Abdominal Hernia and Pannus Support Device

October 24, 2012

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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, which are not adjustable to larger bodies and are ineffective in supporting large amounts of weight. Our clients, Dr. Sarah Oltmann and Dr. Jacob Greenberg, desire a supportive device that will provide their patients with an upward lifting support 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 rigid fabric for the waist belt, an elastic fabric for the abdominal covering, and low-profile ratchet straps for vertical supports would be most effective. A design will be fabricated, tested, presented to the clients and some of their patients, then modified based on their feedback, and hopefully distributed to multiple patients struggling with similar medical conditions.

TABLE OF CONTENTS

ABSTRACT 1

INTRODUCTION 3

BACKGROUND AND CURRENT SOLUTIONS 4

PROBLEM STATEMENT AND DESIGN SPECIFICATIONS 5

DESIGN COMPONENTS 5

MATERIALS 6

RUBBER BANDS 6

ELASTIC MATERIAL 7

RIGID MATERIAL 7

FASTENING MECHANISMS 8

PROPOSED DESIGN 10

CONCLUSION 12

FUTURE WORK 12

BIBLIOGRAPHY 13

APPENDIX 14

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 waist line [1].

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. 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). Without these essential oblique and abdominal muscles offering full support, the digestive and other abdominal organs protrude past the waist line in a hernia sac which pulls down with gravity [4]. The other consumer group, morbidly obese patients, must also deal with an abdominal protrusion or heavy pannus, which is essentially excess fat extending over the waist line [2]. Both of these consumer groups have large tissue masses in the abdominal region and lack the muscular strength to support large amounts of weight and to counteract the downward pull of gravity.

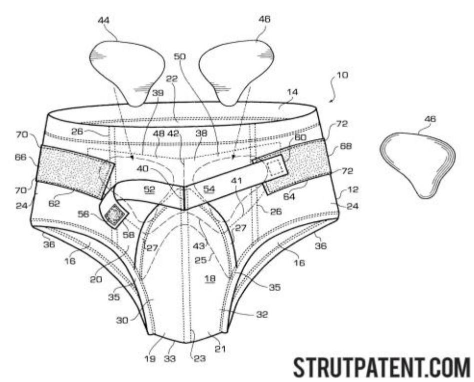
Because both consumer groups do not have the necessary muscle support to naturally lift the large amounts of weight concentrated in their abdominal region, both groups acquire serious health problems. Muscle strain, lack of blood circulation, back pain, and poor digestion are just a few of the health conditions that result from the pulling force of gravity on the hernia or pannus [2]. 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 [3].

Background and Current Solutions

Figure 2: Maternity brace currently used by hernia/obese patients to support excess weight [5].

Figure 3: Abdominal binder currently used by hernia/obese patients to support excess weight [6].

Our client, Dr. Greenberg, 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 2, 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 3, 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 crushing the sensitive skin of the hernia even further [4].



Figures 4 & 5: Example patent sketches for current design prototypes of pelvic hernia support devices [7].

Patents for hernia support devices do currently exist but we sound them ineffective for our prospective consumer groups due to their focus on pelvic hernias rather than abdominal hernias (Figures 4 & 5). These current designs demonstrate a tightening force, which wraps around the abdomen and focuses on restraining smaller pelvic hernias; no lifting force is present to provide the support our clients need to aid their patients with extremely large abdominal hernias [4]. We determined that these current solutions are ineffective in achieving our clients' design specifications because they do not adjust to the large body types our consumers have, they lack an essential upward lifting force, they stretch or deform over time, and they irritate the sensitive skin of the hernia sac.

Problem Statement and Design Specifications

Our goal is to create a prosthetic 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 often wait between 6-12 months before being able to undergo corrective surgery and for some, surgery is not 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, so the device must be durable. In order to ensure proper sanitary needs, the device must also be easily disassembled for washing and made with washable components. A breathable material must be used to provide comfortability since, on average, patients will be wearing this device for 10-14 hours a day. The material used must also not irritate the skin tissue covering the hernia sac, as this can cause damage to the internal organs of the patient.

Design Components

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

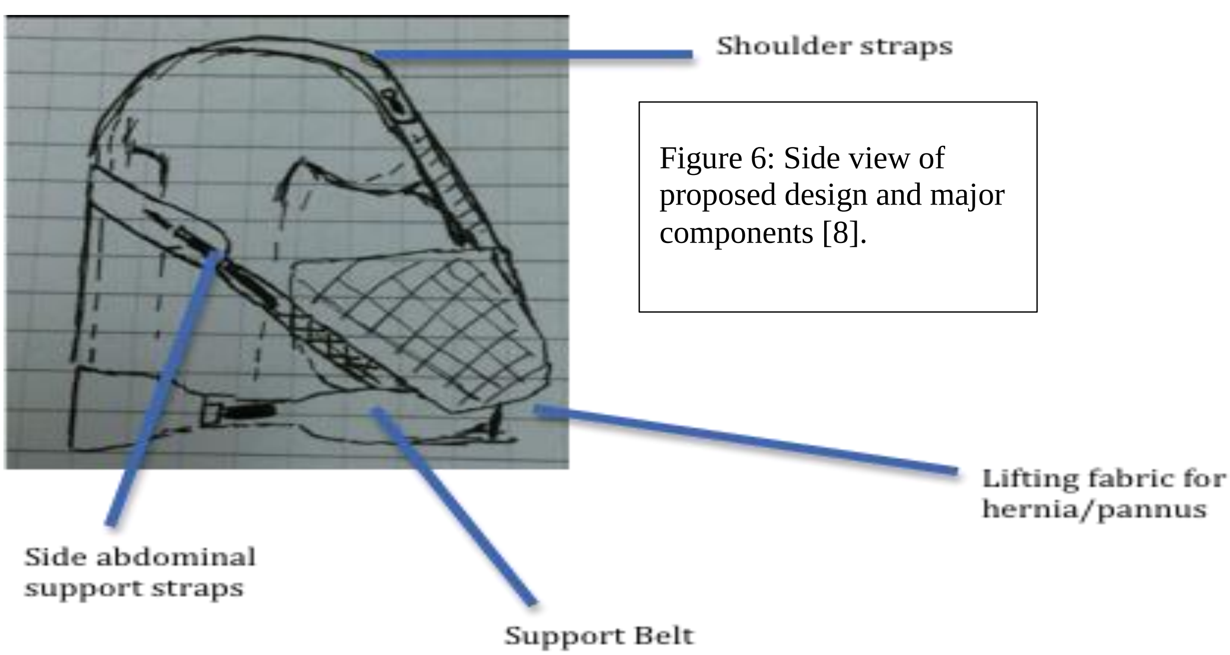


Figure 6: Side view of proposed design and major components [8].

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 6). The abdominal support straps are necessary to provide additional lifting support, and also to imitate oblique abdominal muscles because with a tear in the central abdominal muscles, the oblique muscles are rendered useless.

Materials

For this project the choice of materials will be critical to our 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 our 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. 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 7). 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.

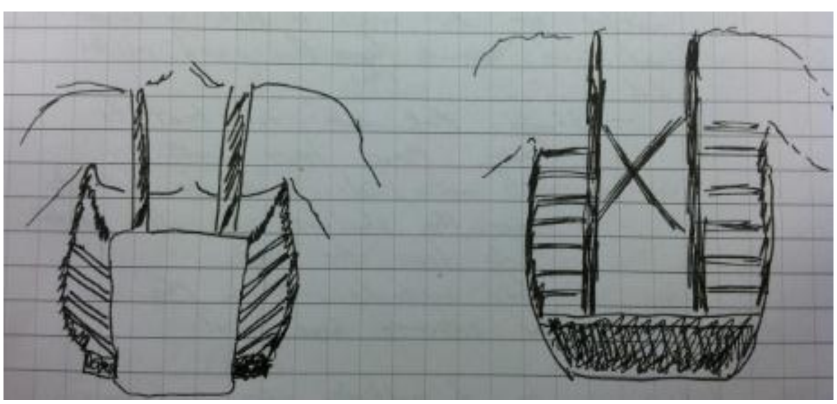


Figure 7: Front and back sketches of brainstormed design using rubber bands as material for side and shoulder supports [9].

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 our 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.

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. Currently, 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 [10].

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.

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. The possibilities for these devices are assessed below.

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.

Fastening Mechanisms

The fastening component of the design is what provides the lifting force to the fabric supporting the hernia or pannus. It is imperative that the component give 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 8). 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 9). Finally, the team discovered an interesting new design (Figure 10). 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 shoe laces are attached on a small circular base.

Evaluation of Fastening Mechanisms

Criteria	Buckle	Ratchet	Winding
Effectiveness (30)	15	28	22
Safety (20)	10	17	14
Concealability (15)	13	8	13
Maintenance (15)	13	13	4
Ease of Use (15)	13	12	12
Cost Effectiveness (5)	4	5	2
Total (100)	68	83	67

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. The buckle being small, plastic, and brittle scored lowest in this category. The winding mechanism scored the next highest because it seemed as if could support more weight since it has bigger components. Finally, the ratchet strap scored the highest in this category as a result of its sturdiness. Ratchets are composed of metal and designed to support larger loads than the other plastic components.

The next measure 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. 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 winding mechanism and the buckle (Table 2).

Concealability is the criterion that the team used to describe the ability of a component to remain discreet and out of sight. The buckle and winding mechanism received equal ratings because they are both small and plastic. If placed on the device, these two components would be markedly noticeable. The ratchet, on the other hand, is a rather large metal piece that would be hard to hide. Because of this the ratchet alternative scored the lowest for concealability.

Maintenance was defined as the ability of the device to be both removed and replaced. 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 insert one end into the other.

Cost effectiveness stems from not only the expense of each component, but also how easy each is to acquire. The ratchet scored slightly higher because these can easily be found for relatively low prices in hardware stores. Similarly, the buckle 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 8: A picture of the insert buckle [11].

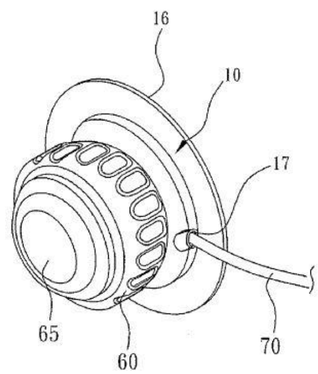


Figure 9: A diagram of the winding mechanism [12].

Figure 10: A picture of a ratchet and strap (chosen fastening mechanism) [13].

Proposed Design

After determining the general idea and needs of our design as well as completing design matrices for the materials and lifting mechanisms, we concluded upon our prototype design. The design, shown in Figure 11, includes a main belt attached to a support for below the hernia,

hernia covering, suspenders and side straps. Each aspect has an important function and the materials for them were considered carefully.

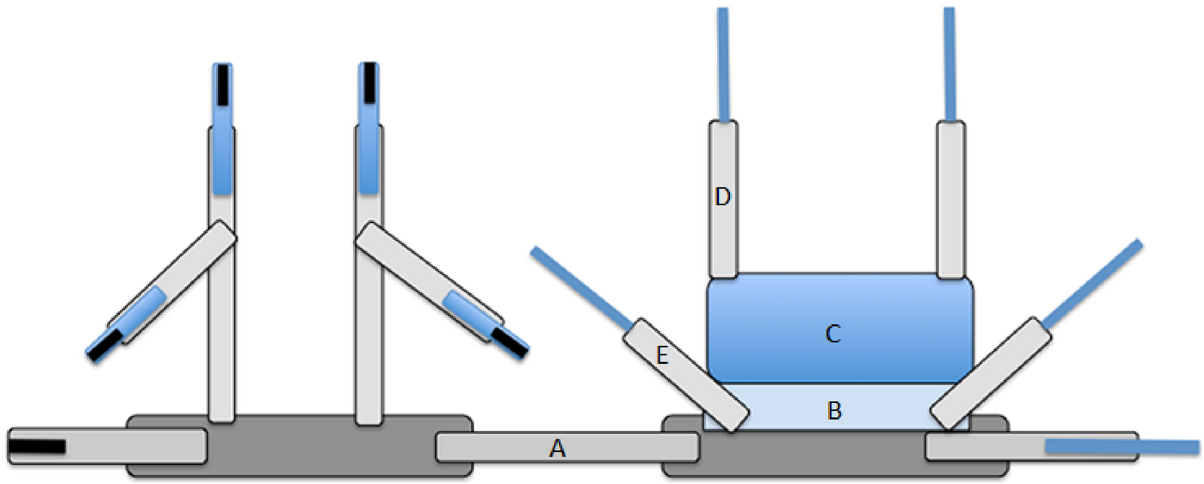


Figure 11 Rendering of the proposed design, created by Cody Williams. Right side is the front view, while the left is the back view. A) Side portion of the belt – belt extends from front and back and will fasten on a side. B) Below hernia/pannus support - the hernia sac or pannus will rest on this. C) Hernia cover - portion that covers the hernia, keeping it in place. D) Suspenders – used to distribute weight over the shoulders and upper body. E) Side support – imitates the oblique muscles, providing additional support and keeping the hernia in the gut region. [14].

Most portions of the design will be attached to the belt (Figure 11 A). The belt will be made out of a rigid, comfortable fabric. 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 will be the below hernia support (Figure 11 B). This support is the fabric that goes directly below the hernia or pannus. It must be made from a rigid fabric to ensure that it doesn't stretch or deform, thus lessening the extent that the entire device supports the hernia sac. The below hernia support is connected directly to both the suspenders and side straps, which provide lifting of the gut weight.

The suspenders (Figure 11 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) and the suspenders will be the main source of support, their strength and integrity are crucial to the lifetime of the product. A rigid fabric will be used for the suspenders as elasticity will diminish the effectiveness of the support and could lead to excessive strain or failure. Cushions may be added below the straps for patient comfort while wearing the device. The side straps (Figure 11 E) will also be made with a rigid fabric in order to ensure maximum support. The primary role of the side straps is to mimic the support of the oblique muscles, which are split due to the hernia. They will lift up and around the body and keep the hernia sac in place, where the intestines normally would be located.

Finally, an elastic fabric would be used for the hernia coverage (Figure 11 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. It will also provide better breathability and movement for the patient than using a rigid fabric.

All connections of the hernia/pannus support device will be made with the ratchets described in lifting mechanisms. These will provide the best lifting, security, and ease of use for the patient. Tightening the ratchet will provide lift for the hernia, and loosening the ratchet will lessen the support and allow the patient to remove the device. The ratchet will lock in place, guaranteeing that there is constant support and no risk of the device coming undone and the hernia falling. These benefits do come with the issue of bulkiness and possible weight, but we will find a lightweight, low profile solution that meets our support needs.

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 front and back are attached with the shoulder straps. Lifting up the front bib will also lift the hernia. Then fastening the ratchets on each shoulder will keep the stomach lifted. Following the shoulders, the side straps will be secured. This will provide more support to the hernia and keep it in the correct spot. Further tightening of the ratchets will provide more support, allowing for adjustments to the optimal level.

Conclusion

Overall, we feel that this design will meet all the requirements we have in terms of support. It provides the most lift we can reasonably give a hernia, both over the shoulder and around the sides. The design also optimizes distribution of weight over the entire upper body. Previous solutions leave most of the weight around the lower back, making it uncomfortable for patients even if they are able to use the devices. This will make it much more practical for users with very large (45 kg or greater) hernias to use the device without adding excessive stress to their torso.

We will decide upon comfortable fabrics to not irritate the patient or damage the hernia itself. The design is also intended to be user friendly, with minimal work needed to attach the ratchets or alter the amount of support it gives. These two aspects are needed to encourage patient use on a daily basis. Especially since the support will increase their health and safety until surgery is an option in six months to a year. With the support this device will offer the hernia or pannus and the user friendliness, this should be an ideal design solution and should be ready to begin prototype fabrication in the near future.

Future Work

We are waiting for Dr. Greenberg to send us measurements of one of his patients. Once we receive the measurements, we can start to gather materials for our proposed design. We will need to find certain elastic and rigid fabrics that will hold up to our required load of 45 kg (100 pounds); low-profile ratchets will also need to be acquired. The prototype can then be fabricated once the materials are obtained.

When our prototype is completed, we will put it under testing for safety and durability. When we are assured it is safe for use, we will deliver it to Dr. Greenberg and Dr. Oltmann for approval. If they approve, we will have them deliver it to their patient and have the patient review our device. If they do not approve, we will take it back into the lab for revisions. Once their patient receives, tests, and reviews our device, we will bring it back to the lab and modify the product to the patient's requests, if any. If the patient and client are happy with the device at this time, we can finalize the product and look for possible ways to bring it into the market for production and patent it.

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Appendix

Abdominal Hernia/Pannus Support Device: Product Design Specifications

October 24, 2012

Clients: Dr. Sarah Oltmann and Dr. Jacob Greenberg of the UW Hospital

Team: Hannah Frank, Devon Moloney, Matt Jensen, Jeff Wu, Cody Williams

Advisor: Sarah Gong

Problem Statement

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 support
• Durable for daily use
• Distributes weight evenly
• Washable, lightweight, breathable material that doesn't irritate skin
• Prototype that can be adapted to market, adjustable to large body types
• 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 45 kg (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*: Must encompass hernia sac while binding around an array of torso sizes and body types.

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*: At least 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.