I, Megan Sullivan, hereby submit this original work as part of the requirements for the degree of Master of Design in Design.

It is entitled:
Beautiful can be Bold: A New Way to Wear the Drain

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Beautiful can be Bold: A New Way to Wear the Drain

A thesis submitted to the
Graduate School
of the University of Cincinnati
in partial fulfillment of the
requirements for the degree of

Master of Design

in the School of Design
of the College of Design, Architecture, Art, and Planning

by

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B.S. University of Cincinnati

May 2015

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Abstract

Breast cancer affects a tremendous amount of women each year, and presents these women with a journey so impactful that it is difficult to even begin to describe. Many of these women find themselves having great frustration in finding clothing to wear after undergoing a mastectomy, especially when they are sent home with surgical drains, which they have to tend to themselves. This study explores the impact of both psychological and physical evidence associated with undergoing treatment for breast cancer, and presents a fashion forward design solution intended to assist in holding the surgical drains in a sophisticated manner. A study was conducted to test the garment solution on actual breast cancer patients, with the intent of assessing its success in both function and emotive impact. The results of this study proved to be substantially more than qualitative data; they became powerful testimonials detailing the desire for and value of having a garment that enhanced a woman’s psychological and physical wellbeing, during a time that both felt severely diminished. The conclusion lies in the creation of a brand; one that is dedicated to guiding women to unveil their self-esteem and rebuild their identity after a diagnosis with breast cancer.
Acknowledgements

A tribute to a great professor and dear mentor, Hanna Hall

There are absolutely no words to give justice to how amazing Hanna was as a person and mentor. I’ve worked closely with Hanna over the past few years, and never in a million years did I expect to graduate college with a professor leaving such an impression on me that it would change my entire life. But that’s exactly what Hanna did. She was so beautiful, strong, motivating, passionate, and altogether wonderful. I loved our weekly meetings that I’ve been so fortunate to share with her the past few years in which she would share stories of her life and family; her smile and laugh were beyond contagious and would just warm your heart. She will live on through the lives of the countless people she’s touched, Hanna was one of those people that made a difference just by being in the same room as you. She will be sincerely missed and never, ever forgotten. For her help on this work and her unwavering guidance, I sincerely and wholeheartedly thank her.

This work has been the most invigorating, pleasing, and passionate endeavor I have ever been a part of. There is a quote that I feel perfectly summarizes my feelings throughout this process. It states, “Be fearless in the pursuit of what sets your soul on fire.” – Jennifer Lee

This passion is driven by those you surround yourself with, and I have been so privileged to have had the most unbelievably supportive network surrounding me from the time this idea even originated. I have to first recognize my mother, who is the greatest role model a daughter could ever ask for, and I do not say that lightly. When I was younger, my mother was diagnosed with breast cancer at the age of 42. To say that she inspired these studies, and the
origination of this idea, would be an understatement. After watching her go through everything she went through, I was exhilarated to do something to help all women who are faced with battling breast cancer. My mother is my best friend, and has been by my side every single day of my life. And for that, I am eternally grateful. She has been one to laugh with on good days, cry with on bad days, and share this incredible journey with. Saying thank you seems so minimal in the scheme of my appreciation for her.

My father has always been that one person in my life who grounds me and keeps me centered, and his support throughout this thesis is perfect testimony to that. Through all of the late nights spent burning the midnight oil, and the regretted, but always-present procrastination, he has been right by my side telling me that I can do it and that he is so proud of me. A father’s pride is not something a daughter ever forgets, although it is something that I think we all appreciate but lack in saying out loud. So here is me saying it dad, thank you. I appreciate your guidance more than you could ever know.

Aside from my amazingly supportive parents, I have had the most honorable team of faculty supporting me from the University of Cincinnati’s DAAP program. I would never have the success of where I am today, and the success of where I am going to be in ten years, if it weren’t for the out-of-this-world support system guiding me throughout my endeavors in college. Phyllis Borcherding, you have been with me on this since the idea first came to me years ago. You have mentored me, guided me, supported me, and given me the wisdom that has transformed this from an idea into my life’s passion. There are few people in this world that I can honestly say have influenced me in such a way that my life will never be the same, but you have been that person for me. I love you dearly, and thank you so much for everything you’ve given me. Dianne Hardin, your mentoring and superwoman qualities have given me the
fire to want to become a better version of myself. You are a best friend to me, a mother, a mentor, and moreover a role model. I know that you were brought into my life for a very special reason, and for that I am so beyond grateful. I love you so much and thank you for everything, from the bottom of my heart. I would also like to thank the individuals, outside of my committee, who have made my time in this graduate program one to cherish. Gerry Michaud, Lora Alberto, and Craig Vogel, thank you all for your continued support and unwavering dedication. It is because of people like you that this university holds such a special place in my heart, and I want to sincerely thank all of you for everything you’ve done for me.

I’d also like to mention a sincere thank you and token of gratitude to the UC Health Barrett Cancer Center. To the entire breast care team who has been involved in helping me with this study, thank you. Your help and support throughout this process has been so greatly appreciated.

Lastly, I would like to thank two very important people who have been by my side, and have made this process a much more enjoyable one. First, I’d like to thank a very best friend of mine, Christina. I never in a million years dreamed that I would be graduating this program having met one of the most important people in my life. We have found a friendship in each other that is so special and makes my life so much brighter, and more importantly, so much more fun. I love you, and thank you for always being there for me. Last, but most certainly not least, I have to thank my amazing boyfriend, Kevin. You have been my rock and my best friend throughout a lot of this process, and I am thankful every day that I have you in my life. You’ve motivated me, inspired me, and made me laugh too many times to count. I love you for that, and am so appreciative that you’ve been a part of this with me.
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Introduction

Treatment for breast cancer is a multi-phase process, and involves a specific mastectomy drainage system in which many women are required to wear the device home from the hospital and attend to the drains under their own care. Women who undergo these mastectomies many times struggle with finding clothing that fits around the drains that they are sent home with, and struggle psychologically with experiencing such a monumental change in their physical appearance. The goal of this thesis is to provide women with an option for concealing the drains through a garment solution, and to understand if this solution betters their physical and psychological experiences. Integration of a successful garment design through a patient’s recovery process will allow her to feel more at ease and regain her self-identity during a time when her self-image is likely feeling altered or diminished.

The foundation of this study began as an undergraduate capstone in which the problem that these women face when caring for their post-mastectomy drains was identified, researched and validated, and ultimately a solution was created. The entirety of this capstone can be found in the appendices of this study. For reference purposes, when referenced throughout this thesis, any capstone work will be furthermore referred to as Appendix 1.
Understanding Breast Cancer and its Impacts

PSYCHOLOGICAL AND PHYSICAL EVIDENCE

The significance of offering women an appropriate and sophisticated way to assist in their drain care is primarily found in statistical research\(^1\) defending the number of women being diagnosed with breast cancer, and is supported with psychological and physical or bodily evidence proving that these patients are in great need of multi-functional levels of support during this time in their treatments. Psychological evidence can be said to be defined as the emotional and cognitive feelings and needs that women have following their diagnosis, while physical or bodily evidence can be thought to include any areas of consideration in which the patient’s body is physically altered, thus creating a need for assistance or differing from what is seemingly typical. Both psychological and physical evidence are of equal importance to each other, and are defined individually in able to identify implications within each that support product design in improving this outcome for the identified target group of women undergoing treatments for breast cancer.

Psychological evidence suggests that a woman is emotionally impacted after her diagnosis with breast cancer in several ways. As mentioned in Appendix 1, overcoming breast cancer is nothing short of a courageous triumph. The roller coaster of emotions that a woman endures from the time she is diagnosed until the time she is in the post-treatment phase is a momentous experience. During this time, there is an overwhelming importance placed on the relevance of a woman’s self-identity, as it is within her identity that a woman feels a sense of self-worth and individuality. That identity is shattered when she is faced with

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\(^1\) According to the National Cancer Institute, 1 in 8 women in the United States will be diagnosed with breast cancer in their lifetime.
overcoming a diagnosis with breast cancer, and she feels an overwhelming sense of loss. This loss can include several things; the first to mention, and likely the most known, is the patient losing her breasts. While the loss of her breasts undoubtedly brings physical implications, the psychological factors and implications should not be unmentioned. Additionally, one of the most considerable losses a woman feels when enduring breast cancer treatments is the loss of her hair following chemotherapy. Again, this loss can be characterized as physical; but the root of the sensitivity that a woman feels following this loss is likely to be psychological. Femininity is in part defined by breasts and hair, as breasts and hair are key components of a woman’s identity. Losing them means losing a significant part of womanhood. In their study, Kourkouta, Iliadis, Mihalache, Prokopiou, & Georgioysi (2014) summarize this loss of womanhood by stating that women with breast cancer have to face not only the specific disease, but also the loss of part of their body that symbolizes their motherhood and sexuality.

Psychological impacts, though heavily focused on the emotional stresses that a woman undergoes after a diagnosis with breast cancer, span far beyond this. There has been a lot of research done to examine positive psychology interventions (which are intended to improve emotional state and behavior) and the overall effect breast cancer has on a woman’s psychological wellbeing. When looking at psychological studies that evaluate the positive impact of interventions among women undergoing breast cancer, it is important to note a few key implications. Casellas-Grau, Font, and Vives (2014) examined the success of multiple positive psychology interventions, one of which is very interesting in that it discusses written expression of positive emotions. This study also found that writing in online social support groups enhanced women’s hope and altruism. They further discuss psychological interventions in their references dedicated to psycho-spiritual interventions.
They found that spiritual interventions enhanced positive emotions while decreasing negative ones. Additionally, psycho-spiritual interventions enhanced hope, happiness, and life satisfaction. Wellbeing was also improved (psychological, physical, spiritual) and patients also reported an increase in energy and improvement in the quality of their social relationships. Psycho-spiritual intervention was also found to increase the sense of control among patients through giving information and using their spiritual resources. They generalize their study by stating that the positive therapies included in this review were capable of enhancing QoL (quality of life), wellbeing, PTG (posttraumatic growth), hope, meaning, happiness, optimism, life satisfaction, and benefit finding in women with breast cancer.

Cerezo and Ortiz-Tallo (2014) comparatively analyze the implementation of positive psychology group intervention, specifically for breast cancer patients, and showed similar results to that of Casellas-Grau, Font, and Vives (2014). Their study investigates whether a psychological group intervention focused on positive psychology could have beneficial effects for women with breast cancer by promoting coping skills related to psychological strengths. They found that the experimental group showed significantly higher scores on wellbeing (cognitive wellbeing, happiness, positive, negative, and total effect), emotional intelligence (emotional attention, clarity, and repair), optimism, resilience, and self-esteem, when compared to the group that did not receive the psychological intervention. Conclusively, the results of their study, similar to that of Casellas-Grau et al (2014), suggest that the application of a psychological group intervention focused on positive psychology may have beneficial effects on the mental health of women with breast cancer. Similar to the conclusions reached from the study conducted by Casellas-Grau et al (2014), Cerezo and Ortiz-Tallo (2014) prove that psychological intervention is both helpful and beneficial
among women undergoing treatments for breast cancer, again proving that psychological
impacts play a major role throughout these patients’ treatment processes.

An explanation of physical evidence is also crucial in understanding the full scope of what
women are faced with following a diagnosis with breast cancer. Physically, a woman’s body
changes a great deal after undergoing surgeries and other treatment methods (i.e.
chemotherapy, radiation, etc.) in the process of treating breast cancer. These changes are
greatly related to a few key areas of consideration, including the differences between
lumpectomies and mastectomies, and the variations in surgical incisions. As outlined in
Appendix 1, lumpectomies and partial mastectomies are both breast-conserving operations
in which the surgeon removes the tumor, along with some normal breast tissue
surrounding it. A lumpectomy followed by radiation therapy is often considered the standard
therapy for women with breast cancer who meet the criteria required to perform this
operation as it gives a better cosmetic result. In their study, Rowland et al (2000) examined
the role of breast reconstructive surgery, and detailed its physical and emotional outcomes
among breast cancer survivors. They found that women in the lumpectomy group reported
statistically significantly fewer problems with their body image and feelings of sexual
attractiveness than women in either the mastectomy with reconstruction or the
mastectomy-alone groups. They found that there were no differences between surgical
groups in levels of pain, skin sensitivity, swelling at the surgical site, or in related problems
in finding suitable clothes. However, mastectomy patients, with or without reconstruction,
experienced more physical symptoms and more discomfort around the surgical site than
women who had a lumpectomy.
Because a mastectomy is a complete removal of the breast, the incision varies from that of a lumpectomy – which is only partial removal of breast tissue. Various surgeries require multiple incisions depending on if lymph nodes are involved; lymph nodes are often examined at the same time the breast tissue is removed, either by extending the incision to the armpit or by a separate small incision under the arm. These variations in surgical incisions help us to understand the wide range and different areas of discomfort that the patient is likely to experience. Physical areas of concern (i.e. areas on the body where women feel the most discomfort) are of crucial importance in understanding areas of pain because these areas extend far beyond the immediate incision site. These physical areas of pain can also be described as the incidence of upper-body morbidity. According to Hayes et al (2012), upper-body morbidity after breast cancer is typically characterized by the presence of sensory or motor symptoms and impairments such as pain, weakness, tightness, poor range of motion, nerve palsies, altered movement patterns or muscle recruitment, numbness, or swelling in the shoulder, arm, and/or breast of the affected side. Upper-body morbidity is typically associated with alterations in the use and function of the upper body and adverse physical, psychosocial, and social ramifications that profoundly influence all aspects of daily life and hence quality of life. Their study goes on to discuss upper-body symptoms and impairments, and states that despite advances in breast cancer treatment methods that have led to less invasive surgical techniques and more refined radiation techniques, upper-body symptoms and impairments that impact function and quality of life remain common. A great example of this is limitations in mobility. Women have extremely limited mobility, many times for months following their surgery and treatments, and this is largely due to the extraneous soreness accumulated around her incision and spreading to her underarm area, ribcage, and supplementary surrounding areas (as shown in Figure 1).
This impacts the patient’s ability to perform simple tasks, such as reaching, lifting; and, in particular, in taking clothing on and off.

Figure 1 – Areas of Concern; Particular Areas of Mention

THE COPING AND CONFRONTING PERIOD

According to Winkler (2015), the mastectomy experience is fraught with anxiety for every patient. This is largely due to the hushed-whisper aura surrounding mastectomies that leaves the patient totally in the dark regarding practical steps of adjustment and physical and psychological rehabilitation. Appearance and clothing are a major concern, but one that the woman feels uneasy discussing with male physicians. This leads to a very important allegation that Winkler makes when stating that there are interim stages (through the patient’s journey) where certain clothing will provide the comfort and appearance so
essential to the patient’s self-esteem. Winkler breaks down a post-mastectomy woman’s clothing needs into three stages: (1) in-hospital, (2) immediate post-hospital, while she is still receiving post-operative care, and (3) long-range, usually about six weeks following surgery. During the “in-hospital” stage, Winkler’s study points out that because mastectomies are generally considered unplanned surgeries (a woman enters the hospital for a biopsy with the hope that a mastectomy will not be necessary) the patient tends to give no consideration to the in-hospital clothes that may be suitable. Even though the patient will spend a lot of time in a hospital gown, it does a great deal for her psychological wellbeing to appear presentable for visitors. This leads to Winkler’s observation of additional, specific considerations present in the “in-hospital” stage. Of great importance is Winkler’s mention of 1) limited arm motion, resulting in the need for a deep armhole, and 2) the temporary brassiere and breast form worn while the patient is still bandaged. Because she will likely want to feel as “normal” as possible, some women may choose to wear this temporary prosthesis when receiving visitors. As Winkler points out, the patient’s nurse will likely want to discuss in-hospital clothing needs with the patient’s family or close friends.

During the “immediate post-hospital” stage, the patient will remain heavily bandaged. In-hospital nightgowns and robes will be suitable for at-home wear as well, both immediately and long-range. As Winkler discusses, one immediate essential is a loose, button-front, deep armhole shirt or blouse. During this period, the woman will be able to wear many of her preoperative clothes, but she may feel awkward and self-conscious until she has been fitted with a special prosthesis and bra. Winkler states that she should be encouraged to wear loose-fitting garments if she is at all apprehensive. Back zippers on garments present a special problem until full range of arm motion has been regained.
Although the patient is long out of the hospital during the “long-range” stage, her needs should have been discussed with her while she was still in the hospital. Bathing suits and other garments that could potentially show her scars from the surgery present a particular issue, but one that may be temporary as the patient recovers and gets back to her usual lifestyle. It is during this time, that she is re-establishing her self-identity, during which many women begin to lose their concern about whether or not any of their scars will show.

Winkler mentions that nightgowns can present a particular problem, especially for a younger woman. When she returns home, she will see her lingerie that may no longer be suitable. While it is true that she can find soft, feminine nightgowns to suit her purpose in virtually any lingerie department, she will, once again, be reminded of what she can no longer wear, and what she has lost. It is especially important to note that any nightgowns or other garments worn without a prosthesis should have fullness at the neckline, so that the lack of symmetry is minimized. In daytime dresses and blouses, she should not wear garments with tight sleeves and armholes because her arm might swell. Tight bracelets and watchbands on the operative arm should also be avoided, as well as carrying heavy bags or packages. Any added stress on her operative arm should be minimized, or altogether avoided if possible, to prevent any further complications throughout her long-range recovery.

A New Way to Wear the Drain

THE JACKSON-PRATT DRAIN

Winkler’s study and the recommendations found in the early post-mastectomy stages lead to the introduction of the post-mastectomy drains. It is during the “in-hospital” stage that the drains are first introduced, however, it is within the “immediate post-hospital” stage that the patient must begin to care for the drains herself, once at home. Understanding
what the Jackson-Pratt drain is proved to be essential in the process of developing design criteria necessary to integrate the drain into a garment design.

The Jackson-Pratt drain is commonly used for draining fluids from an incision site after undergoing surgery for breast cancer. According to NIH (National Institutes of Health), a closed suction drain is used to remove fluids that build up in areas of the body after surgery. Although there is more than one brand of closed suction drains on the market, the drain used by many surgeons and hospitals is often called a Jackson-Pratt (JP drain). The JP drain is made up of two parts: 1) a thin rubber tube, and 2) a soft, round, rubber squeeze bulb. One end of the rubber tube is placed in the area of the body where fluid may build up. The other end comes out through a small incision. A squeeze bulb is attached to this outer end. The JP drain measures approximately 7 inches in circumference around its widest point; 5 inches tall, and 2 ½ inches wide.
WHAT WOMEN CURRENTLY TURN TO

Once the drains are in place and the patient is discharged, they are expected to wear the drains home from the hospital and to find a way to comfortably dress themselves. They truly want to do this with dignity and personal finesse, but both having the drain and having to conceal it is extremely stressful. Current market options, and issues present in these current designs, offer great insight into what women currently turn to when looking for solutions for holding their drains. Several key factors go into the process of choosing appropriate clothing that accommodates her after surgery, since the garments ultimately need to allow the drains to function properly. These factors can be broken down into three major requirements: 1) they need to fit around the drainage bulb(s); 2) they need to be able to be put on easily because after surgery the tissue around the breast(s) is extremely sensitive and arm movement is extremely limited, making it impossible to put anything over the head; and 3) they need to hang and fit loosely, because avoiding tops that are tight fitting following treatments is highly recommended by breast surgeons. Women often prefer draped silhouettes, tops that wrap or button down the front, and soft, natural fabrics when recovering from breast surgery. What is even more popular among recovering women is the importance of looking and feeling as normal as possible, which directly supports the psychological evidence detailed at the beginning of this study. Every woman that enters the stage of recovery from breast cancer develops her own little “tricks” for restoring her femininity, and this is vitally important to her self-esteem. Again, this draws back to the psychological evidence previously specified – maintaining a woman’s femininity is of great priority throughout this process, and it largely influences her buying power when seeking out clothing and other products during the duration of her recovery and beyond.
Numerous methods of retaining the drains currently exist. A popular solution for holding the drainage system is centered around the waist and usually includes some form of a cumbersome Velcro belt that is uncomfortable and hard to conceal for the patient. This Velcro belt wraps around the waist and has pockets to hold the drains, but many women complain that it is troublesome, difficult to conceal, and altogether distressing.

Another solution currently offered is a compression bra, also known as a surgical bra. Compression bras offer patients comfort and support, but some, which feature elements to hold the drainage system, leave the bulb suspended. This can be intrusive for the wearer because it hangs loosely from her body. The drains are bulbous and already hard to conceal, so letting them hang from a clip attached to the bottom of the compression bra can cause them to fit awkwardly against her body.

Robes and jackets are also currently on the market to hold the drainage system. These garments primarily feature interior pockets to hold the drains, but the garments themselves are very sleepwear and loungewear based. As Winkler discussed in her study, it significantly, positively impacts her psychological wellbeing for a woman to be able to look presentable and “like herself” when receiving visitors (2015). This leaves a lot of women not wanting to have to resort to wearing lounge attire. Many women also find themselves returning to work and other daily activities both while their drains are still in or shortly after, when they still need clothing that accommodates their soreness and limited mobility, and need other options that are more sophisticated.

ADDRESSING THE NEEDS – THE CREATION OF THE PROTOTYPE
The existing methods do perform for their overall intent and do hold the drainage system, but they also present various issues in comfort and function for the patient. The materials and design of the current offerings are very hospital focused – they are also very expensive and according to user research women tend to feel like they are “bringing the hospital home with them” because of their low appeal. This leads to a significant opportunity to develop a garment that includes an interior system meant to house the drains and make the wearer as comfortable as possible, while keeping style and sophistication in tact. An opportunity to design fashion-forward garments drives the aesthetic, while also considering technical details that allow for optimum drain care.

This new, ideal garment solution must integrate all of the key design features that relate to the patient’s needs, including these three major factors: 1) it accommodates the drains, 2) it’s easy to put on, and 3) it hangs and fits loosely. As important as the finesse and aesthetic of the garment are, the interior workings are of equal importance to the success of concealing the drains. The proposed garment design solution is originative in that it utilizes an interior stabilizing system to not only hold the drains, but the woven stabilizers help to distribute the weight of the medical device so that, even when full of fluid, it does not drag, pull, or otherwise become intrusive and uncomfortable for the patient. These woven stabilizers encompass a very crucial part of this system as a whole: the interior pocket. Because concealing the JP drains is largely centered around the drainage bulb that is connected to the surgical tubing, a method for holding this mechanism and assisting in its function is extremely important. The designed garment utilizes a pocket for several reasons: 1) it can hold the drainage bulb snugly while still allowing the patient to access the device easily and comfortably; 2) a pocket doesn’t leave the

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2 User research has been conducted through both online outlets and support group meetings, outside of and prior to this study, in which multiple women have given their insight and opinions. *The support group meetings were conducted at Good Samaritan North Hospital Breast Center.*
bulb suspended freely like the surgical bra does; and 3) the placement of the pocket allows the drains to be held at optimal level so that the tubes are able to drain properly and efficiently.

Figure 3 above shows the interior woven stabilizing system (illustrated in grey), as well as an enlarged view of the JP drain positioned in the interior pocket.

Once design considerations have been identified and addressed, the creation of the prototype follows. The prototype is crucial to this study because a viable physical, working product must be developed and tested. Additionally, all of the previously mentioned relevant considerations became characteristics of an actual, tangible garment. The creation of the prototype, as addressed in Appendix 1, began with the use of a dress form, draping tape, and the JP drain. A dress form and draping tape were utilized to look at tension points and areas that a mastectomy or other incision might cause discomfort. After identifying the primary areas of
concern on the body, which were identified in the physical evidence mentioned earlier in this study, taping the dress form in these areas proved to be an efficient way to identify them and drape the garment around them. After establishing the primary areas of concern, the drainage system was attached to the dress form so that the tubing that would be placed into the incision was marked and attached to the form. The remaining tubing was then situated against the form similar to the way it would hang against the patient’s body. Special consideration was taken to ensure that the tubing was hanging loosely and comfortably, so that the drainage system would function properly without pulling or tugging at the incision site.

The drainage bulb was placed on the form to mimic its natural placement on the body. The result improves upon existing methods by situating the drains snug and comfortable against the patient’s body.

Once the drainage system was established on the form, fabric could be draped onto the form and manipulated in different ways to identify the most beautiful and systematic way to conceal the drainage system underneath it. One key aspect noticed in the silhouette of the final solution is the neckline. As Winkler (2015) pointed out in her study, fullness at the neckline helps to minimize the lack of symmetry that is present after the loss of breast tissue. When draping on the form, adding fullness at the neckline not only helped to minimize focus on the bust area, but it helped to distribute some of the weight of the drainage bulb so that the front of the garment wouldn’t pull or look distorted in any way. While experimenting with different weights of knits and different techniques of manipulating the fabric, such as adding fullness at the neckline, various solutions were identified to conceal the system most effectively. It was within these solutions that the prototype was formed, and conclusively perfected through a series of flat pattering, modifications, and sub sequential draping.
METHODS FOR TESTING THE GARMENT

The underlying purpose of creating this garment remains one that is multi-faceted. The solution is especially inventive because the garment silhouette and aesthetic as a whole are design-based rather than strictly function-based. The garment is much more than a way to hold the medical device, it’s a fashion-forward solution to a problem many women face, which allows them to keep their self-identity and sense of style in tact throughout this rigorous journey. As the relevant considerations concluded on the creation of the prototype, it is here that further observation is needed. Many hypotheses have been formed in the requirements and expected successes of these requirements being implemented, which lend an opportunity for additional studies. Testing the constructed prototype on breast cancer patients undergoing treatments, whom specifically are caring for surgical drains, is of the utmost importance in validating and proving that this proposed solution is valuable, successful, and desired.

Testing was completed at the UC Health Barrett Cancer Center, with their breast care team. The designer (and author of this paper) met with members of the team, specifically surgeons, nurses, care managers, etc., to explain the depths of this study and to gain their support in recruiting patients. From there, the team reviewed their upcoming mastectomy and breast reconstruction candidates, whom specifically would be tending to breast drains, and began recruiting patients who were willing to participate. These patients were presented with an overview of the scope of the study and were shown the garment prior to their surgeries so that the garment could be fitted and comfortably tried on before their drains were in place. This was done in the hopes that any issues in fit or need for understanding how the garment works
could be explored prior to soreness and limited mobility setting in once the recovery from surgery commenced. At the time that the patient was given the garment and additional related materials, they were also presented with a Confidentiality Agreement, which can be found in the appendices of this study, that detailed their personal anonymity in the study, as well as guidelines for keeping any and all information gathered throughout their time participating confidential.

To begin the process of outlining and defining the methods involved in testing the garment prototype, test objectives must first be identified. These testing objectives highlight the key areas of focus for testing, and can be defined as three major targets: 1) pocket placement, 2) pocket size, and 3) the wrap system. Each of these has an objective and criteria, which is crucial in understanding their role and success in the functioning of the garment. For instance, the objective of pocket placement analysis is to understand if the pocket is correctly placed to compliment but not inhibit the functioning of the drainage system, while also analyzing the success of the pocket to hold the drainage device at a proper distance away from the incision. Likewise, the objective of looking at the size of the pocket is to understand if the pocket holds the drainage bulb securely without making it difficult to access when caring for the drains. The wrap system is included as a key area of focus to better understand if the wrap feature adequately conceals and comfortably holds the stabilizing system while allowing the drains to be accessed simply and efficiently. In addition to looking at objectives, in the Test Plan\(^3\) included in the appendices at the conclusion of this study, evaluation criteria is outlined and room for adjustments in the garment to be made after testing are allotted.

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\(^3\) The Test Plan is included in full detail in the appendices, located at the end of this study. The references in this writing are meant to act as a summary of pertinent data that can be found in the entirety of this Test Plan.
Following the **test objectives**, the **test strategy** is another major area of focus in defining the methods of this study. Of special importance is the **test level responsibility**. The **test level responsibility** states: Patient personas will be used to define test level responsibilities. Once users are defined by test subject enrollment, patient personas will determine test qualifications. For instance, newly diagnosed patients in a terminal level diagnosis may not be suitable to participate in this test study. Patient personas will vary by demographics and diagnosis, but certain personas will be deemed an inappropriate fit. This statement is of such great importance because it is crucial to recognize the ethics and special circumstances of this study. The testing of these garments involves a very sensitive and vulnerable group of women willing to be test subjects and it is important to remember that ethical standards remain the highest importance.

Included in the **test strategy** are the **test type and approach**, which outline the overall approach and hopes of the outcomes of this study. The **test type** is broken into three categories: 1) wearability, 2) functionality, and 3) emotive. Wearability refers to the functioning of the fabric in terms of comfort, wash and wear capabilities, and how well the garment fits when placed on the body; functionality refers to how well the device is able to meet patient needs when used in conjunction with the garment, and the emotive category assesses how the wearer’s mood and self-image are either improved, stay the same, or decrease when wearing the garment.

As outlined, the designer met with the surgeons and breast care team prior to beginning testing to discuss these approaches and give an explanation of the entirety of this study. The participants were given the opportunity to try the garment on to ensure proper fit prior to the test study beginning. The goals, functions, and priorities were outlined to the breast care team and participants, with the goal being especially worth noting. The goal of the project is to better
understand the role, both physically and emotionally, of concealing the mastectomy drainage system in a sophisticated way. As such, one of the main goals of the garment is for the user to feel that their femininity and self-image remain intact. This is imperative in understanding if the garment is successful or not; it can not only be successful physically, it must also prove its success in emotive impact.

Once the participant and breast care team understood the project brief, the participant was given a journal and instructions on documenting their insights while wearing the garment prototype. Key insights desired included: what works well while wearing the garment, what needs to be improved, what needs to be removed, what needs to be added, how the garment makes the participant feel, and if wearing the garment invokes a better feeling than other garment options available to the participant. The goal of the journal was for the participant to be able to give feedback in a fluid, non-restricting way. Participants were given discussion prompts, rather than a “Q&A” type of survey in order for them to feel like they could openly discuss their experiences without feeling pressured or interrogated.

Participants were also given the option of offering feedback in the form of an online survey, which was executed on a survey platform. The participants were given the choice of using either the journal or the online survey, or both if they so chose. The purpose of having both options of journaling and an online survey was meant to offer different ways of giving feedback in case participants were more comfortable with one way versus the other. With the garment and journal that the breast care team gave to the participants when they agreed to participate was an instructional pamphlet that detailed the instructions for how to wear the garment, care instructions, and ways to offer feedback.
Participants were each asked to wear the garment at their leisure for the duration of the time that their drains were in place. This leads into the third noteworthy section of the Test Plan, the *test environment*. This portion is also a key part of the *test strategy*, and covers the important characteristics and determinants expected of the environment in which the testing would take place. Each individual participant determined her own test environment. Participants were expected to wear their garment prototype, as they saw fit, for the length of the study. They were given the opportunity to do so in a way that was most comfortable for them.

Determinants were specified in the following ways: 1) the wearer was expected to wash and wear the garment throughout her day. She was given care recommendations based on the fabric content, and she was given instruction on how to handle special circumstances (such as stains, rips/tears, etc.) If any permanent damage was documented, such as a rip or tear, the wearer was instructed to notify the designer immediately so that proper provisions could be implemented. 2) The wearer was expected to wear the garment through daily activities, but more importantly, she was expected to wear it to dinner, shows, social functions with others, etc. so that she could evaluate emotive impact in circumstances where she wanted to feel her most sophisticated. And 3) the wearer should wear the garment for a minimum of 3-5 hour time periods per day. If she chose to remove the garment to replace it for another pre-existing option, she was expected to document why she implemented a replacement of the prototype.

Following the *test environment* are the *testing metrics*, which are intended to cover three crucial areas: 1) how well the garment fits, 2) how well the device functions when interacting with the garment, and 3) how or if the wearer feels positively emotively affected when wearing the garment. The garments were produced in multiple sizes with the hopes of being able to recruit more patients, specifically in standard Women’s Small and Medium sizes. Fit was
evaluated on how well the garment fit in the size category specified by the wearer, as well as individual fit on each specific model.

The final, crucial portion of the Test Plan is the *entry and exit criteria*. Testing was considered completed when either of the following situations occurred: 1) the wearer defined the garment as unwearable, unfit, uncomfortable, or defined any other circumstance in which they felt the garment was not functioning properly; or 2) the duration of the drain care was fulfilled and documentation was completed by the wearer. At this point, the designer was able to speak with the breast care team to receive information and feedback regarding the patient’s test period and to review additional upcoming patient recruiting.

### Outcomes and Conclusions

#### ADJUSTMENTS IN TESTING CRITERIA

One of the most crucial takeaways from this study is the importance of qualitative data collection. In fact, it seems somewhat inappropriate to even refer to the results as “data collection.” The results collected at the conclusion of this study are much more powerful than simple data; they are personal testimonies which document a very impactful and sensitive time for women recovering from breast surgery. Before understanding the depths of these results, it is first important to understand the means of the testing at the Barrett Center.

Throughout the course of the testing, several adjustments were required from the original testing criteria. The most essential changes were in the following areas:

- The number of recruited participants
- Garment sizing
• Administering the fit session
• The duration of the patients’ wearing periods
• The establishment of the test environment
• The methods of data collection once the patient was ready to offer feedback

Each of these areas was adjusted so as to ensure the highest comfort of the patient was met and the integrity of the study could remain intact. First and foremost, the number of participants had to be adjusted based on the number of viable patients the breast care team was able to recruit. Because their goal is primarily breast conservation, the number of mastectomy surgeries they administer is sometimes low. The presentation of patients requiring mastectomies is subject to times of variability, which is admirable in the hopes that women are able to receive other, less invasive treatments. But, since this study is completely dependent on women undergoing surgeries that require drain care, a low number of mastectomy patients means a low number of study participants. The benefit of establishing a relationship with the Barrett Center, however, is that the breast care team is continuously administering the garment and fitting it on as many patients as possible, even after the summation of this study. This study is ongoing; the conclusions reached at this point are crucial but not limited.

Garment sizing proved to be another area requiring adjustment from the original plan. The original prototype was made with the specific intention of being fit to a fit model\textsuperscript{4}, or sample size, under the specifications suggested within the fashion industry. This proved to require modification when dealing with a diverse range of women receiving breast treatments, with many different body types. Originally, garments were going to be produced in three sizes, with three of each garment per size (i.e. 3 Small, 3 Medium, 3 Large; in standard S, M, L Women’s

\textsuperscript{4} A fit model is a person who is used by a fashion designer or clothing manufacturer to check the fit, drape, and visual appearance of a design.
size specifications). However, after meeting with the breast care team and discussing goals of testing, it was decided that only one size would be tested at first so that, prior to having the garment made in multiple sizes, it could be validated and modifications could be suggested. Once multiple patients had been fitted for this garment, the decision was made to have one additional, larger size sewn to accommodate the diversity of the patient population. This ended up being a compromise between making three sizes and just making one, and allowed more patients to be fitted, while leaving room for modifications to be made.

Next comes the topic of administering the fit session. Prior to beginning testing, the designer was intending to be present at any fit session administered by the surgeon, or other medical staff part of the breast care team, with the explicit disclosure of the patient. However, prior to the first patient being fitted in the garment, the decision was made to leave the fit sessions exclusive to the patient and her medical caretakers. This was mainly decided to ensure that the discretion and absolute privacy of the patient remained the highest priority. The process of a patient witnessing and caring for her drains when they are first in place is not a situation to be taken lightly. Once the patient comes out of surgery and has the drains in place, she goes through an extremely sensitive and emotional experience while learning to accept her drastically altered appearance. Because this is such a delicate time between the patient and her surgeon, it seemed only fitting that the care team be the ones to administer the fitting, without the designer present.

The duration of the patients’ wearing periods, and the establishment of the test environment, became additional areas in need of adjustment. The duration of the patients’ wearing periods was set to be the length of the time that their drains were in place, and the test environment was defined so that the patients could wear the garment in a way that felt most comfortable.
for them, while being given instruction so that crucial aspects of the garment design could be noticed and assessed. Once the breast care team began fitting the garment on various patients, several developments arose, the most considerable being the fit of the garment. Many of the patients struggled to get the garment on because it was too small; others found that, once the garment was on, it was too constricting in places to wear once their drains were in place. Because the surgeons administered the fit session prior to the patients receiving their surgeries, this altered the course of action for the test environment to be implemented. The bulk of the results collected throughout this testing took place during the fit sessions; both in the presence of the surgeons and at home before their drains were placed.

Because the duration of the patients’ wearing periods and scope of the test environment required revision, the methods of data collection needed to be re-evaluated to best suit the fit sessions taking place. Originally, patients were asked to journal and answer online survey questions, but at the request of the patients and breast care team, other ways of providing feedback were adapted. One method that proved to be very rewarding was having a phone conversation. One of the patients who was able to try the garment on offered to provide feedback by speaking with the designer personally. This allowed her personal experience to be explained in great detail and she was able to offer several suggestions. Another method that was successful in receiving feedback was by the patient relaying her comments to the surgeon and care team, who were then able to communicate those comments to the designer. This allowed the patient, and her family in some cases, to feel at ease in trying the garment on, while still being able to relay feedback that the designer could utilize.

**THE POWER OF PERSONAL TESTIMONIES: THE RESULTS**
Revising the Test Plan led to the discovery of invaluable testimonies. What is so important to recognize is that within these findings lies so much more than an analysis of strict data; these findings house a great deal of emotional impact and personal insight. The diversity of the patients that were able to participate in fit sessions was phenomenal, and they each valued the garment in their own way. One patient, who is a young, working mom in her late 30’s, avid gym goer, and possessor of a fashionable wardrobe, found that this garment was an option that she very much desired, and couldn’t find anywhere else. She was a candidate of breast reconstruction, and offered great insight into the process of having tissue expanders leading to implants. She went from being able to enjoy normal things and go leisurely about her day, to not even being able to pick anything up. She found that the tissue expanders are a huge point of discomfort, especially because the breast tissue expanders are placed under the arm. She described them as “feeling like a football,” and said they expand right up under her armpit. Normal breast tissue does not do this, so the sensation this creates is not only uncomfortable but also very unfamiliar. She receives saline fills every week, and when this happens she feels like she is “back to square one” because they leave her feeling so distressed from the discomfort. This is especially limiting in regards to arm movements; she has trouble completing normal tasks, like lifting things, and even turning the steering wheel when she’s driving.

Because her surgery entailed bilateral mastectomies with reconstruction, she had four drains in total, two on each side. After her drains had been in place for 10 days, one set was taken out; then the following week, the second set was removed. She mentioned that some women with implants even end up having drains put in again, so she was regretful that when her drains were taken out, she gave away the mastectomy top that she had been wearing. The mastectomy top that she was given held her drains, and functioned as it was intended to, but it was not what she would have preferred to wear. She wanted something that was more
fashionable, and aligned to her normal style of clothing. She can no longer wear a lot of her normal clothes; she mentioned even having trouble wearing some of her looser fitting jackets because she was too uncomfortable. Her go-to wardrobe following her surgery primarily includes cotton tank tops and cardigan sweaters, which open easily and can stretch to get her arms into them. She also wears a lot of her gym clothes because they are thin, lightweight, and stretchy. But she would like options other than these. She especially desires business attire; she is asking herself the question, “When I go back to work, what am I going to wear?” What is especially challenging is that she will only be going back to work for a short amount of time before she is set to have surgery again to place the implants; but during this time, she will need something business appropriate.

When the surgeon administered the garment during her fit session, she was not able to get it on because it was too small. There were, however, aspects of the design that she favored. She found value in the fact that it was a wrap closure, rather than having to be put on over her head. Sometimes she’s had to force herself to stretch painful muscles just to get dressed, but the idea of a top that wraps diminishes this pain and can be put on easily and comfortably. She favored the overall design and aesthetic of the garment, and said that it was something that she would wear outside of even having surgery. She enjoyed the blousy and comfy fabric, and said that even the fit of the sleeves would have been perfect had the rest of the garment fit.

Though she was not able to wear the garment home, she did have several very key suggestions on how to make improvements. First of all, she suggested that a way to compliment the success of the wrap closure might be to eliminate the seam under the arm, and instead include metal snaps or ties. She mentioned that she appreciated that the design excluded Velcro as a means of closure because she had a mastectomy camisole that utilized
Velcro and it was unfavorable. Additionally, she mentioned that the seams under the armpit were a bit too high and intrusive; the drains and the incision create a very sensitive area under the arm, lending a need for extra room in this area to feel more comfortable. When asked how she felt about the pocket placement, and the fact that the pockets were permanent to the garment rather than removable, she made a very interesting and important observation. She said that she favored having the pockets permanent, and used the analogy of a suit jacket. “A suit jacket has pockets on the inside that you never remove. You may not need them all the time, you may not even need them ever, but you’re glad they’re there in case you do.”

All in all, she made several very important statements to define the journey she is currently undergoing. She even referred to a story from her very first check-up after surgery. She said that her friend walked in on her trying to put makeup on, and was puzzled as to why she was even bothering with trying to do this. She told her that even though the eyeliner was smearing all down her face, it was worth trying to do because it might make her feel better. She said that all she wanted was to feel like herself. She especially wished she had a stylish line of clothing, and had looked on eBay, Amazon, and even Google to try to find fashionable mastectomy tops, but couldn’t find any “normal-looking” clothes at all. She said safety pinning her drains to the inside of her clothing was not comfortable, but she desperately wanted to look and feel as much like her normal self as possible. Because she is young and only in her 30’s, she said that the emotional part of this process was far worse than any physical pain she had ever endured. She even referenced losing her hair, and said that she had long, blonde hair before the treatments, and that even in the hospital, people would stop and compliment her beauty. She said, “Most women identify with their hair. Throughout this process, you lose everything that you identify with. You lose a lot of confidence.” She also said, “You go through this and you’ve lost your hair. You’ve lost your breasts. The last thing you want is to lose your identity.”
Another very powerful testimony to the value of this garment came from another patient who was recommended by the breast care team as a possible participant. This patient, in particular, had a very different story and an extremely different use for the garment than the patient previously mentioned. This patient has dementia, and is under the care of her family, primarily her daughter. They would have opted for her to be a lumpectomy patient, but because of the risk of her being restless and feeling the urge to move, they had to do a mastectomy. The surgeon and breast care team felt that she would be an excellent fit for trying the garment because, with her having dementia, they were very concerned about her tugging and pulling at the drains after they were in place following her surgery. The team felt that this top might be a perfect solution to keep the drains out of her immediate access, and would keep her from feeling the urge to pull on them. She and her family were given the garment prior to her having surgery so that they could check the fit and make sure that she could get in and out of it easily before she was sent home with the drains. Her daughter was going to write in the journal for her as different situations arose, so that they could offer feedback on how well the garment helped her. Unfortunately, the garment was found to be too small for her to wear comfortably. However, the possibility of this garment being able to assist with needs outside of the ordinary, such as patients with dementia, is extremely valuable.

**TAKING IT A STEP FURTHER: THE FUTURE AWAITS**

The summation of this study is more a beginning than it is an end. The relationship that has been built with the Barrett Center over the past few months is invaluable, and will continue to thrive as this study continues. The breast care team has agreed to continue finding patients to
participate in this trial, and the garment will have the opportunity to transform as suggestions are offered and modifications are made.

The most important conclusion to be made from all of this is that of the impact this study and garment can have on the people it embraces. This study is the creation of a brand, and one that has a very defined mission. It’s not only about the success of the garment, it’s about guiding women to unveil their self-esteem and rebuild their identity after a diagnosis with breast cancer. That is where this study will be reborn time and time again. The mission is rooted in accentuating the beauty of a woman’s body. Because, after all, “Beautiful can be Bold.”
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Appendices

Appendix 1
B. Bold – A Collection Designed by Megan Sullivan
B. BOLD

A COLLECTION DESIGNED BY
MEGAN SULLIVAN
MY MOTHER

When I was nine years old, my mother was diagnosed with Stage III breast cancer at the age of 42. As her only child and daughter, I was scared beyond all belief. The cancer had spread to her lymph nodes, so her surgery was extensive and recovery was long and strenuous. After her surgery, she went through chemotherapy, and radiation followed. Like many women who undergo breast cancer, she was sent home with a drainage bulb immediately following her surgery to allow the fluids to drain from her incision site. The drainage system they sent her home with was attached to a Velcro strap that fit around her waist, and the tubes connecting the incision site to the bulb were so bothersome that she would attach them with a safety pin into her robe.

After watching my mother go through everything she went through, I was inspired to do something to help all women who are faced with battling breast cancer. I specifically worked to find a solution through garment design that would work around the mastectomy drainage system.

*B.Bold* is a luxurious collection that conceals the mastectomy drainage system in a sophisticated way, while allowing all of the functions of the medical device to perform properly.
THE PROOF IS IN THE STATISTICS
1 IN 8 WOMEN WILL BE DIAGNOSED WITH BREAST CANCER IN THEIR LIFETIME.

*According to the National Cancer Institute*
THE IMPORTANCE OF BEING EDUCATED

With any medical condition, education about the condition is the first step to understanding what the condition is and what its associated risks are. Understanding what breast cancer is is the first step to taking preventative measures and caring for those who have been diagnosed with breast cancer.

What is particularly important to understand is that breast cancer is becoming something that is on more and more people's radars. It is no longer a cancer that people associate with a small demographic of older women. It is more understood now that breast cancer is something that a young woman, or even a man, could be diagnosed with. With this raise in awareness comes more people participating in preventative measures and taking a more active role in their breast health, along with people wanting to become more involved in the strong community of breast cancer survivors and in the support of the loved ones of those less fortunate who have lost their lives to the disease.

STAND-OUT STATISTICS

Every 3 minutes a woman is diagnosed with breast cancer.

813 women are diagnosed with breast cancer every day.

Every 13 minutes a woman in the U.S. loses her life to breast cancer.

Over 250,000 women under the age of 40 in the U.S. live with a breast cancer diagnosis.

About 2.6 million female survivors of breast cancer live in the U.S.

96% of women who find and treat breast cancer early will be cancer free after 5 years.

*Note that these statistics are specifically reflecting women in the United States.
02
THE PERSONAS
MARIE

25 years old
Graduated from the University of Colorado with a degree in Psychology
Environmentalist
A history of breast cancer runs in her family, and at her last check-up, her doctor found a small lump in her left breast which she recently found out was cancer

LIANE

68 years old
Retired journalist
Avid gardener
Loving mother to three daughters
Nature enthusiast
Diagnosed with breast cancer at age 50 in her right breast; now re-diagnosed and opting to do a double mastectomy
**BROoke**

34 years old  
Book editor in New York City  
Blogger  
Single and happy being independent  
Diagnosed with breast cancer in her right breast; the cancer has spread to her lymph nodes, so she is deciding to have a double mastectomy

**JENNA**

40 years old  
5th Grade English Teacher  
Keeps a journal and writes her thoughts in it every day  
Single mother of a son and a daughter  
Recently diagnosed with breast cancer in her left breast; treatment involving a partial mastectomy, chemotherapy, and radiation
03
IDENTIFYING A NEED IN THE MARKET
THE RELEVANCE IS RISING

A brief glance at current statistics proves that the relevance of knowledge about breast cancer is on the rise.

With so many women being diagnosed with breast cancer, and with the age that women are being diagnosed notably dropping, the importance of understanding what a diagnosis with breast cancer really means is becoming more and more prevalent. Along with the spread of knowledge of what breast cancer is comes the need for people to understand the physical and psychological issues a diagnosis with breast cancer brings to the patient and their loved ones. This concept of helping women along the journey to recovery is really coming to the front of the market, and offers a vast opportunity for products that both strengthen the self identity and confidence of breast cancer patients, and it also supports innovation in products and devices that solve problems present in the stages of treating breast cancer.
04

THE BEAUTY LIES IN THE TRANSFORMATION
LIVING WITH THE SCARS

Overcoming breast cancer is nothing short of a courageous triumph. The roller coaster of emotions that a woman endures from the time she is diagnosed until the time she is in the post-treatment phase is nothing short of a momentous experience. An endless array of emotions crowd her mind and soul. There is nothing more beautiful than a woman’s self identity, and much of that identity feels shattered when she is faced with losing her breasts. One of the most beautiful things about these emotions, however, is that throughout this time of healing and recovery, a new sense of self is unearthed and she learns to love herself again. Her womanhood is reborn. Sometimes it takes months, sometimes it takes years, but there are little things and people along the way that either subtly or abruptly rebuild her self-image. Some women look at their scars as soon as they get home from the hospital, others put off looking at them for a very long time. But it is at this moment, when a woman learns to appreciate her beauty for all that she has, that a new era is born.

FINDING STRENGTH IN THE RECOVERY

While a diagnosis with breast cancer can be very discouraging, there is something very beautiful about the moment a woman no longer sees herself as a victim, but rather sees herself as a fighter. This unwavering strength that unravels during a woman’s recovery from breast cancer may easily be one of the most empowering movements ever to exist.

“My mother is grateful for the benefits and blessings she has received regarding her bout with breast cancer. She believes that breast cancer survivors, those currently undergoing treatment for breast cancer, and those whose lives have most recently been turned upside down because of a mysterious lump are truly a sisterhood and family whose collective motto includes strength, determination, optimism, love, and prayer.” -Son of a breast cancer survivor

“I was thirty-six years old and six months pregnant when I was diagnosed, and had a mastectomy and chemo treatments during my pregnancy. I certainly never expected this at a time that should have been so happy, but we are certainly happy now. My child and I are both survivors!” -Mom and breast cancer survivor

THE COLOR PSYCHOLOGY BEHIND THE COLOR PINK

Pink: a universal symbol of breast cancer. Take the "pink ribbon" for example; this ribbon has been a symbol of hope for breast cancer patients, their loved ones, and all breast cancer supporters for innumerable years. While this truly remains an icon, and while the "pink ribbon" stands as a beacon of hope for many, not all survivors and supporters of breast cancer choose to celebrate their victories or support awareness with the color pink. Many patients and survivors, and their loved ones alike, find hope and courage from helping others who are faced with a breast cancer diagnosis. They see hope more as a motivation to find a cure, and to be there for those along the way who face the challenges that they themselves have overcome.

“I usually choose not to wear the "pink ribbon" myself. For me, the one reason that I do support wearing the "pink ribbon" is during the month of October. I am always hopeful that a woman who doesn't take care of her breast health will see that ribbon and will be motivated to get her yearly mammogram. I wear it as a reminder to all women to be diligent in taking care of themselves. I do, however, feel good when my daughter wears a pink ribbon; I feel support and love from her. It's almost like it's my secret, it's a reminder of my cancer when I've tried so hard to get away from it. But it's powerful, and supports a strong message.” -Breast cancer survivor
05
UNDERSTANDING THE TREATMENT PROCESS
Many women not only experience tender areas immediately following their cancer treatment, but research and blog analysis shows that women experience a great deal of rib pain that can be reoccurring years after their surgery.
LUMPECTOMY VS. MASTECTOMY - WHAT IS THE DIFFERENCE?

Lumpectomies and partial mastectomies are both breast-conserving operations in which the surgeon removes the tumor, along with some normal breast tissue surrounding it.

Women who have this type of breast cancer surgery usually:

Have a single breast cancer less than approximately two inches in diameter

Have enough tissue so that removing surrounding tissue would not leave a misshapen breast

Are medically able to undergo surgery and follow-up radiation therapy

A lumpectomy followed by radiation therapy is often considered the standard therapy for women with breast cancer who meet these criteria. Large studies have shown similar survival rates for both breast conservation with radiation and removal of the whole breast, but a lumpectomy gives a better cosmetic result.

VARIATIONS IN SURGICAL INCISIONS

Because a mastectomy is a complete removal of the breast, the incision varies from that of a lumpectomy - which is only partial removal of breast tissue.

Various surgeries require multiple incisions depending on if lymph nodes are involved; lymph nodes are often examined at the same time the breast tissue is removed, either by extending the incision to the armpit or by a separate small incision under the arm.
**POST-SURGERY TIMELINE WITH ESTIMATED MILESTONES**

**POST-OP**

- **Surgery/immediately following surgery**

- **Patient will stay in hospital for 24 hours (or more)**
  - The patient will be considered outpatient or will be discharged within a day or two

- **Post-Op drains**: Patient will empty drains every day (at home)
  - **1-2 weeks**: The Post-Op drains will be used until drainage drops to an acceptable level

- **Surgical wound is covered with a bandage - the patient won’t see their chest for a few days**

- **Surgeon or recovery room nurse will give the patient instructions**

- **Surgical bra**: The patient will either be wearing a surgical bra following the surgical procedure
  - OR they may not be allowed to wear a bra when the Post-Op drains are in

**RECOVERY/POST-RECOVERY**

- **Mastectomy bra**: The patient will begin wearing a mastectomy bra once the drains are removed

- The patient is still experiencing symptoms, especially soreness

- Potential for lymphedema to develop

- Compression clothing still recommended during this time

- **3-4 months**: The recommended amount of time for the patient to wait to resume wearing a normal bra

- **The patient is likely considered “back to normal”**

*Note: Most women who have surgery to treat breast cancer don’t experience much pain from the surgery itself. Pain is usually experienced during the healing process.*
06
TESTIMONIALS
"The daughter of a breast cancer survivor gave me a button-front nightshirt to wear in the hospital. The morning after my surgery, I washed up and put on this bright nightshirt. I felt feminine again. The button-front allowed me to deal with the drains." - Diagnosed with breast cancer at age 43; teacher, Maryland

"I had a bilateral mastectomy and felt like I was a tangle of drains and tubing. I found that the easiest way to deal with the drains was to string all of them on a long shoelace and tie it around my waist." - Diagnosed with breast cancer at age 40; magazine editor, New Jersey

"I bought some large button-front men's shirts to wear after my surgery. They were comfortable and easy to get in and out of." - Diagnosed with breast cancer at age 47; administrative assistant, Massachusetts

"Because I had mobility problems with my arm, I was overanxious to succeed in putting on a tee-shirt. Well, I did it . . . but then I couldn't get it off! I live alone. I ended up wearing the tee-shirt for a few days." - Diagnosed with breast cancer at age 49; symphony musician, Wisconsin
07

WHAT IS THE DRAINAGE SYSTEM?
"I had a bilateral mastectomy and felt like I was a tangle of drains and tubing. I found that the easiest way to deal with the drains was to string all of them on a long shoelace and tie it around my waist."

-Diagnosed with breast cancer at age 40; magazine editor, New Jersey
**THE JACKSON-PRATT DRAIN**

The Jackson-Pratt drain is commonly used for draining fluids from the incision site after undergoing surgery for breast cancer. According to NIH (National Institutes of Health), a closed suction drain is used to remove fluids that build up in areas of the body after surgery, or when someone has an infection. Although there is more than one brand of closed suction drains, this drain is often called a Jackson-Pratt, or JP drain.

The JP drain is made up of 2 parts:

A thin rubber tube

A soft, round, rubber squeeze bulb

One end of the rubber tube is placed in the area of the body where fluid may build up. The other end comes out through a small incision. A squeeze bulb is attached to this outer end.

The JP drain measures approximately 7 inches in circumference around its widest point; 5 inches tall, and 2 1/2 inches wide.
08
THE SOLUTION IS IN THE GARMENT
*The woven fabric is intended to act as a stabilizer to distribute the weight of the drainage bulb, which is concealed in a small pocket against the body located on the interior panel.
The drainage system (the Jackson-Pratt drain) can often be troublesome and uncomfortable, and many women have to resort to home remedy solutions for holding all of the medical tubing and the bulb itself.

An opportunity presents itself when considering how the design of a garment could efficiently and stylishly conceal, and more comfortably hold the drainage system in place, while allowing the wearer to more easily go about her day.

A few considerations are important to note when looking at the design of the garment. Garments that accommodate her after surgery need to fit around the drainage bulb(s), they need to be able to be put on easily because after surgery the tissue around the breast(s) is extremely sensitive and arm movement is extremely limited, making it impossible to put anything over the head, and they need to hang and fit loosely because avoiding tops that are tight fitting following treatments is highly recommended.

IT ALL STARTED WITH A CONCEPT

The initial purpose of this garment was to solve a problem for a market of women going through a medical treatment that had needs that weren’t being met in garment design. When taking those initial concepts and applying them to the creation of a cohesive and fashion-forward collection, some design elements were revised.

RE-DESIGN OF THE GARMENT

The way the garment was previously designed, the wrap on the inside of the top and the wrap on the outside were placed directly over what could potentially be a sensitive spot of breast tissue.

Depending on the type of mastectomy, the placement of the wraps could be designed to fit comfortably around an incision area and/or a breast reconstruction. Marketing to specific mastectomies could add a valuable touch to the collection.

POCKET DESIGN

A question to consider when looking at the design of the pocket is: What is the actual shape of the drainage bulb, and how can the pocket be shaped to be the most sleek and contoured to the garment and the medical device?
09
UNDERSTANDING THE PRESENT TO IMAGINE A BETTER FUTURE
ISSUES PRESENT IN CURRENT DESIGNS

A popular solution for holding the drainage system is centered around the waist and usually includes some form of a cumbersome Velcro belt that is uncomfortable and hard to conceal for the patient.

Compression bras offer patients comfort and support, but some which feature elements to hold the drainage system leave the bulb suspended which can be intrusive for the wearer.

Robes and jackets are currently on the market to hold the drainage system, but the materials and design are very hospital focused - they are also very expensive and according to user research* women tend to feel like they are “bringing the hospital home with them” because of their low appeal.

*User research has been conducted through both online outlets and support group meetings in which multiple women have given their insight and opinions.
"Camisole tops made of a nice silk were my favorites during treatment. I bought several loose jackets and blouses like jackets, and wore them over the tops or a dress."

-Breast cancer survivor; diagnosed at age 65
SOCIAL MEDIA AND THE DIGITAL WORLD TAKE OVER

Social media and the internet have grown immensely with resources and support for cancer patients, especially breast cancer patients.

Pinterest and various blogs offer personal support and testimonials from men and women all over the world - these online outlets allow people to communicate on public (and personal, if they so choose) levels to allow them to receive the support and guidance they need.

When looking at support for clothing, especially during the period post-mastectomy, Pinterest has become a place for women to share tips and advice, and ideas for what has worked for them that may work similarly for others. From a design standpoint, this offers great insight into their needs and personal solutions.

WHAT WOMEN TURN TO MOST

As stated previously, garments that accommodate her after surgery need to fit around the drainage bulb(s), they need to be able to be put on easily, and they need to hang and fit loosely. Draped silhouettes, tops that wrap or button down the front, and soft, natural fabrics are especially popular among women recovering from breast surgery. What is even more popular among recovering women is the importance of looking and feeling as normal as possible. Every woman that enters the stage of recovery from breast cancer develops her own little "tricks" for restoring her femininity, and this is vitally important to her self-esteem.

"I always applied skin care products and makeup daily, so I never looked sick. Friends would always comment on how good I looked, and before long I started feeling that way." -Breast cancer survivor; diagnosed at age 35

"Camisole tops made of a nice silk were my favorites during treatment. I bought several loose jackets and blouses like jackets, and wore them over the tops or a dress." -Breast cancer survivor; diagnosed at age 65

"It's important to have really comfortable jammies. I did a lot of lounging around my apartment, and my purple flannel pj's almost never came off my body." -Breast cancer survivor; diagnosed at age 24
THE CREATION OF A FASHION-FORWARD COLLECTION

**Fabric research** - What kinds of fabrics will work best to create the optimum comfort for the patient while maintaining the trends for fashion-forward materials?

**Expand collection** - How can the collection be expanded upon to make a full line of garments that all work cohesively together using the fundamentals previously established in concept design?

**Life cycle of the garment** - What will the life cycle of the garment be to ensure the best use for the consumer?

**Trend research** - Where are the trends going?

**Color psychology** - How can colors and color psychology aesthetically be incorporated into the collection? How can prints & patterns be used to effectively communicate to the patient/user - how will these make them feel - while still considering trends?

**Technical details** - What knowledge is needed to understand the medical drainage system to ensure that the medical device works properly and comfortably when the patient is wearing these garments? Style remains an important driver of the collection, but the ultimate goal of this garment is to help solve a very specific problem in the patient's journey through cancer.

**Construction / prototype** - How can a dress form and draping tape be utilized to look at tension points and areas that a mastectomy or other incision might cause discomfort or other issues?

**Re-design / adjusting the garment design** - How can the garment be re-designed to re-visit the needs discovered through research and studies?

**Re-design for fashion forward collection with equal functionality** - How can the garment be re-designed to be coherent with the current and future fashion trends - how can it be re-designed to change with the trends?

**User testing** - How can user testing implement the studies and design elements in a constructive way, and to prove their legitimacy?
10

THE DRAPING PROCESS
"I bought several beautiful nightgowns, a fabulous wig, great hats, and new makeup. I always wore the wig, and I always dressed impeccably, no matter how awful I felt. It was important to me that no one think of me as sick."

--Diagnosed with breast cancer at age 45; mother, widow, speaker, Massachusetts
THE CREATION OF THE PROTOTYPE

A dress form and draping tape were utilized to look at tension points and areas that a mastectomy or other incision might cause discomfort or other issues. After identifying the primary areas of concern on the body, taping the dress form in these areas proved to be an efficient way to identify them and drape the garment around them.

After establishing the primary areas of concern, the drainage system was attached to the dress form so that the tubing that would be placed into the incision was marked and attached to the form. The remaining tubing was then situated against the form similar to the way it would hang against the patient’s body. Special consideration was taken to ensure that the tubing was hanging loosely and properly so that in the case of the drainage system functioning, it would function properly and without pulling or tugging at the incision site.

Since there are various solutions on the market to allow the patient to attach the drainage bulb to a clip under a bra, or slip into a pocket on the inside of a camisole, the placement of the bulb on the form was meant to mimic its natural placement on the body.

Once the drainage system was established on the form, fabric was able to be draped onto the form and manipulated in different ways to identify the most beautiful and systematic way to conceal the drainage system underneath it. While experimenting with different weights of knits and different techniques for manipulating the fabric, various solutions proved to conceal the system most effectively.
WHERE ARE THE TRENDS GOING?
LOOKING INTO THE FUTURE

Cascading drapes, voluminous necklines, and boxy silhouettes that hang away from the body are being noticed in up-and-coming fashion. Sporty but sophisticated combinations are present in street style shots, and comfortable, slouchy styles are unearthing a new edge. Sophistication is being redefined to include fabric manipulations that suggest a more innovative, but seemingly sleek style. While structured garments continue to hold their place in fashion, the lack of structure in the more relaxed appearance is a focal point in future trends.

A perfect example of a designer that experiments with cascading drapery and asymmetrical lines is Lucas Nascimento. His collections beautifully exhibit the manipulation of knits into a highly sophisticated aesthetic. According to Vogue, Lucas Nascimento garners a reputation for his sophisticated and alternative take on knitwear - producing silhouettes and garments not so typical to the genre. In his S/S 2015 collection, Lucas Nascimento’s signature pieces include slit knits, toga t-shirts, and sophisticated sarongs.
12
THE IMPORTANCE OF CHOOSING THE RIGHT FABRICS
FABRIC REQUIREMENTS

"For hot flashes brought on by chemo, invest in a powerful air conditioner and wear cotton clothing."
-Breast cancer survivor

Hot flashes and skin rashes from chemotherapy are two examples of things to consider when choosing fabrics for garments that will be worn during, and following treatment. Fabrics that compliment these, and other issues women face when going through treatments for breast cancer, need to have the following properties:

They need to be breathable, especially for women enduring hot flashes brought on by chemotherapy, they should be comfortable, soft and airy, they especially need to be washable - and have an easy care routine, they need to be made of natural fibers, and they need to possess moisture wicking properties.

WHY BAMBOO KNITS?

Bamboo knits offer a gorgeous and sumptuous feel, they are extremely soft, and drape beautifully over the body. They are not too heavy to interrupt being smooth and flowing, but they are not so light that they are at risk of being overly delicate. They are, in fact, extremely durable and stable. Bamboo knits are eco-friendly and sustainable, and are made from bamboo fibres, which classifies them as a natural fabric when used in the production of textiles. They are breathable and cool to wear, and extremely hydroscopic (water-absorbing); one of their best known properties is their moisture wicking capability. Bamboo fabrics do not require the use of chemical antibacterial agents, which makes them a viable choice for clothing that comes in contact with incision areas and medical devices.
13
COLOR PALETTE
The “Core Collection,” as illustrated in the collection looks, is intended to be the primary palette of the collection that allows staple pieces to be beautifully interchanged. Rich slates and neutral undertones span the collection to create a palette of colors that pair effortlessly together.

A palette of “pop” colors allows the collection to follow trends and change from season to season. A collection of warm hues paired with soft, subtle cool tones creates a palette driven from nature. Bold pops inflect vibrance and saturation, while soft, understated blues serve as neutralizers.

**CORE COLLECTION**

Neutral staples and shades of grey span the collection to create a palette that is rich and organic. Deep, saturated plums compliment the lighter, more opaque pearl tones of the taupe. Black accents the neutrals and grounds the palette with effortless combinations.

**POP COLLECTION**

Inspiration from Pantone’s Spring 2016 color forecast suggests a collection of nature-inspired warm hues, paired beautifully with muted cool tones. The softness of the warmth pairs elegantly with the silky blues, making the warm palette perfectly compliment the crisp, cooler shades.
14 THE COLLECTION
Women’s Long Sleeve Cowl Neck Top
$68.00
XS, S, M, L, XL

Women’s Sleeveless Cowl Neck Top
$52.00
XS, S, M, L, XL

Women’s Signature Legging
$34.50
XS, S, M, L, XL

Women’s Wrap Maxi Skirt
$42.50
XS, S, M, L, XL
Women’s Long Sleeve Knit Open Jacket

$48.50
XS, S, M, L, XL

Women’s Sleeveless Basic Shell Top

$48.00
XS, S, M, L, XL

Women’s Wide Leg Knit Pant

$54.50
XS, S, M, L, XL
Women’s Draped Front Crossover Top
$58.00
XS, S, M, L, XL

Women’s Signature Knit Pencil Skirt
$28.50
XS, S, M, L, XL

Women’s Long Draped Front Crossover Top
$68.00
XS, S, M, L, XL

Women’s Signature Crop Legging
$24.50
XS, S, M, L, XL
Women’s Sleeveless Easy Knit Vest

$34.50
XS, S, M, L, XL

Women’s Long Sleeve Basic Shell Top

$54.00
XS, S, M, L, XL

Women’s Basic Maxi Skirt

$36.50
XS, S, M, L, XL
Women’s Long Sleeve V-Shaped Cowl Neck Top
$68.00
XS, S, M, L, XL

Women’s Signature Knit Pencil Skirt
$28.50
XS, S, M, L, XL
Women's Draped Front
Crossover Knee-Length Dress

$78.00
 XS, S, M, L, XL
15
B.BOLD IN
BOUTIQUES
AND ONLINE
Beautiful can be BOLD

100% Natural.
Bamboo knits offer a luxurious feel and beautiful drape.

Feel the Love.
Know that by purchasing from B.Bold, you are enhancing your inner strength and empowering your self-image.

Support the Cause.
B.Bold will donate a portion of every purchase to cancer research in the hopes of one day finding a cure.
B.BOLD’S MISSION

B.Bold will primarily sell through an online presence, and through boutiques designed specifically to generate an impressionable experience. The online outlet will offer access to a larger audience, while boutiques will help provide a sophisticated and empowering environment. B.Bold is dedicated to guiding women to unveil their self-esteem and rebuild their identity.
RESOURCES
INFORMATIONAL RESOURCES

http://www.breastcancersociety.org/
http://www.nationalbreastcancer.org/
http://www.breastcancer.org/
http://www.nlm.nih.gov/medlineplus/
http://www.ucsfhealth.org/
http://ww5.komen.org/
http://www.cancer.org/

IMAGE RESOURCES

https://unsplash.com/
https://www.pinterest.com/
http://www.raumrot.com/
http://picjumbo.com/

STYLE, TREND & RUNWAY RESOURCES

http://www.stylebistro.com/
http://www.pantone.com/

TESTIMONIAL RESOURCES

Uplift: Secrets from the Sisterhood of Breast Cancer Survivors
by Barbara Delinsky
Appendix 2

B. Bold – Mastectomy Drainage System Garment Prototype, Test Plan
B. Bold - Mastectomy Drainage System Garment Prototypes

Test Plan

Purpose: The purpose of this test plan is to outline and propose the systematic approach to user testing of the post mastectomy collection of apparel.

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Author</th>
<th>Description</th>
</tr>
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1. Overview

1.1. Purpose

The purpose of this document is to outline and propose the approach to user testing of the post mastectomy garment prototype. This document will define:

- The test scope, focus areas and objectives
- The test responsibilities
- The test strategy
- The test schedule and major milestones
- The test deliverables

1.2. Scope

This document details the testing that will be performed by the designer for the post mastectomy garment prototype. It defines the overall testing requirements and provides an integrated view of the project test activities. Its purpose is to document:

- What will be tested;
- How testing will be performed;
- What resources are needed, and when they will be needed
2. Testing Summary

2.1. Scope of Testing

2.1.1. In scope

From a testing perspective, the designer aims to complete user acceptance testing to better understand modifications necessary to be made to the standing prototype.

2.1.2. Out of scope

Defined users will perform usability testing; future modifications will be defined and implemented. Beyond these modifications, further endeavours are currently out of scope for this research test.
### 3. Progression Test Objectives

<table>
<thead>
<tr>
<th>Function</th>
<th>Test Objective</th>
<th>Evaluation Criteria</th>
<th>X-Ref</th>
<th>P</th>
</tr>
</thead>
</table>
| Pocket placement | • To understand if the pocket is correctly placed to compliment but not inhibit the functioning of the drainage system  
• To hold the drainage device at a proper distance away from incision  
• Does the pocket placement adequately allow access to the drainage device?  
• Can the drainage system function properly with the pocket in its current placement?  
• Do the drains hang low enough from the incision site to allow for proper drain circulation? | Evaluation scale from 1-5  
• Does the pocket need to be adjusted in reference to its placement on the interior panel?                                                                                                                | Evaluate                                                                 | Does the pocket need to be adjusted in reference to its placement on the interior panel? |
| Pocket size     | • To understand if the size of the pocket holds the drainage bulb snugly without making it difficult to access when caring for the drains  
• Is the pocket big enough to access the drains easily and comfortably?  
• Is the pocket small enough to hold the drainage bulb snugly? | Evaluation scale from 1-5  
• Does the pocket need to be adjusted in reference to its size?                                                                                                                                       | Evaluate                                                                 | Does the pocket need to be adjusted in reference to its size?     |
| Wrap system     | • To understand if the wrap feature adequately conceals and comfortably holds the stabilizing system while allowing the drains to be accessed simply and efficiently  
• Does the exterior panel sufficiently wrap over the interior panel?  
• Are the drains adequately concealed beneath the exterior wrap panel?  
• Is the placement of the interior wrap closure comfortable when placed on the body?  
• Is the placement of the closure on the exterior wrap panel comfortable and safely secured (to ensure the drains are secure within the interior system)? | Evaluation scale from 1-5  
• Does the wrap feature need to be adjusted?                                                                                                                                                            | Evaluate                                                                 | Does the wrap feature need to be adjusted? |
Progression Test Objectives – Terminology Explanations:

*Cross reference (X-Ref) is being defined as an evaluation scale

*Priority (P) is being defined as whether or not the function needs to be fixed/adjusted
4. Test Strategy

4.1. Test level responsibility

- Patient personas will be used to define test level responsibilities. Once users are defined by test subject enrollment, patient personas will determine test qualifications. For instance, newly diagnosed patients in a terminal level diagnosis may not be suitable to participate in this test study. Patient personas will vary by demographics and diagnosis, but certain personas will be deemed an inappropriate fit.

4.2. Test Type & Approach

- The test type will be broken into three categories and will be defined as follows:
  1. Wearability
  2. Functionality
  3. Emotive

  **Wearability** refers to the functioning of the fabric in terms of comfortability, wash and wear capabilities, and how well the garment fits when placed on body; **functionality** refers to how well the device is able to function when used in conjunction with the garment; and the **emotive** category assesses how the wearer's mood and self image are either improved, stay the same, or decrease when wearing the garment.

- The test approach will be implemented as follows:
  - Designer will meet with participant and give explanation of the study.
  - Participant will have the opportunity to try the garment on to ensure proper fit prior to test study beginning. (See details of fit session in “Test Environment”)
  - Designer will outline the **goals**, **functions** and **priorities** to the participant as follows:
    - The **goal** of the project is to better understand the role, both physically and emotionally, of concealing the mastectomy drainage system in a sophisticated way.
    - The **function** of the project is in regards to the functioning of the garment while interacting with the drainage device. If the device functions properly, the function of the test will be deemed successful.
    - The **priority** of the project, as outlined in the project goals, is for the designer to review not only if the device functions properly while implemented into the garment system, but the emotional impact of the garment on the wearer will also be vital to understanding the success of the test.
      - One of the main goals of the garment is for the user to feel that their femininity and self-image remain intact.
  - Once the participant understands the project brief, the participant will be given a journal and instructions on documenting their insights while wearing the garment prototype. Key insights desired include: what works well while wearing the garment, what needs to be improved, what needs to be removed, what needs to be added, how the garment makes the participant feel, and if wearing this garment invokes a better feeling than other garment options available to the participant.
• Participant will wear the garment at their leisure for 2 weeks, assuming the length of their drainage device being used covers the length of this time period (*this time can be adjusted across the various participants).

• Designer will collect the garment and journal from the participant at the end of their 2-week wearing period. At this time, designer will complete a final survey with the participant for further data collection. Participant will rate the garment across several categories, similar to the insights from their journal, but with the purpose of collecting comprehensive data across the span of the study.

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Overall) Garment Wear Test</td>
<td>The objectives are to verify that the garment:</td>
</tr>
<tr>
<td></td>
<td>• Meets the defined requirements;</td>
</tr>
<tr>
<td></td>
<td>• Performs and functions accurately;</td>
</tr>
<tr>
<td></td>
<td>• Correctly handles any instance where a malfunction occurs</td>
</tr>
</tbody>
</table>

4.3. Test Execution Schedule

• See “Test Milestones and Schedule” below for detailed test schedule

4.4. Facility, data, and resource provision plan

4.4.1. Test environment

Each individual participant will determine test environment. Participants will be expected to wear their garment prototype, as they see fit, for the length of the study. They will have the opportunity to do so in a way that’s most comfortable for them.

Determinants will be specified in the following ways:

• Wearer will be expected to wash and wear the garment throughout her day. She will be given care recommendations based on the fabric content, and she will be given instruction on how to handle special circumstances (such as stains, rips/tears, etc.) If any permanent damage is documented, such as a rip or tear, the wearer will be instructed to notify the designer immediately so that proper provisions can be implemented.

• She will be expected to wear it through daily activities, but more importantly, she’ll be expected to wear it to dinner, shows, get togethers with friends, etc. so that she can evaluate emotive impact in circumstances where she wants to feel her most sophisticated.

• During the 2 week period that the wearer is expected to wear the garment, she will need to wear the garment for a minimum of 3-5 hour time periods per day. If she chooses to remove the garment to replace it for another pre-existing option, she’ll be expected to document why she implemented a replacement of the prototype.

4.4.2. Testing Requirements

Each person involved in testing will need the following access:

• They will need to have access to at least one post mastectomy surgical drain

• They will need to have access to online surveys

• They will need to be able to document the specified process throughout the wear trial
4.5. **Testing Tools**

The following tools will be used for testing:

<table>
<thead>
<tr>
<th>Process</th>
<th>Tool(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Garment functioning</td>
<td>Garment prototype</td>
</tr>
<tr>
<td>Device functioning</td>
<td>Post surgical drainage device and accompanying system</td>
</tr>
<tr>
<td>Wearer result recording</td>
<td>Journal, access to online surveys, voice recorder</td>
</tr>
<tr>
<td>Designer result recording</td>
<td>Journal, Microsoft Excel, creation of online surveys, video recording for documentation of fit session</td>
</tr>
</tbody>
</table>

4.6. **Testing Metrics**

The metrics to capture are as follows:

- How well does the garment fit?
  - *Garments will be produced in 3 sizes, with 3 of each garment per size (i.e. 3 Small, 3 Medium, 3 Large; in standard S, M, L Women’s size specifications)*
  - *Fit will be evaluated on how well the garment fits in the size category specified by the wearer, as well as individual fit on each specific model*
- How well does the device function when interacting with the garment?
- How does the wearer feel positively emotively affected when wearing the garment?

Designer will capture metrics using the following tools:

- Journal
- Online surveys
- Voice recording
- Video recording (*of fit session*)
5. Test Environment Plan

5.1. Test Environment Details

5.1.1. Testers

- Number of testers will be defined as follows:
  - 5 – Low # of testers
  - 8 – Ideal # of testers
  - 10 – Recruit # of testers

5.2. Establishing Environment

<table>
<thead>
<tr>
<th>Task</th>
<th>Requirements</th>
<th>Responsibility</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fit session</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wear period</td>
<td></td>
<td></td>
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</tbody>
</table>

5.3. Environment Control

Control measures that will be placed on the environment include:

- Number of hours that wearer is expected to wear the garment
- Wash and wear instructions
- Defined destinations where garment is expected to be worn
- Home specifications and daily activities that wearer is expected to wear garment to complete (such as doing laundry if they feel up to it, having company over, etc.)
6. Entry and Exit Criteria

Testing will be considered completed when either of the following situations occur:

- The wearer defines the garment as unwearable, unfit, uncomfortable, or defines any other circumstance in which they feel the garment is not functioning properly
- The duration of the 2 week test period has been fulfilled and documentation has been completed by wearer
7. Administrative Plan

7.1. Test Milestones and Schedule

Detailed below are the high-level testing milestones.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Planned End Date</th>
<th>Actual End Date</th>
<th>Resource</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify test partner</td>
<td>10/30/15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify participants</td>
<td>11/6/15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruit participants</td>
<td>11/11/15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Train participants</td>
<td>11/18/15</td>
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<tr>
<td>Fit sessions</td>
<td>11/20/15</td>
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<tr>
<td>Testing</td>
<td>12/4/15</td>
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<tr>
<td>Debrief session with participants</td>
<td>12/9/15</td>
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<tr>
<td>Data compilation</td>
<td>12/11/15</td>
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<td>Data analysis</td>
<td>12/18/15</td>
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<tr>
<td>Write conclusions</td>
<td>12/18/15</td>
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7.2. Training

The following training requirements have been identified to ensure testing can commence:

<table>
<thead>
<tr>
<th>Training Requirement</th>
<th>Date Completed</th>
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<tr>
<td>Institutional Review Board (IRB)</td>
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<tr>
<td>Additional protocol requirements (if any)</td>
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# 8. Definitions

The following acronyms and terms have been used throughout this document:

<table>
<thead>
<tr>
<th>Term/Acronym</th>
<th>Definition</th>
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# 9. References

The following documents have been used to assist in creation of this document.

<table>
<thead>
<tr>
<th>#</th>
<th>Document name</th>
<th>Version</th>
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</table>
10. Points of Contact

The following people can be contacted in reference to this document

<table>
<thead>
<tr>
<th></th>
<th>Primary Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Dianne Hardin</td>
</tr>
<tr>
<td>Title/Organisation</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
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<table>
<thead>
<tr>
<th>Name</th>
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<tr>
<td>Email</td>
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Appendix 3
B. Bold – Confidential Disclosure Agreement
CONFIDENTIAL DISCLOSURE AGREEMENT

It is understood and agreed to that the below identified discloser of confidential information may provide certain information that is and must be kept confidential. To ensure the protection of such information, and to preserve any confidentiality necessary under patent and/or trade secret laws, it is agreed that:

1. The confidential information to be disclosed can be described as and includes:

Invention description(s), technical and business information relating to proprietary ideas and inventions, ideas, patentable ideas, trade secrets, drawings and/or illustrations, patent searches, existing and/or contemplated products and services, research and development, production, costs, profit and margin information, finances and financial projections, customers, clients, marketing, and current or future business plans and models, regardless of whether such information is designated as “confidential information” at the time of its disclosure.

2. The recipient agrees not to disclose the confidential information obtained from the discloser to anyone unless required to do so by law.

3. This agreement states the entire agreement between the parties concerning the disclosure of confidential information. Any addition or modification to this agreement must be made in writing and signed by the parties.

4. If any of the provisions of this agreement are found to be unenforceable, the remainder shall be enforced as fully as possible and the unenforceable provision(s) shall be deemed modified to the limited extent required to permit enforcement of the agreement as a whole.

Wherefore, the parties acknowledge that they have read and understand this agreement and voluntarily accept the duties and obligations set forth herein.

Recipient of Confidential Information:

Name (Print or Type):

Signature:

Date:

Discloser of Confidential Information:

Name (Print or Type):

Signature:

Date:
Appendix 4
B. Bold – Instructions Pamphlet

*Example of participant materials*
Beautiful can be BOLD

Collection designed by: Megan Sullivan
University of Cincinnati: School of Design
Fashion Design Product Development Track, 2015
Master’s of Design Program, 2016

B. BOLD
A COLLECTION DESIGNED BY MEGAN SULLIVAN
Firstly, I would like to extend my deepest gratitude for your willingness to wear this garment and provide feedback. Your input is absolutely invaluable, and I cannot begin to tell you how thankful I am to receive your insight!

In this pamphlet, you will find wear instructions for wearing the garment, instructions for providing feedback (including multiple options for how you can offer comments), care instructions for how to maintain the integrity of the garment, and contact information for how you can contact me with any comments, questions, or concerns.

At any time throughout this process, please do not hesitate to contact me! I am always available to speak with you and answer any questions you might have.

Again, I would like to extend my greatest appreciation for your time and willingness to wear this garment.

Thank you again for your greatly appreciated insight!

HOW TO CONTACT ME:
You can contact me at any time either by phone (call and/or text) or email.

Phone: (937) 261-1266
Email: sullimg@mail.uc.edu

I am always available to talk and answer any questions you might have.

My sincerest thank you!
WEAR INSTRUCTIONS:

You will have the opportunity to wear this garment in a way that’s most comfortable for you. Your comfort is of my highest concern!

I would like you to consider wearing the garment through daily activities, especially to dinner, shows, get togethers with friends, etc. so that you can evaluate emotive impact in circumstances where you want to feel your best. During the time that you have the garment, I would like for you to wear it for a minimum of 3-5 hour time periods per day. If you choose to remove the garment to replace it for something else, please document why you chose to substitute it with another option so that I can understand how I could make improvements if necessary.

HOW TO PROVIDE FEEDBACK:

There are two ways in which you can provide feedback at any time throughout the period of wearing the garment. You can use one or both of the below methods, whichever you find easiest.

1) You may write in the journal provided to you, which will be returned to me at the end of the wear period. Prompts for journal entries can include (but are not limited to): Are the drains easily accessible and comfortably concealed within the garment? How do you feel when wearing the garment? (i.e. comfortable, stylish, ready to conquer the day, etc.)

   The journal is meant to be a leisurely way to write down your findings and feelings when wearing the garment.

2) You may type in the link below and take an online survey of questions. This survey is intended to be used at the end of your wearing period, as a summary of your insights.

   https://www.surveymonkey.com/r/BreastCancerSurgicalDrainGarmentSurvey

CARE INSTRUCTIONS:

Please use the following care instructions in order to maintain the integrity of the garment. If you have any questions, please don’t hesitate to contact me!

You will be expected to wash and wear the garment throughout the time that you wear it. Please wash the garment when you feel it’s necessary throughout the time that it’s in your possession. I will have the garment professionally cleaned once it is returned to me, so please don’t worry about doing so. When you wash the garment, please wash it as listed below:

Machine wash on delicate, cold water
Hang to dry, please do not put garment in dryer to avoid shrinkage*

HOW TO HANDLE SPECIAL CIRCUMSTANCES:
(such as stains, rips/tears, etc.)

If any special circumstances arise, such as minor stains, please handle at your discretion. Please don’t hesitate to contact me with questions!

If any permanent damage is documented, such as a rip or tear, please notify me immediately so that I can properly assist you.