Retractor for Breast Surgery

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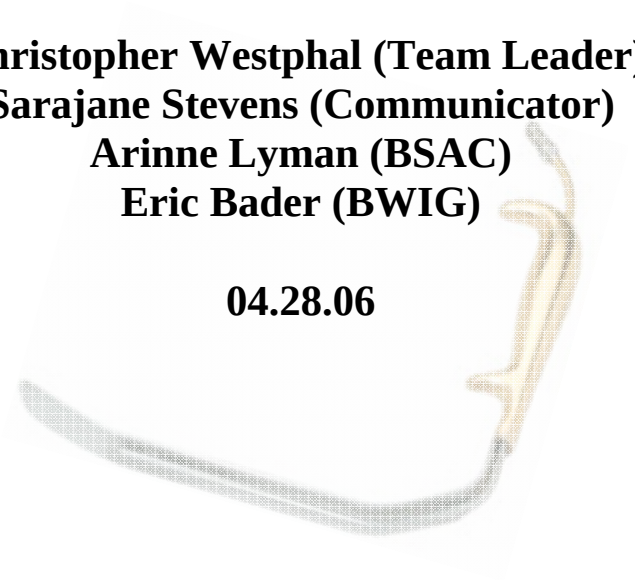
04.28.06



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 Raisin' combines a familiar motion of a bar clamp, specifically the IRWIN® Quick-Grip®, which allows a simple squeeze to actuate a vertical movement. It is self-standing on any horizontal surface and has vertical increments 8.636mm. Modifications of the first prototype included decreasing the blade length, widening the base, thickening the lower blade, and adding a rib support, all of which served to strengthen the prototype and increase the applied force of the moment. The second prototype was able to sustain a force of 22.6kg under a point load at the tip of the blade. Maximum displacement of the top blade was 2.5cm. Fiberoptics were beyond our budget limits, thus testing of intensity could not take place. Suction ports will be tested upon use by the client to determine if specifications were met.

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Background Information

Project Motivation

In the United States, an estimated 335,000 breast augmentation procedures were performed in 2004 [6]. Breast retractors are commonly used devices in these procedures to aid the surgeon in holding up the breast tissue while an electrocautery tool cuts 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 force value was an estimate from the surgeon performing the surgeries. 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 light and suction 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 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.

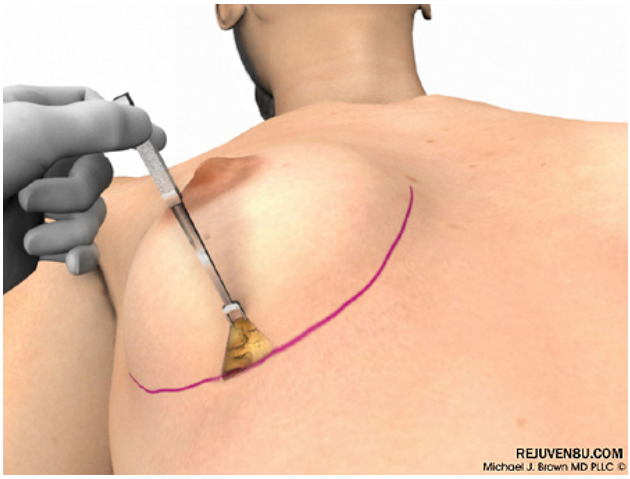

Figure 1: *Small Incision.* A little retractor is initially used to open up the incision in order to start the operation [3].

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 [3]. The breast pocket is usually created underneath the pectoralis muscle, and the electrocautery instrument finishes cutting the pocket to the required size [3]. 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 [3].

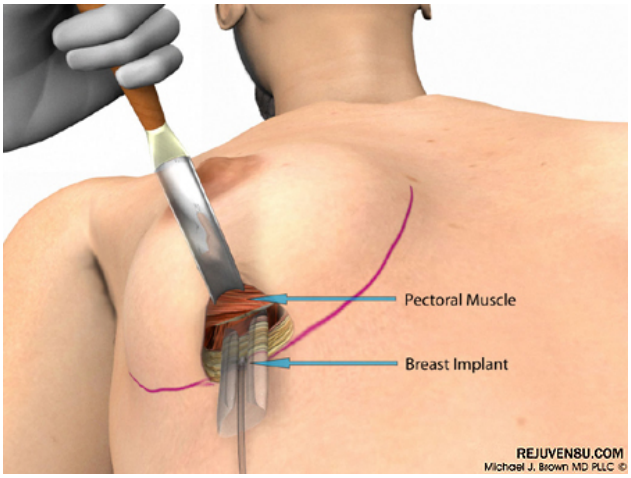

Figure 2: *Implant Insertion.* The implant is rolled up and slipped into the breast pocket while the retractor holds up the tissue [3].

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 [3]. 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 type of material for our device is preferred since it 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 [2]. 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 [2]. 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) [2]. 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 in medicine-- 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].

Figure 3: *The Stanger™ C.* This retractor from ASSI® includes a light and suction source underneath the blade [1].

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 is the current device that is used by our client. 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 4: *Angle Retractor*. This retractor only has a fiber optic which located beneath the blade [1].

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.

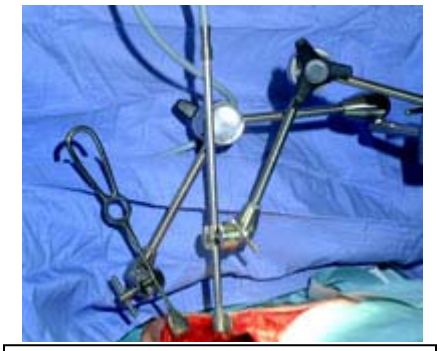

Figure 5: *Mechanical Arm*. Using these elbow-like joints, deep surgical fields can be held open [9].

Figure 6: *Neon Retractor.* This retractor is single-use and utilizes a light reflective polymer for light distribution [8].

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.

Current devices also have a suction mechanism to remove smoke that is caused by electrocauterization of the breast tissue. These devices contain hollow medical grade steel or titanium tubes that run along the inferior side of the blades. This type of material is required to ensure that the device can withstand autoclaving. At the end of the handle, these tubes have barbed fittings as seen in Figure 3. Soft flexible tubing is connected from the wall-mount suction source to the retractor via the barbed fittings.

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 40lb (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 at the yield strength of human rib, which is 93.9GPa [7]. The force of the retractor also cannon exceed the force required to fracture a rib, which is between 39N or 65N for ribs 4 and 5 respectively [5].

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 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.

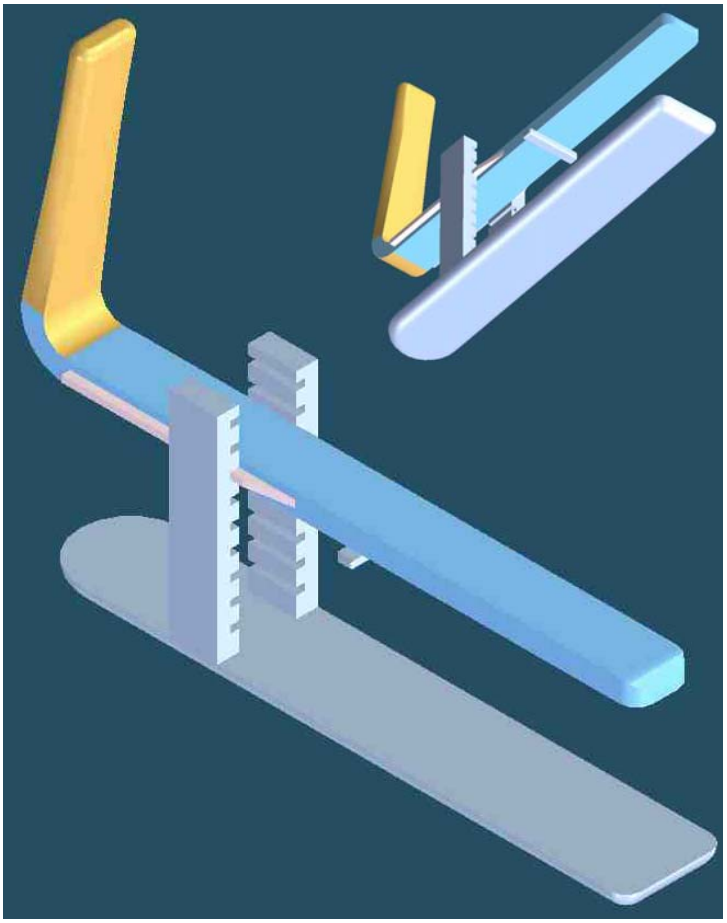

Figure 7: *The Jack*. With rails on each side of the bar, the top bar can slide along the notches at different heights.

The Spreader

The Spreader does not contain much metal, giving it the potential of being slightly more cost effective but slightly weaker. 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.

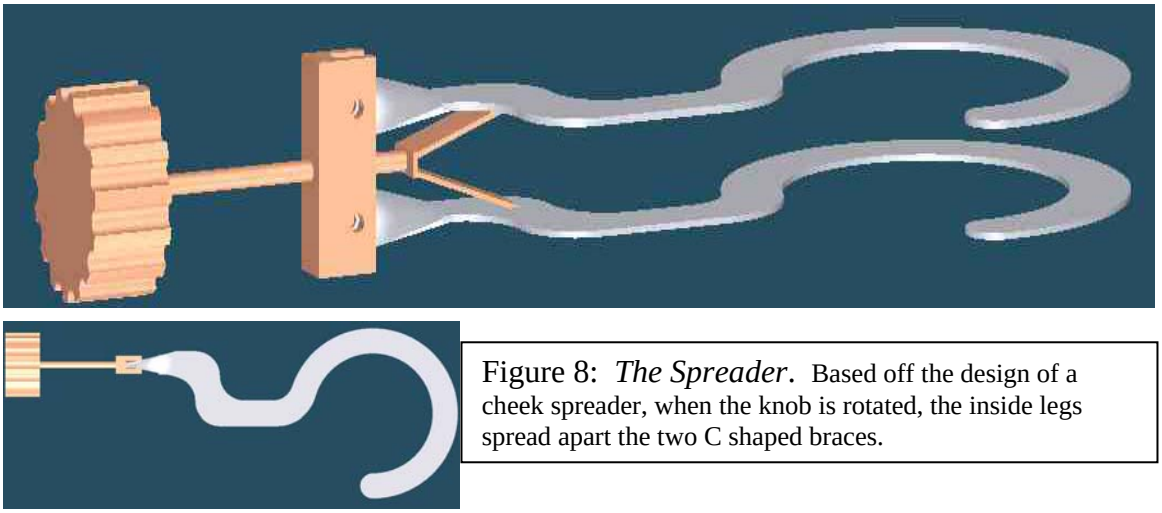

Figure 8: *The Spreader*. Based off the design of a cheek spreader, when the knob is rotated, the inside legs spread apart the two C shaped braces.

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. However, due to stress concentrations at the pivot point, the maximum force this device can support will be compromised.

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 8.636mm. The adjustments are relatively continuous allowing the surgeon to increase the size of the pocket as he/she desires. 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.

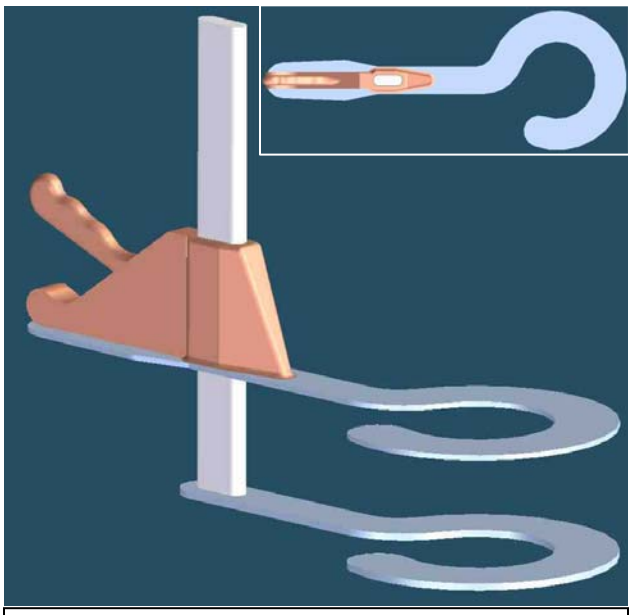

Figure 9: *The Raisin'*. Like a bar clamp, when the handle is depressed, the top "C" brace is raised up.

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. Another disadvantage would be the bulkiness of the handle outside of the incision. This minimizes the viewing area of the incision as well as limiting the available space the surgeon has to insert the tools into the incision. In addition, the free movement of the surgeon's tools outside the pocket will be lost since the handle will block the area 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 five main areas. These areas received a rating out of 15 and included

the ability to be self-standing, provide a clear field of view, supporting sufficient force, allowing ease of use, and feasibility of manufacturing. The remaining criteria were less important to the doctors, thus the ratings were out of ten. A pivot in the design was an extra criterion that would increase the height of the cavity resulting in a weight of five points. Lastly, the cost of the project was based on the amount of metal that would be required for each design (refer to Table 1).

The first design, The Jack, received the lowest rating with a total score of 60 points. Since this design is simple, involving only a few moving parts, it received the highest scores in the manufacturing and force categories. This design is sturdy with thicker pieces of metal used which will translate to supporting a larger load. 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. In addition, the fitting of the blade into the correct slot may be difficult to match up precisely, thus the lower ease of use score.

The second design, The Spreader, received a total of 68 points. This design received high ratings in its ability to be self-standing and capability of pivoting. The self-standing score is 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 pivot mechanism may not support 30lbs due to stress concentrations at the central pivot point and the attachment points of the two legs to the blades.

Our last design called The Raisin' received the highest rating with a total score of 75 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 low 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.

Table 1: Design Matrix

Design Matrix

Criteria	Jack	Spreader	Raisin
Self-Standing (15)	9	14	14
Pivot (5)	2	5	1
Clear Field of View (15)	2	13	11
Force (15)	13	4	12
Ease of Use (15)	9	10	14
Cost (10)	7	9	6
Safety (10)	5	3	9
Manufacturing (15)	13	10	8
Total	**60**	**68**	**75**

Manufacturing

In order to make our first prototype, we constructed a 3D-model rendering in Solid Edge. This was to allow the group a visual representation of what we were going to construct and present to our client. Our initial step in the manufacturing process was cutting out the two C-blades from 1/8" steel. This was done by one of our teammate's family members who works in a metal shop. The next step was to obtain an IRWIN® Quick-Grip® sliding bar clamp in order to use as a reference and key components. With our 3D-model made, instructions for making the

handle were created. Two handle halves were cut out on a CNC end mill with a 1/4" mill bit out of a 1/4" steel plate and 3/8" steel plate. Once cut out, a dado (groove) was made for the sliding bar as well as the brake lever spring. To finish up the handle, a recess was milled out in order for the squeeze handle to fit around the handle. Taking components off the IRWIN® clamp, the prototype was assembled, welded, and tested for functionality.

When the prototype failed under a force of 8.2kg (18.04lbs), some of our design parameters had to be changed, such as shortening the moment arm and reinforcing the bottom C-blade. This was accomplished by increasing the slope of the handle proximal to the blades as well as adding a rib support to the bottom blade, which was also made of thicker steel. A flared end was added to the bottom blade to increase surface area in order to reduce risk of injury. In order to make these changes, a band saw was used to increase the slope and the end mill was used to make a pocket for the rib to slide in when the handle is in the compressed configuration. Another change that was made was removing some material on the distal end of the handle. It was determined that this material was not needed, and would not effect the sliding action of the squeeze handle if removed.

The Raisin' also contains multiple light sources in the form of fiber optics encased in Aluminum tubing. The fiber optics were obtained from Anchor Optical Surplus and would eventually come from a medical surplus company. The lights are 2mm in diameter, jacketed acrylic lights with a refractive index of 1.492. The metal tubing surrounding the optics is 1/8in in diameter. The Raisin' contains three separate light sources angled around the C-shape blade per client specifications and must be tested for its ability to illuminate a dark cavity. These three light sources will be combined together into one fitting such as a Storz, Wolf, ACMI, or Olympus. Suction tubes follow the fiber optic tubing and have two separate ports around the C-

shape blade per client specifications. Tubing is made out of simple mild steel and is 3/16in in diameter. Additional tubing and barb fittings were also obtained to affix to the end of the tubes.

Testing

Once our design was welded, we used an Instron Model 1000 with a 100lb load cell. We tested our device in a "worse-case scenario" situation which was done by placing the point load source on the end of the C-blade as shown in Figure 10. In our first test, the load/displacement curve reached a plateau at 8.2kg (18.04lbs) with a maximum displacement of 0.023876m (0.94in). After our modifications, the load/displacement curve did not reach a plateau because the test was stopped as the required load was exceeded. The maximum load that it did reach was 22.6kg (49.72lbs) with a maximum deflection of 0.024892m (0.98in).

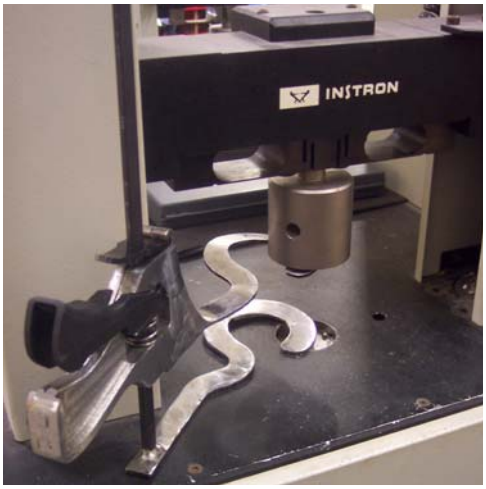

Figure 10. *Load Testing*: Using an Instron load cell, our device was tested in a worse-case-scenario.

The raising mechanism was also tested for its continuity in motion. One depression of the handle corresponded to 8.636mm increase of height inside the cavity. The Raisin' is capable of reaching heights of 10cm, however, only a height of 5-7.5cm is needed by the client for most general augmentation procedures.

Materials and Costs

Shown in Table 2 is the estimated cost of our design if made out of titanium, specifically Ti6Al4V Grade 5. The cost was not figured for stainless steel as this would cause the design to be much heavier.

Table 2: Estimated cost of materials for final prototype,

Cost of Materials

	Width [in]	Length [in]	Thickness [in]	Titanium [6Al-4V]
Sliding Bar	0.5	12	0.375	$39.24
Handle	3	12	0.375	$235.47
Squeeze Handle	2	12	0.5	$199.16
Top C-Blade	12	12	0.125	$344.18
Bottom C-Blade				
			Total Cost	**$818.05**

Our costs incurred for this design was mainly from the tubing, fiber optics, barb fittings, solder and flux, the IRWIN® Quick-Grip®, CPR dummy, as well as transportation costs to and from stores to obtain these items. These costs are included in the Appendix.

Future Work

After the first prototype was constructed, there were many drawbacks of the design that were unnoticeable. Our team came up with this new design not only to account for weakness in the design itself but to also account for the ergonomic issues that were previously not considered. One of the main drawbacks of our device from an ergonomic point of

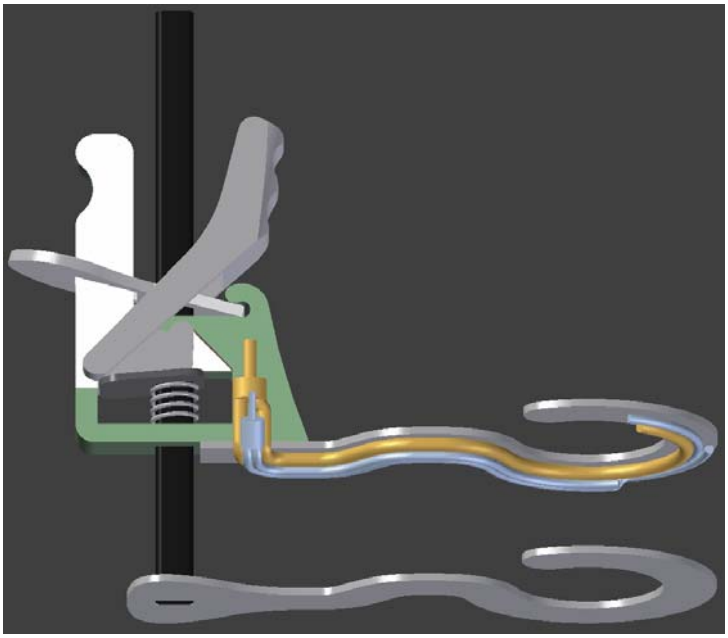

Figure 11. *Future Design*: With this design, the handle is in a more ergonomically correct position.

view is the handle design. The existing design requires the surgeon to rotate his/her wrist 45 degrees in order to actuate the driving mechanism. This is a relatively unfamiliar motion for the surgeon to perform, and may require extra practice. In our new design seen in Figure 11, the handle will be created so the surgeon can keep his/her hand inline with their forearm. This is a familiar position for the surgeons because the current retractors required the surgeon to hold up the tissue with this type of grip. This position of the handle minimizes the strain placed on the hand and wrist because the limb is in the proper posture.

Another flaw in our design is that the device didn't perform to our expectations during the compression tests. Our second prototype had an ultimate load capacity near 50lbs, but the deflection that occurred was unacceptable. At a load of 49.72 lbs, the deflection of the top blade was 0.98 inches. Although the maximum load was near our desired value, the extent of the vertical deflection would minimize the area that the surgeon has to create the pocket. This significantly reduces the effectiveness of our device. Our new design accounts for this drawback because the moments placed on the device would be decreased. The length of the C-blades was too long thus creating a long moment arm which increased the bending (vertical deflection) of our device due to the increased moment (M=Fd). The new design accounts for this by minimizing the length of the C-blades. As the distance decreases, the force required to produce the same moment increases. The new design will be able to withstand greater force and still have the desired components that our client specified.

Future work would also include constructing the new design entirely out of medical grade stainless steel or titanium alloy. Ideally, we would like the device constructed from titanium alloy due to its strength verses weight ratio. Having the entire device constructed of this material

is necessary to ensure that this device can withstand autoclaving. Also, the device must satisfy all FDA regulations.

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. The risk of using our device on patients was also analyzed. One such cause for concern is the force placed upon the chest cavity under 30lb loading conditions which may cause a bruise or tissue trauma to the patient.

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.

Conclusions

In summary, The Raisin' design best fits the specifications of our client. The Raisin' is self-standing on any horizontal surface, as well as under simulated maximal load conditions. It will also be tested for its self-standing capability on a CPR dummy to mimic the curvature of the chest.

The dog-leg mechanism satisfied the client's requirements of a clear field of view by keeping the sliding bar out of the way of medical instruments. All modifications made to the second prototype served to increase the applied force and decrease the moment arm of the blades,

thus making the retractor stronger and able to withstand a larger compressive load. All testing was done with the assumption of an inframammary procedure per client specifications.

The risk of using our device on patients was also analyzed. One major cause for concern is the force placed upon the chest cavity under 30lb loading conditions. The device may cause some minor bruising of muscle or bone if used incorrectly, so perhaps a sleeve can be designed to cover the bottom blade to reduce the force of the metal on the patient. This may provide some cushioning and be less likely to injure tissue. Improper positioning of the device could also cause injury should the Raisin' accidentally slip off the torso. Care and caution should be put into making sure the surgeons know how to use the device properly.

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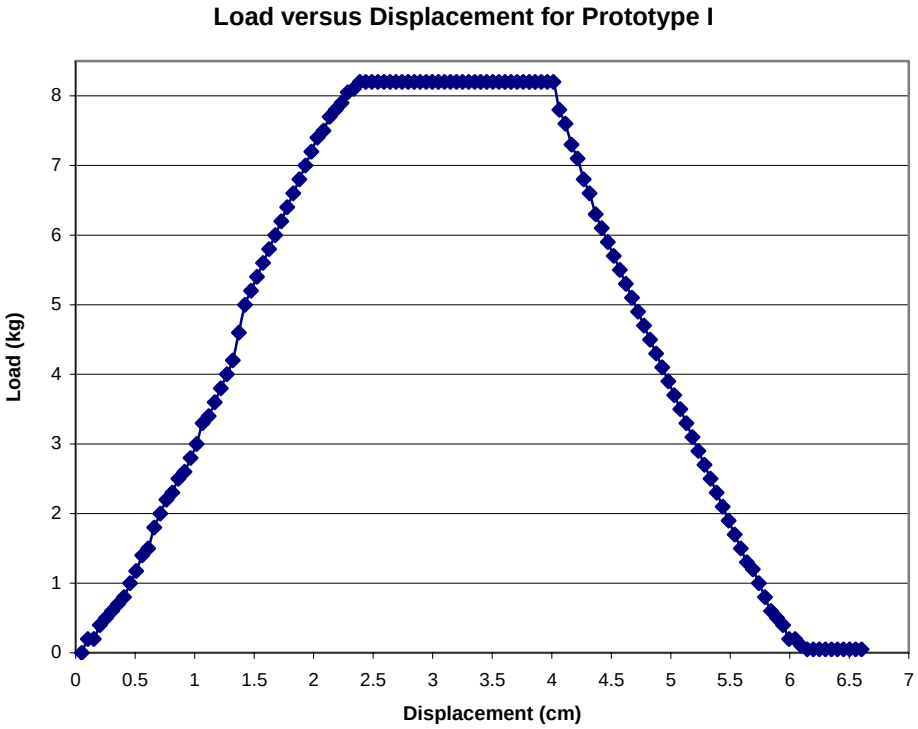
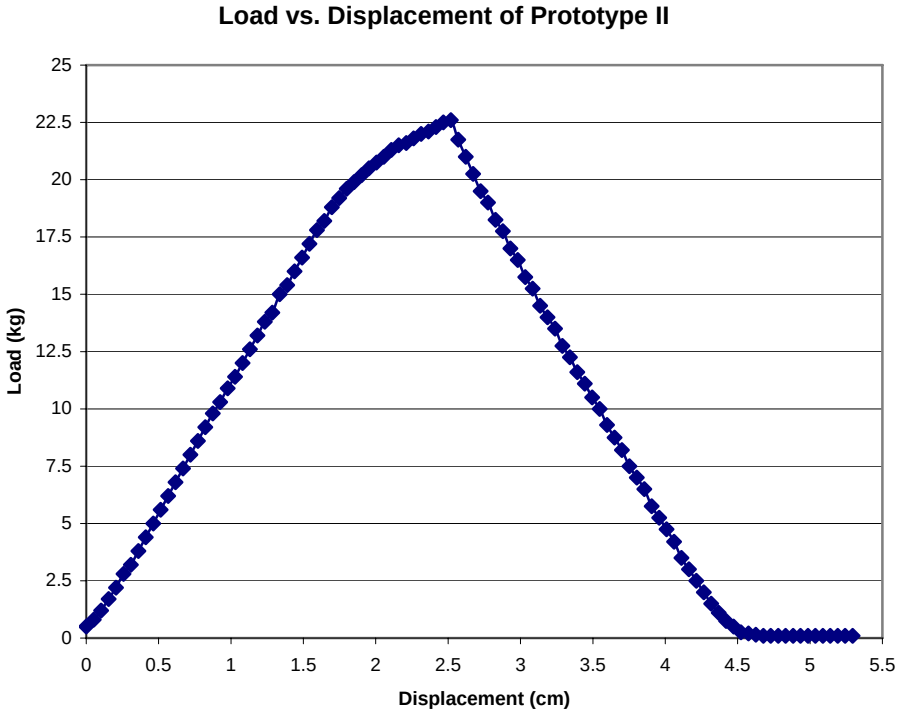
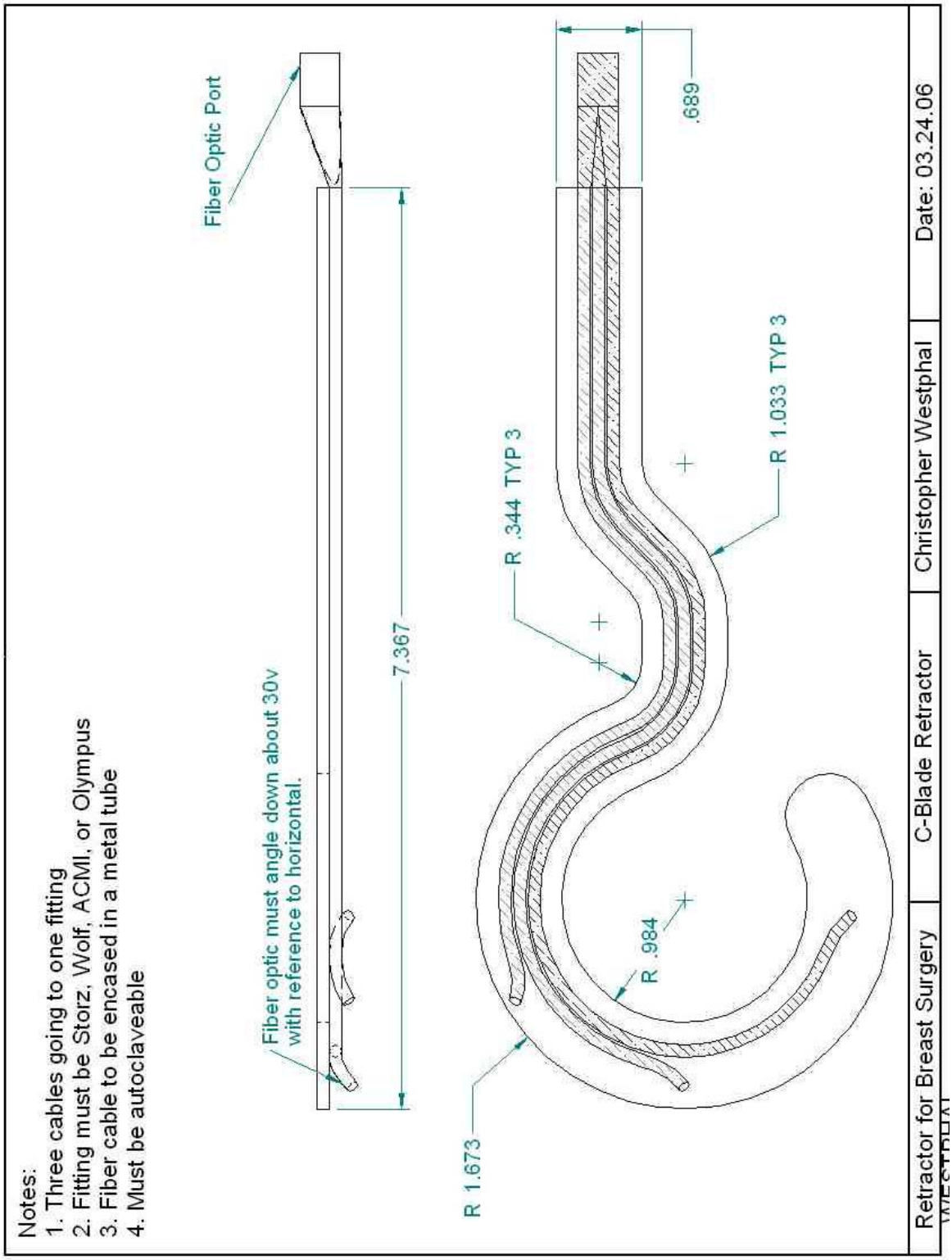
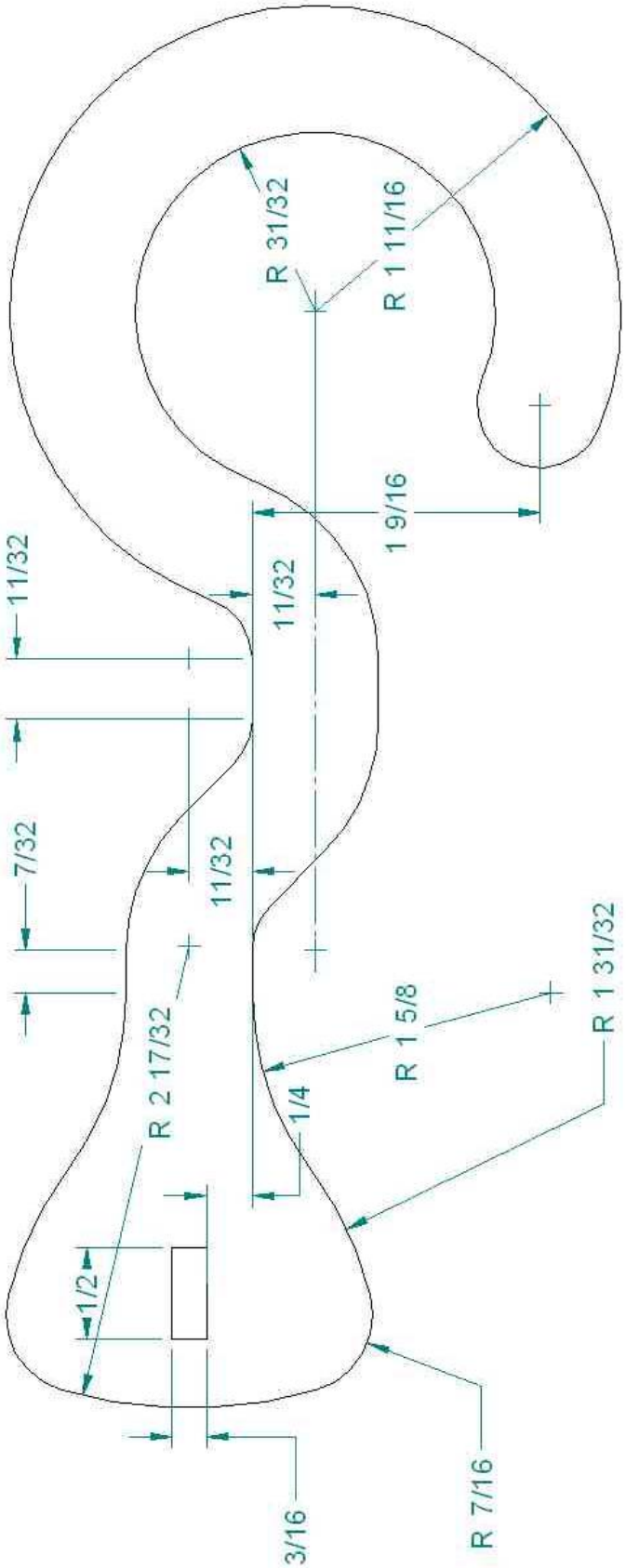
Appendix A: Testing





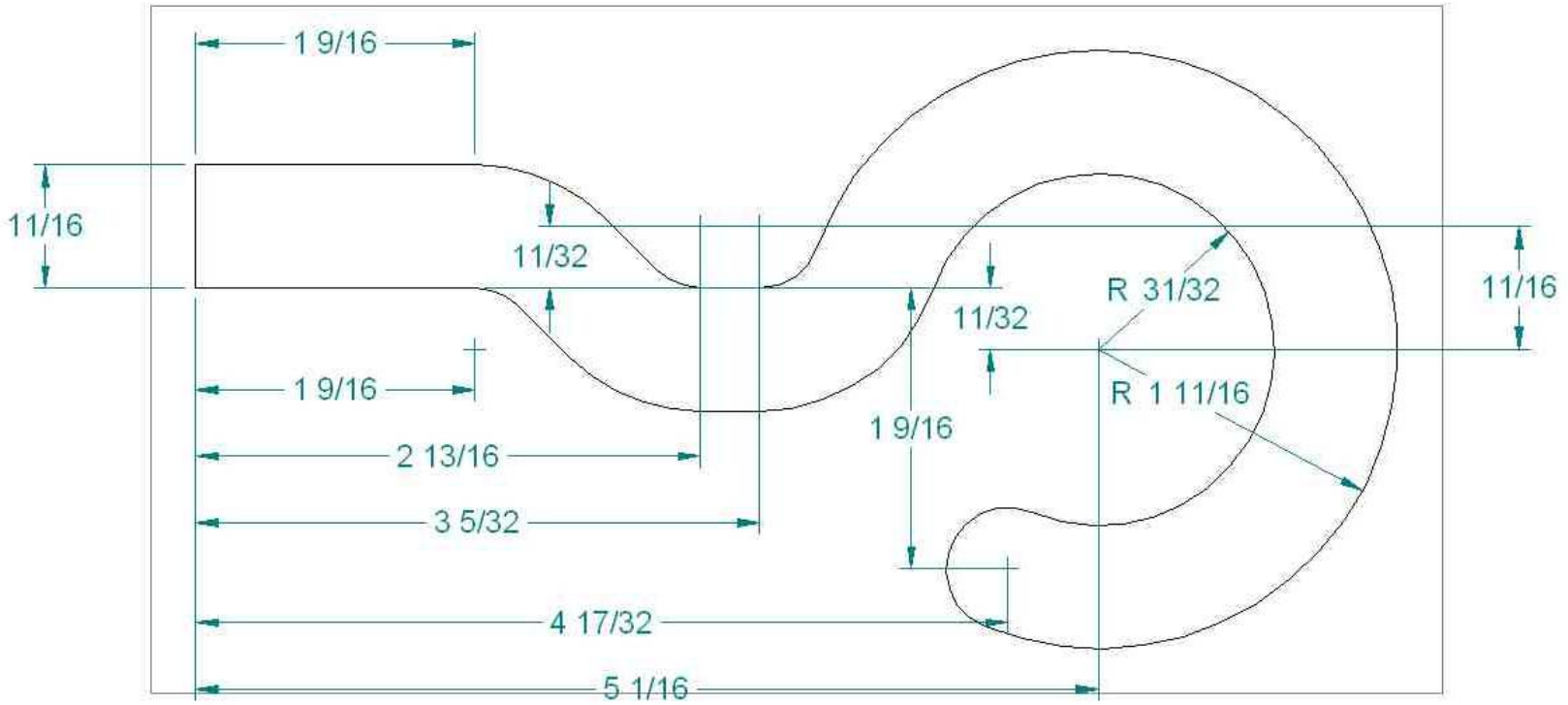
Appendix B: Design Drafts



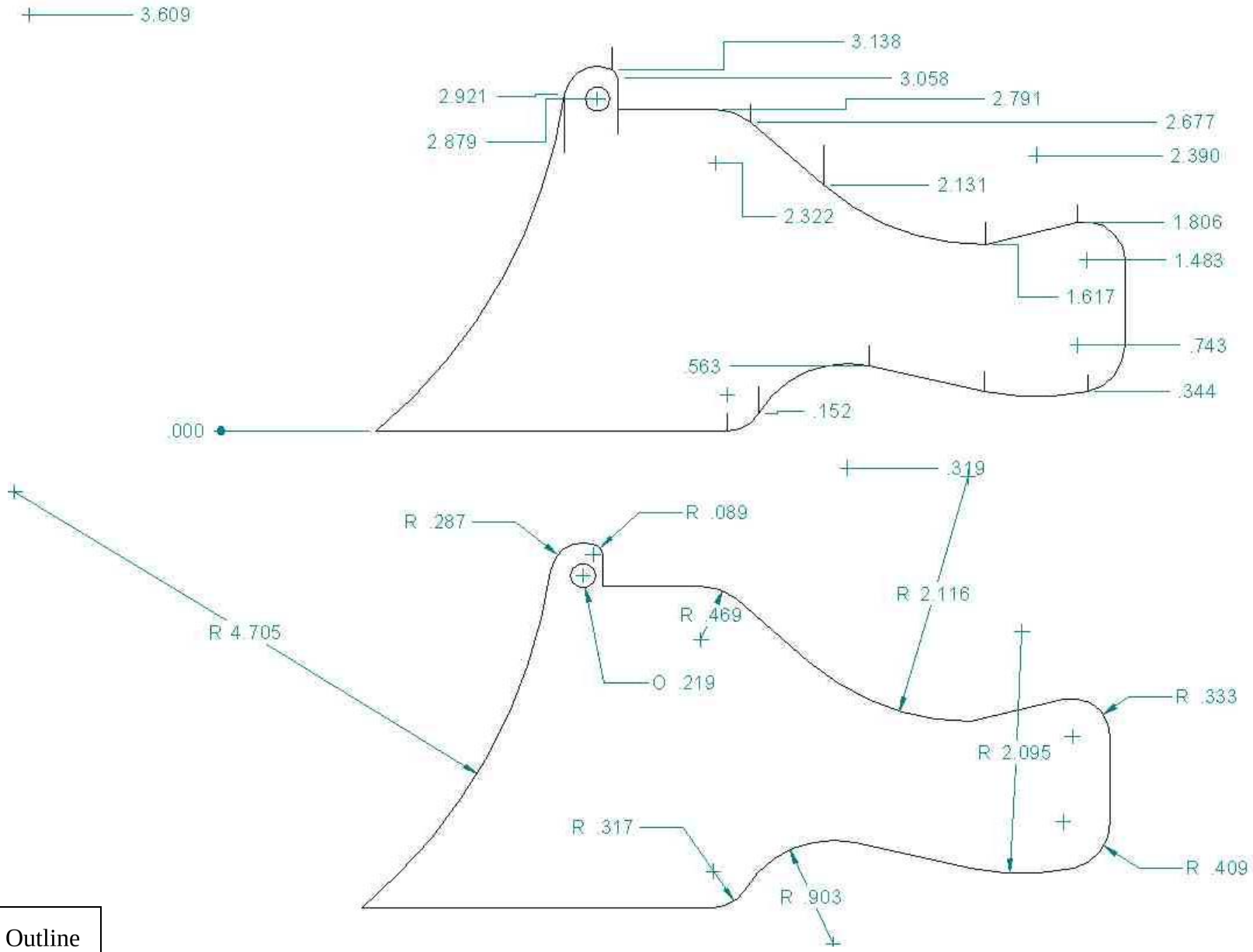


Bottom C-Blade

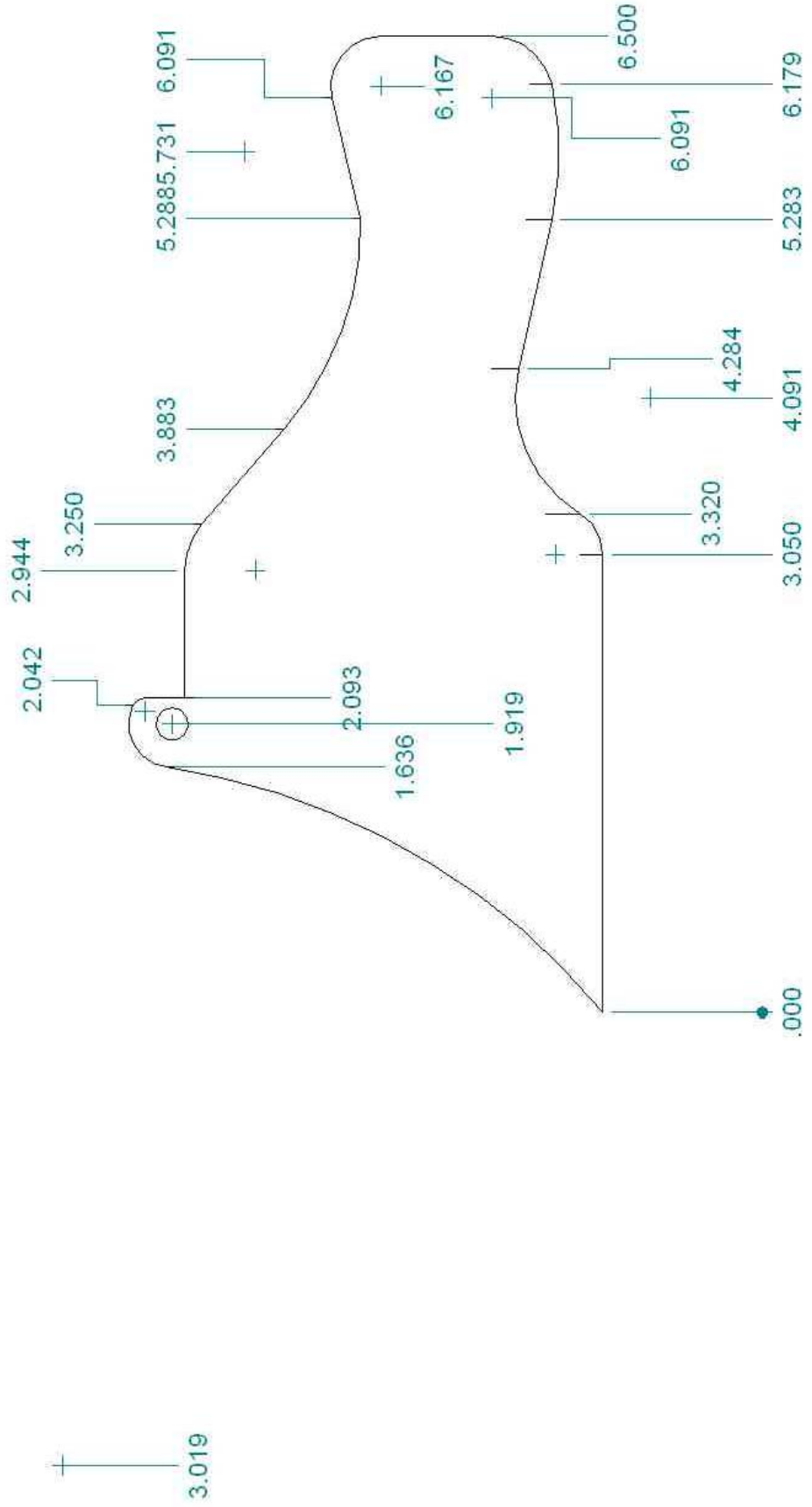
Notes:
All radii unless specified are 11/32"



Top C-Blade



Handle Outline



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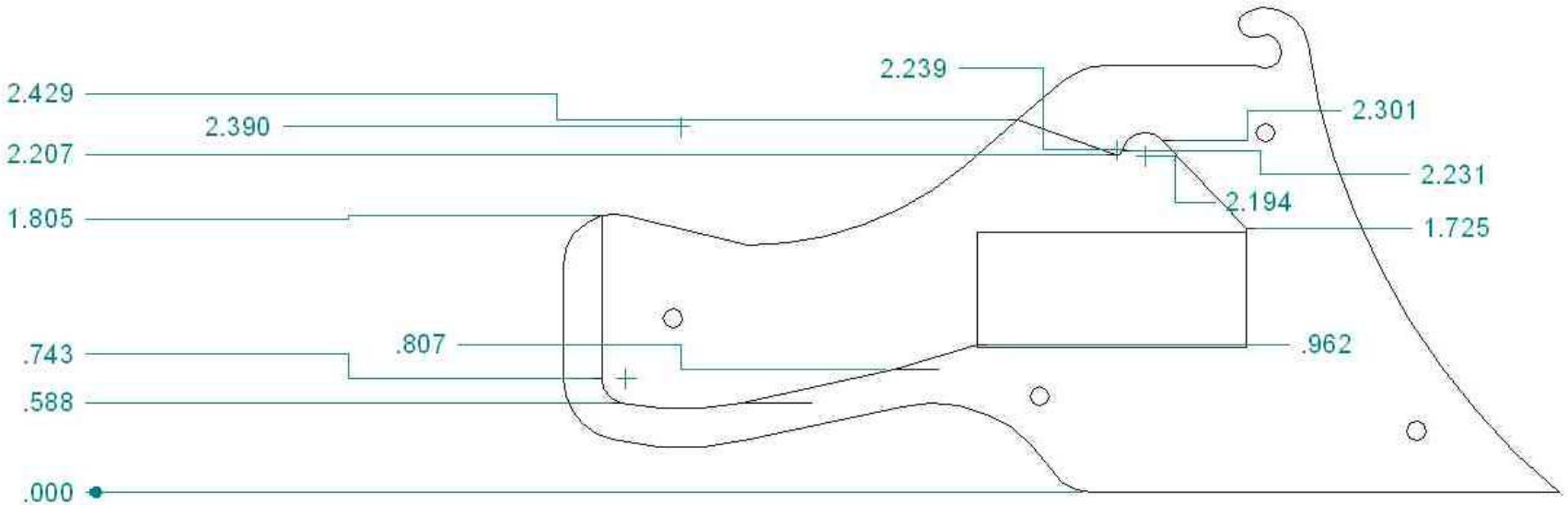
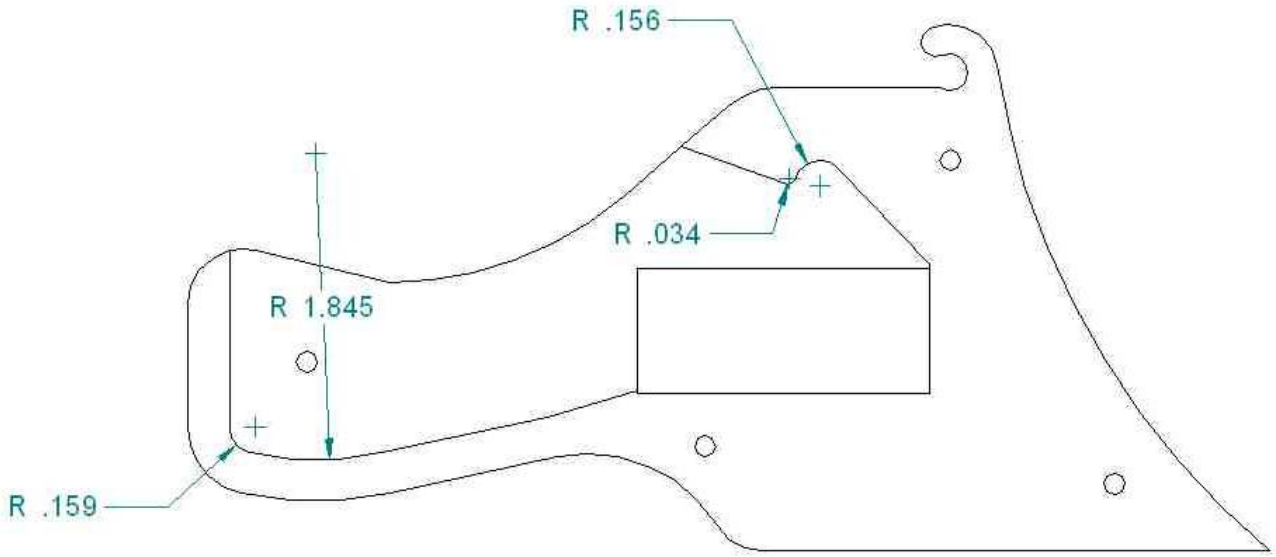
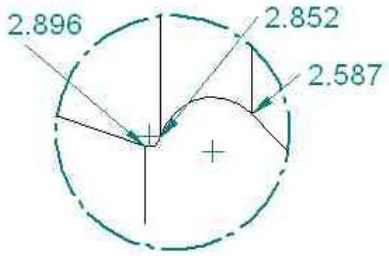
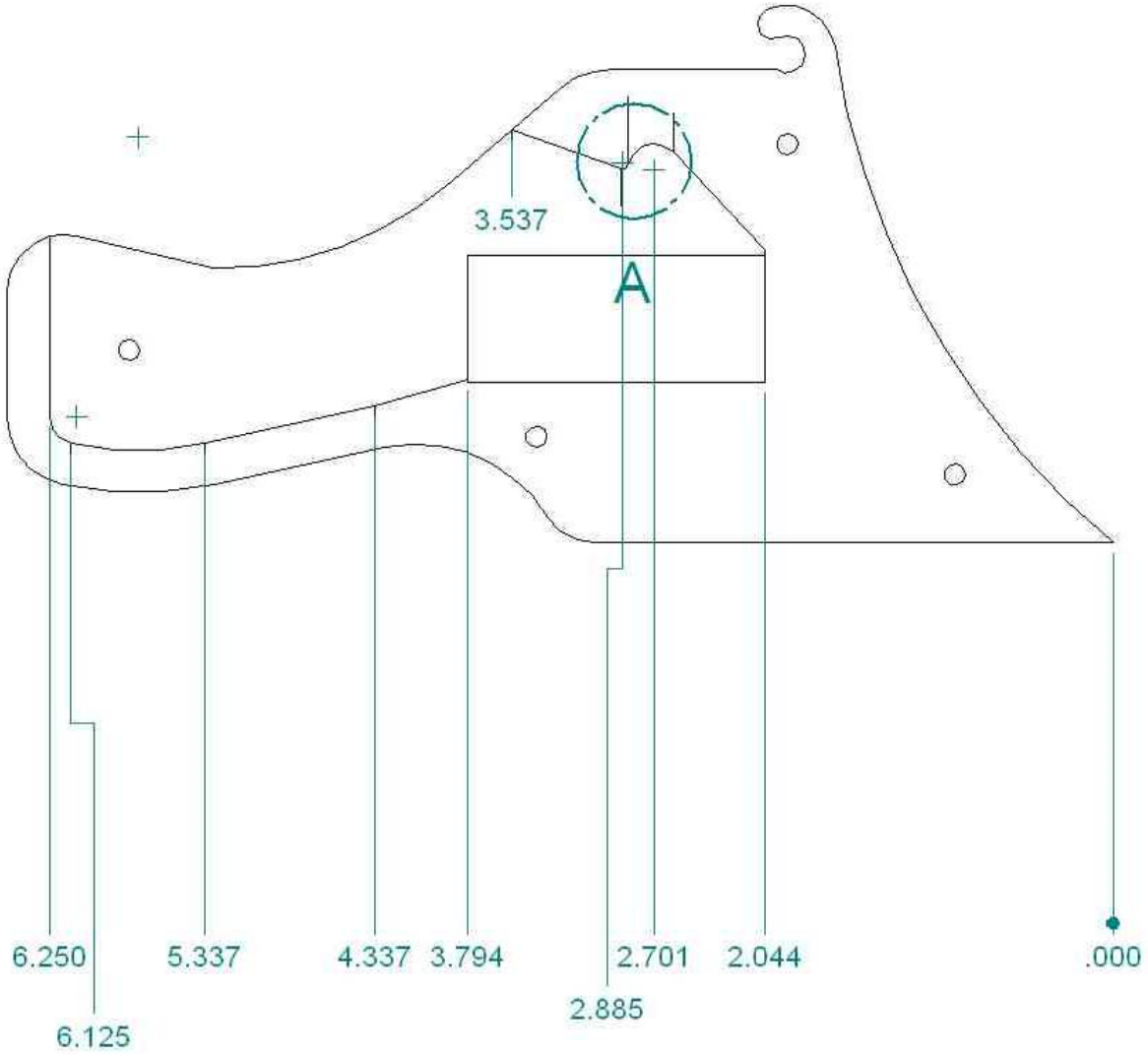




Handle Recess



DETAIL A



Handle Recess

Appendix C: Prototype Costs

Materials and Costs

Materials	Quantity	Cost
Fiber Optics	1 kit	$24.75
Light Tubing	3 packs	$5.97
Tube Benders	1 pack	$5.00
Barb Fittings	2	$3.98
Nipple Fittings	2	$3.98
CPR Dummy	1	$24.00
Solder & Flux	1	$17.50
Quick Grip	1	$11.70
Brakeline	1	$4.60
Gas	10 gal	$30.00

Total	**$131.48**

Appendix D: 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.