Retractor for Breast Surgery

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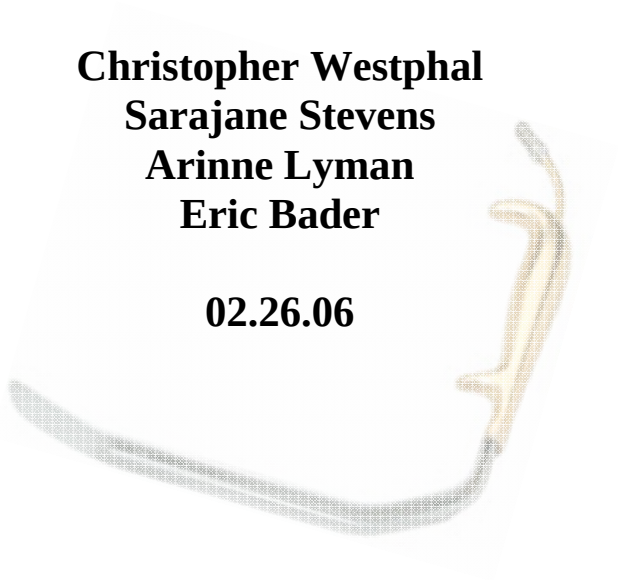

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Abstract

Current breast augmentation surgeries require a surgeon to constantly pull on the breast tissue which results in surgeon fatigue. A device is proposed that will be self-standing, allowing the retractor to support the tissue instead of the surgeon in addition to evenly distributing light and suction throughout the entire cavity. The device must support a tissue loading of 60lbs with a safety factor of two. Three designs have been proposed and through the use of a design matrix, one has been chosen that fits all the required criteria. The Raisin' combines a familiar motion of a bar clamp, specifically the IRWIN® Quick-Grip®, which allows a simple squeeze to actuate a vertical movement. The rest of the semester will consist of creating the prototype and then testing for sufficient force, light, and suction requirements. Modifications of the proposed design will be made as necessary.

Background Information

Project Motivation

In the United States, an estimated 335,000 breast augmentation procedures were performed in 2004 [5]. Breast retractors are commonly used devices in these procedures to aid the surgeon in holding up the breast tissue, while the surgeon uses an electrocautery tool to cut muscle and other tissues to form a pocket. During this process, smoke is formed inside the breast cavity, thus retractors have built-in suction ports to remove the smoke. In addition, the cavity is quite dark; proper lighting of the area is essential for precise completion of the pocket formation. Today, breast retractors require

the surgeon to hold up the breast tissue while simultaneously forming the breast pocket. A constant upward force of about 30lbs is required of the surgeon. This can strain the surgeon's arm since the procedure takes around 45 minutes for both breasts. Furthermore, today's breast retractors contain light and suction sources, but our client states that they are not sufficient for his procedure. Currently, the suction source is confined to one small area of the cavity reducing visibility. Similarly, the light source (usually fiber optics, light reflective polymers, or LEDs) only emits light in one direction. Optimally, our client would like a retractor that contains many ports for suction and light so these sources are more efficient at illuminating and removing smoke from the entire cavity. In conclusion, our goal for this project is to develop a surgical retractor for breast surgery that will minimize the force required by the surgeon, while simultaneously providing a powerful light source and multiple suction ports.

Procedure

The breast augmentation surgery is one of the most common cosmetic surgeries performed in the United States. It is a relatively simple surgery, lasting from 30 minutes to just over an hour in length for both breasts. The surgical incision can be made in one of four places: axillary (armpit), inframammary (below breast), transumbilical (through the naval) or around the areola (nipple) [4]. The most common surgical approach is performed using an inframammary incision. The incisions range in length, but most are about 3-4 cm long, just large enough to accommodate the deflated saline implant and surgical instruments. The surgeon initially makes a pre-operative mark along the inframammary crease to serve as a reference point and begins the incision along this

same line. A small retractor initially holds open the incision to expose the fat and glands under the breast as seen in Figure 1.

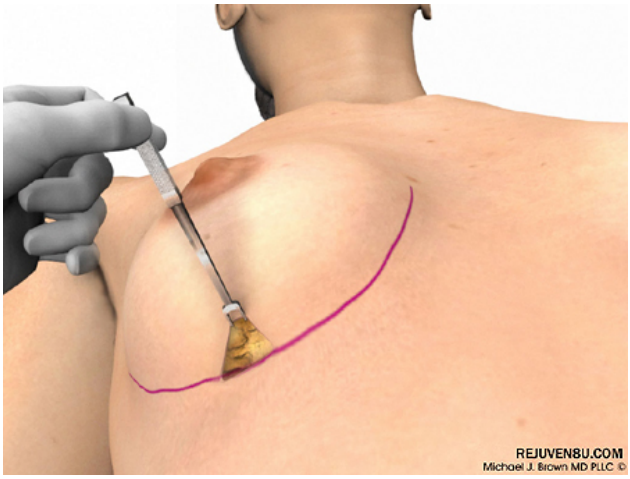

Figure 1: *Small Incision*. A little retractor is initially used to open up the incision in order to start the operation.

The tissue is cauterized with an electrocautery instrument to create the breast pocket, while a larger retractor is placed in the subcutaneous tissue to expose the pectoralis muscle. The breast pocket is usually created underneath the pectoralis muscle, and the electrocautery instrument finishes the pocket to the required size. The deflated breast implant is rolled up and placed into the incision under the muscle as seen in Figure 2. Silicone implants are first stretched and fed slowly through the incision.

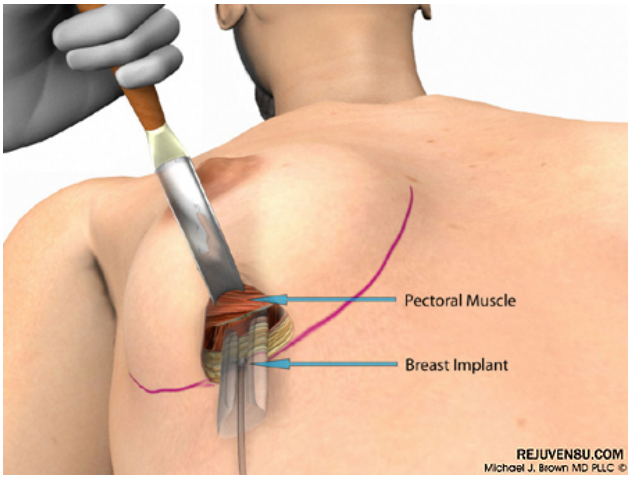

Figure 2: *Implant Insertion*. The implant is rolled up and slipped into the breast pocket while the retractor holds up the tissue.

After placement, saline fills the implant to the desired size through a tube connected to the top of the implant. Silicone implants come pre-filled and do not require

this step. After placement, the tube is removed and symmetry of both breasts is confirmed. The incisions are then closed using dissolvable sutures spanning three different tissue layers: subcutaneous fat, dermis, and epidermis. Minimal scarring is observed with the inframammary incision.

Materials

At the initial client meeting, the client suggested medical grade stainless steel and titanium since these metals are already used in surgical settings. This decision means that the device will need to survive the sterilization process that medical tools typically endure. The process, called autoclaving, subjects the materials to temperatures around 121 ºC.

The main type of stainless steel used in medical applications is stainless steel grade 420. One of the distinguishing characteristics of this material is that it must contain between 12% and 14% chromium content as it helps fight against corrosion of the metal. The typical tempering temperatures for grade 420 range from 204ºC to 650ºC. The different tempering ranges give the metal different inherent properties related to tensile strength (between 655-1600MPa). The recommended range of operating temperature is not to exceed the temperature at which the metal was tempered. When autoclaved the characteristics of the metal will be unchanged. The density is approximately 7.750g/cm^3 - an important property that will determine the weight of our final product. The elastic modulus, a measure of the force required to elongate the material, is 200GPa and is sufficient for the requirements of the device [2].

A second material the client suggested was a titanium composite. One of the main composites of titanium used in medical applications is designated as Ti6Al4V

Grade 5. Its composition includes traces of C, Fe, N_2, O_2, Al, and V. This is the main titanium alloy used in almost every application - over 70% of titanium alloys are derived from this alloy. Its density is 4.42g/cm^3, which is lighter than the stainless steel described and could be significant depending on how much material is needed. The melting range for this metal is 1649 ºC, which is more than sufficient for our needs. Its tensile strength is 897MPa and its elastic modulus is 114GPa. A few different grades (specifically 24, 25, and 29) offer greater resistance to corrosion by adding small amounts of palladium, ruthenium, or nickel. These grades may need to be considered to ensure the material does not pit after repeated use [2].

Current Device

There are a number of breast retractor devices currently on the market for the breast augmentation procedure. One of the newer models developed by Accurate Surgical and Scientific Instruments Corporation (ASSI®) is a C-shaped retractor as seen in Figure 3. This retractor has an 8.5cm outer diameter and a 5.0cm inner diameter with a blade width of 1.75cm to fit inside a small incision. Usually made out of titanium, these retractors cost $868.00 including a fiber optic light source and a suctioning device built into the handle. They are $770.00 with just a fiber optic light source and $306.00 without either fiber optics or suction. It measures 14.0cm tall with a 9.0cm handle grip for the surgeon.

Figure 3: *The Stanger™ C.* This retractor from ASSI® includes a light and suction source underneath the blade.

Figure 4: *Angle Retractor*. This retractor only has a fiber optic which located beneath the blade.

ASSI® also makes L-shaped Angle retractors which are more common (Figure 4). The retractor itself is 15.0cm in total length with a 12.0cm handle. These also can come with a light source and suctioning device located in a sheath at the bottom of the retractor. They cost $660.00 with an endoscopic scope sheath and $315.00 without it.

Sheffmed also has a breast retractor designed to hold open deep surgical fields (Figure 5). It provides constant stability with its three-joint mechanical arm to mimic the shoulder, elbow, and wrist of the surgeon. It contains a locking mechanism to hold the retractor in place and has a built-in fiber optic light. This retractor is used more in mastectomies and breast reconstructions than in the breast augmentation surgery.

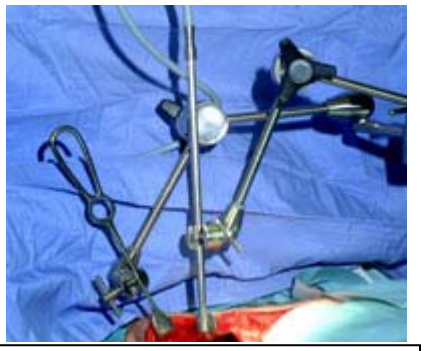

Figure 5: *Mechanical Arm*. Using these elbow-like joints, deep surgical fields can be held open.

Figure 6: *Neon Retractor*. This retractor is single-use and utilizes a light reflective polymer for light distribution.

Sheffmed has created an L-shaped breast retractor incorporating light reflective polymers along the length of the blade to distribute light in all directions as shown in Figure 6. These polymers are both strong and lightweight and are disposable.

Design Criteria

The primary design constraints as defined by our client include:

- Self-standing
- Contain well distributed light and suction sources
- Fit through a 3-4cm transverse incision
- Stretch the breast cavity 10.5cm with increments of 0.5-1.0cm
- Sustain a maximum force of 60lb (given a safety factor of 2)
- Withstand the high temperatures of an autoclave (121°C)

Due to the large amount of force the pectoralis muscle can exert on the device, the retractor must be self-standing in such a way that it does not pierce the thin muscle between the ribs, which could result in puncturing the lung. The standing force of the retractor cannot exceed that which would cause the ribs to break. The retractor must not obstruct the operating field of view, which is through the incision. A "window" of preferred dimensions of 3.0cm by 2.5cm is required for the placement of instruments such as the electrocautery tool, tissue suction, and other retractors.

The retractor should have a life-in-service time of five years; however, due to the advancement in technology, the light source may become outdated before the function of the retractor is compromised.

Alternate Designs

The Jack

The Jack is a simple device constructed of solid metal parts (Figure 7). The bottom blade attaches to two side supports that have notches every 1.0cm. The upper blade is solid metal with two rails that align inside the notches. A stop bar prevents the surgeon from completely removing the upper blade from the grooves. In operation, this

device begins with the two blades together. Upon inserting the device through the incision into the cavity, the surgeon can raise the upper blade up to the next notch. This is achieved by lining up the un-railed portion of the top blade with the vertical supports. The surgeon lifts up until the rails line up with the notches and inserts the rails into the notches by pushing forward. If another increase in height is desired, the surgeon will pull back on the top bar, lift the blade up to the next desired level, and align the rails in the notches.

This design is uncomplicated because there are smooth increments and the design lacks any threaded materials, springs, or gears. This simplifies the autoclaving process of the device after the breast augmentation procedure is finished. The manufacturing process of this device is also relatively straightforward as the design contains many straight edges. The straight blades of this design make it suitable for various procedures of breast augmentation. Conversely, the shape of the blade compromises the stability of the device due to the decreased surface area when standing

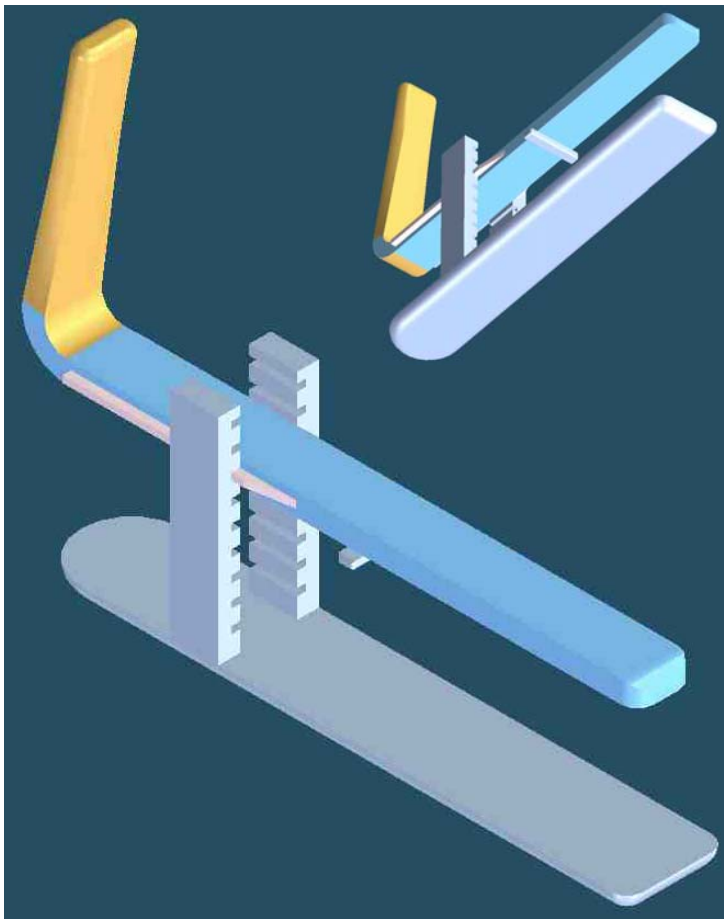

Figure 7: *The Jack*. With rails on each side of the bar, the top bar can slide along the notches at different heights.

alone in the cavity. Additionally, there is no pivot point on this device which would allow an increase the internal height of the cavity without stretching the skin at the incision beyond its yield point. Finally, the two supports that separate the top blade from the bottom blade may interfere with the surgeon's field of view and working space.

The Spreader

The Spreader does not contain much metal, giving it the potential of being slightly more cost effective. As seen in Figure 8, when the knob is rotated, it pushes against a plate that is connected to two small legs. As the hinge advances forward, the angle between the two legs becomes greater, resulting in an increase of vertical excursion at the distal end of the device.

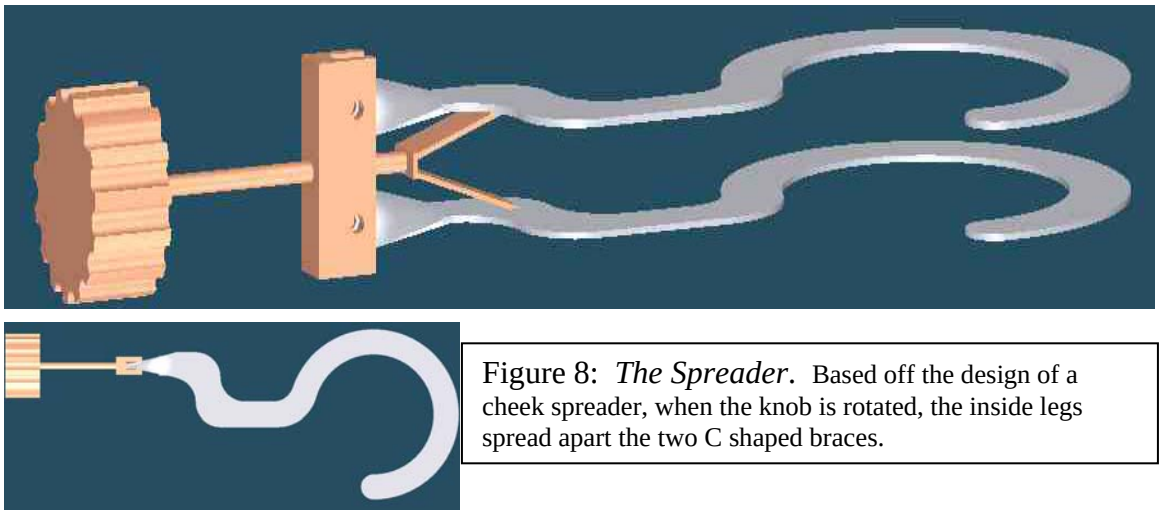

Figure 8: *The Spreader*. Based off the design of a cheek spreader, when the knob is rotated, the inside legs spread apart the two C shaped braces.

The Spreader has a doglegged design near the pivot point to reduce the amount of obstruction the device will make once inside the pocket. The C-shape allows the upward force to be dissipated along the total area of the device. Using an appropriate thread per cm ratio, an acme screw could be used as the threaded shaft in order to obtain the desired amount of vertical increment for one revolution of the knob.

The disadvantage to this design is the potential that the knob could press against the patient's ribs and cause trauma to the surrounding tissue. The knob can be difficult to rotate as it is near the patient's body, therefore reducing the amount of torque that can be applied.

The Raisin'

The Raisin' device consists of two C-shaped retractor blades: one to rest on the chest wall during the procedure and the other to rise inside the breast pocket and stretch the tissue. The retractor is raised using a ratchet mechanism similar to that of woodworking clamps (Figure 9). By squeezing the handle, the retractor advances in a single click of 0.5cm. It will be a smooth and near-continuous adjustment for the surgeon. Also located on the handle is a quick release trigger to bring the retractor back into contact with its base for removal.

One of the advantages of this design is that it has a wide, circular base to provide support when standing alone. It can be easily adjusted by squeezing the handle, a motion both simple and familiar to the surgeon. Additionally, since only the bar of the mechanism will be visible when the retractor is raised, the operating field of view will be minimally obstructed.

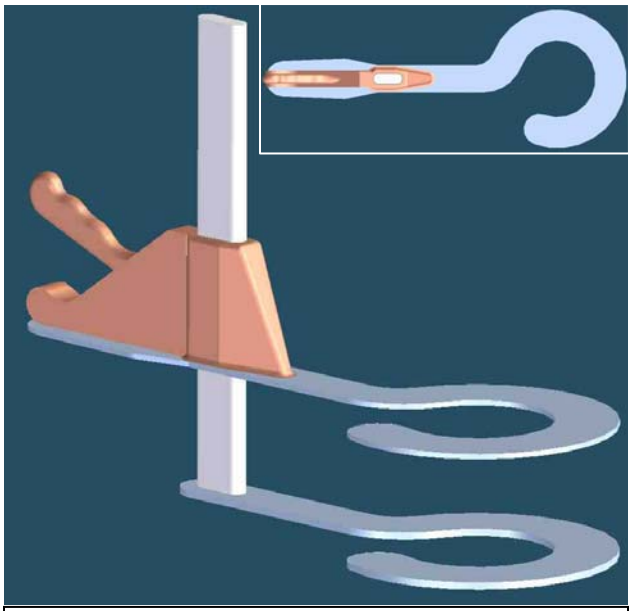

Figure 9: *The Raisin'*. Like a bar clamp, when the handle is depressed, the top "C" brace is raised up.

One disadvantage to the Raisin' design is the lack of a pivot point at the incision to allow for greater displacement inside the breast pocket. Hopefully, with a little more research, this can be resolved. Another disadvantage would be the bulkiness of the handle outside of the incision. Lastly, if the mechanism cannot be fully covered, the parts may be difficult to autoclave.

Design Matrix

A design matrix was set up to give certain criteria a higher weight than others. Our client was mainly concerned with four main areas. These areas received a rating out of 15 and included the ability to be self-standing, provide a clear field of view, allowing ease of use, and feasibility of manufacturing. The remaining criteria were less important to the doctors, thus the ratings were out of ten. The cost of the project was based on the amount of metal that would be required for each design.

The first design, The Jack, received the lowest rating with a total score of 48 points. Since this design is simple, involving only a few moving parts, it received the highest scores in the ease of use and manufacturing categories. The main disadvantage of this design is that the field of view is compromised. Most of the mechanism exists outside of the incision and limits the viewing area that the doctor requires.

The second design, The Spreader, received a total of 61 points. This design received high ratings in its ability to be self-standing and capable of pivoting. The self-standing score is also due to the wide, stable C-shaped base. The pivoting mechanism is a major advantage to this design because it provides maximum pocket formation with minimal stretching of the incision. The Spreader received a poor rating for force because the doglegged mechanism may not support 60lbs.

Our last design called The Raisin' received the highest rating with a total score of 62 out of a possible 100. The highest scores came from the most significant areas of self-standing and ease of use, each with a score of 14. This score was assigned for self-standing because of the wide C-shaped base that will minimize the possibility of instability. The ease of use also received a high score since it works by simply squeezing the handle which actuates the ratchet mechanism. The zero rating for pivoting is the major flaw in this design because it is currently incapable of pivoting at the point of incision. This is important so that the breast pocket is maximized without any further increase in the incision height.

From these three designs, slight modifications to The Raisin' will be the optimal design choice for the team to pursue this semester.

Criteria	Raisin'	Spreader	Jack
Self-Standing [15]	14	14	9
Pivot [10]	0	8	5
Clear Field of View [15]	11	13	2
Force [10]	8	3	9
Ease of Use [15]	14	10	11
Cost [10]	6	9	7
Safety [10]	9	4	5
Manufacturing [15]	8	10	13
Total [100]	**62**	**61**	**48**

Future Work

The rest of the semester will entail determining the best method of construction for our final design choice. Depending on the number of components involved, the device may be completely constructed by the design team, or parts may be farmed out to other companies to produce. The components will be put together to create the first prototype, after which testing will begin. The force limitation that has been set is 60lbs with a safety factor of two. The device will be tested to ensure that it will safely support the tissues in the breast area throughout the entire procedure. In addition, the light and suction distribution will be tested subjectively with the client to make certain that it is sufficient for their needs. If our design fails in any one of these areas, the team will return to the original design to make modifications where needed.

Ethical and Intellectual Property Considerations

Our device enters the human patient and is in contact with exposed tissue. For this reason, it is important that we design the device to be autoclaved after each surgery. We would also need to make sure that it would not be abused for applications other than the original intention.

There are many current devices on the market made by ASSI and Sheffmed. Our device should not infringe on any patents and our design should be unique and distinct from the current retractors produced by ASSI and Sheffmed or any other competitors that may be currently unknown.

References/Works Consulted

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Appendix (PDS)

Breast Retractor

(03.02.06)

Team Members: Christopher Westphal, Sarajane Stevens, Arinne Lyman, and Eric Bader
Advisor: Professor William Murphy
Clients: Justin Piasecki, M.D.
Karol Gutowski M.D.

Function: The goal of this project is to develop a breast retractor that will allow doctors to use both of their hands during surgery. Currently, breast retractors are C or L shaped. The breast retractor allows the surgery to be done through an incision of only about 3-4cm which only produces a small scar. Our client would like us to create a breast retractor that is self-standing, provides a constant upward force, sufficient light distribution, and a suction source into the breast cavity. The light allows the doctor to see where he/she is cutting away tissue and the suction is to remove smoke produced from the electrocautery tool. The retractor's blade should be able to be raised up so that it stays in a free-standing set position. The total traveling height will increase by increments of 0.5-1.0cm to a total height of 10.5cm. The blade should be blunt as not to slice through the rib muscle and not break any ribs when being ratcheted.

Client Requirements:

The retractor must:

- ★ Be self-standing
- ★ Be autoclavable
- ★ Contain multiple light sources
- ★ Contain multiple suction ports
- ★ Be stretched to a height of 10.5cm in 0.5-1.0cm increments
- ★ Work for an inframammary operation
- ★ Not obstruct the surgical field of view
- ★ Be cost effective
- ★ Be simple to manufacture

Design Requirements:

1. Physical and Operational Characteristics

A. *Performance Requirements* – The retractor should be self-standing but have a large surface area to prevent breaking rib bones and puncturing muscles. It must contain a light source in which light is spread around the entire cavity and multiple suction ports that are not too convoluted. The retractor should be able to be raised to 10.5cm with 0.5-1.0cm step size.

B. *Safety* – Using an electrocautery tool next to a metal retractor could cause undesired burning of tissue. The force of the skin acting on the retractor should be spread across a wide base in order to prevent breaking rib bones or puncturing through muscles. The retractor blade should have smooth edges and be insulated in a way that prevents accidental grounding of the electrocautery tool resulting in the shocking of the patient and doctor. This insulation should be disposable or autoclavable. Sterilization of the device is necessary in order to keep the operating site free of infection.

C. *Accuracy and Reliability* – The ratcheting mechanism must be precise within a range of 5-10%. The lights should always work and the majority of suction ports remain clear throughout each procedure.

D. *Life in Service* – The retractor should have a lifetime of up to 5 years. The light source may become out of date before the function of the retractor is compromised.

E. *Shelf Life* – The shelf life of the retractor should be 5-10 years.

F. *Operating Environment* – The retractor will be stored and operated at room temperature (~20°C). While in operation the environment will be sterile, also requiring the retractor to be sterile. Retractor must withstand autoclave temperatures of 121°C.

G. *Ergonomics* – The design of this device is to eliminate the doctor from holding onto the device. The handle should be modeled like others currently on the market.

H. *Size* – A handheld device that has a blade that can slide into a transverse incision of 3-4cm and can be stretched 2-3cm superior to the chest wall. Current retractors can be14cm tall with a 9cm handle grip.

I. *Weight* – The total weight of the retractor should be less than 2kg, but of course the goal is to be as light as possible.

J. *Materials* – The retractor should be made of a non-porous material. Medical grade plastic, titanium, and stainless steel are possibilities. It should also be autoclavable.

K. *Aesthetics, Appearance, and Finish* – A shiny handle that is of different material than the blade (i.e. brass) which will complement the dull steel blade. The blade should not be shiny in order to reduce glare from the light source.

2. Production Characteristics:

A. *Quantity* – Only one prototype is requested at this time.

B. *Target Product Cost* – The cost should be kept to a minimum, but a budget of $200 is provided by the client.

3. Miscellaneous:

A. *Standards and Specifications* – The only standard at this time is requiring the blade to be constructed out of surgical grade titanium or stainless steel. The device should not cause additional harm outside of its intended use.

B. *Customer* – The client would prefer that the handle on the retractor that activates the jacking mechanism be like a brake handle on a bike. This will allow for an easy motion for the doctor to perform during surgery.

C. *Patient-related Concerns* – The retractor will need to be autoclaved between uses in patients.

D. *Competition* – ASSI® Gram and Sheffmed are companies that make current devices which are very similar to what our client is requesting.