

I. Abstract

Ostomy surgeries (including colostomies and ileostomies) are performed on patients suffering from gastrointestinal diseases, cancer, or trauma in which the intestine is transected and redirected outside the body through the abdominal wall. Waste is output through the portion of the intestine that remains outside of the body. Though the procedure vastly improves patient quality of life the patient always loses continence and patients must collect and manage their waste output with disposable plastic ostomy bags that adhere to the abdomen. However, the ostomy bag is prone to failures, creating a large gap in medical care. Patients report frequent adhesive failures, skin irritation, and bad odor—all of which are primarily caused by or are associated with waste leakage, which persists for years after the ostomy surgery. Thus, there is a need for a biocompatible, manageable, discreet, comfortable, and safe product that collects and manages physical waste, and prevents leakage, both during continuous use and bag transition. Our solution, the OstoCare Ostomy Continence Device, is designed to eliminate leakage experienced by patients using ostomy bags. As an accessory to the current system of ostomy bags, our device transports all waste output from the intestine through an open valve into the ostomy bag without risk of leakage. By creating a tight seal that directs all waste into the ostomy bag, our device addresses the shortcomings of current ostomy care methods during daily use and during bag transition. There are no current technologies on the market that prevent waste output during bag replacements to the same degree of success that our device can achieve. Our solution is a simple and easy-to-use method to solve the major problems associated with current ostomy bag systems.

II. Description of Clinical Need

Ostomy surgeries (such as colostomies and ileostomies) are life-saving procedures performed on patients suffering from various gastrointestinal diseases such as cancer, Crohn's Disease, and Ulcerative Colitis, or from general trauma or injury to the gut. In this surgery, a part of the intestine may be resected and the remaining portion of the intestine is redirected outside the body through a surgical incision (Figure 1). This opening is referred to as a stoma. The procedure vastly improves patient quality of life, but the patient always loses continence, as the rectum is bypassed. Therefore, waste output is passively collected in plastic ostomy bags that adhere directly to the abdomen around the ostomy and must be replaced every 2-3 days. Unfortunately, the ostomy bag is prone to failures, creating a large gap in medical care that ostomy patients believe is not being address by major manufacturers in an effective way.

According to the United Ostomy Associations of America (UOAA), there are more than 700,000 people living with an ostomy in the US and Canda alone, with more than 130,000 people undergoing ostomy surgeries every year [1]. A survey we conducted in conjunction with the UOAA (n = 542) found that the majority of ostomy bag-related issues experienced by users were leakage, at 49%, or leakage-related (i.e. skin irritation, moisture) (Figure 2). In fact, 86% of long term ostomy bag users regularly experience waste leakage during bag use and while replacing full bags. Also, nearly 70% of patients had these issues one to five times a month. These issues persist for years after surgery. Specifically, during daily use there is leakage due to an improper seal between the abdomen and

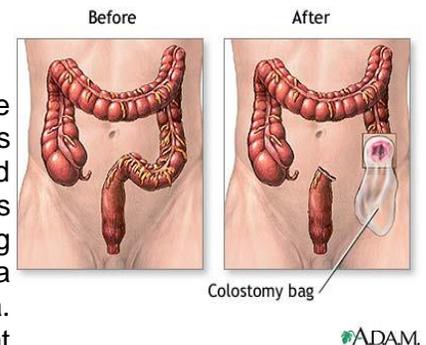


Figure 1: Illustration of intestine before and after an ostomy surgery

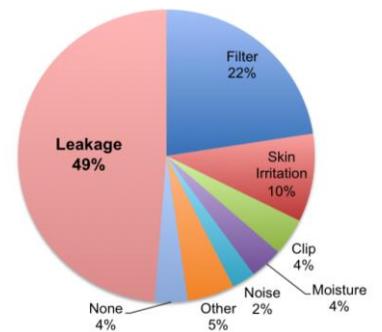


Figure 2: Most Common Ostomy Bag Problem Areas. Preliminary Ostomy Patient Survey (Jan. 2015, OstoCare/UOAA)

the wafer of the ostomy bag. During the lengthy bag-replacement process, fecal waste is continuously output from the stoma.

With no major breakthroughs in technology over the past 60 years, the primary device used for ostomy care, the ostomy bag, fails to meet basic customer needs. Commonly, an improper seals between the bag and the abdomen causes waste to seep out onto skin and clothing. This leads to other problems such as skin irritation and infection, which can cause embarrassment, distress, and general discomfort. There is a need for a biocompatible, easy-to-manage, discreet, comfortable, and safe product that collects and manages waste, prevents leakage, and staunches flow while changing the bag. We want to revolutionize the way ostomy patients deal with their ostomy waste by addressing these large gaps in care.

III. Design

A. Documentation of Final Design

The Ostomy Contenance Device (OCD) (figure 3) is comprised of three main parts, (1) the cannula, (2) a flat wafer, and (3) a valve. The three components combined form a device that enable the ostomy patient to collect and manage their physical waste while preventing leakage and simplifying the bag changing process. A description of each component and its functionality is as follows.

The cannula (1) is a tube that is inserted into the ostomy, featuring an inflatable cuff that wraps around the tube. It operates in a manner similar to an endotracheal tube with the inflatable cuff creating a seal with the intestine wall, thus ensuring that the waste only flows through the tube and not around it. The inflatable cuff has its pressure limited by a pressure release valve, ensuring that the pressure placed on the intestine wall from the cuff does not exceed the capillary perfusion pressure, reducing the risk of pressure necrosis.

The flat wafer (2) is at the end of the cannula, placed so that it remains outside the abdomen while the majority of the tube is inserted within the abdomen. This wafer, made from a biocompatible material such as silicone, provides a wide and flexible surface to which the patient is to adhere their ostomy bag. It is soft and flexible so that it does not impede the body's motions and is comfortable to wear. It is made from silicone so that it does not pose health risks to the patient and is impermeable to waste so that it is easy to clean should it come in contact with intestinal waste, such as when the ostomy patient replaces his/her bag.

The valve (3) is used to staunch intestinal waste flowing through the cannula and tube when changing the ostomy bag. It is designed to remain open when the bag is adhered to the wafer and closed while the patient changes their ostomy bag. During the bag-changing process, fecal waste continues to pass through the ostomy. The ability to close the ostomy during this time, allows for a quicker and cleaner bag-change. The risk in the valve is waste backup within the intestine, which our clinical advisor assured would only cause minor discomfort similar to a sensation of feeling full, or needing to use the restroom. Failure of the valve while in use causes waste output instead of staunched flow, leading to waste leakage and the subsequent required cleanup.

The OCD is not an implantable device and can be used by patients without medical supervision. Figure 4 shows the utilization schematic for our device.

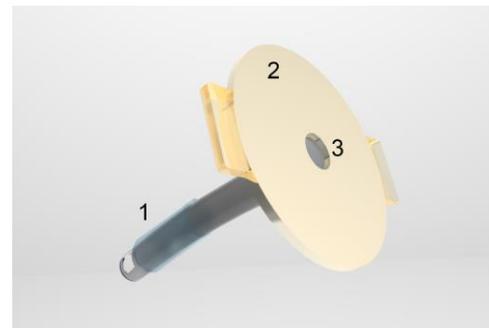


Figure 3: Rendering of the Device

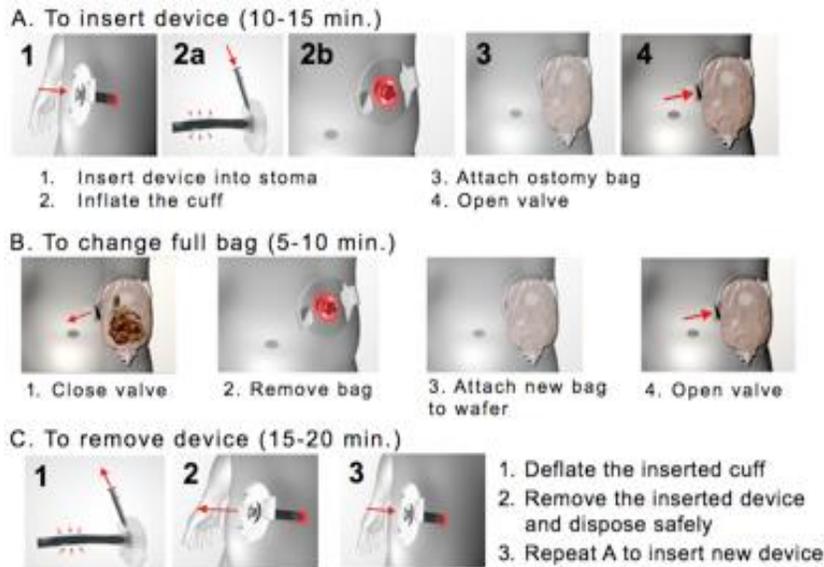


Figure 4: Utilization schematic for our device.

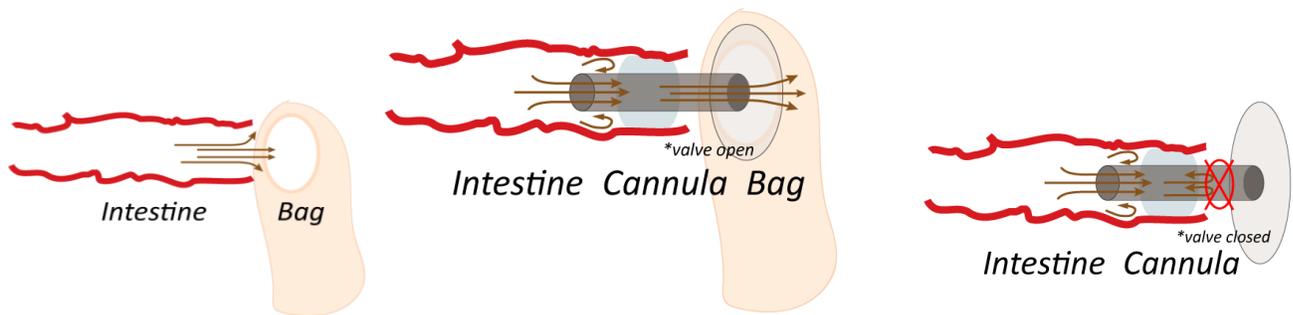


Figure 5: Illustration of our device in action. (Top) Typical path of waste flow using only the ostomy bag without our device. (Middle) Waste flow through our device into the ostomy bag. (Bottom) Blockage of waste flow when our device's valve is closed.

B. Prototype of the Final Design

The prototype of the final design was composed of the three elements, however the materials used and manufacturing techniques employed differ from that of our envisioned final product.

The tube inserted within the ostomy is made from polyvinyl chloride (PVC), a flexible yet rigid material used to make disposable medical devices. The inflatable cuff is also made of PVC. Tests using silicone polymer demonstrated that both materials were also effective in creating a seal in the intestine, as desired by our design; yet the material was not as available as PVC. The flat wafer used to attach ostomy bags with improved adhesion was made from precision laser-cut silicone. The prototype is currently being used to test for the optimal thickness of silicone to be used for this application. The valve mechanism of our device was made from cast acrylic. Other materials such as FDA-approved acrylonitrile butadiene styrene (ABS) and polyethylene plastics are currently being explored as alternatives for implementation into our prototype as they can be custom molded for a more compact design. This prototyping process

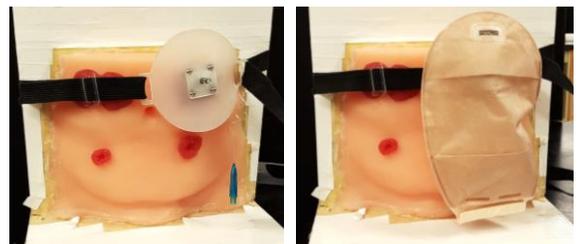


Figure 6. Our prototype inserted in artificial abdomen (left) with ostomy bag attached (right)

has been solely conducted by our team (the authors of this report), with mentoring and occasional machining support from the university's lab staff.

IV. Evidence of Working Prototype

The functionality and safety of our device were both tested in a bench-top setup, utilizing bovine small intestine, with stained water as our waste analogue. A syringe pump was used to move waste analogue through the bovine intestine at physiological flow rates (5-20 mL/min) to simulate an operational digestive tract (Figure 8, testing set-up). The biggest safety concern for our device lies in the inflated cuff to create a leak-proof seal between the device and the intestine wall—the cuff pressure must remain below the perfusion pressure of capillary beds within the intestine wall (40 cmH₂O) in order to avoid pressure necrosis of intestine tissue. At a cuff pressure of 30 cmH₂O and flow rates ranging from 5-20 mL/min, there were no measurable volumes of waste leakage between the bag and the silicone wafer, as well as between the intestine and the inflated cuff, demonstrating that it was possible to prevent leakage at physiological parameters while remaining safe to use. Repeating this testing with a closed valve found no waste leakage at the relevant interfaces. We compared the volume of waste analogue transferred into the ostomy bag using our device to the volume transferred into the ostomy bag without our device (the ostomy bag was attached to an artificial abdomen), and demonstrated a significant improvement in waste transfer while using our device. Our test bed is shown in the image below, along with volume transfer measurements from the intestine into the ostomy bag.

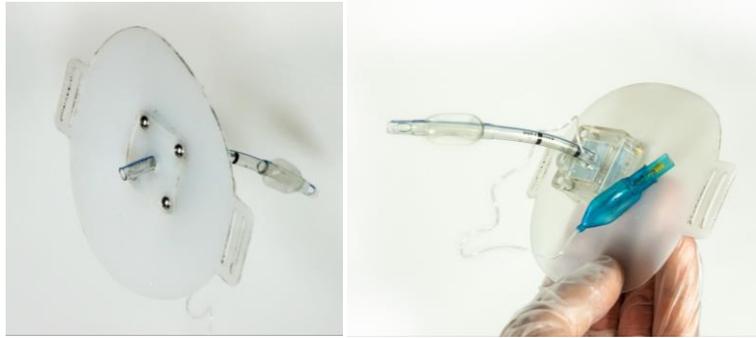


Figure 7. Prototype of our device design, front view (L) and rear view (R)

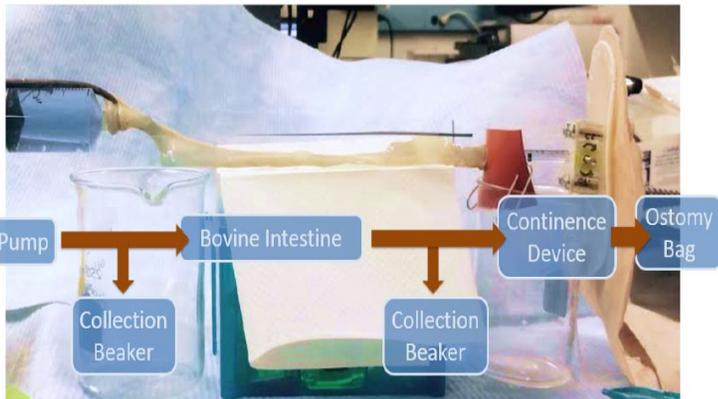


Figure 8: Bovine experiment testing bed (Left) and results from seal verification testing (Right)

VI. References

[1] Beck, David, Janice Rafferty, and Marlene Muchoney. "New Patient Guide." Ed. Ian Settlemire. *Phoenix Magazine* 2012: 3. Web.