

OstoSeal: Waterproof and Reusable Ostomy Pouch Cover

Preliminary Report

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Introduction

Motivation

Ostomy surgery is a surgical procedure that creates an opening, known as a stoma, in the abdomen to allow bodily waste to exit the body when normal digestive or urinary functions are impaired. An estimated 725,000 to 1 million individuals in the United States live with an ostomy, with approximately 100,000 ostomy surgeries performed annually [1]. These procedures may be necessary for patients experiencing colorectal cancer, inflammatory bowel disease, bladder cancer, or many other medical conditions [2]. Following surgery, many patients rely on an ostomy pouching system consisting of a collection bag and an adhesive wafer that attaches to the skin surrounding the stoma. Maintaining a secure adhesive seal is essential for preventing leakage and protecting the surrounding skin. Peristomal skin complications are a common concern for these patients. A review reports that complication rates range from 36.3% to 73.4% [2]. These complications can cause discomfort, interfere with daily activities, and negatively affect quality of life. Medical adhesive-related skin injuries, including irritation and skin stripping, present additional challenges for patients who regularly apply and remove ostomy appliances [3]. Although many ostomy pouching systems are designed to tolerate showering, some individuals prefer additional protection from water exposure to keep their pouch and adhesive wafer dry. This creates a need for a comfortable, reliable, and reusable waterproof covering that supports daily hygiene without interfering with the normal function of the ostomy.

Existing Devices and Current Methods

Several products are currently available on the market and aim to protect ostomy pouches and their adhesive wafers during showering. The three primary types of existing solutions include belt pouches, adhesive squares, and scrunch pouches. Belt pouches use an adjustable strap that wraps around the user's waist to secure a protective covering over the ostomy application [4]. Although these devices provide coverage without requiring direct skin adhesion, they may be uncomfortable for individuals with varying abdominal contours. Adhesive squares provide an alternative approach by using a waterproof film that adheres directly to the skin surrounding the ostomy appliance [5]. While these products offer protection against water exposure, excessive adhesive strength may cause discomfort during removal. Lastly, scrunch pouches use an elastic opening to fit around the ostomy bag without requiring additional adhesives or waist straps [6]. However, these designs do not fully protect the wafer adhesive from water exposure. Although each of these existing solutions offers certain advantages, limitations in comfort, skin adhesion, and overall waterproof coverage demonstrate the need for a more versatile and reliable protective device.

In addition to commercially available products, several patents describe alternative methods for protecting ostomy appliances from water exposure. U.S. Patent US9750633B1 describes a waterproof cover designed to protect both the ostomy pouch and adhesive wafer, with reusable and disposable versions available [7]. Similarly, U.S. Patent US9204990B1 describes a

waterproof cover that attaches to the skin using an adhesive flange and may include a resealable opening for emptying the ostomy pouch without removing the cover [8]. Another design, described in U.S. Patent Application US20190321213A1, uses a bowl-shaped barrier secured around the abdomen with an adjustable belt [9]. Although these designs offer different approaches to waterproofing, they introduce considerations involving adhesive contact, ease of use, and comfort. These existing designs demonstrate the importance of developing a compact, flexible, and reusable cover that provides reliable waterproof protection while accommodating different ostomy appliances and body shapes.

Problem Statement

Individuals living with an ostomy rely on pouching systems that require proper protection and maintenance during everyday activities, including showering. Current methods of keeping ostomy pouches and wafer adhesives dry can be unreliable, uncomfortable, or inconvenient, potentially negatively impacting users' quality of life [3]. Existing solutions may also lack the flexibility needed to accommodate variations in pouch sizes and abdominal contours. Therefore, there is a need for a safe, comfortable, and effective waterproof covering that protects both the ostomy pouch and its adhesive wafer during showering. The device must be compact, durable, and easy to apply and remove to support daily use while maintaining a reliable waterproof seal without interfering with the normal function of the ostomy appliance.

Background

Due to the various reasons that an ostomy may be performed, there are many kinds of ostomies. The three main types are colostomies, ileostomies, and urostomies. A urostomy redirects the ureters to a stoma where urine exits, and a colostomy redirects the colon (large intestine) to a stoma where stool exits. An ileostomy redirects the ileum (end of the small intestine) to a stoma where softer stool exits [10].

Before surgery, the ideal stoma location for the patient is determined and marked. The particular stoma location for the patient is determined by considering the patient's anatomy. This includes the location where the digestive or urinary tract is being redirected from, as well as any folds or creases on the outside of the body. Urostomies and ileostomies are often placed on the right side of the body, and colostomies are typically placed on the left. Also considered is the point at which the patient's clothing waistband hits the abdomen. Proper stoma placement ensures comfort for the patient and proper adhesion of the ostomy pouch to the body [11][12].

After surgery, skin irritation from leaking waste is the most common issue [13]. Another common issue that affects more than 80% of patients is PMARSI, which stands for "peristomal medical adhesive-related skin injury." PMARSI includes various injuries caused by adhesion removal such as skin stripping, skin tears, skin erosion, and erythema (redness of skin relating to an increase of blood flow to the tissue). PMARSI may arise from the patient developing an allergy to the adhesive used (allergic dermatitis), moisture becoming trapped under the adhesive

barrier, inflammation from hair removal or trapped bacteria, or other mechanisms. The best way to prevent PMARSI is by performing routine skin assessments, ensuring that the right product is being used for adhesion, and practicing correct technique when removing adhesive [3]. Allergic dermatitis can be caused by skin that is repeatedly stripped, especially in a humid environment. Humidity can also further aid penetration of an infection and facilitate sensitivity [14].

Choosing to shower with or without an ostomy pouch is a personal decision, and both options can be safe and hygienic. Ileostomies and urostomies tend to be more unpredictable and active than colostomies when showering, which is important to consider when deciding whether to shower with an ostomy pouch. During showering, with ostomy pouches including a filter, it is important to ensure that the filter does not get wet. Water buildup can block the filter and interfere with effectiveness. After showering, the adhesive of the pouch may get stickier if it is wet [15].

The client, Mrs. Tami Mlodik, has a permanent ileostomy and showers with her ostomy bag. But she would prefer that the bag and adhesive wafer remain completely dry as it is more comfortable and avoids skin irritation.

This project seeks to design a safe, comfortable, fully waterproof ostomy bag shower cover to prevent skin irritation and any discomfort due to the pouching system getting wet while showering. The cover should in no way interfere with the function of the ostomy bag itself, and it must be both durable and easy enough to use for daily utilization in the shower. Further specifications for this design can be found in Appendix I.

Preliminary Designs

Design 1: Adhesive Mix and Match

This design's cover entirely encases the user's ostomy bag with an outer shell. The design includes an adjustable strap made of biothane elastic. The product-to-skin seal is only located directly around the user's ostomy bag adhesive. The majority of the waterproof seal is provided by the combination of a silicone adhesive and silicone gasket. The gasket provides a channel to divert water away from coming into contact with the adhesive. The small disposable acrylic adhesive adds to the strength of the product-to-skin seal of the design.

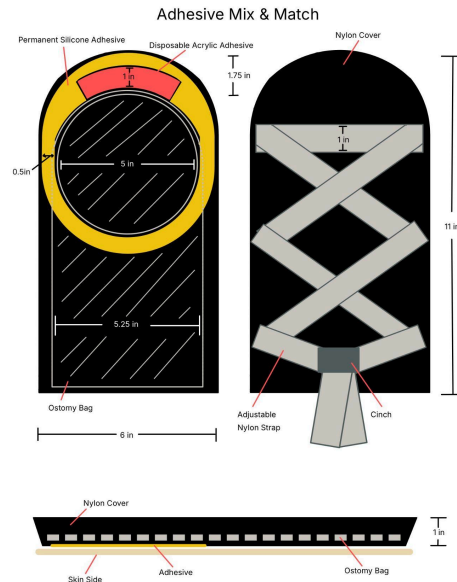


Figure 1: Adhesive mix and match design

Design 2: Adhesive Strips on Flaps

The Adhesive Strips on Flaps design consists of a two-part system: a waterproof nylon pouch cover and four waterproof adhesive strips. The pouch cover is a one-piece system, with the bag and base fabricated together. A hole through the base of the nylon allows for the client's ostomy bag to be fed through. The base of the pouch is shaped into a square with four 5" x 1" flaps. During the application process, the four adhesive strips would be applied on top of the four flaps, overlapping at the corners and providing a waterproof seal. While the nylon bag of the cover is reusable, the adhesive strips would need to be replaced after each use.

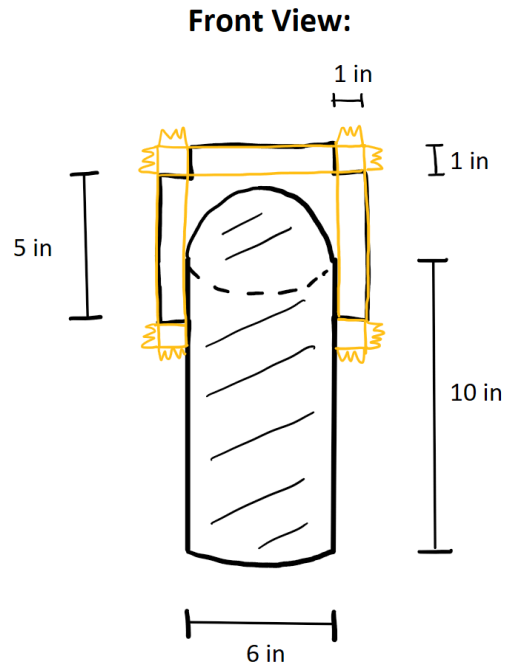


Figure 2: Adhesive strips on flaps design

Design 3: Silicone Cup Design

The silicone cup design involves one rigid silicone cover that is attached to the skin with waterproof adhesive strips. The device is designed to encapsulate the entire ostomy pouch, including both the bag and bag adhesive. With being 5" x 5", it covers minimal skin but would require the ostomy pouch to be emptied before usage. The pouch would need to be rolled up to fit into the cover. The rigid cover portion is reusable and the strips need to be replaced every shower.

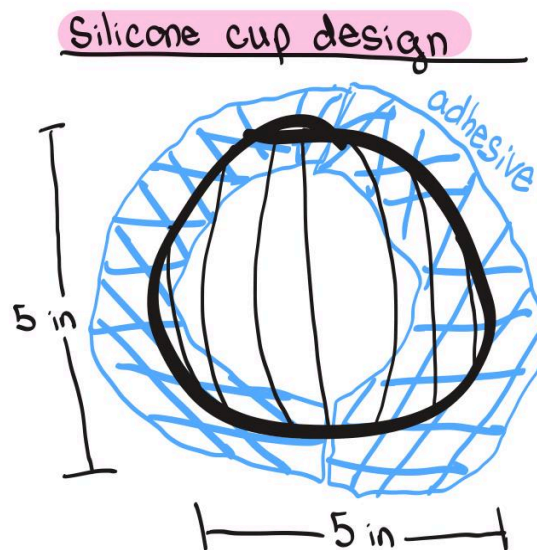


Figure 3: Rigid silicone ostomy cover design

Preliminary Design Evaluation

Ostomy Shower Pouch Design Matrix

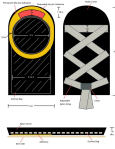
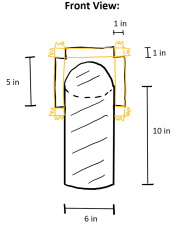
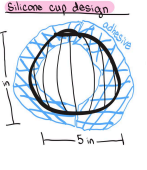
		Adhesive Mix and Match 		Adhesive Strips on Flaps 		Silicone Cup Design 	
Criteria	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Waterproofness	25	4/5	20	5/5	25	2/5	10
Ease of Use	20	4/5	16	3.5/5	14	5/5	20
Reusability	15	3/5	9	2/5	6	5/5	15
Comfort	15	4/5	12	4/5	12	2/5	6
Ease of Fabrication	10	3/5	6	4/5	8	5/5	10
Adjustability	10	5/5	10	2/5	4	0/5	0
Cost	5	4/5	4	5/5	5	5/5	5
Total	100	Sum	76	Sum	74	Sum	66

Figure 4: Design Matrix, with ranking of each design

Design Criteria

- 1. Waterproofness:** The waterproofness criterion evaluates the estimate of how much water the design allows through its adhesive seal and waterproof cover. The ideal product would let absolutely no water through this barrier and would therefore earn a perfect score. Because this criterion addresses the core issue that this product aims to resolve, waterproofness has a stronger score weight than any other criterion. The Adhesive Strips on Flaps design received the highest score of 5/5 because it uses the most pouch material and adhesive to thoroughly ensure no water leaks through the barrier. The Adhesive Mix and Match design received a slightly lower score of 4/5 because of the small area where the barrier is only composed of silicone adhesive, which has not been as thoroughly tested for waterproofness as the disposable adhesive. The Silicone Cup design received the lowest score of 2/5. The nature of the one-suction design that the silicone cup utilizes might allow for leakage as the user moves, which could be quite often during usage. Because in-shower use has never been the intended use of a silicone cup, very little testing of the waterproofness of the product has been carried out.
- 2. Ease of Use:** The ease of use criterion assesses how easily the product can be applied, removed, and stored by the client. The product should be able to be quickly and easily applied by the user to the area surrounding the stoma and ostomy pouch. After showering, the user should then be able to remove the product easily, without damage to the ostomy pouch, and store it until the next use. The Silicone Cup Design received a score of five because there is no adhesive that would need to be removed and replaced in between uses. Also, the ostomy bag could be easily inserted and removed from the opening in this cover and there are no absorbent materials in this design that might retain water post-shower. No retention of water allows for quick, easy drying of the pouch before storing. The Adhesive Mix and Match Design received a lower score of four because one of the adhesive components is removable and disposable and would need to be replaced periodically. The ostomy bag itself would still be able to be easily inserted and removed from the opening in the cover, and there are no absorbent materials that might retain water after showering. The Adhesive Strips on Flaps Design received a score of 3.5 because there is no permanent silicone component to the adhesive design. So, the entire adhesive component would need to be applied/replaced. However, this design also allows for easy insertion and removal of the ostomy bag and does not include absorbent materials.
- 3. Reusability:** The reusability criterion addresses the ability for the entirety of the contraption to be used for multiple showers. The waterproofed compartment of the design should last for at least 35 showers without any damage inflicted on the material causing leakage. For the adhesives, the quantity of adhesives needing replacement between showers should be minimized to reduce waste. The entire contraption should be able to withstand repeated contact with shampoo, condition, soap, and any other shower products the client may use, while retaining its integrity and ability to adhere. The Adhesive Mix

and Match Design received a rating of four in this category. Both the waterproof bag system and the silicone seal can be continually reused, and only the small acrylic adhesive located at the top of the design must be replaced after every shower. Similarly, the four large adhesive strips must be disposed of after every use in the Adhesive Strips on Flaps Design. Despite the reusability of the bag, this design causes large amounts of waste each use, resulting in a reusability rating of two. In contrast, the Silicone Cup Design received a rating of five due to the fact that the entire contraption can be completely reused without causing any waste. The silicone cup simply has to be cleaned and set out to dry after use. Overall, the Silicone Cup Design received the best rating in the reusability criterion because of the ability to reuse 100% of the contraption.

4. **Comfort:** The comfort criterion assesses how comfortable the product is to wear during the user's regular shower activities, such as washing the body or bending to shave. It is based on weight, bulk, and the freedom of movement the device allows. The design should allow the user to shower normally without causing discomfort or irritation. The Adhesive Mix and Match and the Adhesive Strips on Flaps designs both received scores of four out of five because they utilize silicone tape. This adhesive requires only minimal, irritation-free contact with the user's skin. Additionally, the Adhesive Mix and Match design incorporates adjustable straps that allow the user to secure any excess length. It is designed to accommodate larger pouches out of the way, reducing unnecessary bulk and interference in the shower. The Silicone Cup Design received the lowest score in this category because the cup used to create suction could become uncomfortable if worn for longer periods of time. This could especially be an issue because the suction needs to be strong enough to create a waterproof seal. Also, this design may require the user to occasionally adjust the cup in the shower, which could add to the discomfort.
5. **Ease of Fabrication:** Ease of fabrication is an important factor for the device because the design needs to be realistically manufactured within the time frame of the semester. A simpler fabrication process will allow more time for testing and making changes to improve the final design. The Adhesive Mix and Match design received a score of three, the lowest of the three designs. This design requires multiple components, which increases the number of assembly and fabrication steps. Comparatively, the Adhesive Strips on Flaps design received a score of four because it consists of a relatively simple cover with adhesives attached to the surrounding flaps. This reduces the number of separate components and makes the assembly more straightforward. Finally, the Silicone Cup design received the highest score of five because it consists of relatively few components and requires minimal assembly once the silicone cup is formed. The adhesive can then be applied around the perimeter of the cup, which is a simple final construction.
6. **Adjustability:** The adjustability criterion evaluates the device on how it can conform to different body and ostomy pouch shapes and sizes. This is particularly applicable to the ostomy cover with differing user waist circumferences and contours. The Silicone Cup

design received a score of zero because it is a completely rigid product that would not conform well to a body. The Adhesive Strips on Flaps design received a two because the product is more flexible with silicone tape strips that adapt to waist shape. However, the hanging bag section has no way to be tightened. The Adhesive Mix and Match has crossing straps over the hanging section in order to adjust to the varying sizes the ostomy pouch might take on. This design received a five because it has a tightening ability and it is also flexible enough to conform to the waist.

7. **Cost:** The cost criterion refers to the expense of each design as a whole. This is important to take into consideration because this product may have to be re-bought - more than a few times - over the course of a user's lifetime. The Adhesive Mix and Match design received a score of four because, while the materials used are not costly, the straps add on to the total expense of the product. The Adhesive Strips on Flaps design received a five because the materials used in the design are relatively inexpensive. Plus, there is not a large amount of total material used, bringing the cost down further. The Silicone Cup Design also received a score of five because of the simplicity of the product and the affordability of the silicone material.

Proposed Final Design

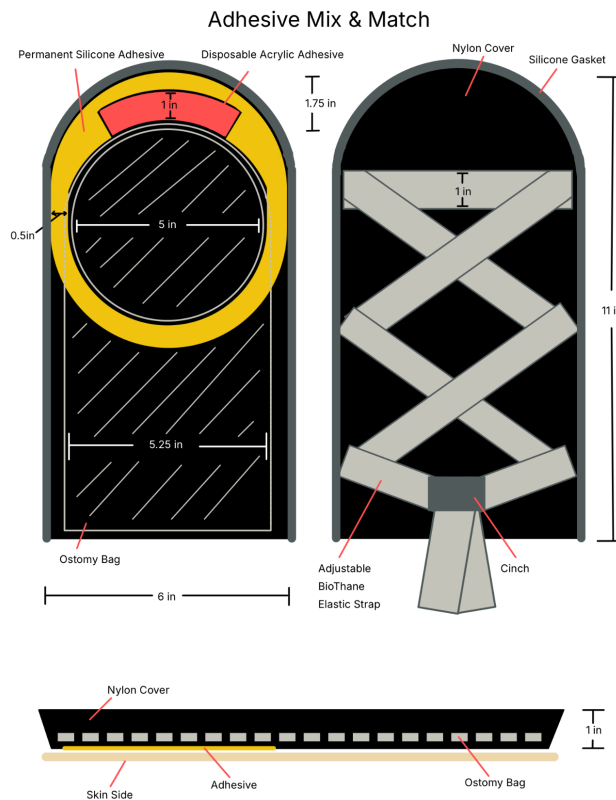


Figure 5: Adhesive mix and match design

Fabrication/Development Process

Materials:

This design's cover entirely encases the user's ostomy bag with a thin waterproof silpoly fabric. [16] The adjustable strap will be made of biothane elastic, which has a waterproof outer layer but is woven with enough stretch to be comfortable for the user. [17] The majority of the waterproof seal is provided by the combination of a silicone adhesive and silicone gasket. The adhesive uses micro-suction to stay in place on the skin, similar to scar tape. [18] The gasket provides a channel to divert water away from coming in contact with the adhesive. The small disposable acrylic adhesive adds to the strength of the product-to-skin seal of the design. This medical-grade adhesive will be nearly identical to the fashion tape used to adhere clothes to skin. [19]

Methods:

The silpoly cover fabric will be cut and sewn together to comfortably fit around the user's ostomy bag. Loops for the adjustable straps will also be sewn onto the cover. The seams will be waterproofed with seam sealant. The adjustable strap will then be cut and looped in, applying the cinch to the bottom straps. The silicone gasket will be attached to the edge of the cover with a permanent adhesive. The silicone adhesive will be attached to a very thin backing ring, which will attach to the cover with a permanent adhesive. A space on the ring with no silicone adhesive will be present to allow the user to attach a small, pre-cut disposable acrylic adhesive.

Testing

Test 1: Waterproofness

To test the cover's ability to maintain a waterproof seal, as outlined in the PDS, the prototype will be exposed to water for 5, 10, and 20 minute increments. An absorbent material will be placed inside the bag to detect moisture. After each trial, the absorbent material and the inside of the cover will be examined for moisture accumulation, and any observed failures will be recorded as external leakage, condensation, or both. The results will be evaluated to determine whether design revisions are necessary to improve waterproofness.

One preliminary test has already been performed to test the behavior of silicone. For this, a common silicone adhesive was cleaned and applied to a clean section of the abdomen. This section of the skin with the adhesive applied was then exposed to a direct current of water. The test was intended to last 30 minutes, the longest duration of shower the client might have. For the first two minutes of the test, the adhesive stayed attached to the body. Very quickly, within about 30 seconds, when in direct contact with the stream of water, the silicone began to fill with water, creating a pocket of liquid between the skin and the silicone. After two minutes, the silicone

adhesive completely detached from the skin. The main issue of the test is the fact that the silicone adhesive was not flush to the skin due to its domed shape, which caused a pocket of air that was not sealed to the body. This created a loose seal between the skin and adhesive, allowing for the adhesive to shift around and allowing water under it. This test was largely unsuccessful due to the loose seal created by the difference in shapes of the skin surface versus the domed adhesive. Further testing should be conducted by adjusting the shape of the silicone adhesive so that it better fits the flat surface of the skin.

Test 2: Adhesive Reusability

To determine how many cycles of soapy water exposure, removal, and reapplication the silicone tape can withstand while still remaining adhesive to both skin and the product, a standardized, pre-cut piece of silicone tape adhesive will be attached to the product and adhere the other side to skin. The tape will be exposed to warm soapy water for 2 minutes and then removed from the device and skin. The tape will be cleaned and allowed to air dry. The test will be repeated until the tape no longer sticks effectively. This will determine how long the tape can be reused for, given proper cleaning.

Test 3: Adjustability

Place objects of increasing sizes inside the cover and adjust the straps to determine whether they can securely hold the bag snugly against the cover without slipping or restricting expansion. Record the largest bag size the cover can accommodate while the straps still provide a secure, close fit.

Discussion

This device will be placed around an ostomy pouch that collects waste exiting an abdominal stoma and protects the stoma from contaminants. There is an ethical obligation to ensure that the device will not harm the stoma or damage the protective pouch in any way. The skin surrounding the stoma must also be considered when it comes to the adhesive of the device. There is an obligation to guarantee that the adhesive will be non-irritating and hypoallergenic, as the adhesive will be used near-daily. All of these safety points will be taken into account, along with water repellency, adjustability, and reusability of the adhesive. Possible points of error from testing the adhesive could stem from the variation of pulling forces that might be used on a given usage. Errors with testing both the bag material and adhesive could also arise from the difficulty of each test demanding a 30-minute duration. This limits the number of total experiments that can be performed.

Conclusions

The goal for this project is to create a safe, comfortable, and reusable cover for the ostomy pouch and wafer adhesive that will keep the two components dry while showering. The Adhesive Mix & Match design, with the combination of silicone and disposable adhesives, will best adhere to the client's body. It provides complete waterproofness alongside the thin waterproof silpoly pouch, and the adjustable strap will ensure the contraption is comfortable during use. Overall, this design prioritizes reusability, adjustability, waterproofness, ease of use, and comfort while ensuring the client's specifications are prioritized.

From preliminary testing completed on the silicone adhesive, it is clear that the adhesive must be flush to the skin to prevent any water from passing under the seal. Additionally, because the edges of the silicone adhesive are prone to buckling when in direct contact with the stream of water, a gasket that would divert the water and protect the edge of the adhesive from direct contact would be increasingly useful. Finally, including a disposable adhesive in addition to the silicone adhesive will provide for a more secure attachment to the body. Overall, the test provided insightful information about the characteristics and waterproofness of a common silicone adhesive by itself, and what improvements need to be made to ensure complete waterproofness of the entire contraption.

Future work

Future testing will be in relation to waterproofness, adhesive reusability, and adjustability. The implementation of a gasket to divert water from direct contact with the edge of the silicone adhesive, and the addition of a second, disposable adhesive, will need to be designed and tested. This contraption should be conjoined with the waterproof cover to complete the prototype. The silicone adhesive must be able to withstand direct contact with the water flow for a maximum of 30 minutes. Waterproofness will be tested by securing a water-permeable paper towel under the prototype and checking if the dryness of the paper towel has been compromised after the 30 minutes. The reusability of the silicone adhesive must also be tested by first repeatedly applying and exposing the adhesive to soapy water for a total of two minutes. Then removing, cleaning, reapplying, and reexposing the adhesive for a total of five times to gauge its reusability. Finally, an adjustability test will be conducted by inserting objects of varying sizes inside the pouch and using the strap to secure the bag more tightly to the object within.

Overall, future work for this device will include further material testing for both the adhesives and the waterproof material of the pouch, and overall prototype fabrication, where the waterproof pouch and adhesive materials will be conjoined. Once the prototype is finalized, further testing on waterproofness, durability, and reusability will be conducted for the entire

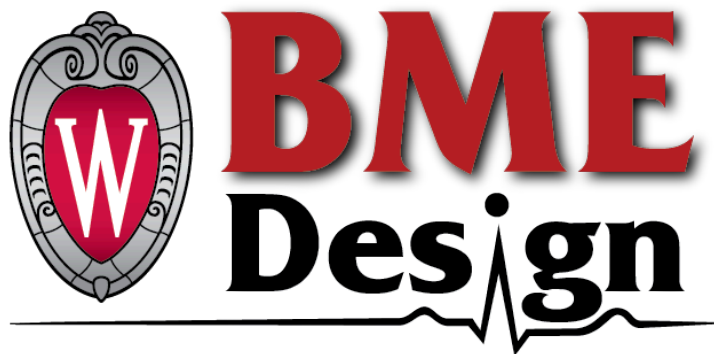
contraption. Additional issues that are found during testing will need to be addressed before moving on to further additions such as the adjustable strap alongside the waterproof pouch.

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OstoSeal

Product Design Specifications

Section 311

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Appendix 1

Product Design Specifications

Function

This project will work towards the creation of a safe, comfortable and effective ostomy pouch and wafer adhesive cover meant to keep the two components dry during showering. Current methods of keeping ostomy pouches and adhesives are often unreliable or inconvenient which negatively impacts the users quality of life. This cover is intended to work with a schedule of at least daily showers, and must be durable and easy enough to use in order to accommodate this stipulation. This device should be firmly waterproof and compact to support a schedule of daily use. Also, it must fit the variety of pouch sizes and waistline shapes and sizes that a person could have.

Client Requirements

- The device must keep all portions of the ostomy bag dry for the duration of a 5 to 30 minute shower.
- The device must be able to be used daily.
- The cover must be reusable for 6-12 months.
- The device must not encircle the waist.
- The device must be flexible and contact a minimal amount of skin.
- The device must not put any portion or working of the ostomy bag in danger of being damaged.

Design Requirements

1. Physical and Operational Characteristics

a. Performance Requirements

- i. The device must be able to endure daily use in the shower for 6-12 months, excepting the disposed adhesive, which can be replaced for each shower. It must be waterproof and resistant to damage caused by soaps.
- ii. The device must stay in place through moderately active movement while the user is showering, and should be able to handle minor incidental jostling.

- iii. The device must be completely compatible with an ostomy bag; under no circumstances should the device interfere with the performance of the user's ostomy bag.

b. Safety

- i. Under Standard ISO 10993-1, the adhesive used to attach the device to the user's body must be tested for biocompatibility with skin [1]. More information about this standard can be found in "Standards and Specifications".
- ii. An ill-fitted ostomy bag cover can cause pinching and prohibit the bag from performing properly, potentially leading to hazardous consequences [2]. OstoSeal must therefore ensure there is sufficient space under the cover for an ostomy bag at its largest expansion.

c. Accuracy and Reliability

- i. The device must endure at least six months of use without any damage or change in performance.
- ii. When a new adhesive is attached to the device, it must consistently endure a shower of at least 30 minutes without slipping or leaking.

d. Life in Service

- i. The device should be designed for repeated use during regular showering. The reusable components should withstand repeated exposure to moisture and warm water, soap, shampoo, and other products the user regularly comes in contact with while showering.
The client has indicated that the waterproof cover itself should be reusable, while the adhesive component may be disposable or replaced between uses.
The reusable cover should maintain its intended functionality, waterproofing performance, and material integrity for at least 6-12 months under recommended use, cleaning, and storage conditions.

e. Shelf Life

- i. The reusable OstoSeal cover should last 6-12 months of regular use, and should be stored in a clean and dry environment. Between uses, the apparatus should be laid out or hung up to allow the product to fully dry after use.
- ii. Each sheet of silicone tape adhesive is reusable for up to 7 days with proper maintenance, that is, being gently washed in warm water and air dried. The adhesive roll given to the client should be able to be stored for at least one year before needing to be replaced [3].

f. *Operating Environment*

The device should be designed to operate in a typical shower environment. During use, it may be exposed to warm water, assuming average warm shower temperatures ranging from 33.0°C to 44.0°C (approximately 91.8–111.2°F) [4] . It may also be exposed to high humidity, steam, soap, shampoo, body wash, and other common personal hygiene products.

g. *Ergonomics*

The device will encircle the ostomy bag and stick to the skin with adhesive tape. The tape will be peeled and applied around the edges of the device before each use, then removed following the use. It should stay firmly adhered to the skin throughout the entire - 5 to 30 minute - duration of use while under continual water contact. The main cover material should be nonabrasive to the skin and unobtrusive in size and shape. It should be small and flexible enough to not pose unnecessary discomfort or harm during the usage period.

h. *Size*

- i. Standard to large ostomy pouches range in length from ~8-12 inches. The width of the adhesive/opening portion can range from ¾” to 4”[5][6].
- ii. The cover should not include excessive extra material but should accommodate different size ostomy pouches and the possibility of growing dimension as it fills.
- iii. The product should not fit tight enough to the ostomy bag that application and removal is hindered.
- iv. The product should be ~14 inches in length and ~6 inches in width.

i. *Weight*

- i. A reference waterproof ostomy shower cover has a weight of approximately 85 g [7].
- ii. The final device should have a maximum weight of 100 g.
- iii. The device should not retain a significant amount of water during use to minimize additional weight during showering.

j. *Materials*

- i. The cover material must be waterproof and resistant to common soaps and body washing products.
- ii. Materials that contact the skin must minimize irritation and damage to the skin. Medical adhesive-related skin injuries can include skin stripping, tears, irritation, and other forms of skin damage [8].

- iii. Materials and adhesives should minimize moisture accumulation against the skin, as prolonged moisture exposure can cause increased susceptibility to skin injury [8].
- iv. Materials should be sufficiently flexible to conform to variations in abdominal contours and pouch sizes while maintaining a waterproof seal [8].
- v. The cover should be reusable and maintain its material properties following repeated exposure to water and soap.
- vi. Adhesive components may be disposable if a reusable adhesive is not feasible or cost-effective, as specified by the client.

k. Aesthetics, Appearance, and Finish

- i. The finished device should have smooth surfaces and edges to prevent scratching, irritation, or damage to the user's skin, ostomy pouch, or wafer.
- ii. The device should minimize unnecessary bulk around the ostomy pouch during use.
- iii. The cover should maintain a clean and discreet appearance appropriate for a personal medical device used on a daily basis.
- iv. Aesthetic features should not interfere with the device's ability to form and maintain a waterproof seal around the ostomy pouch and wafer.

2. Production Characteristics

a. Quantity

The final design will include one showerproof ostomy bag and a roll of adhesives. The showerproof ostomy bag can be reused, but the adhesives will have to be replaced after every use. Providing the client with a roll of adhesives will allow for multiple applications before they run out.

b. Target Product Cost

As per the client, there is not a set budget for this project, but the total costs are estimated to not exceed \$100 based on preliminary research. Money will be allotted to cover all the raw materials for the adhesives and the waterproof ostomy bag shower cover. Additional costs may include filament for 3D printed prototypes, if needed. Only the materials listed above will count towards the budget, whereas any equipment or facilities used will be excluded. Existing showerproof ostomy bags cost anywhere from \$19.99-\$45.58 for the entire contraption[9], and the final design will likely be on the lower end of that range.

3. Miscellaneous

a. Standards and Specifications

The product will need to comply with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" [10]. The materials that we are considering for the cover are outlined in Section B of Attachment G [11]. However, due to the adhesive of our product, as outlined in Table G.1 Exclusion Characteristics, our product would need to undergo traditional biocompatibility testing. Per Part 876.5900 of Title 21, Chapter 1, Subchapter H, this product is exempt from the premarket notification procedures in subpart E of part 807 of this chapter [12][13]. For feedback or meetings regarding medical device submissions, the Q submission program can be used [14][15].

b. Customer

- i. The product should cover minimal skin surrounding the stoma for comfort and to allow for bathing as much of the body as possible.
- ii. Belt designs are disliked as they do not adhere to the above criterion and have varying performance in staying fully waterproof.
- iii. The product should be easy to store.
 1. Belt designs are larger and stay wet for longer as parts of the belt may absorb water making them less desirable.

c. Patient-Related Concerns

The device must keep both the covering and adhesive portions of the ostomy bag dry under continual contact with water. It must be flexible in order to be easily maneuvered around. It also must be compact and contact a minimal amount of skin to ensure user comfort. In addition to this, the device must be able to be taken on and off quickly and easily, and not cause excessive pain during adhesive removal.

d. Competition

The main forms of ostomy bag waterproof covers on the market are belts, adhesive pouches, and adhesive patches. Belts are very prevalent, most of which employ a flexible bag cover attached to an adjustable strap that fastens around the waist. YEYSXSY advertises a belt where the ostomy bag is tucked into a thin cover that lies flat against the stomach [16]. This belt reportedly keeps the ostomy bag and its adhesive from getting wet, but is uncomfortable for individuals without flat waistlines. The adhesive patch is also common, with EveryMarket advertising large squares of adhesive that have gauze-like material in the middle to keep the ostomy bag from getting stuck. This product received a majority of reviews reporting effective waterproofing, but came with complaints on the excessive stickiness of the material [9]. Pouchwear avoids this issue with a

pouch that simply elastically holds itself around the ostomy bag [17]. However, this product does not keep the adhesive around the ostomy bag dry. A firmly attached, comfortable, and painless waterproof cover is needed to effectively keep both the adhesive and bag around the ostomy dry.

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