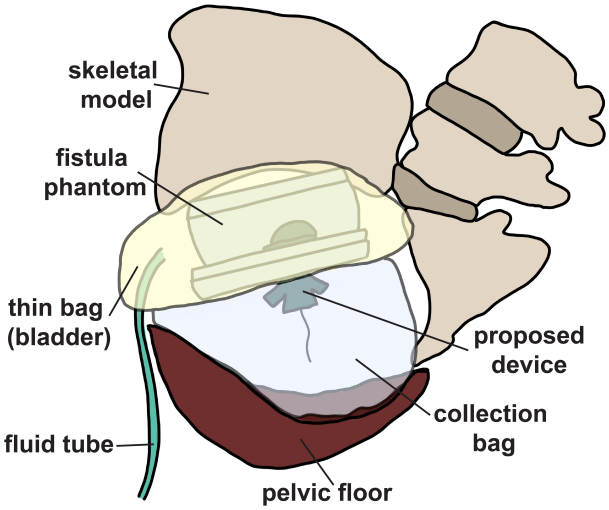

Fig. 4: A diagram of the urodynamic testing experimental set up. The silicone fistula phantom was placed inside the bladder model. The bladder pressure was measured while continuously filling the bladder. The collection bag under the bladder was monitored for leakage.

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 urodynamics testing setup. This pressure testing setup was designed and conducted by obstetrics and gynecology (OB-GYN) 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 also 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 500mL, a typical maximum bladder capacity [34]. The fluid-filled bag was squeezed to mimic the high pressures of a typical urodynamics test, where the patient coughs to cause a spike in the bladder pressure. The pressure was recorded as the OB-GYN 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 to the maximum bladder pressure of 60 cmH2O / 5.9 kPa [15] was 1.85 N (Eq. 2). We used this value in Section 4.1 as the minimum pull-out force the device must withstand.

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

$$F_{equivalent} = 60cmH2O \times \pi \times (1cm)^2 = 1.85N \tag{2}$$

3.2 Buckling Analysis

We performed structural analysis to ensure that the middle disc does not buckle and potentially misalign the device. The uniform pressure on the surface of the disc from the stretching of the bladder wall should be less than the critical buckling pressure for a disc. Let R be the radius of the disc and ε be the strain of the bladder tissue. The modulus of elasticity of the bladder material is 125 kPa [15] and of the disc is 729 kPa [35]. We used the expression for critical buckling pressure of a disc [36] and calculated this inequality as follows:

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

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

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

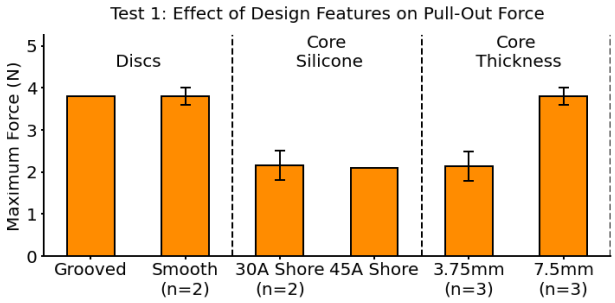

Fig. 5: Comparison of the effect of various design features on pull-out force. Error bars represent the range of values.

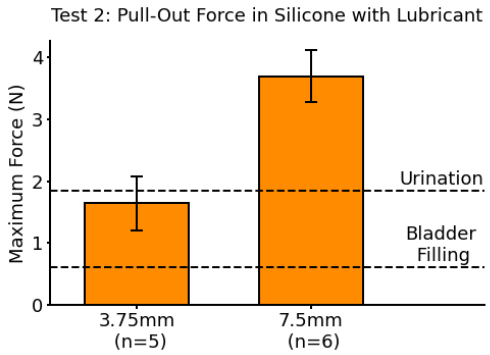

Fig. 6: Comparison of the pull-out force of thin- and thick-cored devices in the lubricated silicone fistula phantom. The threshold forces corresponding to bladder filling and urination pressures are indicated.

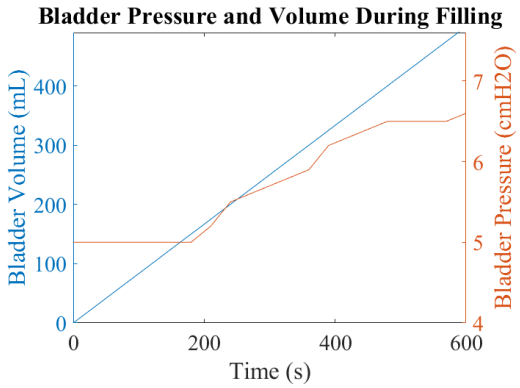

Fig. 7: Plot monitoring the urodynamics setup over time. Liquid was introduced to the simulated bladder at a steady rate, and internal pressure was recorded. No leakage was detected throughout the bladder filling process.

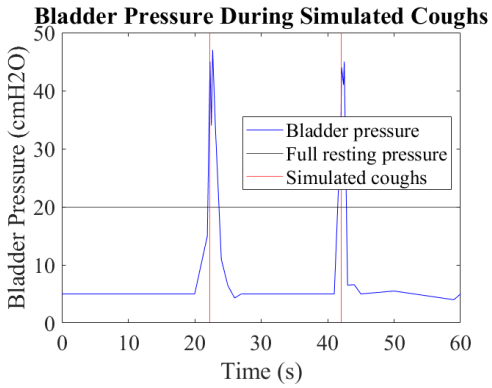

Fig. 8: Bladder pressure during two simulated coughs. The red lines show the cyclic pressurization pulses, and the black line shows the physiological bladder resting pressure when it is full. No leakage was detected throughout the experiment both at resting pressure and through simulated coughs.

4 Results

4.1 Pull-out Force Testing

Pull-out force testing was performed as described in Section 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.

First, we used this test to determine how varying device design features affects pull out force. This test was then repeated on the final design to ensure repeatability. The design features that were varied were type of discs (grooved or smooth), core silicone stiffness (30A or 45A [37]), and core diameter (3.75 mm or 7.5 mm). When controlling for core thickness, neither disc 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 to 3.8 N as shown in Fig. 5. We then tested 5 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 Section 3.1, with a pull-out force of 3.69±0.42 N, which is analogous to a bladder pressure of 120 cmH2O (11.8 kPa) as shown in Fig. 6.

4.2 Water-tightness and Pressure Testing

As indicated by the functional requirements, the water-tightness of the device is of utmost importance. Preliminary testing is described in Section 2.4.2 and the testing setup is shown in Fig. 3(b). The device successfully withstood pressures up to 100 cmH2O, 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 [15].

We performed similar testing in a more complex anatomical model as described in Section 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 500mL 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 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 disc 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 cmH2O, which is consistent with the results discussed in 4.2.

5.2 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 [38]. The majority of risks identified are negligible or low level risks that may be easily mitigated upon identification. Marginal risks that require medical attention, such as vaginitis and some cases of vaginal discharge, were identified at low or medium frequencies and may be easily treated with a course of antimicrobials [39]. Other complications such as tissue erosion, bleeding, and pain may be mitigated by ensuring that the device is appropriately sized to the fistula [38]. In rare cases of extreme complications, the device should be removed [39].

5.3 Limitations and Future Work

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 bladder tissue samples *ex vivo* and the device should be subjected to cyclic lifetime testing. Additionally, the device performance must be tested *in vivo* to withstand normal body motion to ensure that the device remains secure despite these movements.

Testing suggests a few ways to augment the current design. 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.

6 Conclusions

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.

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7 Supplemental Material

A Insertion Strategy

The device was designed for easy and intuitive insertion to satisfy FR 6. The device components were optimized to balance structural stability in the fistula and the ability to be collapsed into an insertion tool. The insertion process is as follows: The device comes in varying sizes folded inside an insertion tool already sterilized and lubricated. The community member inserts a speculum, a tool commonly used by midwives and gynecologists to perform vaginal examination. The community member identifies and locates the fistula either visually or using tactile feedback. They then size the fistula using tactile feedback by hand, similarly to how they would assess cervical dilation during childbirth, and select the correct sized device to insert. An insertion tool with the device inside is inserted into the fistula. The tip of an insertion tool is similar to a tampon applicator tip to avoid any discomfort and ensure ease of use. The sheath is retracted partially to allow the bladder-dwelling cap to unfurl; the tool is pulled until the bladder-dwelling cap is flush with the bladder wall; the sheath is retracted the rest of the way to allow the middle disc and vaginal tapered plug to unfurl. The placement and stability of the vaginal tapered plug is checked visually and by lightly tugging the string. The device will remain implanted until the surgeon removes it during the permanent fistula repair surgery. The device and an example of insertion tool are shown in Fig. 9.

Fig. 10 shows how the user will insert the device. There is tactile feedback when each disc is expanded from the tool. There is also feedback when the user pulls back on the device to make sure the first disc is flush against the bladder wall. In this way, this device can be inserted exclusively transvaginally, satisfying FR 5. This method is designed for straight path insertion, and must be adapted to accommodate curvatures in the insertion path.

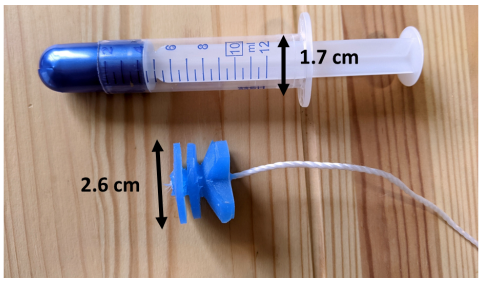

Fig. 9: The device and insertion tool shown for scale. We used a 10 ml syringe with a tip adapted from a tampon applicator.

Fig. 10: The device being deployed by an insertion tool, shown with the first disc of the device opening up inside the bladder.

B Risk Analysis Table

Risk	**Grade [38]**	**Frequency**
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