Design of Wound Protector/Retractor for Thyroid Surgery

Molly Krohn (Leader), Kim Maciolek (Communicator),
Armand Grabowski (BWIG), Naomi Humpal (BSAC)

University of Wisconsin-Madison - Biomedical Engineering Department
Clients: Dr. Rebecca Sippel and Dr. David Yu Greenblatt
Advisor: Professor Mitchell Tyler

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1. Abstract

Metal retractors that are currently used in thyroid surgery cause ischemic tissue damage and scarring as a result of uneven pressure distribution. Our clients requested a modification of a device used in abdominal surgeries, the Alexis® Wound Device (Applied Medical, Rancho Santa Margarita, CA), to distribute the force evenly around the circumference of the incision.

The final prototype consists of two top oval rings (4 by 6 cm), one bottom round ring (6 cm diameter) and a shorter polypropylene tube (5 cm) to fit the varying anatomy of the neck. Force distribution tests using floral foam were performed to analyze the pressure distribution and chicken breast was used to mimic human tissue and visually observe the force distribution. This confirmed that the revised Alexis® device distributes force evenly.

A survey sent to the American Association of Endocrine Surgeons found that eighty-five percent would be interested in an improved device. Also, the revised Alexis® device is not limited to thyroid surgery; it can be applied to other surgeries in the neck and head, tumor or lymph node removal and even abdominal pediatric surgery. The potential sale of the revised Alexis® device in thyroid surgery is $4.33 million in 2020, but can greatly exceed that and can exceed that when used in other applications.

2. Introduction

2.1 Thyroid Surgery

2.1.1 Thyroid Gland

The thyroid gland is located at the front of the neck, surrounded by various muscles and fatty tissues. It has two lobes, one located on each side of the trachea and joined at the center by a bridge of thyroid tissue known as the isthmus. Its function is to produce hormones that regulate the body's metabolism. However, as people age certain complications may occur concerning the thyroid that may require partial or full removal of the thyroid.[1]

2.1.2 Conditions requiring removal of the thyroid

Examples of conditions that can require removal of the thyroid include hyperthyroidism, goiter, and thyroid cancer. Hyperthyroidism is a condition in which the thyroid produces too many hormones. It is also known as an "overactive thyroid."[2] A goiter is a sudden enlargement of the thyroid gland. A goiter can reach a variety of sizes; however, removal is only typically required if the goiter grows large enough to impair eating or breathing.[1] There are many different ways to treat thyroid cancer, depending on the severity of the case; however, thyroid surgery is the most common (and arguably the most effective) choice.[3]

2.1.3 Thyroid Surgeries

The amount of thyroid removed depends on the severity of the condition. The general procedure for thyroidectomy (surgical thyroid removal) is as follows: First, as shown in Fig.1, a 3.5 to 4 cm incision is made above the base of the neck, located just above the collarbone. Then, retractors are used to pull apart the muscles and fatty tissues covering the thyroid, exposing the gland. Finally, the thyroid is separated from the trachea, the tissue between the lobes is transected, and the gland is removed. For a full thyroidectomy, the procedure usually lasts 60-90 minutes. Partial thyroidectomies are typically much shorter at about 45 minutes.[1]

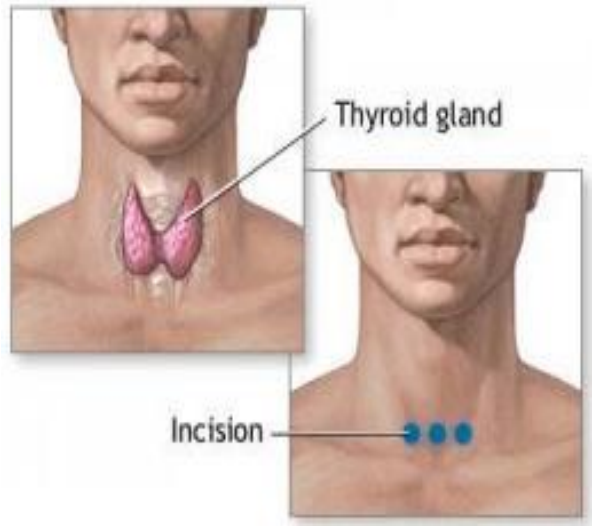

Figure 1: The image on the left shows the Thyroid gland. The incision is shown on the right.[5]

2.1.4 Forms of Thyroid Surgery

Though the basic procedures for thyroid surgery all follow the process listed above, there are many different forms of thyroid surgery. In a total thyroidectomy, the entire thyroid is removed. This is the most common form of thyroid surgery, and is typically used for thyroid cancers, especially in particularly severe cases. A

partial thyroidectomy, on the other hand, is a partial removal of the gland[1]. Typically, half of the thyroid, or one lobe, is removed. This is reserved for cases of thyroid cancer that are either unaggressive or localized to a specific part of the thyroid. In a thyroid lobectomy, only one-fourth of the thyroid gland is removed; this is rarest form of thyroid surgery, and is seldom used for cancers, as the cells must be small and unaggressive for the procedure to be effective.[6] It is, however, sometimes used for hyperthyroidism[2].

2.1.5 Thyroid Surgery Data

According to the National Hospital Discharge Summary and the National Survey of Ambulatory Surgery from the Center for Disease Control, 75,836 thyroid surgeries were performed in the United States in 2006. As shown in Table 1[6], there is a projected increase of 12.49 percent to 86,658 total thyroid surgeries in 2020.

	2006	2020	Increase
Complete Thyroidectomy	22,943	24,743	7.27%
Unilateral Thyroid Lobectomy	26,931	30,139	10.64%
Partial Thyroidectomy	16,477	20,226	18.54%
Excision of Thyroid Lesion	9,485	11,550	17.88%
Total	**75,836**	**86,658**	**12.49%**

Table 1: Number of Thyroid Surgeries in 2006 and Expected for 2020 (adapted from Bhattacharyya et al.). Thyroid surgeries are expected to increase by 12.49 percent from 2006 to 2020.

2.1.6 Risks of Thyroid Surgery

As our clients have stated, thyroid surgery is a difficult procedure. Much of this is due to the complex and intricate anatomy in the neck. As such, many complications can result from thyroid surgery of any kind. Laryngeal nerves are very close to the back of the thyroid; damaging them can cause problems with vocal chords and hoarseness of voice. This is a fairly rare occurrence (approx. 1/250 cases), but it can be permanent in some cases.[1]

The issue with which our clients are most concerned, however, is that of scarring of the neck postoperatively. Newer, minimally invasive procedures are being implemented to reduce scarring. The scars received from the operation can still be rather unsightly, especially since they are in a very visible location. This problem owes itself not only to the incision itself, but to the retractors used to expose the gland.

2.2 Current Methods for Wound Retraction

Currently, metal retractors are the most commonly used devices to expose the thyroid; however, the current devices apply force unevenly throughout the neck, causing unnecessary damage. The Gelpi retractor and spring retractor are examples of metal retractors (see Appendix A for illustration).

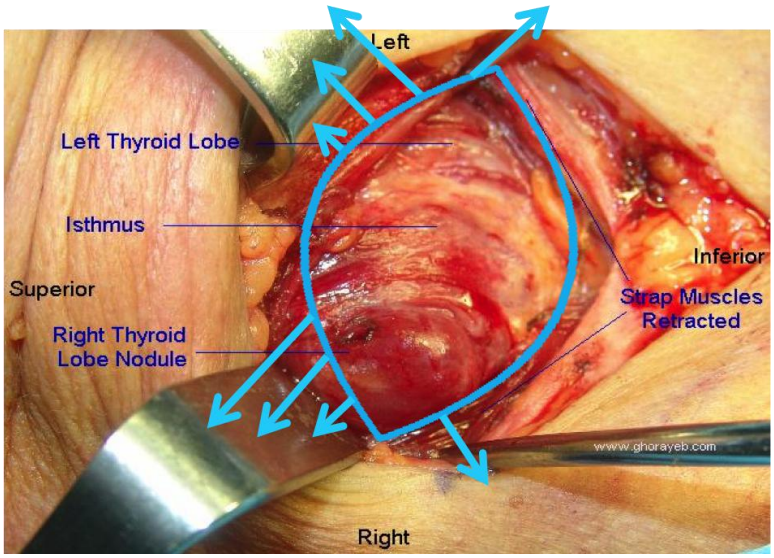

Figure 2: Metal retractors hold skin in desired position (football shape) for surgery[7]. Light blue arrows indicate relative force distribution. Ischemic trauma is a result of uneven pressure distribution.

The metal retractors are not ideal because, as illustrated in Figure 2, force distribution is not even along the perimeter of the incision. Thus, tension is created which ultimately results in damaged tissue, bruises and scarring. Metal retractors also obstruct the view of the wound for surgeons.

2.3 Pressure and Tissue Damage

Tissue damage from pressure is time dependent. As seen in Figure 3, pressures over time greater than or equal to the red line are known to cause tissue damage. Instantaneous pressure greater than or equal to 32 kN/m^2 and a sustained pressure below 9.25 kN/m^2 for two hours were found to cause tissue damage[8]. Pressures over time less than or equal to the blue line do not cause tissue damage. Instantaneous pressure below 26 kN/m^2 and a sustained pressure for two hours below 5.23 kN/m^2 were found to not cause tissue damage. The effect of pressures over time in the area between the curves can vary. Therefore, the area between the curves is considered a region of uncertainty.

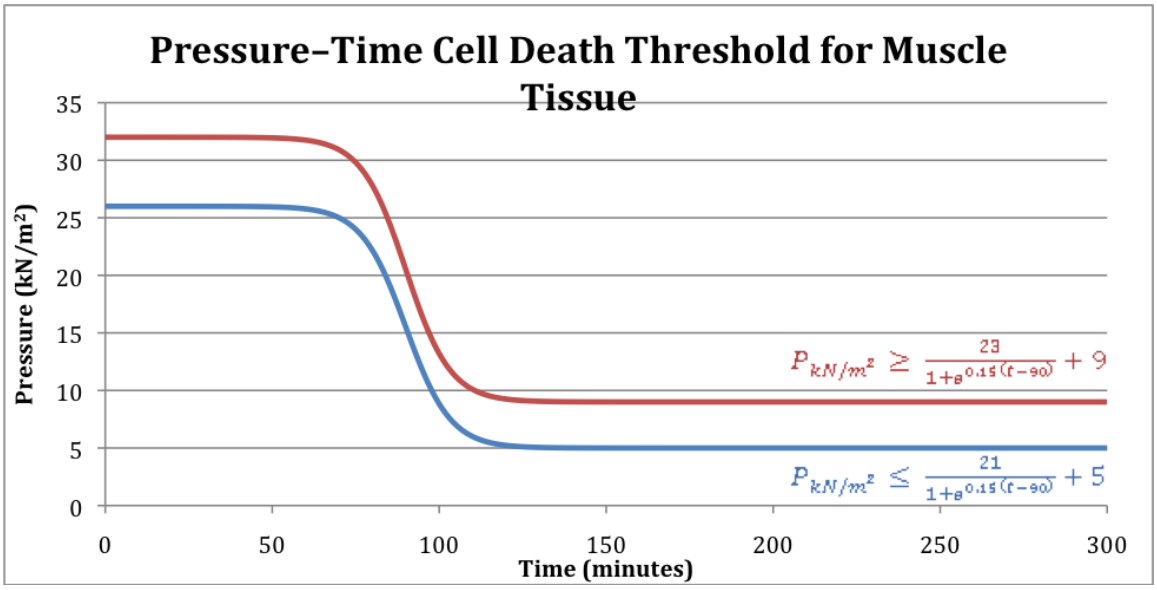

Figure 3: Graph adapted from Linder-Ganz et al. The area above the red curve corresponds to tissue damage, the area below the blue curve is non-damaged, and the area in between the curvesis a region of uncertainty.

2.4 Alexis® O-Wound Device

A device currently used in abdominal surgeries is the Alexis® O-Wound Retractor (Fig.4). The Alexis® device is constructed of two rings connected by a plastic material, polyurethane[8]. Unlike the metal retractors, this retractor distributes the force evenly around the incision that results in an optimal field of view[8]. The polyurethane has natural antimicrobial properties that decrease infection; the continuous covering maintains moisture at the incision[9].

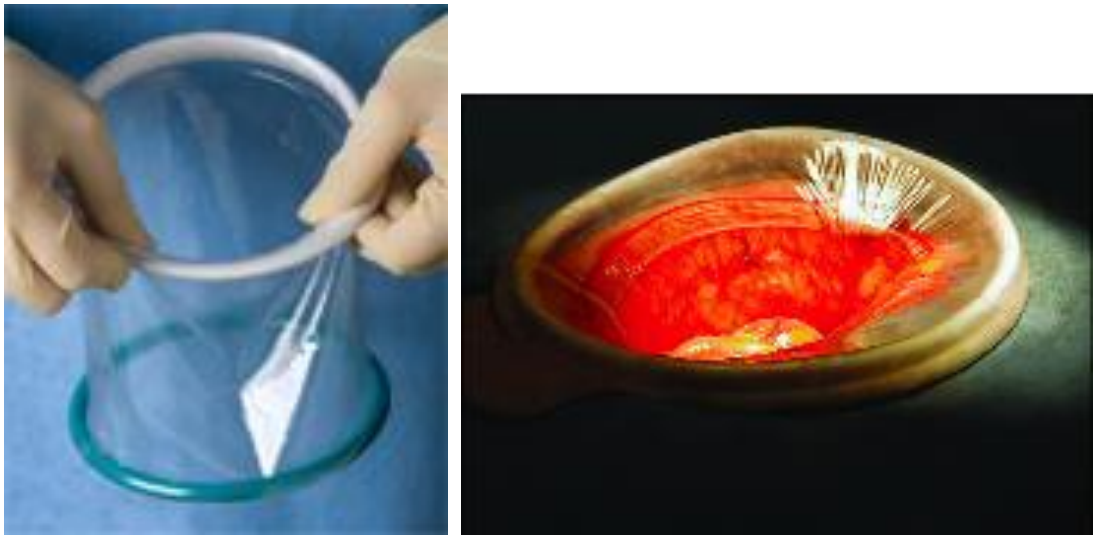

Figure 4: Alexis® O Wound Retractor (left) and in the wound (right) distributes force evenly over the entire incision.

Our clients used this device in thyroid surgery and determined that a modification of this retractor would be very beneficial. Even distribution of pressure is ideal for thyroid surgery to prevent ischemic trauma that results in scarring. Scarring from thyroid surgery is extremely visible since the incision is made on the neck (see section *2.1.3 Thyroid Surgeries).* Applying this device to thyroid surgery would eliminate the trauma, thus resulting in less scarring.

2.5 Problem Statement

Our goal is to design a retractor to fit the varying anatomy of the neck in thyroid surgery. It will distribute the force evenly, thus eliminating scars. It must be compatible with an incision of 3.5 cm. and an opening of 3 by 4 cm. It is our intent to design a device that rectifies this problem by distributing force equally across the incision site, while ensuring patient safety.

2.6 Product Design Specifications

Specific design requirements are listed in the Appendix. A key point for the construction of the modified Alexis® retractor is that it must protect the skin from electrocautery.

3. Designs

3.1 Design Options

Initially when discussing the design with our client, a large emphasis was placed upon making a reusable, environmentally friendly device. Many thin plastic materials or soft, pliable materials are not able to withstand repeated sterilization necessary for a reusable device. Therefore, focus was shifted to designing a metal retractor. Many different devices were considered. These designs, however, were not pursued due to sheer number of metal devices already available for purchase. Moreover, the other designs more greatly occluded the surgical field, and did not provide as even of pressure distribution. Reusability is an ideal feature that should not come at the loss of functionality: an inferior reusable device is not better than a single use superior device.

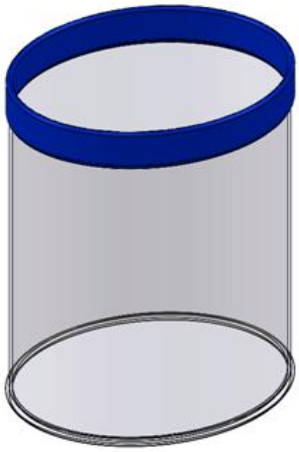

Figure 5: Design 1 is a revised Alexis® device with oval rings and a shorter tube.

An ideal device provides all of the visual and protective features of the Alexis® device (see section *2.4 Alexis® O-Wound Device*) and is able to withstand repeated sterilization. To the authors' knowledge, there is no material compatible with these ideals. Considering these circumstances, three designs were created. The first and second designs are revised versions of the Alexis® device, and the third device is a revised metal spring retractor.

The first design, as seen in Figure 5, is a revised Alexis® device with a shortened polyurethane tube and oval shaped rings. The polyurethane tube will be shortened from 14.5 centimeters to five centimeters. The Alexis®

device is designed to be used in abdominal surgery in which there is an excess of tissue and therefore a long tube is necessary. The neck typically does not have as much tissue, and thus to fit the incision, the original Alexis® device must be rolled many times. This excess rolling bunches the tubing and obstructs the surgical field. In addition, different materials – hard (wire, PVC plastic) or soft (silicone, plastics) – and sizes of the rings will be tested to determine which secures the device and limits the bunching the best.

Figure 6: Design 2 is a revised Alexis® device that has the features of Design 1 as well as a supportive mesh structure surrounded on both sides by the polyurethane tube.

Similarly, the round rings of the original Alexis® device are suspected to increase the bunching of the polyurethane tube, especially at the corners of the desired football shape of the incision with retraction which constricts the surgical field. In addition, the oval shape (ideally four by six centimeters to allow for variability in the incision size) is similar to the desired football shape while allowing for some variability of the device placement. For example, it is speculated that if the rings were football shaped the device would have to be inserted in perfect alignment to allow the corners of the rings to match the corners of the incision and may need to be repositioned throughout the case if it were to shift. The oval rings, however, can be inserted at any position relative to the incision and will not need to be shifted. The effectiveness of football shaped rings will be tested to verify this theory.

The second design, as seen in Figure 6, is also a revised Alexis® device that has all of the features of the first design as well as a wire mesh reinforcement surrounded by layers of polyurethane tubing. The wire mesh, similar a large cardiac stent, provides additional support for retraction and to prevent bunching of the polyurethane tube at the corners of the incision. The mesh will either be wrapped around the rings or inserted into the ring for attachment. A layer of polyurethane surrounds the inside and outside of wire mesh; the mesh will not be in contact with the tissue or surgical instruments. Ideally a non-conducting metal will be selected for the wire mesh to prevent burns if the device comes in contact with electrocautery or the harmonic scalpel; the polyurethane tubing provides some protection if contact is made.

Figure 7: Design 3 is a revised metal spring retractor with larger, angled plates and reduced spring constant.

The third design, as seen in Figure 7, is a metal spring retractor designed to provide a more even distribution of force which reduces trauma. As compared to the existing model the plates have a larger surface area to better distribute force. The plates are also bent inward to align the plane of contact parallel to

the skin. Excess trauma would be further minimized by reducing the spring constant to allow least amount of force applied to maintain retraction. Additional features include an antimicrobial and heat resistant coating; Teflon or similar materials were considered for this purpose, but more research is still required.

3.3 Designs Tested

Upon viewing the various designs (see *3.1 Design Options*), our clients requested a design most like the Alexis® O-Wound device: the Revised Alexis® Device with oval rings. Therefore, the focus shifted from constructing and testing all three designs to constructing a revised Alexis® Device with adjustments to fit the anatomy of the neck.

4. Procedure

4.1 Materials Tested

4.1.1 Rings of Modified Alexis® Device

Two different materials were tested in the prototypes of the ring: polyvinyl tubing (Ace Hardware) and rubber silicone tubing (Peep Sights Tubing, Gander Mountain). The polyvinyl tubing was discovered to be very difficult to flip when constructed as a prototype, therefore it was quickly eliminated as an option since it cannot flip easily like the Alexis® Device.

4.1.2 Body of Modified Alexis® Device

Polyurethane is the ideal material to construct the body of the revised Alexis® device. But, due to the limited availability, synthetic nitrile (FC2 female condom) was utilized to construct some of the prototypes tested. This material is very weak and can easily tear, so polyurethane is the best option.

4.2 Assembly

The prototype was made out of three main parts: the top (flippable) ring, polyurethane or nitrile tube, and bottom ring. The top ring was constructed out of two rings. Each ring was made by cutting 3/8" silicone rubber archery peep sight tubing to 17 cm, inserting approximately 19 cm of 20 gauge wire, bending the tubing and wire into a circle with overlapping wire, and securing the ends with super glue. The two individual rings were super glued together to form the upper ring assembly. The tubing was repurposed from either an Alexis® device or a FC2 female condom, cut to 7 cm long, and glued to the top ring. The bottom ring was also repurposed from either an Alexis® device or a condom, and super glued to the tube.

4.3 Prototypes

The prototypes were tested in comparison with metal spring retractors provided by our client. The pressure exerted by each retractor and its area of

distribution was determined in ten trials, with measurements at the beginning and after two hours, which is the approximate length of a thyroid surgery.

First, an incision was made in floral foam. The incision was a 3 by 4 cm football shape, which is roughly the shape and size of an open incision. The retractor was then inserted, and initial measurements were made of the displacement. Displacement measurements were made at the corners of the metal retractors, and around the top ring for the modified Alexis® prototype. The same measurements were again made to determine displacement at the end of two hours. This test was performed with three different Alexis® prototypes and two different metal retractors, and ten trials for each device.

Tests were also performed on the floral foam. This was done using a weight set and small plastic stands (pizza savers) which provided minimal contact area with the foam. The amount of displacement was then graphed in comparison with the weight per area of contact. This test was repeated with 4 different weights and 100 trials with each weight.

5. Survey

In order to determine the marketability of our project, a seven question survey was sent out to 383 members of the American Society of Endocrine Surgeons with 75 responses, a response rate of 20%. The survey consisted of seven questions, with five about retractors, and two about the surgeons themselves (see *10.2 Thyroid Survey Tissue Retractor Survey* for questions).

The survey confirmed that a new tissue retractor is needed for thyroid surgery. More than 85% of respondents said they would be interested in an improved tissue retractor. This is even higher than expected because 37% had been performing surgery for more than 20 years, so it is surprising that they would be willing to change after that much experience. The fact that many surgeons are not satisfied with the retractors currently available is also visible in the changes between the devices used in surgical training, and the devices used now (for more detailed results see *10.4 Survey Results*).

The survey also helped to confirm the changes that needed to be made to the retractor itself. The main responses were for a smaller device and more even pressure. These were the two main issues our clients had indicated needed to be changed.

6. Testing and Results

6.1 Pressure Testing

A floral foam (Floracraft ® Desert Foam®, Ludington, MI) model was used to compare the pressures of the metal spring retractors and the revised Alexis prototypes. Floral foam was chosen because it is widely available, inexpensive, easy to manipulate, limited elasticity and has a fine texture that allows for accurate impressions. Limitations of this method include error associated with inter- and intra-observer variability and manufacturing inconsistencies between blocks even if purchased from the same manufacturer. First, the material properties of the floral

foam were tested to create a correlation between displacement and applied pressure. Second, the pressure for each of the devices was quantified.

6.2 Floral Foam

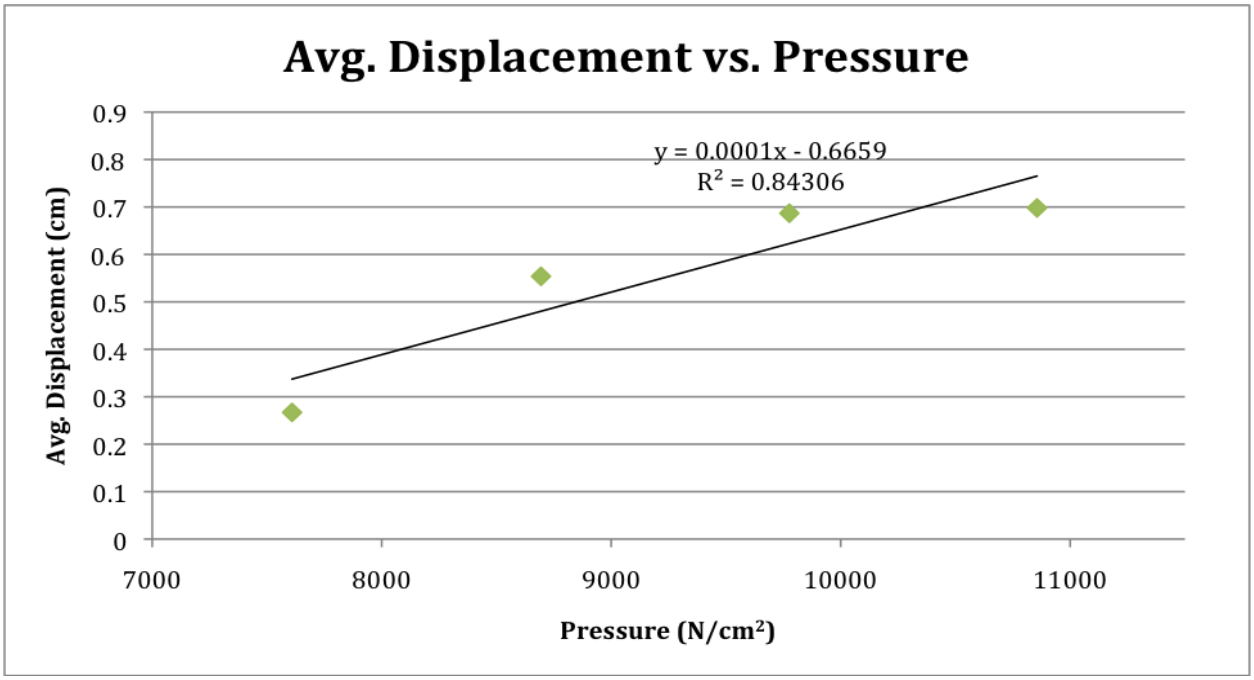

Figure 8: A linear relationship between pressure and average displacement was determined for weights of 700, 800, 900 and 1,000 grams (n=100).

A combination of a plastic pizza saver and various weights were used to test the material properties of the floral foam. The displacement associated with weights of 700, 800, 900 and 1,000 grams was measured. Care was taken to ensure that displacements were on the same side of the floral foam that the retractors were tested on to increase accuracy and precision. The definition of pressure was used to calculate the pressure associated with each weight. One hundred trials were done for each weight. After graphing, a linear correlation was observed between the pressure and displacement for the floral foam and the following equation was calculated:

0.0001

This equation was then used to calculate pressures exerted by each device.

A logarithmic correlation was also considered due to the general shape of the data points was not included. The logarithmic correlation, however, resulted in similar pressures for the metal spring retractors and the revised Alexis prototypes; this trend opposes observed effects. Therefore, a logarithmic correlation was not chosen.

6.3 Prototypes

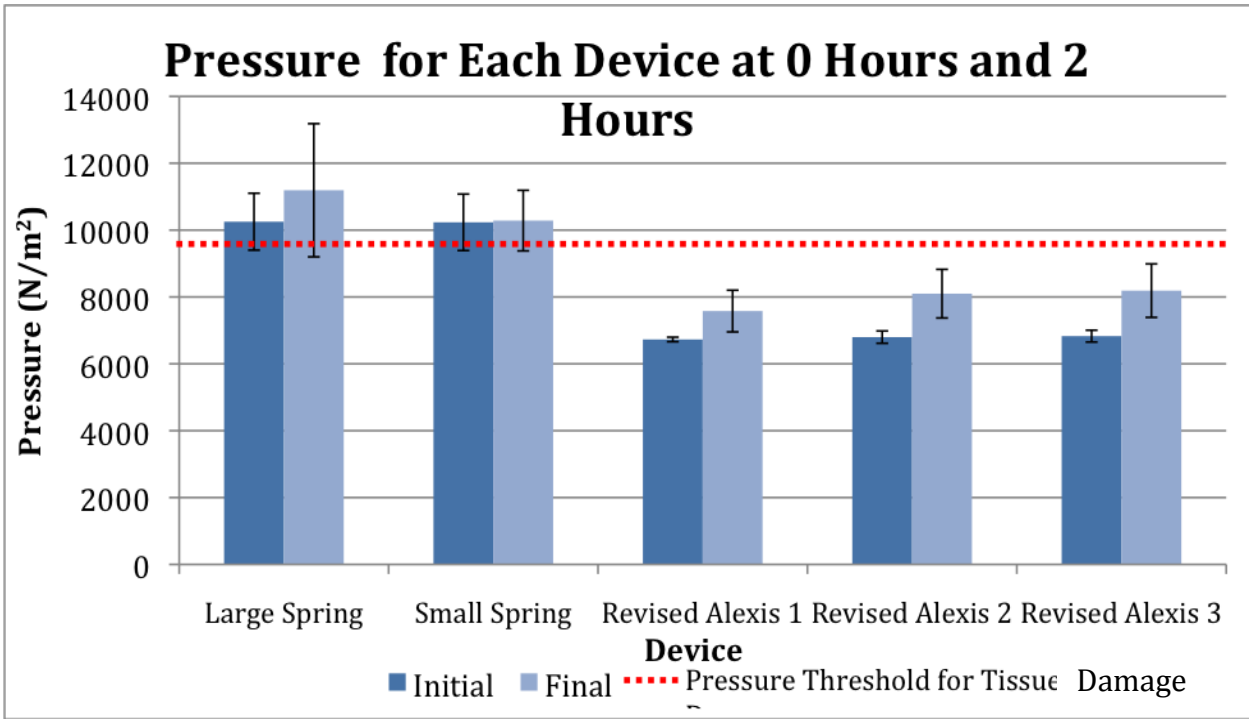

Figure 9: Pressure was measured in floral foam for the metal retractors and the prototypes (n=10). The red dotted line represents the tissue damage threshold for 2 hours[8].

Both the metal retractors and the revised Alexis prototypes were tested in floral foam to determine the amount of pressure exerted by each device. The revised Alexis prototypes were pre-rolled to minimize excess displacement upon insertion. Ten trials were done for each device. Figure 9 shows the average of these trials. Measurements were taken immediately after the device was inserted (initial) and after two hours.

The metal spring retractors were found to exert the largest amount of pressure, approximately 10.2 kN/cm^2 initially and 11.2 kN/cm^2 for the large metal retractor and 10.3 kN/cm^2 for the small metal retractor after two hours. The pressure after two hours exceeds the 9.25 kN/cm^2 exceeds the pressure threshold of tissue damage. This indicates that during a typical thyroid surgery the metal retractors would cause damage, which is verified by observations from our clients. This was also an expected outcome which to a small degree verifies our testing methods.

The difference in final pressure values for the large and small metal retractors can be explained by the difference in spring constant.

All three prototypes were well below the threshold for tissue damage both initially and after two hours. The lowest pressure (7.6 kN/cm^2) was associated with the revised Alexis 1 (polyurethane tubing and rings). It was observed that the pressure was roughly distributed evenly around the circumference of the top and

bottom rings. Future testing will be done quantify pressures exerted transversely by tubing.

6.4 Tissue Model Testing

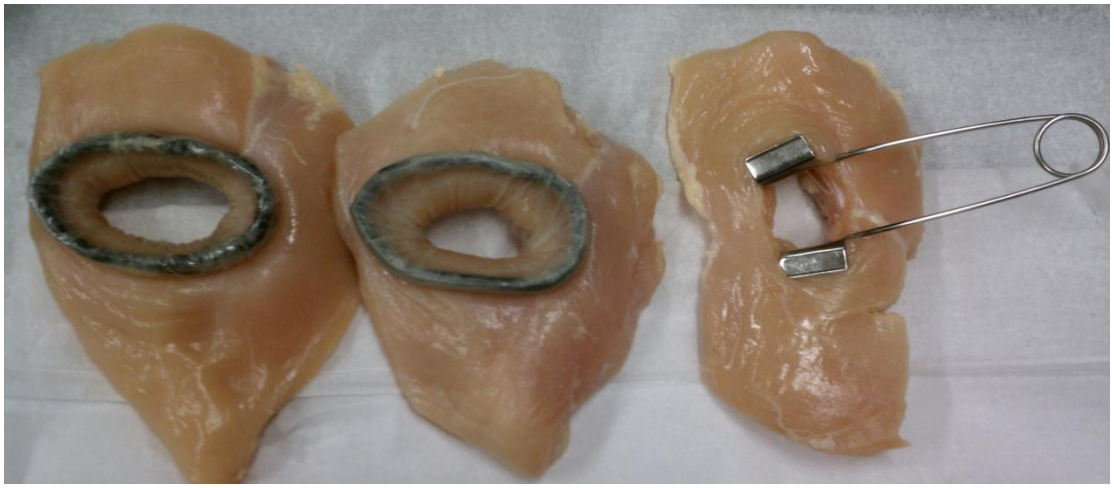

Figure 10: The function of the metal spring retractors and the revised Alexis prototypes were tested in chicken breast. From left to right, revised Alexis 1 (polyurethane tubing and ring), revised Alexis 2 (synthetic nitrile tubing, polyurethane ring), large metal retractor.

The overall function of the metal spring retractors and the revised Alexis prototypes were testing in a tissue model. Due to strict regulations, it was impossible to test our prototypes in a live animal or human. Therefore, chicken breast was chosen as an alternative. In addition, chicken breast is widely available, relatively inexpensive and structurally similar to human muscle. This method, however, does not account for the other tissues found in the neck, including skin, adipose tissue and ligaments.

The revised Alexis 1 prototype, as seen in Figure 10, provided the largest opening and most effective retraction. The combination of the silicone top ring and the polyurethane tubing also allowed easily rolling of the device to adjust the length and tension. The smaller polyurethane bottom ring allowed easy insertion of the device through the incision. The device could be rolled while the top was round (easiest) and then the top ring could be formed into the desired shaped. Under enough tension, the bottom ring also formed into a similar oval shape. Oval-shaped rings on the top and bottom not only provided the most efficient retraction but also reduced the amount of bunching of the polyurethane tubing thereby maximizing the total incision size.

The revised Alexis 2 prototype functioned very similar to the revised Alexis 1 prototype. The large size of the bottom ring, however, made it very difficult to insert. In addition, this ring did not conform well to the oval shape and there appeared to be more bunching of the tubing in the incision.

The revised Alexis 3 prototype produced a smaller opening and less effective retraction. The synthetic nitrile was not as elastic as the polyurethane and therefore it was difficult to roll the device once the tubing was under tension.

The metal spring retractors, as seen in Figure 10, provided adequate retraction. Over time it was noted that the metal retractors was actually increasing the length of the incision. Upon removal, visible indents were left in the muscle tissue where the metal retractors were positioned.

6.5 Final Design

A final design was selected based upon the pressure testing in the floral foam and the overall function in the tissue model. The final design is the revised Alexis device with two top silicone rings reinforced with 20 gauge wire, bottom polyurethane ring, and shortened polyurethane tubing (6 centimeters). The top rings have a radius of 5.4 centimeters and the bottom ring, 6 centimeters. This design was the easiest to use, exerted the least amount of total force around the circumference of the rings, and the most durable.

The final design was also the most durable. Although cheaper and more widely available, the synthetic nitrile from the female condoms was not able to withstand the stress associated with repeated rolling and often tore. Similarly, vinyl tubing was initially tried as a cheaper substitute for the silicone tubing. This was very stiff and made rolling difficult. Therefore, this material was not tested or pursued further.

7. Future Work

Now that the early models have been created, our next goal is to design more durable, practical models, preferably using materials similar to those used for the Alexis retractor. The device must be biocompatible. There is also the need for more extensive testing on our device's efficiency in force and pressure distribution, as well as the practicality of its use in surgical procedures. Ideally, this would be done with an animal model.

As for marketability, while it is true that our device is highly derivative, we feel it has a lot of potential. According to the survey we sent out to thyroid surgeons across the country, we have verified the desire and demand for a more practical, less damaging retractor for thyroid surgery. We hope that Applied Medical, the company that produces the Alexis device, will be able to see the potential that our retractor holds. In addition, there are other fields of surgery that we feel the Alexis device can be modified to fit- pediatric surgeries, for example. In any case, the potential for marketability of this product is certainly present, and we can only hope that Applied Medical and others will take notice of it as well.

8. Conclusion

Metal retractors used in thyroid surgeries cause much ischemic damage as a result from the sharp, pointed edges that distribute a large amount of force in a small surface area. But by modifying the Alexis® Wound Retractor to fit the varying anatomy of the neck, a feasible design was constructed that distributes the force evenly around the incision.

The final design consists of is a modified Alexis® device consisting of two top oval rings (4 by 6 cm), one bottom round ring (6 cm diameter) and a shorter

polypropylene tube (5 cm) to fit the varying anatomy of the neck. Testing was performed using floral foam and chicken breast to obtain quantitative and qualitative data, respectively. This confirmed that it could hold the incision open with even force.

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15. All Medical Supplies.com Web. <http://www.allmedicalsupplies.com>
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10. Appendix

10.1 Images of Metal Retractors Currently In Use

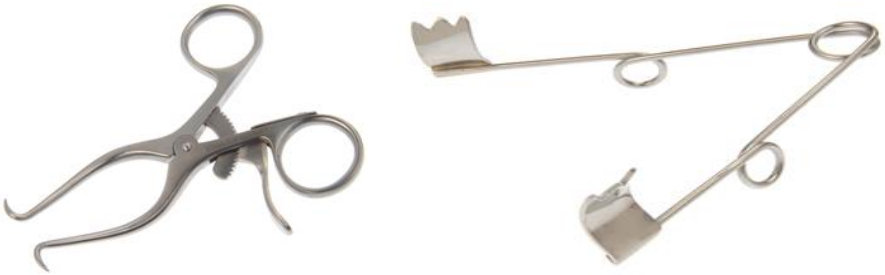

Figure 11: Gelpi Retractor (left) and a Spring Retractor (right) are shown above. Each retractor provides a great amount of force for a small surface area. The small, sharp edges may puncture skin or dig into skin further causing damage[10].

10.2 Thyroid Survey Tissue Retractor Survey

1. What type of tissue retractor do you currently use in thyroid surgery?
    - Gelpi retractor
    - Weitlaner retractor
    - Rake retractor
    - Senn retractor
    - Handheld retractor (ie army, navy, or deaver retractor)
    - Self-retaining spring retractor
2. Is there anything that you would change about the retractor you currently use?
    - Smaller size
    - Larger size
    - Less pressure
    - More pressure
    - More even distribution of pressure
    - Other (Please specify)
3. What device(s) did you use in your surgical training?
    - Gelpi retractor
    - Weitlaner retractor
    - Rake retractor
    - Senn retractor
    - Handheld retractor (ie army, navy, or deaver retractor)
    - Self-retaining spring retractor
4. Would you be interested in an improved device?
    - Yes
    - No

5. Please list any other ways that a retractor could improve your ability to do thyroid surgery.

These next questions are to get a better idea about who could possibly be using our device. All information is strictly confidential.

6. How long have you been performing thyroid surgery?
    - <5 years
    - 5-10 years
    - 10-15 years
    - 15-20 years
    - >20 years
7. What is your gender?
    - Male
    - Female

10.3 Retractors Included In Survey

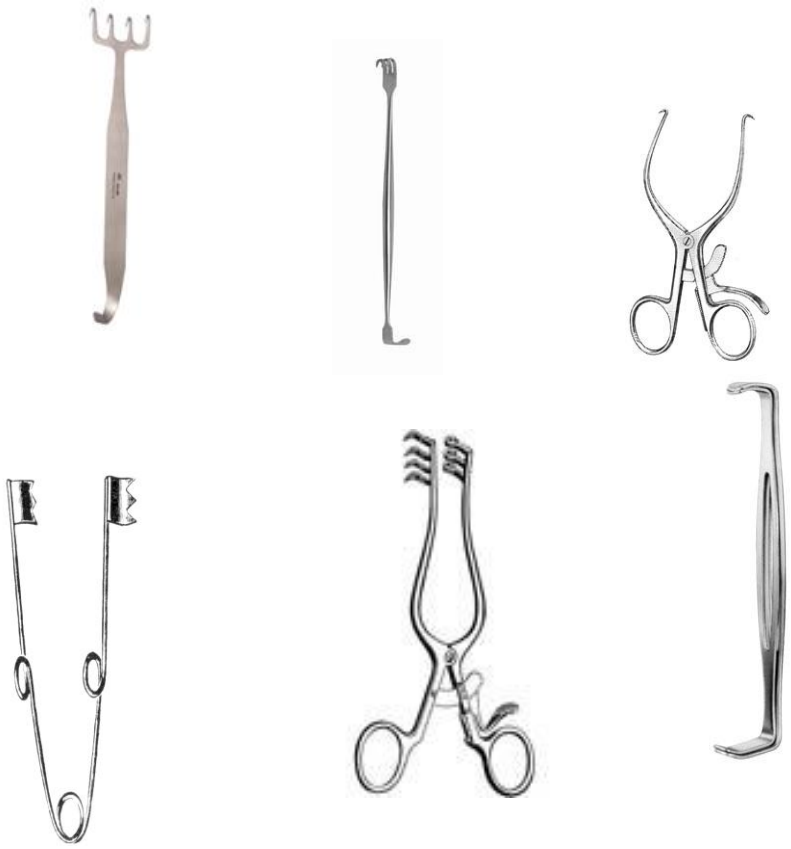

Fig. 12 Retractors listed on survey. Rake retractor[11] (top left), Senn Retractor[12], Gelpi Retractor[13], self-retaining spring[14], Weitlaner retractor[15], handheld(army navy) retractor[16].

10.4 Survey Results

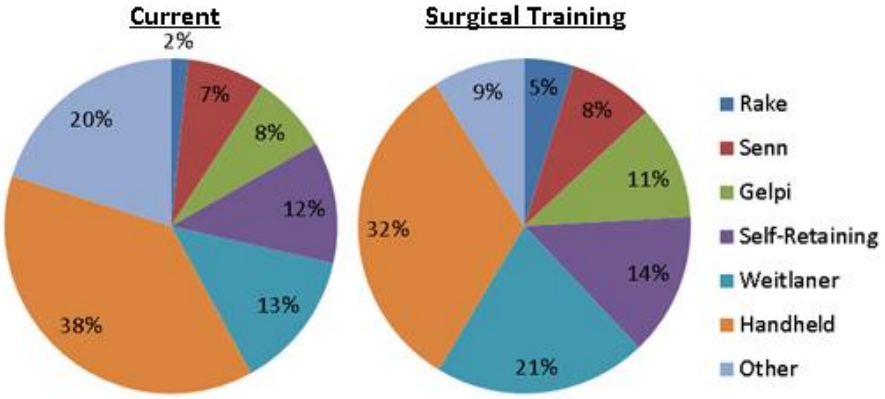

Figure 13: The handheld retractor is the most popular retractor today. It was also the retractor that the surgeon's used in their surgical training. The large shift away from non-traditional retractors (9 to 20 percent) shows that there is an openness to new devices.

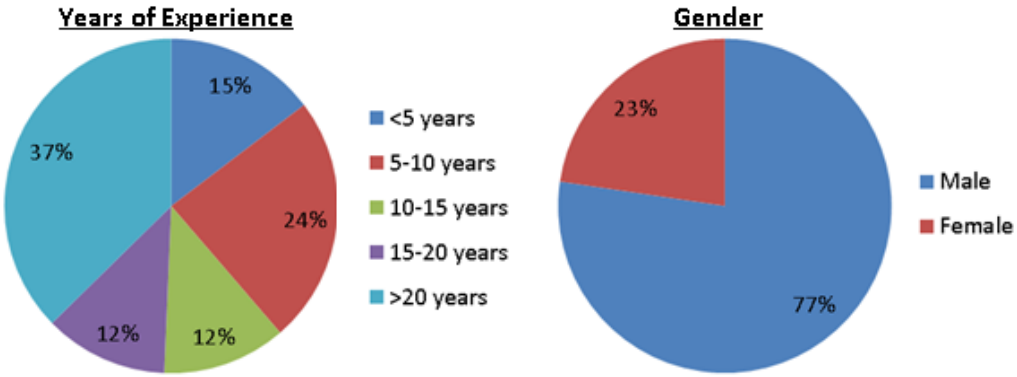

Figure 14: The population that completed the survey was predominantly male and has greater than 20 years of experience. The effects of this observation upon the data is unknown.

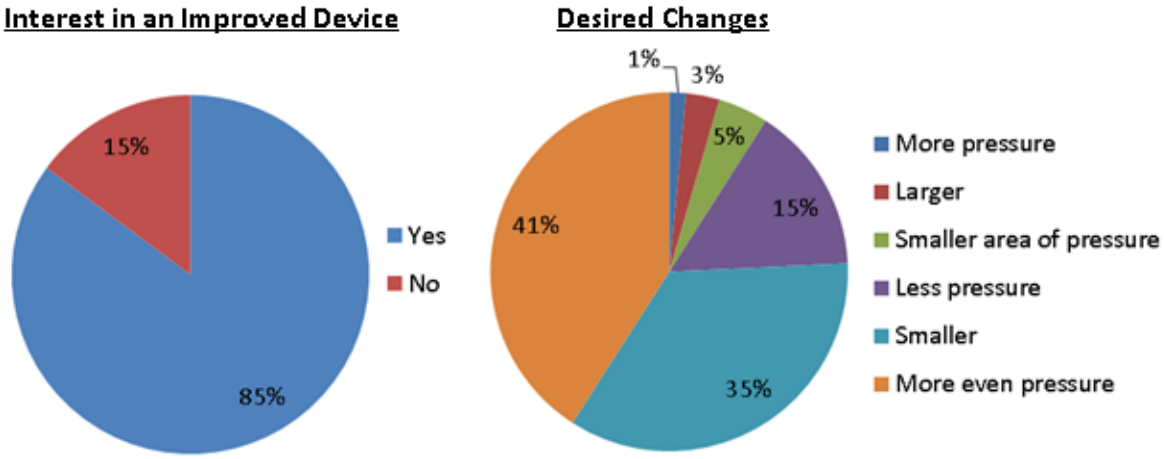

Figure 15: Eighty-five percent of the surveyed population are interested in an improved device, which not only demonstrates a need for new device but also a market for our prototype.

10.5 Product Design Specifications

Function:

Because of the risks of scarring, smaller incisions are being used in thyroid surgery. These small incisions still require retractors to keep the site visible, but most traditional retractors are incompatible with the smaller incisions. The currently used metal retractors distribute pressure unevenly across the incision site, which can cause ischemic trauma to the local tissues. On the other hand, our client tested the Alexis ® device (a round, flexible wound retractor used for abdominal surgery) and requests a similar device for thyroid surgery. The goal is to construct a device that is precise, provides a comfortable fit, and is capable of evenly distributing pressure across the site of incision.

Client Requirements:

Our client wants a retraction device that meets the following requirements:

- Delocalizes pressure over a large contact area
- Is compatible with varying anatomies
- Opens the wound in an "eye" shape (ellipse with pointed edges)
- Minimizes damage to tissue
- Is compatible with electrocautery (i.e. insulating)
- Ideally reusable

Design Requirements:

1. **Physical and Operational characteristics**

   a. Performance requirements: The retractor must retract the skin for a variety of anatomies with less damage and provide equal distribution of pressure around entire incision. Uneven distribution of force causes localized damage to the tissue which results in bruising and scarring. The incision should be held open by the retractor in a football shape or reasonable close (ie oval). The device also should be easily inserted and removed (see *1.g.Ergonomics*).

   b. Safety: The retractor should be able to insulate the skin from heat and possible burning by electrocautery (see *f. Operating Environment).* It must be biocompatible and cannot increase risk of infection.

   c. Accuracy and Reliability: The device should be able to maintain retraction under normal surgical conditions. The retractor must be compatible with varied anatomies. The factor safety must account for the wide range of anatomies that the device will be used with. Ideally the retractor could be used in other surgical procedures.

   d. Life of Service: The retractor must last length of surgery (approximately 60 to 90 minutes), including exposure to electrocautery.

   e. Shelf Life: The retractor must be durable enough to the withstand room temperature storage while maintaining sterilization.

   f. Operating Environment: While in the operating room, the retractor will be exposed to electrocautery which creates frequency upwards of 100 kHz and power of 120 watts.

g. Ergonomics: The retractor must be easily handled by one person and apply enough pressure to hold incision open but not enough pressure to damage tissues. One person must be able to not only insert and remove the retractor at the start of the operation but also adjust the view throughout the operation. The retractor should slow down or inhibit the standard course of events in the operating room. In addition, the device should not have excess bulk as to obscure the surgical field (see *1.h. Size, 1.i. Weight*).

h. Size: The retractor must fit in 3.5 to 4 centimeter incision and have a depth of 2 to 4 centimeters. It cannot obstruct access or view of surgical field.

i. Weight: The specific weight was not specified by client. The device, however, should not have excessive weight to damage tissues (approximately 8 ounces).

j. Materials: Materials must be biocompatible. Ideal materials provide desired device safety features (see *1.b. Safety).*

k. Aesthetics, Appearance, and Finish: The retractor should have a smooth surface to avoid skin damage. If possible, it should be transparent. The spring metal retractor must not have sharp edges that will penetrate the skin.

2. **Production Characteristics**

a. Quantity: Two reusable (ie revised spring metal retractor) or three single-use (ie revised Alexis design) retractors should be made.

b. Target Product Cost: Total budget should not exceed $500. Individual retractors should not exceed $100 per unit.

3. **Miscellaneous**

a. Standards and Specifications: The retractor must meet FDA requirements for clinical trials. IRB approval is required for testing in animals. The device must be able to function in a tissue breast model.

b. Customer: The client would prefer a device that is easy to use and provides natural retraction with equal force. The device would ideally be reusable but not at the cost of functionality.

c. Patient-related concerns: The retractor must be small enough to reduce visible scarring from surgery (see *1.a. Performance Requirements)*. Also, the retractor must be compatible with a wide range of anatomies (see *1.c.Accurarcy and Reliability)*.

d. Competition: The Alexis O Wound Retractor and the Gelpi retractor are two products currently used in thyroid surgery. Neither is ideal; the Alexis device is too long, and the Gelpi retractor is too damaging.