Abstract

Ileostomy patients face ongoing challenges with hygiene, autonomy, and skin health due to continuous stoma output and limitations in current ostomy products. This study presents the design and evaluation of a controllable stool management system that enables temporary stoma closure and intentional waste release. The system comprises a soft silicone plug with radial anchoring fins, a tricuspid-style duckbill valve for one-way flow control, and a quick-connect interface for attaching a disposable collection bag.

Bench testing evaluated the system against key functional requirements. The anchoring mechanism produced an average radial pressure of 15.76 mmHg, within the safe range of intestinal wall pressures. The valve sustained pressures up to 128 mmHg without leakage in nearly all trials, indicating robust sealing well above normal intraluminal conditions. Pullout force tests confirmed secure retention exceeding physiological pressures while remaining below thresholds for tissue damage. These results validate the system's mechanical feasibility for in vivo use.

The bag attachment force remains untested, representing an area for future work. Additional refinement is needed in valve fabrication, usability, and material durability. Overall, the proposed system offers a novel, user-controlled approach to improve comfort, reduce leakage, and support greater independence in ileostomy care.

Introduction

Ileostomies are a subset of surgical procedures called ostomies which involve the creation of a stoma, an opening into the abdominal wall, to allow waste to exit the body [1]. In particular, ileostomies result in the small intestine being sutured to an opening in the abdomen such that waste is redirected and the large intestine is bypassed [2]. While ileostomies can greatly improve health outcomes for individuals with severe gastrointestinal conditions such as ulcerative colitis, colorectal cancer, and Crohn's disease, managing a stoma can be both time consuming and difficult for ostomates. Living with an ileostomy presents both physical and emotional challenges, often leading to lower mobility, lower sexual activity, increased levels of depression, and higher rates of social anxiety in addition to changes in diet and clothing choices [3, 4]. With as many as 1,000,000 people in the United States living with an ostomy, the need for innovative solutions to adequately address quality of life concerns is high [5].

In an effort to connect with the end user and collect insights into the world of ostomate worries, a survey was sent to a number of people through Facebook support groups and various stoma management technologies were researched. Focusing on complications of existing stoma/stool management methods, patient demographics, and rates of various ostomy procedures, a composite end user persona affectionately nicknamed "Winnie" was created. Winnie is an active, middle class 38 year old living in a suburban area who was diagnosed with ulcerative colitis at 34 and underwent an ileostomy a year and a half later. While Winnie has adapted well to life with an ostomy bag, they still live with anxiety as a result of the realities of operating with a stoma bag including: stoma output noises, peristomal skin irritation, the inconvenience of changing or emptying their bag in public restrooms, bag gas build up, and the frustration of cleaning their peristomal skin with an almost constant flow of waste.

Choosing to focus on ileostomy technology was both a strategic and logical choice. First, ileostomies represent a nearly equal distribution in ostomy procedures when compared to colostomies [5, 6]. Second, complication rates including skin irritation, parastomal hernia, dehydration, pneumonia, and urinary tract infections are higher in ileostomates than colostomates due to the more liquid nature of ileostomy output [7]. Lastly, when discussing current stoma care products with survey respondents, it was found that modern filters and venting systems fail at higher rates for ileostomates when compared to their colostomate counterparts.

Using Winnie as the target end user, a controllable waste management system to enhance the autonomy of people with ileostomies and abdominal stomas was designed. By enabling users to control the opening and closing of the stoma, and allowing for attachment without the use of adhesives, the developed stoma plug system creates a cleaner, more hygienic environment during bag changes, thereby reducing the risk of peristomal infections and empowering users to manage their care with greater ease and confidence.

Background

Anatomy and Physiology of the Small Intestine

The small intestine is a highly regenerative organ in the gastrointestinal (GI) system that is responsible for digestion of carbohydrates, proteins, and lipids [8, 9]. Connected to the stomach and cecum mediated by way of biologic valves (the pyloric and ileocecal sphincters), the small intestine is divided into three segments: the duodenum, the jejunum, and the ileum [10]. Measuring 3.05 meters in length with an external diameter of about 25 millimeters, the small intestine can be understood to act as a flexible, sponge-like tube that is both highly vascularized and layered [10]. As shown in Figure 1, the anatomy of the small intestine is similar to that of other organs within the alimentary canal, containing (in order from the lumen outwards) the mucosa, submucosa, muscularis propria, and serosa [11]. Of particular note are the submucosal glands and mucosal layer. Submucosal glands are responsible for secreting the mucus that coats the inside of the intestine wall, creating a low friction surface for chyme to travel along and aiding in through the GI tract [11, 12]. The mucosal layer is equally important as it encompasses the epithelial lining, lamina propria, and muscularis mucosae, the layers of the intestinal wall that come into direct contact with the chyme and/or form the hair-like villi that help propel the chyme down the GI tract by moving the secreted mucus [11, 12]. In between the villi protrusions are intestinal glands that secrete about 0.95 to 1.9 liters per day of alkaline (7.4 to 7.8 pH) intestinal fluid [11].

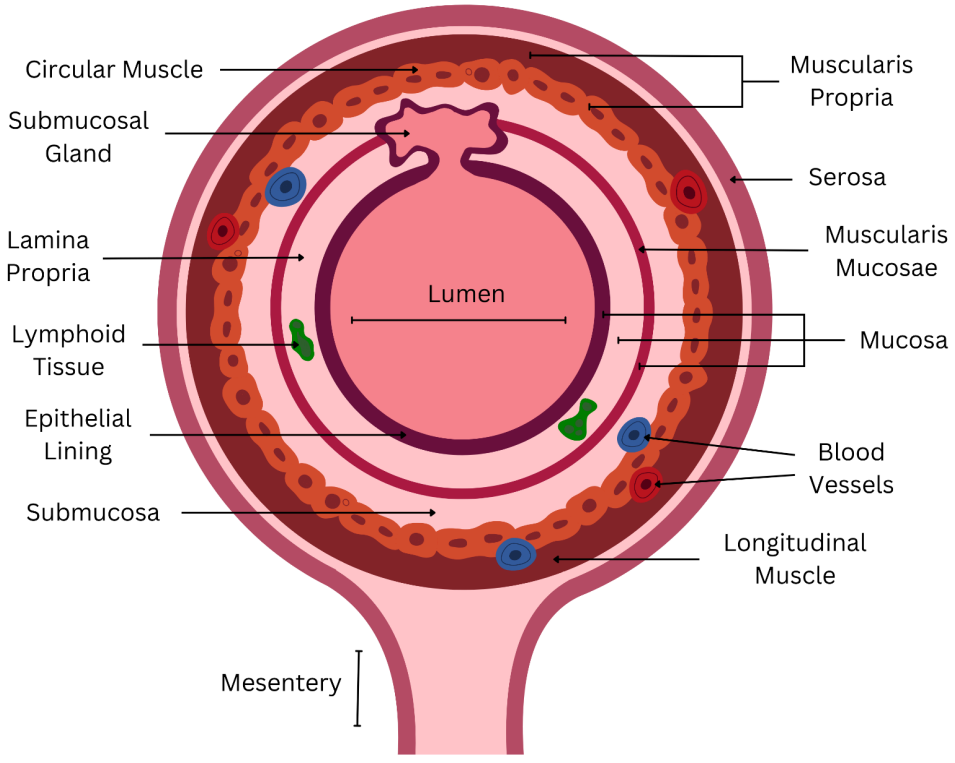

Figure 1: Diagram of the layers and major components of the small intestine wall.

Force in and on the intestines plays an important role in maintaining human health, moving chyme down the digestive tract and adding digestive fluids to the mixture. When chyme arrives at the duodenum from the stomach, a form of peristalsis (the waveform contractions of

the GI tract) known as migrating motility complexes and segmentation work together to mechanically combine chyme with intestinal and pancreatic fluids and force the mixture further down the GI tract [13]. In healthy people, the abdominal cavity exerts a constant pressure across the outer surface of the small intestine, ranging between 0 to 5 mmHg in healthy patients [14]. The average total force inside the lumen of the small intestine (due primarily to the presence of chyme and peristalsis) ranges from 10 to 20mmHg with an increase of about 6 to 7mmHg when obstructions are introduced [15, 16]. However, in the event of blockages in the lumen, concentrated loads past 250 mmHg can compromise small intestine health; within 3 to 4 hours after onset, extreme pressure can cause conditions such as ischemia, perforation, ulcer formation, and mucosal villi necrosis to occur, leading to potentially dangerous and irreparable harm [17].

It should be noted, at this point, that stool is typically defined as the solid, undigested waste material stored in the rectum after the entire digestive process has taken place whereas chyme is a viscous semifluid consisting of partially digested food and digestive fluids found in both the stomach and intestines [18]. While ileostomate stoma output is more chemically akin to chyme, the word "stool" will be used due to the function that the stoma provides as an exit for undigested waste material [19].

Limits of the Small Intestine

With regards to the development of the stomal plug medical device, it is necessary to understand several key properties of the small intestine: modulus of elasticity, pressure, and friction. Modulus of elasticity describes the overall stiffness of a material and is determined by the relationship between a material's stress and strain [25]. The stress-strain relationship of the small intestine is complex, with a low elastic modulus of approximately 120 kPa at low strains of 0 to 20% and increasing to approximately 2.69 MPa at higher strains [26]. Simply put, the material is initially easy to deform and then becomes more than 20 times harder to deform as it continues to strain.

Intraluminal pressure describes the pressure within the lumen, or the hollow inner portion of the small intestine. It will set our limit based on the maximum force and duration of application any object can apply to the intestinal wall before damage occurs. Normal operating intraluminal pressure of the small intestine is 10 to 20 mmHg, but flow obstruction and mechanical blockage can quickly cause dangerous increases in pressure [15]. Physical damage such as perforation and ulcer formation can occur at pressures in excess of 250 mmHg [27]. Ischemia, a significant reduction of blood flow, can also occur at elevated pressures, causing mucosal villi necrosis within 3 to 4 hours after onset [17]. Convatec Flexi-Seal™, an existing FDA approved balloon anchored rectal catheter designed for use for up to 29 continuous days, applies a pressure of approximately 128.5 mmHg. Assuming that the risk of damage from a prolonged pressure applied to rectal tissue, as validated by Convatec's clinical trials, is similar to the risk of the same pressure applied to the small intestine, 128.5 mmHg was chosen to be the maximum safe intraluminal operating pressure. Future work will determine and validate a more precise pressure limit.

Operating in the small intestine presents a complex challenge due to the continuous motion of peristalsis, presence of intestinal mucosa and stool, and complex geometry of villi. Characterization studies of friction are highly specific to the materials and geometry involved

and research was unable to identify a target value for the specific use case of an in vivo silicone-based, complex geometry device. Qualitative observations with e*x vivo* small intestine and stool also presented vastly different conditions based on the amount of high friction stool present compared to low friction mucosa, further complicating evaluation. To simplify device development while providing conservatively positive test results, olive oil was used as a lubricant to produce a lower coefficient of friction than would be experienced in a real intestine. The ability to anchor in the lower friction test bed, therefore, implies the ability to anchor *in vivo*. Future work will be required to quantify the coefficient of friction between our specific materials and geometries.

Ileostomies at a Glance

In general, ileostomies are performed as a life saving and/or quality of life improving procedure by which the end of the ileum is pulled through a surgically created opening in the abdominal wall [2]. Ileostomies can be described by their duration (temporary or permanent) and formation style (loop or end) [2]. Temporary ileostomies are commonly used as a method of healing to alleviate strain on the large intestine because they can be reversed by a surgeon [2]. As necessitated by their impermanence, temporary ileostomies are typically in the loop style and do not remove the colon [20]. Permanent ileostomies, as the name implies, are created with the intention of being in place for the rest of the patient's life. In permanent ileostomies, generally, some or all of the colon is removed and they are more commonly constructed in the end style [20]. A loop ileostomy is the creation of a stoma by which a section of the small intestine is pulled through an opening in the abdominal wall, cut to produce two ends (the "upstream" opening exuding stool and the "downstream" opening secreting gastrointestinal mucus), and then both ends stitched to the abdominal wall [21]. An end ileostomy is the technique by which the ileum is pulled through an opening in the abdominal wall and cut to produce two openings before the "downstream" opening is sealed shut and the "upstream" end is stitched to the abdominal wall [21].

For the sake of simplicity while also targeting an underserved demographic in the ostomate community, it was decided to operate under the assumptions of a fit and medically stable end ileostomy patient who has adjusted to the technical difficulties of caring for a stoma. Thickness of the abdominal wall and stoma length vary greatly based on patient sex, comorbidities, genetics, lifestyle, and the initial surgical procedure (38 ± 17mm and 22.5 ± 2.5 mm respectively) [22, 23]. In contrast, the intestinal wall was found to be relatively consistent across patient demographics and the parts of the small intestine at 1.5 ± 0.5mm [24]. Figures 2 and 3 depict some of the critical physiology and physics of an ostomate's abdomen after an end ileostomy procedure, including the mesentery (responsible for small intestine vascularization) and the hypothetical pressures that might be generated from a stomal plug device via internal and external attachment.

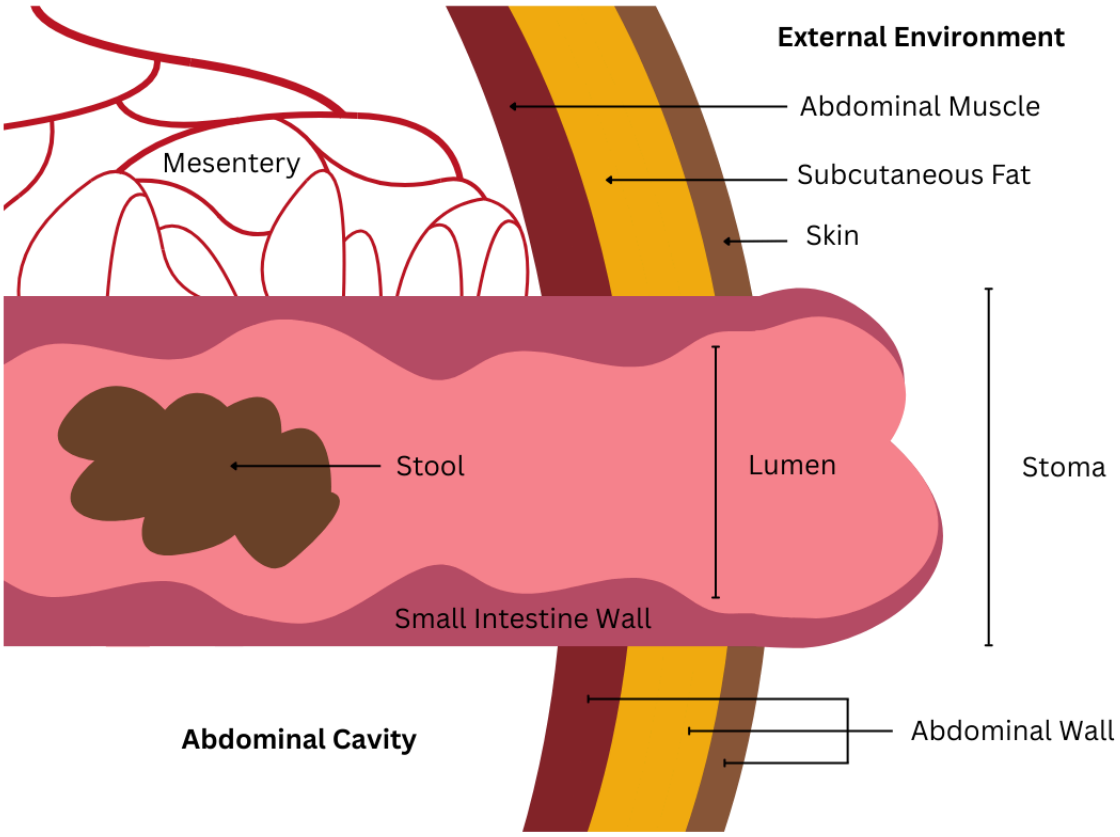

Figure 2: Abdominal anatomy after an ileostomy.

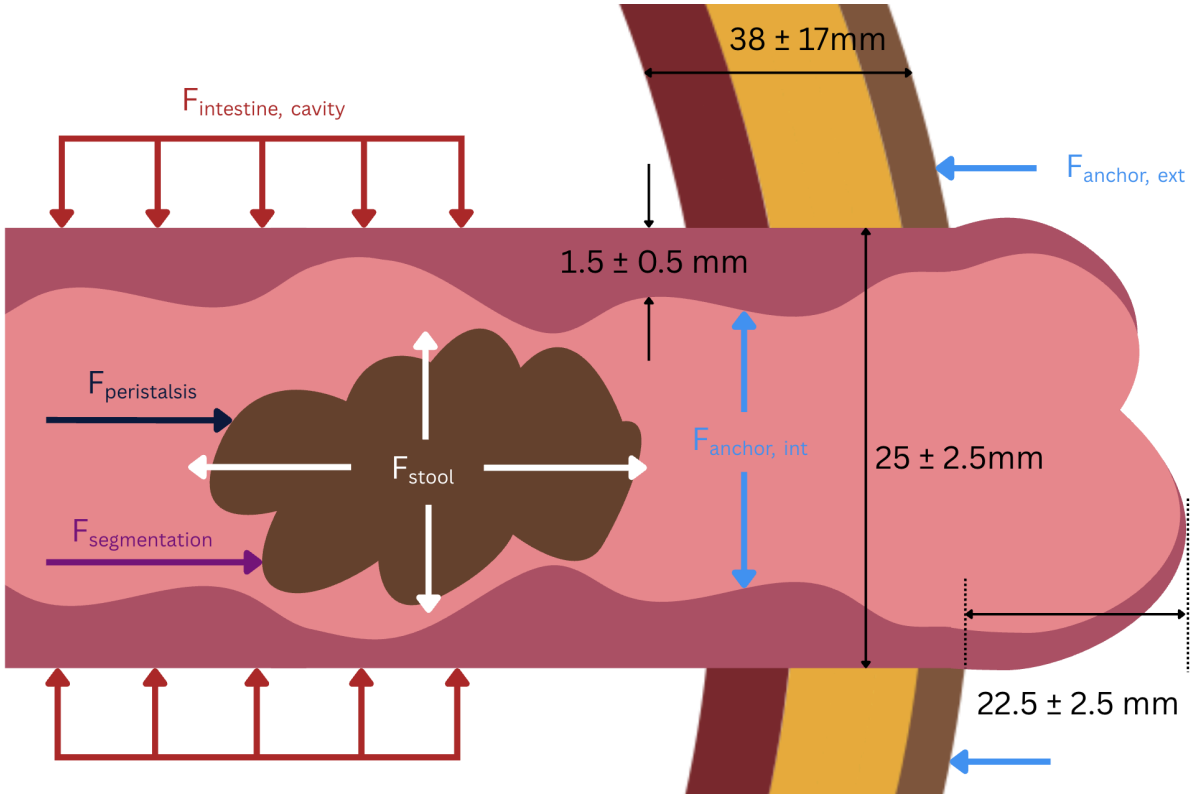

Figure 3: Dimensions of and forces on the major components of the body after an ileostomy.

The History of Ostomies and Current Technologies

The problem of digestive tract disease has been recorded since at least Ancient Greece with the first recorded account of a surgical approach to small bowel obstructions being attributed to Praxagoras of Cos, a fourth century B.C.E. surgeon and medical philosopher [29, 30]. The earliest recorded successful stoma patient was George Deppe in 1706 who lived for 14 years with a prolapsed colostomy [30]. In the 18th century, stoma care was restricted to collection via tin cans and absorption by cloth tied around the abdomen, culminating in the invention of a leather pouch to collect waste attached to the stoma by French surgeon Daguesceau in 1795 [30]. Innovation mostly stagnated at that point until World War II when the dramatic increase in abdominal injuries made new technologies for colostomy and ileostomy patients a necessity [30]. As shown in Figure 4, patents resembling the modern stoma bag appear as early as the 1930s [31]. By the mid-1900s, surgical and device based treatments such as the magnetic ring controllable stoma and Kock pouch emerged alongside the budding stoma bag industry. Today, medical device manufacturers such as Hollister, Convatec, and Coloplast dominate the market for stoma care products, incorporating lightweight material, hydrocolloid rings, and water resistant fabrics [32, 33, 34]. However, when comparing the products illustrated in Figures 4 and 5, it becomes clear that despite advances in science and engineering, the average ostomate is utilizing medical technology architecture that has evolved little in almost 100 years.

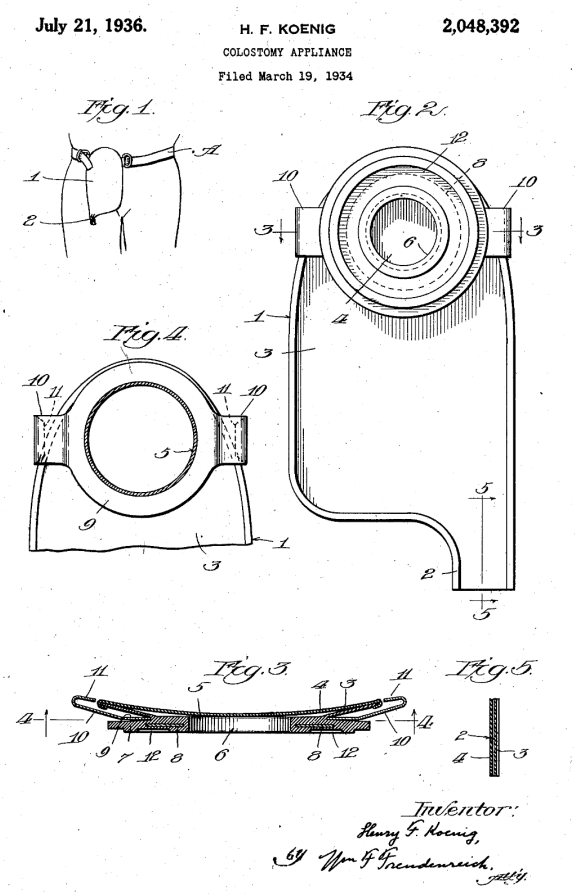

Figure 4: A 1936 United States patent for a stoma pouch by Henry F. Koenig.

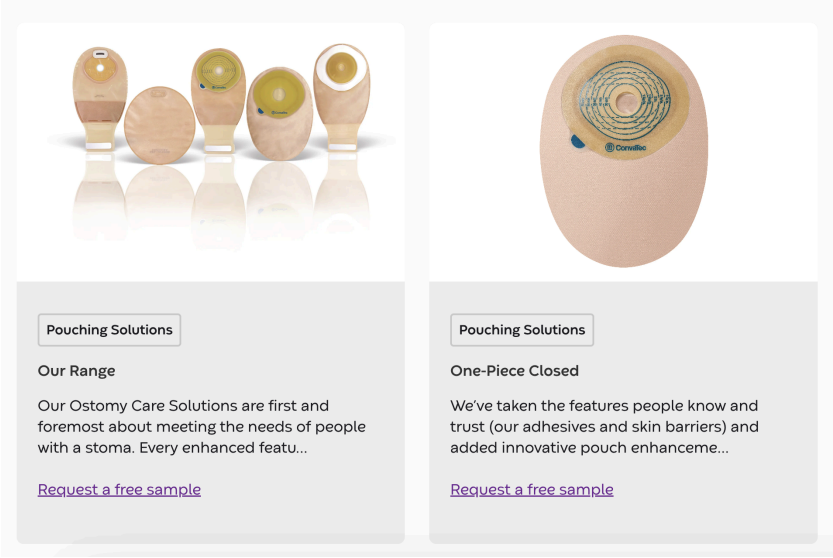

Figure 5: Convatec ostomy products in 2025.

Functional Requirements

The development of the stool management system was driven by key insights from anatomical studies, physiological constraints, and user-centered research. With a clearer understanding of the small intestine's structure and behavior, as well as the real-world challenges faced by ileostomy patients like Winnie, essential design criteria for a safer, more effective, and more dignified stoma care solution was outlined. These criteria informed every aspect of the design process. The resulting system, described below, was engineered to meet these needs while remaining simple, comfortable, and reliable in daily use.

Requirement	Value
Leak prevention during normal use	$\geq$ 20 mmHg without leakage
Controllable stool flow	Holds $\geq$ 30 mmHg external pressure
Safe attachment to the body	20 mmHg < Pressure exerted on intestinal wall < 128 mmHg
Secure bag connection	$\geq$ 10 N to detach the bag

Table 1: Device functional requirements and their associated values as determined by literature reviews and user interviews.

Design

Overview

The stool management system includes two subsystems: the stoma-inserted anchoring-valve (also referenced simply as the "plug") and external bag. In Figure 6, the plug is shown in blue and serves as the interface between the stoma and the external waste collection system. It is designed for insertion into the stoma with light to moderate squeezing force, relying on a combination of geometry and compliant material to conform to the anatomy of the small intestine and stay securely in place. Also in Figure 6 is the external waste bag (shown in gray) which is constructed out of both rigid and compliant materials to allow for optimal device connection and stool transport in addition to stool storage, respectively.

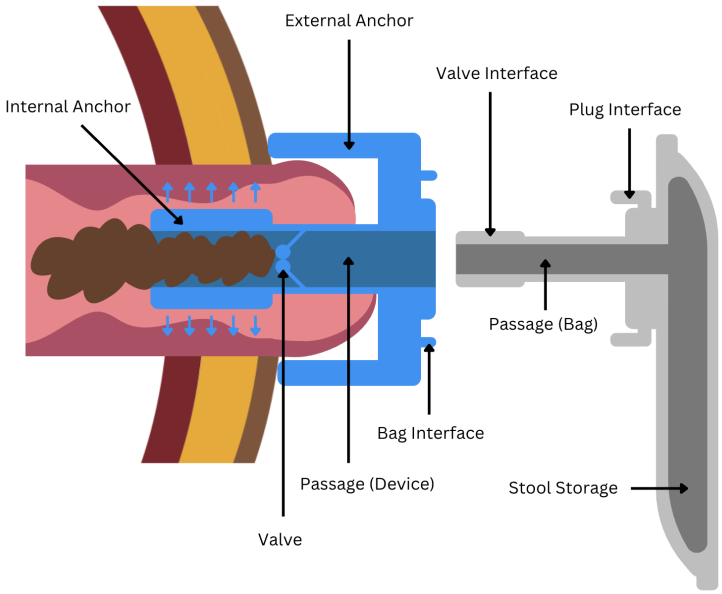

Figure 6: Stool management system components and architecture.

Anchoring Mechanism

Figure 7 depicts the cross-sectional view of the anchoring mechanism consisting of integrated radial fins inspired by an oil pour spout (shown in Figure 8). The design is engineered to maximize gripping area, maintain positional stability, and minimize user discomfort during wear. The plug base is molded from soft silicone, allowing it to gently conform to the natural contours of the stoma. This soft interface not only ensures comfort but also acts as the primary seal between the internal passage and the valve system.

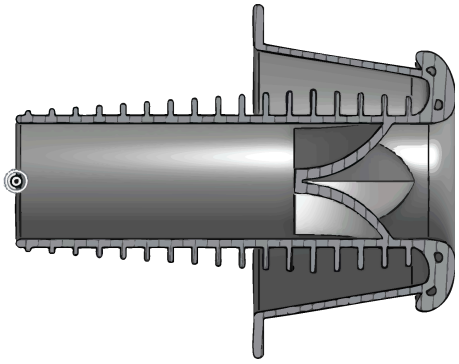

Figure 7: Cross-sectional view of the stomal anchoring mechanism.

Figure 8: Oil spout flanges that served as inspiration for the device's anchoring [35].

The multiple thin, flexible fins that extend outward from the plug body are designed to press gently against the inner walls of the intestine or stoma tract along the abdominal wall. These fins expand radially once inserted, increasing frictional engagement with the surrounding tissue to prevent dislodgement or rotation during daily activities. Their geometry is optimized to balance firm anchoring with low insertion force, ensuring both secure placement and ease of use.

One-Way Check Valve

To control stool flow and improve cleanliness during bag changes, our system integrates a tricuspid-style valve with a duckbill design, combining directional control with reliable sealing performance, as shown in Figure 9. The valve operates similarly to the Jabsco Joker valve, permitting the passage of solids while preventing backflow. Under normal intestinal pressure, the valve remains securely closed, effectively sealing the stoma and preventing unintentional leakage or gas release. It opens only when the external valve interface from the bag is inserted and connected to the collection system, enabling intentional and controlled discharge of stool. This design not only minimizes continuous outflow during bag changes, but also ensures that most output flows easily when opened, helping to prevent blockages and maintain reliable operation.

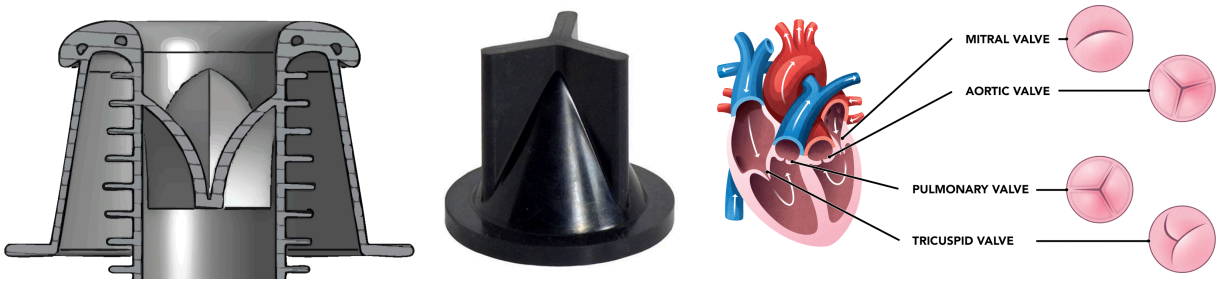

Figure 9: A comparison of the novel stool flow blocking valve (left) to the Jabsco Joker (center) and tricuspid (right) valves [36, 37].

The valve is fabricated using silicone casting, followed by precision cutting to create the cross-slit geometry. This process ensures high sealing reliability and consistent performance across units. The inherent flexibility of silicone allows for low insertion force of the catheter or connector without compromising the integrity of the seal, enhancing both user comfort and operational safety during use.

Quick Connect

At the external end of the plug is the bag interface, shown in white in Figure 10, is a critical component that provides a secure mechanical connection to the waste collection bag. This interface utilizes a quick-connect design that enables fast and intuitive attachment of the bag's connector with minimal effort. The design allows the bag to engage with the plug from any orientation, guiding it into place and locking it securely with low insertion force, while providing tactile and audible feedback to confirm successful engagement. This user-friendly mechanism enhances usability and reduces the risk of improper or incomplete attachment.

The interface is currently fabricated using 3D-printed rigid components, which ensure structural integrity and dimensional accuracy during repeated use. In addition to facilitating mechanical connection, the quick-connect interface also serves to reinforce the valve housing, preventing deformation of the plug structure under load. This structural support helps maintain the sealing performance of the internal valve, ensuring consistent, leak-proof operation throughout the device's intended lifespan.

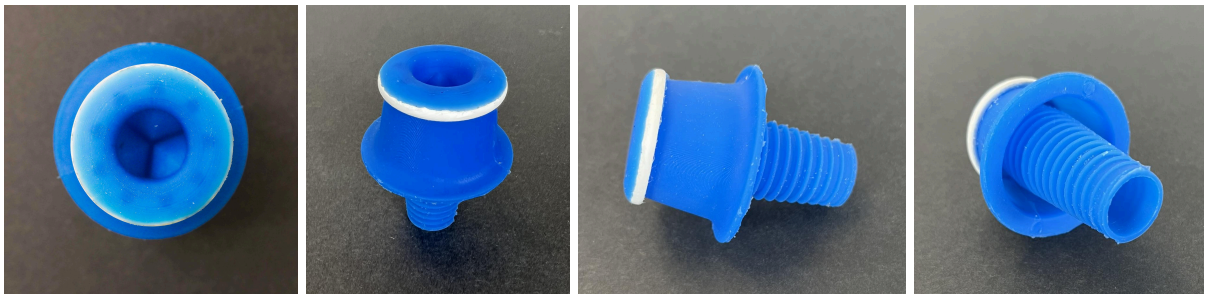

Figure 10: Final prototype with rigid quick connect ring.

The bag subsystem consists of several key components: a quick clip, anti-suction nubs, adhesive strips, and a TPU film layer shown in Figure 11. The quick clip is engineered to securely engage with the plug's interface, ensuring proper alignment and a reliable seal. Once connected, the bag creates a direct channel for stool to flow from the plug's internal valve into the collection chamber. Integrated anti-suction nubs help prevent suction effects during attachment, facilitating smoother engagement and detachment.

To improve stability during wear, the bag features adhesive strips, shown in Figure 11, designed to adhere closer to the skin. This minimizes dangling and provides external anchoring, reducing the force transferred to the plug as the bag fills with stool. Since the plug reliably seals the stoma and prevents leakage, small adhesive patches can be used safely without risking peristomal skin irritation, offering a secure and skin-friendly fit.

In the current design, the entire bag is intended to be fully disposable. This single-use approach enhances hygiene, simplifies user maintenance, and reduces the risk of contamination or leakage associated with repeated handling or cleaning.

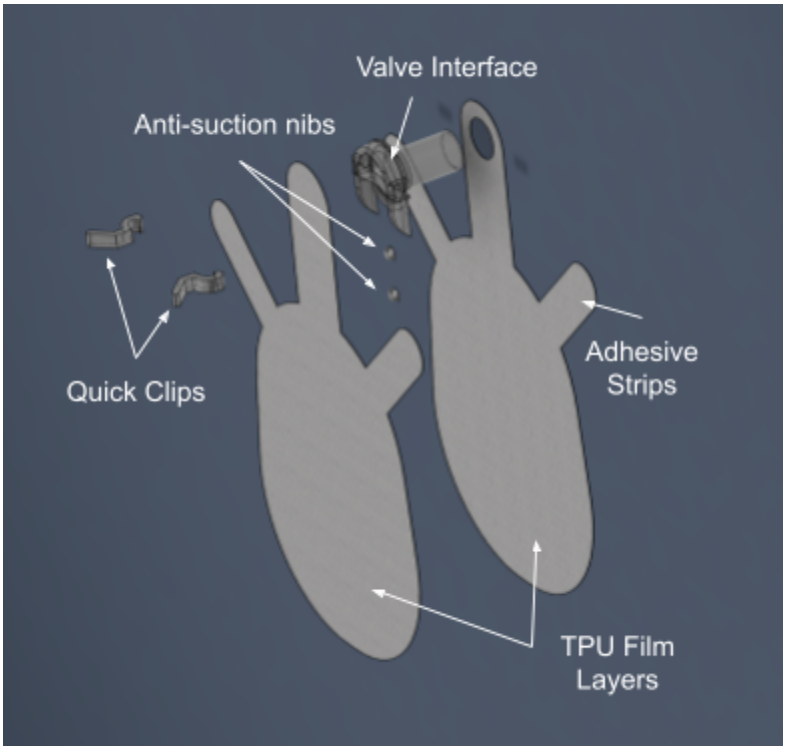

Figure 11: Exploded view of the final version of the bag system.

Testing & Results

Flexi-Seal™ Operating Pressure

Convatec's Flexi-Seal™ is a balloon anchored rectal catheter consisting of a plastic balloon that is inflated to a maximum of 45 mL air. To determine the operating pressure, a balloon was submerged in water, inflated with 45 mL of air, and the displacement was measured. Using the mass of water displaced and relating it with its density, it was possible to accurately calculate the volume displaced by the balloon when inflated. At room temperature, air is sufficiently close to an ideal gas and thus using the ideal gas law, the pressure of the air inside of the balloon was calculated to be 128.5 mmHg. Assuming that this pressure is directly applied to the rectum, this forms the basis of maximum pressure limit. This is an initial number and will need to be refined and validated in the small intestine with future work.

Wall Pressure Test

To determine the internal anchoring pressure exerted by the device against the abdominal wall, a phantom intestine made from Ecoflex 45 silicone was created. Measuring 10 cm in length with an inner diameter of 22 mm and outer diameter 25 mm, the silicone cylinder was created to simulate the internal environment of the small intestine. Ecoflex 45 is rated to a 100% modulus of 12 psi (82.7 kPa). Because the silicone based material is elastic, it can be assumed that the stress-strain response is linear and thus is a good approximation for the 120 kPa Young's modulus of the intestine identified in literature. To measure the wall pressure, the prototype was inserted into the phantom and the outer diameter was measured after stretching. Four outer diameter measurements were taken per trial with 15 discrete trials conducted. Figure 12 shows the general setup of the wall pressure test with the plug component of the device inserted into the phantom intestine.

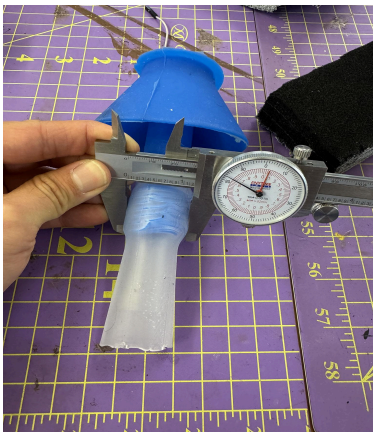

Figure 12: Wall pressure test setup.

Results (displayed in Figure 13 and Table 2) document the average measured radial pressure exerted by the plug as 15.76 mmHg against the phantom wall, falling within the physiological range of normal intestinal pressure (10–20 mmHg) and indicating that the radial pressure exerted on the intestinal wall by the anchoring method is not a significant concern.

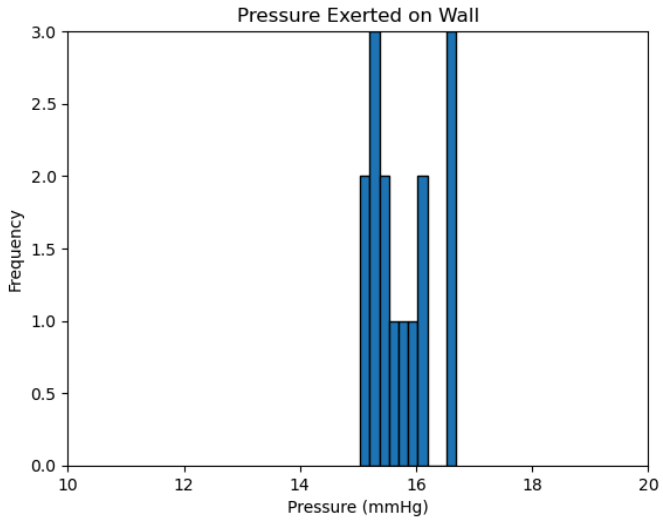

Figure 13: Histogram of trial results for radial wall pressure exerted by anchoring fins (n = 15).

Number of Trials	15
Average Pressure	15.76 mmHg
Minimum Pressure	15.04 mmHg
Maximum Pressure	16.69 mmHg

Table 2: A breakdown of the pressure data exerted by the plug on the phantom intestine walls.

Valve Leakage Pressure Test (Water Column Simulation):

The second test evaluated the leakage pressure threshold of the prototype valve design. Leakage pressure was defined as gross leakage, the pressure at which the leak-by past the valve transitioned from drops into a steady stream. Steady stream flow rate was decided to be the recorded failure point because steady flow occurs only after the valve opens enough to allow continuous flow and represents full failure of the one way valve. The experimental setup consisted of 12 feet of tubing with a funnel attached to one end and the valve to the other end. This apparatus was hung vertically in a stairwell next to a measuring tape which allowed us to measure the height of the water column. By using water, a fluid of known density, an accurate observation of the amount of pressure subjected on the valve was able to be obtained. The experimental setup is depicted in Figure 14.

Figure 14: Valve leakage pressure test setup

Measurements were taken with two observers, one at the bottom of observing the outlet of the valve and the other videotaping the changing height of the water column. The funnel at the top of the experimental setup allowed for a controlled continuous inflow of water. Figure 15 displays the viewpoint of the bottom recorder to demonstrate the accuracy in the water column measurement tests.

Figure 15: Water column test measurement

Twelve trials were conducted and in all except one trial, the valve successfully withheld leakage up to 128.5 mmHg. The trial with high holding pressure was due to the way the valve seated with pressure from the water column holding it shut. This result indicates a need for more precise manufacturing techniques (for example machined cutting of the valve opening) for consistent performance. Despite this, the majority of valve leakages occurred under the set maximum pressure, illustrating that it is feasible to design a valve that fails and relieves pressure prior to exceeding safe pressure. Results displayed in Figure 16 show that the most frequent leakage occurred around 115 mmHg which is well within safe limits.

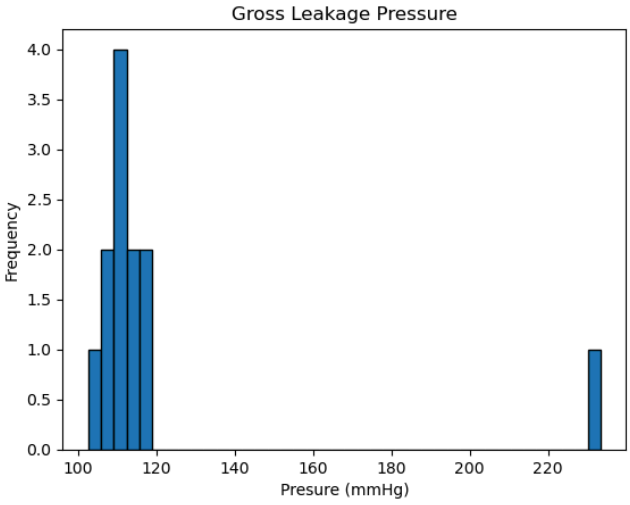

Figure 16: Histogram of valve leakage pressure trial results (n = 12).

Pullout Force Test:

The purpose of the pullout force test was to experimentally determine the maximum force that the anchoring fins can resist before the device is dislodged from the simulated stoma. The addition of olive oil as a lubricant is qualitatively more conservative (lower coefficient of friction) than was observed in ex vivo porcine samples. While factors such as microvilli texture and peristaltic motion were not simulated, the results of the pullout test will inform the feasibility of the prototype and form the basis for more biologically accurate tests.

The setup consisted of one end of the phantom in a vice with the other end open and lubricated with olive oil. The olive oil was applied with a cotton swab and allowed to gravity drain, leaving a thin layer. The prototype was hooked up to a force gauge with accuracy of 1 g, fully inserted into the phantom, and pulled vertically from static until the prototype ejected from the phantom. The maximum reading of the force gauge was recorded for 11 trials. The force applied to the cross sectional area of the intraluminal area was recorded as the maximum pressure applied. The cross sectional area was calculated to be the averaged inner diameter of the radial wall pressure test with the phantom distended by the anchored prototype. Figure 17 shows the results from the pullout force test with Table 3 further denoting the maximum and minimum pressures.

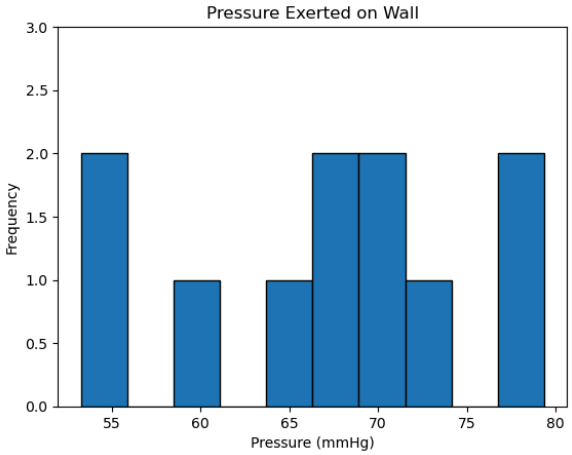

Figure 17: Individual trial results for pullout force measured as equivalent pressure (n = 11).

Number of Trials	11
Average Pressure	67.41 mmHg
Minimum Pressure	53.28 mmHg
Maximum Pressure	79.35 mmHg

Table 3: A breakdown of the pullout force test results.

The average pullout force corresponds to an equivalent pressure of 67.41 mmHg, which is significantly higher than normal operating intestinal pressure (20 mmHg) and well below the

maximum safe pressure (128.5 mmHg). The difference between the normal operating pressure and minimum pull out equivalent pressure (33.28 mmHg) represents the capacity of the bag, that we cannot utilize a bag that would apply more than 33.28 mmHg pressure from its mass hanging off the prototype outlet. The differential between the maximum operating pressure and maximum pull out equivalent pressure (49.2 mmHg) shows that the plug will eject prior to reaching maximum operating pressure, providing a safe but less desirable alternate pressure release method. It should be highlighted that the results are highly conservative due to the use of olive oil as the lubrication medium. The most significant conclusion of this test is that the prototype plug is feasible.

Discussions

The results of the testing indicate that the current prototype meets the tested functional requirements outlined for the stool management system. Of the four functional requirements, leak prevention during normal use, control of stool flow, safe attachment to body, and secure connection to the bag, all were able to be validated except for connection between the body and bag which was not tested due to time constraints.

The anchoring mechanism demonstrated an average radial pressure of 15.76 mmHg, which lies comfortably within the normal intestinal pressure range of 10–20 mmHg. This suggests that the device provides sufficient retention without risking user discomfort or injury. Furthermore, the narrow variation across 15 trials highlights the design's consistency and repeatability—an essential factor for clinical reliability and user confidence.

The valve leakage test confirmed that the tricuspid-style duckbill valve effectively prevents unintended stool flow, withstanding pressures up to 128.5 mmHg in nearly all trials. This sealing threshold far exceeds typical and even elevated physiological pressures experienced in daily activities, offering reassurance that the valve can maintain a reliable seal during use. One outlier trial, however, revealed early leakage, emphasizing the need for tighter manufacturing tolerances. Specifically, variability introduced through manual slit cutting should be eliminated in future iterations by adopting high-precision manufacturing or mold-integrated solutions to ensure consistent valve geometry and performance.

In the pullout force test, the anchoring fins demonstrated robust mechanical retention, with an average equivalent pressure of 67.41 mmHg, which is significantly above normal intestinal pressure and well below harmful thresholds. These results confirm the device's ability to stay securely in place under physiologically relevant conditions. Notably, testing was conducted under conservative conditions (e.g., olive oil lubrication with minimal friction), implying that actual performance in vivo may be even stronger due to natural tissue resistance and mucosal friction.

While these tests validate the core functionality of the plug in terms of anchoring, sealing, and retention, one functional requirement remains untested: the secure connection to the bag, which requires a detachment force of at least 10 N to prevent accidental disconnection. This feature is critical for reliable daily use and will be prioritized in future mechanical interface

testing to evaluate the strength, usability, and safety of the quick-connect mechanism under real-world loading conditions.

Together, these findings support the feasibility of the current design as a non-invasive, user-controlled alternative to traditional ostomy bags. They also reveal key areas for improvement, particularly in valve fabrication precision, usability during insertion and removal, and mechanical locking of the bag interface—all of which are addressed in the following section on future work.

Future Works

While this prototype establishes a functional foundation, several limitations remain that inform opportunities for future improvement.

First, the valve manufacturing process requires tighter tolerances to ensure consistent and reliable performance. The current valve is fabricated using silicone casting with 3D-printed molds, and the slit is manually cut using a blade. This introduces variability in geometry and performance. Future iterations should explore precision machining or mold-based manufacturing to improve repeatability. Once refined, the valve will require additional leakage pressure testing to validate performance. Moreover, extended duration testing under constant pressure should be conducted to evaluate how long users can remain bagless without leakage, and to assess risks of valve blockage or small bowel obstruction.

Second, the insertion and removal process presents a design challenge. The device may require the development of an applicator to facilitate easier, safer, and more consistent use. An applicator would help ensure rigid and accurate placement during insertion, improving usability and reducing the risk of improper positioning.

Third, material durability must be evaluated in pH and degradation testing, given the device's prolonged exposure to intestinal waste. Human waste contains degradable enzymes and varying pH levels that may compromise device performance over time. Durability tests should determine how long the device can be safely worn before needing replacement. Additionally, materials must be assessed for biocompatibility with the stoma environment and evaluated for sterilizability if reusable components are considered.

Fourth, the bag interface requires further development to improve its locking mechanism. In its current form, the quick-connect design may be vulnerable to accidental disengagement due to movement or external forces. A more robust mechanical lock would enhance user confidence, prevent leaks, and increase control over the system during daily activities.

Finally, the anatomical diversity of ileostomy patients ranging from pediatric to elderly users requires a scalable design. The plug must accommodate a range of stoma depths, diameters, and abdominal wall thicknesses. Future development should include a family of size variants or an adaptable modular system to support broader usability and improved fit across the patient population.

Conclusions

This study presents the development and initial evaluation of a controllable stool management system designed for individuals with ileostomies. The proposed device integrates a soft silicone plug with compliant radial anchoring fins, a tricuspid-style one-way valve for directional control of effluent, and a mechanical quick-connect interface for waste collection. The system aims to address key limitations of current ostomy care products by providing users with temporary stoma closure capability, improved hygiene during bag changes, and reduced peristomal skin irritation.

Functional testing demonstrated that the prototype meets key physiological and performance criteria. The anchoring mechanism achieved an average radial pressure of 15.76 mmHg, within the range of normal intestinal pressures, while maintaining consistency across trials. The valve withstood pressures up to 128 mmHg, well above typical intraluminal conditions, indicating robust sealing performance. Pullout force tests showed secure retention exceeding expected physiological loads, while remaining below thresholds associated with tissue damage. These results validate the mechanical feasibility and functional safety of the core subsystems.

However, the secure connection between the plug and bag has not yet been quantitatively evaluated. This represents a critical area for future testing. Additional work is also required to improve valve manufacturing tolerances, evaluate material performance under extended exposure to gastrointestinal fluids, and explore ergonomic improvements for insertion and removal. The design must also be adapted to accommodate anatomical variability across the patient population through scalable or modular sizing strategies.

The prototype demonstrates strong potential for enhancing user autonomy and clinical outcomes in ileostomy care but further refinement and testing will be necessary to support clinical translation, regulatory clearance, and broader adoption.

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