Abdominal Hernia and Pannus Support Device

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GROUP MEMBERS

Team Leader: Devon Moloney

Team Communicator: Matt Jensen

BSAC: Cody Williams

BWIG: Jeff Wu

Procurement: Hannah Frank

CLIENTS

Dr. Sarah Oltmann & Dr. Jacob Greenberg,
UW Hospital Dept. of Surgery

ADVISOR

Sarah Gong, Biomedical Engineering Dept.

ABSTRACT

Both patients awaiting abdominal hernia repair surgery as well as morbidly obese patients suffer from health issues that impede movement and cause pain. This is due to large amounts of weight concentrated in the abdominal region with little to no muscle support participating in effective weight distribution. Proper lifting support of the abdominal area would decrease the stress on other muscles of the body and increase blood flow in the internal organs. Current solutions to these health conditions include abdominal binders and maternity braces; however, they are not adjustable to larger bodies and are ineffective in supporting large amounts of weight. Our clients, Dr. Sarah Oltmann and Dr. Jacob Greenberg from the Department of Surgery at UW Hospital, desire a supportive device that will provide their patients with an upward lifting force and will relieve the discomfort experienced from the centralized weight of the hernia or pannus. In order to create a single prototype that would follow our clients' specifications, be under budget, and safely support the pannus or hernia, our design type focused on several design components: an upward lifting support belt, side straps, shoulder straps, and material encompassing the hernia or pannus. After comparing several different designs, materials and fasteners for each component through design matrices, it was decided that a support device comprised of a thick wicking for the waist belt, a breathable, performance material for the abdominal covering, and low-profile buckles for vertical supports would be most effective. A design was fabricated, tested, presented to the clients with measurements for a specific patient, and will eventually be modified based on their feedback and hopefully distributed to multiple patients struggling with similar medical conditions with a long term goal of getting a similar product to market.

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INTRODUCTION

Left: Front view of patient C.V. 14 months after abdominal exploration for blunt trauma. Note the extreme protrusion of the viscera. *Right:* Front view of patient C.V. 14 months after abdominal wall reconstruction.

Figure 1: Patient photos before and after hernia repair surgery. Photo on left shows separated abdominal muscles and hernia sac extending over the waistline [2].

The two prospective consumer groups that this design project targets are patients who are awaiting abdominal hernia repair surgery and morbidly obese patients that have a large abdominal pannus. A hernia occurs when there is a defect in the abdominal wall that allows the inner contents of abdomen to protrude through the wall. Most hernias develop in the pubic region as inguinal hernias. Only 8-10% of all hernias are incisional hernias, which is the kind this project looks to help with [2]. After a patient undergoes an extreme emergency abdominal surgery, sometimes that scar tissue does not properly heal and the abdominal muscles do not fuse back together in the center of the abdomen (Figure 1). This may occur due to infection, too much tension on the healing area, malnutrition, or intra-abdominal pressure. About 5-10 % of abdominal incisions result in incisional hernias of varying magnitudes [2]. This leaves the patient with a split down the Rectus Abdominus and the because of the split, renders the external abdominal oblique muscles useless in trying to support the hernia as well as the weight of the pannus (Figure 2). A skin graft is placed over the incision in an attempt to contain the internal organs. However without these essential oblique and abdominal muscles offering full support, the digestive and other abdominal organs protrude past the waistline in a hernia sac, which is pulled down gravity [5]. The other consumer group, morbidly obese patients, must also deal with an abdominal projection or heavy pannus, which is essentially large amounts of excess fat extending over the waistline [3]. Both of these consumer groups have large tissue masses

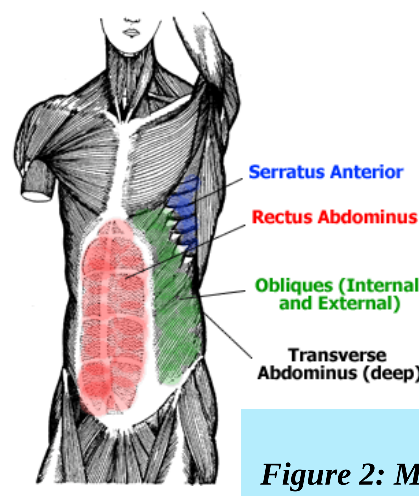


Figure 2: Main muscles of the abdomen [6]

in the abdominal region and lack the muscular strength to support the needed weight and counteract the downward pull of gravity.

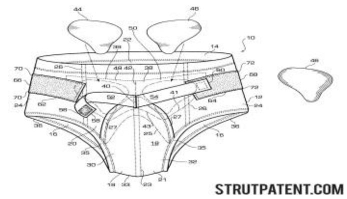
Because both consumer groups do not have the necessary muscle support to naturally lift the large amounts of weight concentrated in their abdominal region, both conditions lead to more serious health problems. Muscle strain, lack of blood circulation, back pain, and poor digestion are just a few of the health conditions that result from the pulling force of gravity on the hernia or pannus [3]. The weight of the tissue mass is not distributed properly, which leads to muscle and back pain, and the internal organs are pressed against the hernia wall, resulting in poor blood flow and digestion issues. Another serious health concern for those awaiting abdominal hernia repairs is skin sensitivity and irritability. After emergency surgery, a thin, fragile layer of skin is the only thing protecting the internal organs from their surroundings; therefore, the hernia sac is very sensitive to heat, pressure, and rough or sharp objects against it but lacks the nerve endings to sense any stimulus [4].

BACKGROUND AND CURRENT SOLUTIONS

Figure 3: Maternity brace currently used by hernia/obese patients to support excess weight [7]

Figure 4: Abdominal binder currently used by hernia/obese patients to support excess weight [8].

The team's client, Dr. Oltmann, as well many other general surgeons, currently use abdominal binders and maternity braces as solutions for their abdominal hernia and morbidly obese patients. As seen in Figure 3, the maternity brace is essentially a cloth harness used by pregnant women to distribute the excess weight in the abdomen experienced during pregnancy; these devices are not manufactured for large body types and stretch over time. Shown in Figure 4, abdominal binders resemble an enlarged ACE bandage and lack an upward lifting force, instead they tighten around the center of the body, applying pressure and ultimately compressing the sensitive skin of the hernia even further [5].



Figures 5 & 6: Example patent sketches for current design prototypes of pelvic hernia support devices [9].

Patents for hernia support devices do currently exist but the team found them ineffective for prospective consumer groups due to their focus on inguinal hernias rather than abdominal hernias (Figures 5 & 6). These current designs demonstrate a tightening force, which wraps around the abdomen and focuses on restraining smaller inguinal hernias in the pelvic region; no lifting force is present to provide the support our clients need to aid their patients with extremely large abdominal hernias [5]. The team determined that these current solutions are ineffective in achieving the team's clients' design specifications because they do not adjust to the large body types many patients have. They lack an essential upward lifting force, are prone to stretch or deformation over time, and they irritate the sensitive skin of the hernia sac.

Problem Statement and Design Specifications

The team's goal is to create a prosthetic device that will help provide a lifting support for either a pannus or hernia sac, both of which can weigh from 2-45 kg (5-100 pounds). Most patients with hernia sacs must wait between 6-12 months before being able to undergo corrective surgery. For some cases, surgery is never a viable option because of certain health factors. These patients need a device that will help carry their hernia sac or pannus on a daily basis, thus the device must be durable. In order to ensure proper sanitary needs, the device must also be easily disassembled for washing and be made with washable components. A breathable material must be used to provide comfort since, on average, patients will be wearing this device for 10-14 hours a day. Finally, the material used must not irritate the skin tissue covering the hernia sac, as this can cause damage to the internal organs of the patient.

The team's design is specific for an anonymous patient of Dr. Greenberg's. The four main components of the team's design are displayed in Figure 6: the shoulder straps, support belt, lifting fabric for hernia/pannus, and the side abdominal support straps.

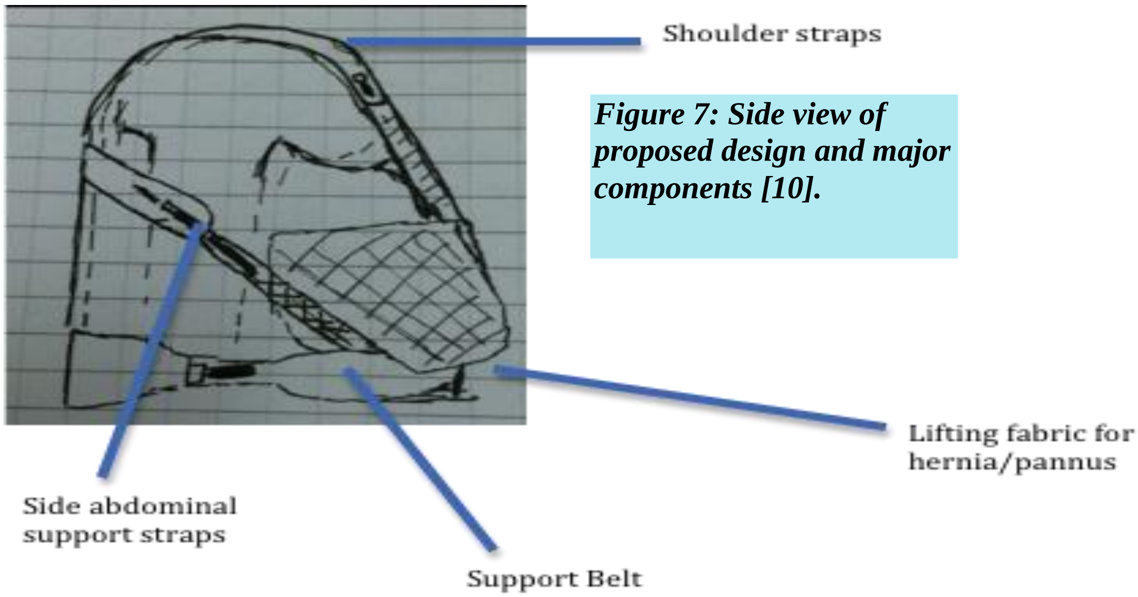


Figure 7: Side view of proposed design and major components [10].

The shoulder straps will help distribute the weight of the hernia/pannus across the body evenly. The support belt goes around the waist of the patient and attached to that is the piece of lifting fabric that will go under the hernia/pannus and provide the lifting support (Figure 7). The abdominal support straps are necessary to provide additional lifting forces and also to imitate oblique abdominal muscles, which are useless when a tear separates the central abdominal muscle.

MATERIALS

For this project the choice of materials will be critical to the team's final design. This project is geared towards fitting a support device that is to be worn daily for many months and that is as discrete as possible while still being fully functional. The test of time must also be endured by the team's device, which means the materials must be durable. The device will need to be washable as well so that it can be used every day. Part of being fully functional will not only be that the device provides enough support but that the device is also comfortable enough to be worn for such an extended period of time. A soft material must be used since the replacement skin covering the hernia is thin and easily agitated. No rough fabric, edges, or seams can touch the delicate skin since reinjuring the hernia will lead to more complications. As one can imagine, the materials and fabrics that provide the most support are often times the least comfortable and vise-versa. This means a balance point must be reached so that the best product may be put forward.

Rubber Bands

One of the first design sketches brought forward by the team was one that used a series of rubber bands as the overall support system (Figure 8). By using multiple rubber bands, the lifting forces applied to the hernia and/or pannus could be tailored in a way that disperses evenly across the body and entirety of the device. There would also be extra support if different types of rubber bands were used. There may be some places that need more lifting support than others and using rubber bands would allow the use of different rubber band types to meet this need and produce maximum comfort to the user. The rubber bands would be the covered in a fabric that does not irritate the skin.

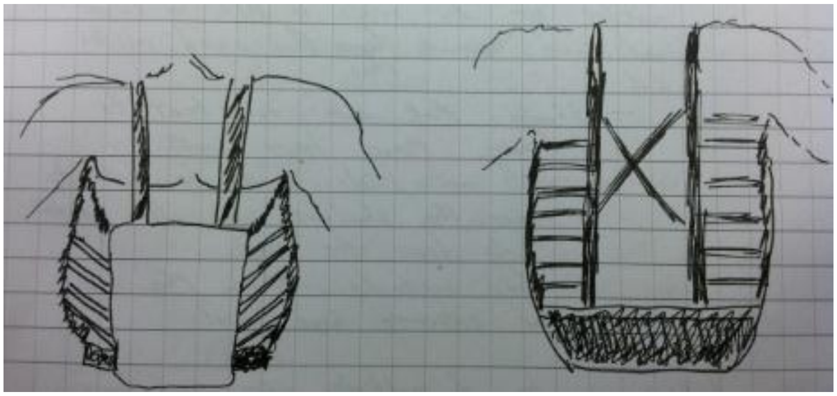


Figure 8: Front and back sketches of brainstormed design using rubber bands as material for side and shoulder supports [11].

There are quite a few drawbacks to using rubber bands, however. One issue is with overall comfort and safety of using rubber bands. Rubber is not breathable nor moisture wicking. If a large amount of area of the user was covered with rubber bands, the user could very easily become uncomfortably warm and wet due to the trapping of heat and moisture given off by the body. Rubber bands would also be difficult to wash properly. It can also be said that donning a device with rubber bands would mean generating forces large enough to stretch the bands further then they would be while the device was worn. This would be very difficult for must users. Another concern is that a rubber band may become compromised or worn out and snap. There is also the increased possibility of pinching due to the use of multiple rubber bands. These are safety factors that need to be assessed if rubber bands were to be used. Because the rubber bands would most likely need to be custom made for the project, the cost of the materials would increase.

Elastic Material

Another material that was thought about was the use of an elastic material such as spandex or fabric laced with elastic material. This would be comparable to the fabric being used in the abdominal binder and maternity belt. There is a vast array of fabrics to choose from that would fit into this category. The plus side of these would be that there are many synthetic fabrics that are specially designed for temperature regulation and moisture wicking at the surface of the skin. This type of material would also be very comfortable and close fitting for the user. It would also be washable.

The downside to this type of material is that it cannot produce the lifting forces needed for the team’s particular set of potential users. This is exactly the problem seen by the current devices being used. Because these fabrics are meant to stretch, any additional lifting forces applied to the device would be reduced due to forces going into simply stretching the material rather than lifting it. With a great deal of stretching taking place, there is also a greater chance of plastic deformation of the fabric in which its stretching properties erode over time.

In order to find a find an ideal fabric at a reasonable price, only samples from local stores were considered in the final design. Focus was placed on comfort as the rigid fabric and straps would be responsible for lifting. This portion is going to be used for lining and covering the upper hernia, which needs to be breathable as well as safe for the patient.

Rigid Materials

The need for a material that could transfer lifting forces without absorbing said forces internally became apparent. A material that is rigid is what is ideally needed for the portions of the device that are subject to applied forces. This material, like the elastic materials, can also be breathable and moisture wicking to ensure comfort between the device and skin. Early on, there is some interest in pursuing material made of PLA fiber. PLA is a corn-based fiber that is shown to have high marks in the areas of tenacity, elastic recovery and moisture wicking [12]. Due to limited availability and high costs, this option had to be turned down. Instead cotton, denim, and synthetic materials were investigated. In order to get an ideal fabric, only choices the team could see and touch were considered for testing, thus the supply was limited to what was available at local fabric stores.

The downside to using such a material is that there is no lifting force generated by the material itself. This means there will need to be an external source of lift. Comfort could also be an issue if there are extreme amounts of forces on the fabric. There may be a need for some additional padding in certain areas of the material in case of large forces.

Evaluation of Materials

Criteria	Rubber Band	Elastic Fabric	Rigid Fabric
Effectiveness (30)	25	15	22
Safety(20)	10	17	17
Comfort(15)	5	13	13
Maintenance(15)	6	13	13
Ease of Use (15)	6	10	13
Cost Effectiveness (5)	1	3	3
Total (100)	53	71	81

Table 1: This figure is the design matrix used to assess the different materials that could potentially be used for the project.

The materials above were assessed in a design matrix, Table 1, which incorporated the pros and cons stated above. It can be seen that the rubber bands scored the lowest and that the rigid and elastic materials shared a number of similarities. It was then decided to incorporate both elastic and rigid materials in a design that would allow for the positive properties of each to be expressed in the overall design. The elastic material would be used to provide extra comfort and coverage of areas not directly being acted upon by the lifting force, and the rigid material would then be subject to the force generated by an external device.

Upon further investigation and trips to local fabric stores, two rigid fabrics and one elastic fabric were selected for possible use in the device. For elastic materials, the emphasis was placed on breathability and comfort as opposed to strength. A performance wear material was selected, it allows for a breathable covering, wicks sweat away from the skin, and soft to prevent skin irritation. Due to limited availability fabrics with these characteristics and the fact that the elastic fabric is primarily for covering as opposed to lifting, no testing will be done on it and this will be used for parts of the final design. The rigid fabrics were 10 oz. bull denim and standard gray cotton samples. In order to determine which is better for the final product, tensile testing will be performed on samples of each. Breaking strengths and comfort of the material will be used to decide which fabric is better for the under-hernia support. All were relatively cheap and did not have a significant impact on the budget. A combination of these materials will be integrated into the final design.

FASTENING MECHANISMS

The fastening components of the design are what provide the lifting force to the fabrics supporting the hernia or pannus. It is imperative that the component gives adequate support to the maximum anticipated load while still remaining light and discreet. With this in mind, the team looked at three different designs for this component. First, a small simple insert buckle (Figure 9). These are commonly found on backpacks as well as other bags. Next, the team looked at ratchet straps, which are commonly used to secure objects (Figure 10). Finally, the team discovered an interesting new design (Figure 11). This fastening mechanism was originally intended for use on boots and shoes to tighten laces. The device is comprised of a small plastic column to which shoelaces are attached on a small circular base.

Evaluation of Fastening Mechanisms

Criteria	Buckle	Ratchet	Winding
Effectiveness (30)	20	24	18
Safety (20)	15	17	12
Concealability (15)	18	8	9
Maintenance (15)	14	12	4
Ease of Use (15)	15	11	13
Cost Effectiveness (5)	4	3	2
Total (100)	86	75	58

Table 2: This table shows the design matrix used to evaluate each of the components, with higher quantities reflecting more desirable attributes.

The criterion first analyzed and with the greatest weight was effectiveness. The team defined this as the ability to continually offer full, fixed support to the load generated by the hernia or pannus. This category was given the highest value of importance because if the fastening mechanisms are not capable of supporting the excess fat seen in most patients, they do not solve the problem of support and are deemed ineffective. The winding mechanism scored the lowest in effectiveness because the exterior is made of plastic and the interior forces rely on fabric friction, which would most likely not be able to support much weight. The buckles scored in the middle because the team was able to find 2" wide plastic buckles that could support more weight since they had larger, sturdier components. The buckles are more effective in supporting large amounts of weight than the winding mechanism, but they still rely on friction force. Finally, the ratchet straps scored the highest in this category because of their sturdiness and material components. Ratchets are composed of metal and designed to support larger loads than the other plastic components, so they are capable of supporting more than enough weight necessary for the hernia support device.

The next criterion examined was the safety of each component. This category is quite similar to effectiveness. The greatest danger of any of the fastening mechanisms is the possible failure of any of the devices due to material deterioration or deconstruction under excess weight. Thus, with greater effectiveness, the device has a smaller chance of failing and receives a greater safety rating. Based on this reasoning, the Ratchet had the highest safety rating followed by the buckle and the winding mechanism (Table 2).

Concealability is the criterion that the team used to describe the ability of a component to remain discreet and out of sight. Patients struggling with obesity or painful abdominal hernias struggle to live normal day to day life due to their medical conditions therefore the team found it extremely important to provide a support device that could be easily hidden under day to day clothing. The buckles received the highest rating because they are small, plastic, smooth, and flat enough to lie against the body and to not protrude while worn under clothing. The winding mechanism is rather thick and would be visible under clothing, and the ratchet is a rather large metal piece that would be hard to conceal. Because of this, the winding mechanism and ratchet alternatively scored much lower for concealability.

Maintenance was defined as the ability of the device to be both removed and replaced. If pieces of the product were to need replacement, fixing, or adjustments such as sizing, maintenance would be extremely important. Since both the buckle and ratchet can easily be removed from the device by simply removing the straps, these two components scored relatively high. However, the plastic winding mechanism must have its base secured to the body of the device, and the straps are secured within the device, making them difficult to remove. The winding mechanism received the lowest score for maintenance (Table 2).

Based on how simply the device functions, ease of use was relatively equivalent across the three components. The ratchet and winding mechanism score lower than the buckle because each of these two components takes multiple cycles to tighten. The buckle simply needs to be tightened by pulling the strap and then inserting one end into the other. The ratchet and winding mechanism also score lower in this category because they are bulkier and heavier, which could potentially restrict the patient's movements or lead to painful pressure on the shoulders. Ease of use was also an important design criterion when considering fastening mechanisms because patients with large tissue masses hindering their movement require devices that they can independently and easily use.

Cost effectiveness stems from not only the expense of each component, but also how easy each is to acquire. The buckle scored slightly higher because these can easily be found for relatively low prices in outdoor or fabric stores. Similarly, the ratchet strap is easily available online. The winding mechanism, unfortunately, was only patented recently, and is hard to find on the market. These attributes are reflected in its rating.

Figure 9: A picture of the insert buckle (chosen fastening mechanism) [13].

Figure 10: A picture of a ratchet and strap [15].

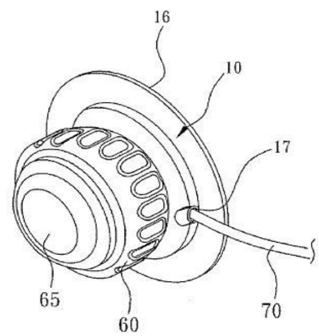


Figure 11: A diagram of the winding mechanism [14].

TESTING

Due to availability of materials and time constraints, testing of the buckles was not feasible. Instead, thorough research was completed on 1" plastic parachute buckles. While no information on the specific brand could be found, general strengths for similar products were found. The strengths of buckles varied widely by product, but all had a breaking weight of over 45.4 kg (100 lbs.). This includes 49.9 – 84.8 kg (110-187 lbs.) for buckles from plastic-buckle.com and a 29.5 kg (65 lbs.) working load limit for buckle and strap from tools2parts.com. While this seems low, the breaking strength was significantly higher, 90.8 kg (200 lbs.). The difference includes factors of safety and the strain of the strap attached to the buckle. Furthermore, the prototype will have two buckles, one on each shoulder, giving twice as much lifting potential, which easily meets the approximate of 45.4 kg (100 lbs.) needed to support a large hernia. Finally, in the final design, 2" buckles were used as opposed to 1" buckles. In all examples found in research, the breaking strength of buckles increased with size.

In testing the two fabrics, considerations in how the fabric was aligned needed to be considered. The strength of fabric depends on the direction the threads are oriented; the directions are called warp and filling. Fabrics are stronger in the warp direction, where threads run the length of the loom. In the filling direction, threads are the length of the fabric and are easier to break since the fabric is not looped back on itself [15] [16].

The team felt that the most crucial part of the device, in terms of strength, was the shelf that was intended to bear most of the load of the hernia/pannus. Ideally, the team would have tested the stitching that held the material together as well as the buckles, which transferred the load over the shoulders, but unfortunately, the team could not construct the stitching without assistance due to time constraints. As an alternative to tensile testing of the stitching and buckles, the team researched buckle strength and relied upon the expertise of a student from the Department of Human Ecology for stitch styles.

However, the team was able to perform tensile testing on the material to be used within the shelf. Tensile testing was performed on a Sintech 10 GL tensile testing machine manufactured by MTS Systems Corporation. Samples of cotton and denim were prepared to a width of 2.54 cm and a gage length of 5 cm. The samples were then stretched until the material tore. The results of the testing can be found in Table 3. The team decided to analyze load instead of stress because the cross-sectional area of the fabric was very difficult to calculate, considering the fraying of the fabric along the edges of the cut. Also the longitudinal area would be more indicative, considering that the fabric will be loaded along that face. The longitudinal area was 12.7 cm^2, while the longitudinal area of the shelf was 2160 cm^2. While the weight of the hernia / pannus will not be uniformly distributed, the team felt that failure at 22.43 kg would be sufficient to support the patient. As seen in Table 3, although the cotton fabric failed at a higher average load, the denim fabric failed more consistently. Also, one of the samples of cotton failed at 24.86 kg, within 15% of the critical value. Based on the consistency of the denim material to fail well over 125% the critical load, the team decided denim was the more appropriate material to include in the device.

Fabric	Strain at Failure	Failure Load (kg)	Fabric	Strain at Failure	Failure Load (kg)
Denim1	0.047	35.29	Cotton1	0.028	24.86
Denim2	0.040	31.71	Cotton2	0.030	40.78
Denim3	0.046	33.61	Cotton3	0.033	45.63
Denim4	0.047	35.88	Cotton4	0.032	44.63
Average	0.045	34.12	Average	0.031	38.97
Standard Deviation	0.003	1.62	Standard Deviation	0.002	8.35

Table 3: The summary statistics from mechanical testing.

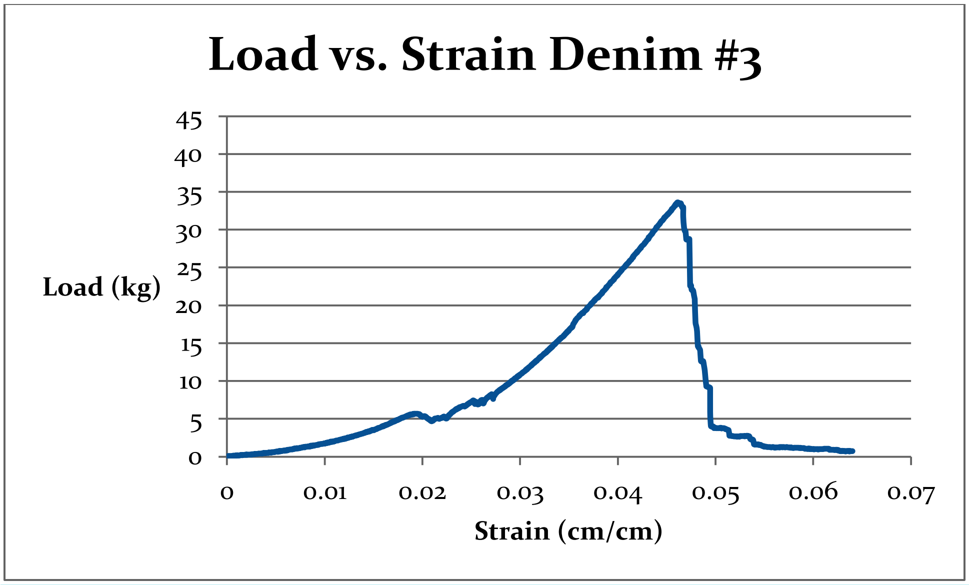


Figure 12 : The load vs. strain for the most representative sample of denim fabric.

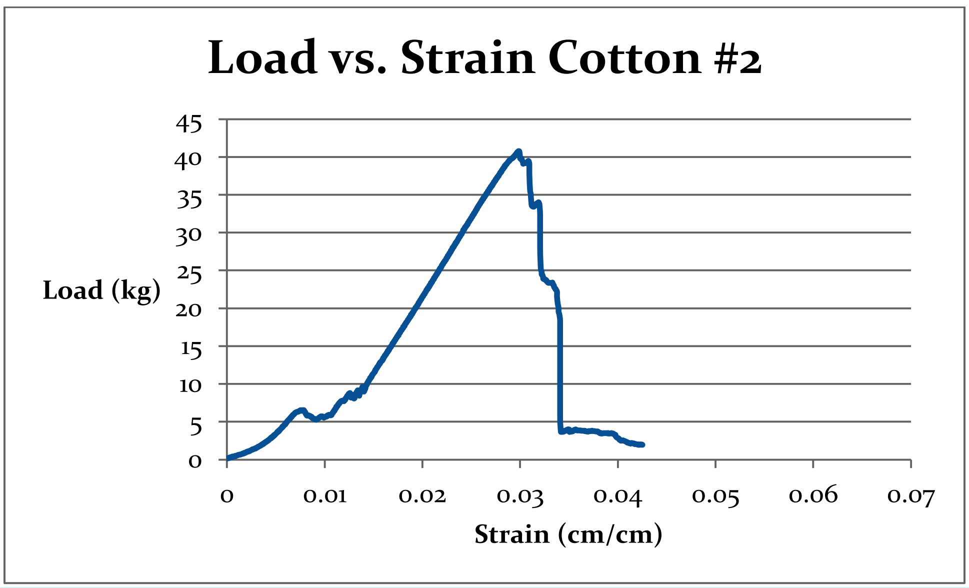


Figure 13 : The load vs. strain for the most representative sample of denim fabric.

FABRICATION

With the recommendation of the Head of the Design Studies Department, Professor Jennifer Angus, a student in the Department of Human Ecology, Sarah Vergin, was hired to fabricate the design.

COST ANALYSIS

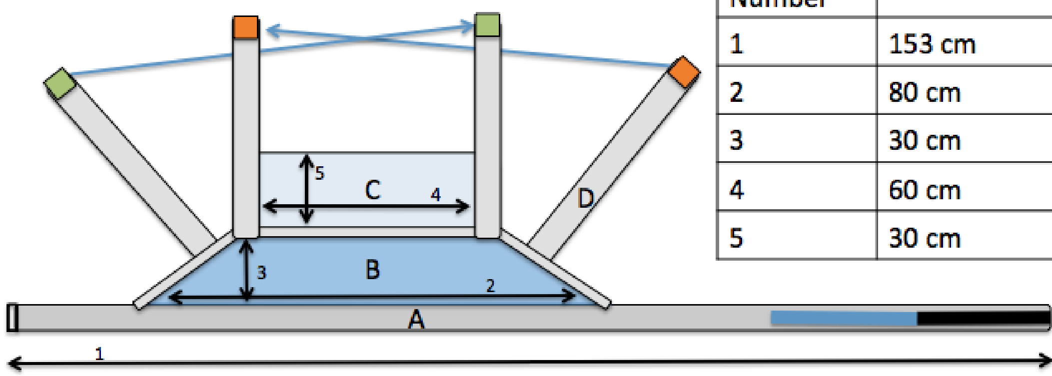
Early in the project, when the team anticipated using ratchets in the design, buckles and nylon straps were ordered using McMaster-Carr. These items were not included in the final design and were later returned. The next purchase made by the team included fabric, buckles, and gel padding for intended use in shoulder straps. The initial fabric purchase consisted of small 15.24 cm samples to be tested and qualitatively evaluated for use in the device. Once the team had decided which materials to include in the product, the team made purchases from both Jo-Ann Fabric and Hancock Fabrics. These purchases consisted of buckles, denim, Velcro, webbing, performance cloth, and upholstery thread. Later, the team decided to include larger straps for increased comfort. To accommodate the larger straps the team had to purchase larger buckles from Hancock fabrics. Also, the seamstress recommended her own constructed padding for the shoulder straps, so the small gel padding was no longer required. The smaller plastic buckles and gel padding were then returned. Thus, the total amount spent on materials for fabrication and testing was $100.62. The hired student from the Department of Human Ecology charged $250 for her services, bringing the total project budget to $350.62

Item	Store	Quantity	Price (Tax Included)
100% Cotton Fabric	Jo-Ann	6"	$1.60
1" White Polypro Belting	Jo-Ann	36"	$2.63
2" Black Polypro Belting	Jo-Ann	36"	$4.21
1" Black Polypro Belting	Jo-Ann	54"	$3.95
Performance Wear	Jo-Ann	76"	$29.70
White Denim	Jo-Ann	56"	$17.97
2" Velcro	Hancock	18"	$2.95
2" Velcro	Jo-Ann	12"	$4.22
Polyester Foam	Jo-Ann	48"	$6.14
2" Black Cotton Belting	Hancock	16'	$19.63
2" Black Parachute Buckle	Hancock	2	$6.31
Upholstery Thread	Hancock	1	$1.31
Fabrication	-	-	$250.00
Total			$350.62

Table 4: The expenses for the entire semester.

FINAL DESIGN

After determining the general idea and needs of the team's design, as well as completing design matrices for the materials and lifting mechanisms, the team concluded upon a final prototype design. The design, shown in Figure 11, includes a main belt attached to a support for below the hernia, hernia covering, and straps that go around each shoulder and cross along the back. Each aspect has an important function and the materials for them were considered carefully.



Line Number	Measurement
1	153 cm
2	80 cm
3	30 cm
4	60 cm
5	30 cm

Figure 14: Rendering of the final design, created by Cody Williams. This is and expanded view of the device with the belt laid flat and the straps unbuckled. A) The belt is secured by velcro. B) The hernia/pannus support- where the hernia sac and pannus will sit. C) Hernia cover- portion that covers the hernia, keeping it in place. D) The shoulder straps that provide the lifting support. The two straps cross in the back and attach in the front with buckles. The arrows show the crossing that is to take place.

Most portions of the design will be attached to the belt (Figure 14 A). The belt is made of two inch woven polyester. It must be able to distribute weight around the lower back and remain in place to ensure the functionality of the other components. Directly attached to the belt is the below hernia support (Figure 14 B). This support is the fabric that goes directly below the hernia or pannus. In the final design, the material used for this portion is denim that has padding and a breathable polyester lining on the inside that will be in contact with the wearer. The use of denim is to ensure that it doesn't stretch or deform, thus lessening the extent that the entire device supports the hernia sac. The hernia support portion is connected directly to both the suspenders and side straps, which provide lifting of the gut weight.

The shoulder straps (Figure 14 D) are needed to distribute the weight of the hernia/pannus over the entire upper body. Since the device should be able to support a pannus up to 45 kg (100 lbs), these straps will be the main source of support; its strength and integrity are crucial to the lifetime of the product. The straps are made of the same two-inch woven polyester as the belt.

This rigid fabric is needed for the suspenders because any elasticity will diminish the effectiveness of the support and could lead to excessive strain or failure. Cushions were added below the straps where the patient's shoulders would be for comfort while wearing the device. Each shoulder strap goes from the upper abdomen, around the back and to where the oblique is located on the opposite side. The primary role of having the straps connect to the side is to mimic the support of the oblique muscles, which are split due to the hernia. This creates a lifting support that not only lifts the hernia and/or pannus but also brings everything closer to the body.

Finally, an elastic and breathable polyester fabric was be used for the hernia coverage (Figure 14 C). This portion does not provide any lifting support, its primary function is to keep all of the hernia/ and pannus above the underneath support. There were also connecting portions added within the coverage portion. This consisted of one-inch woven polyester, the same material as the belt and straps. This created a skeleton aspect that allowed for all of the rigid, load bearing fabrics to be connected without compromising the elastic covering. It was also used to line the interior of all the rougher, rigid fabrics of the design. In the belt and hernia support portion, there was also padding added for added comfort.

The shoulder straps (Figure 14 D) are adjustable and connect in the chest region of the patient by two-inch plastic buckles. It was found that these buckles are able to withstand the necessary loads as well as provided adjustability and low invasiveness. The buckles are easily concealed under the patients clothing and are in a location that allows the best adjustability and detachment to take place.

In order to wear the support device, a specific set of instructions will be set to ensure safe and effective use. First, the belt is securely fastened slightly below the waist; it is then raised up into position underneath the hernia or pannus. From here, the shoulder straps may be put on, noting that they must cross along the back. Once the straps are on, they may be tightened as necessary. The current design allows for adjustability on both sides of each buckle. This will provide more support to the hernia and keep it in the correct spot.

FUTURE WORK

The team's clients would like to pursue a patent for this design, so the team will be contacting the Wisconsin Alumni Research Foundation in the near future. The team may continue to pursue this project once feedback is obtained from clinical tests.

In addition to patient feedback, the team believes that future research into synthetic materials would help increase the comfortability as well as breathability of the design. The current shoulder straps could be replaced with material that is as rigid but will be more breathable; the current Velcro on the support belt could be replaced with a softer material that is not as sharp.

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APPENDIX

Abdominal wall hernia and/or pannus support prosthetic

Product Design Specifications

Devon Moloney (Leader), Cody Williams (BSAC), Matt Jensen (Communicator), Jeff Wu (BWIG), Hannah Frank (Procurement)

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Function:

Morbidly obese patients as well as patients with abdominal hernias often have abdominal and back pain due to the effect of gravity on either the stomach or hernia sac. Current commercially available devices such as abdominal binders do not offer any lifting support for large abdominal hernia sacs, and only provide slight pressure on the hernia sac against the body. The goal of this project is to create a device that will help support hernia sacs and/or the pannus of morbidly obese patients both before and after surgery.

Client requirements:

- Lift the hernia sac/ pannus upward, providing 5 – 100 lb. (2 – 45 kg) support
- Durable for daily use
- Distributes weight evenly
- Washable, breathable material that doesn’t irritate skin
- Prototype that can be adapted to market
- Within budget: $1000 grant
- Aesthetically pleasing

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: Device must support hernia sac/ pannus through lifting force, distributing weight and alleviating pain. Should be durable and comfortable for daily use.

b. *Safety*: Device must be made such that it does not irritate sensitive skin or possibly puncture or harm the hernia sac/ pannus. Device should also distribute the weight evenly to avoid patient strain or discomfort.

c. *Accuracy and Reliability*: Device must remain securely fastened and provide continuous lifting support throughout daily use. Should also maintain constant, reliable support throughout life of service.

d. *Life in Service*: Device should remain functional for 6 – 12 months, the typical waiting period for corrective surgery. Device must be capable of being repeatedly washed without losing durability.

e. *Shelf Life*: Device must be comparable to current commercially available abdominal binders.

f. *Operating Environment*: The device should withstand everyday conditions experienced by the average person. Device will be worn close to body and must withstand all bodily secretions and temperature changes. Device must be able to support up to 100 lbs. throughout constant use.

g. *Ergonomics*: Device must distribute weight equally in a comfortable fashion and not irritate sensitive skin. Must not restrict motion of patient. Should be easily fastened and removable.

h. *Size*: The patient had a maximum ccircumference of 170 cm, and a circumference around the waist of 150 cm. To encompass shelf of the device is 80 cm wide and 30 cm tall. The fabric above the shelf intended to contain excess is 60 cm wide and 30 cm tall.

i. *Weight*: Device should not be cumbersome, and ideally minimal is best.

j. *Materials*: Materials should be breathable, washable, durable, and non-irritating.

k. *Aesthetics, Appearance, and Finish*: Should be inconspicuous, as it will be worn underneath everyday clothing.

2. Production Characteristics

a. *Quantity*: Only one functional prototype is required. Design should be conscious of possible mass production and altercations for different body types.

b. *Target Product Cost*: Design should be cost conscious.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is not required.

b. *Customer*: Design should be adaptable and comfortable for various body types.

c. *Patient-related concerns*: Design needs to provide lifting support.

d. *Competition*: Current devices do not provide adequate lifting support and lack sizing abilities. ACE wraps, maternity braces, abdominal binders.