Design of Wound Protector/Retractor for Thyroid Surgery

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1. Abstract

Currently, metal retractors are used during thyroid surgery. These retractors, however, provide an uneven distribution of force. As a result, tissue damage, bruising and scarring occurs. Our clients, Dr. Rebecca Sippel and Dr. David Yu Greenblatt of the University of Wisconsin Hospital, request that we modify the Alexis® O Wound device or metal spring retractors to be more appropriate for thyroid surgery. Ideally, the device will be reusable but it must be compatible with the incision size and varying anatomy of the neck, as well as being compatible with what must occur during the surgery itself (moving the opening to make different parts of the thyroid visible).

Three designs were created: 1) revised Alexis® device with oval rings, 2) revised Alexis® device with wire mesh, and 3) revised metal spring retractor. The designs were evaluated based upon categories of importance to our clients. The first design, revised Alexis® with oval rings, ranked the highest and will therefore be fabricated. The pressure distribution and ease of use will be tested in an animal model.

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 that are located on each side of the trachea and are 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 require the 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

Approximately 34,500 thyroid surgeries are performed each year.[4] How much of the thyroid is 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 3.6-4 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]

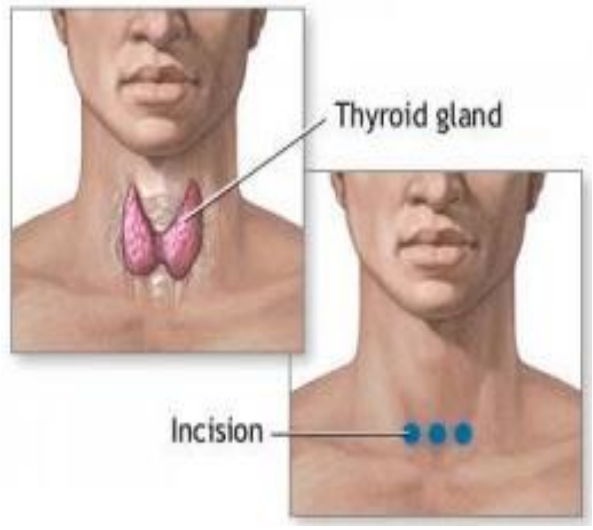

Figure 1: The image on the left shows the Thyroid gland. The incision is shown on the right.[5]

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 full thyroidectomy typically takes 60 to 90 minutes. 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. Partial thyroidectomies typically take 45 minutes[1]. In a thyroid lobectomy, only 1/4th of the thyroid gland is removed; this is the most rarely used 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 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).

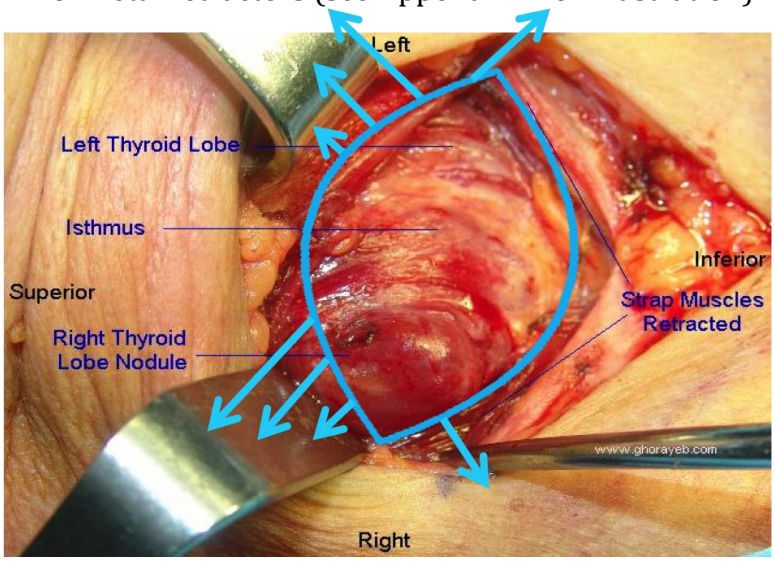

Figure 2: Metal retractors hold skin in desired position (football shape) for surgery[7]. Light blue arrows indicate force distribution. Ischemic trauma is a result of uneven pressure distribution.

The metal retractors are not ideal because, as illustrated in Figure2, 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 Alexis® O-Wound Device

A device currently used in abdominal surgeries is the Alexis® O-Wound Retractor (Fig.3). 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[8].

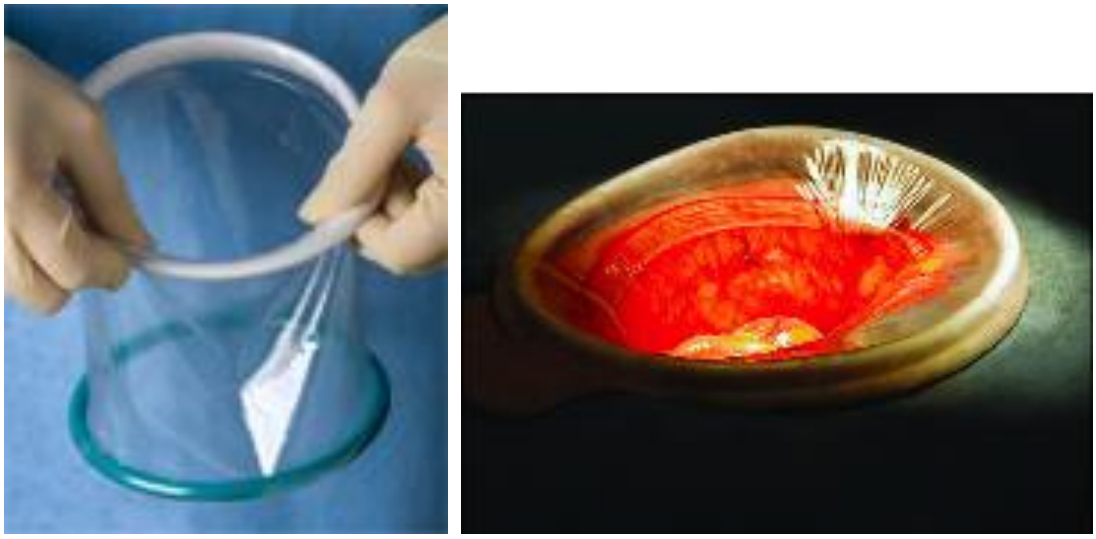

Figure 3: Alexis® O Wound Retractor (left) and in the wound (right) distributes force evenly over the entire incision.

Our clients implemented 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.

2.4 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.

2.5 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.

2.6 Sterilization

Sterilization removes biological contaminants between uses for the safety of the patient; it is important when designing anything to be used in surgery. Surgical equipment must be sterile before use; the type of sterilization used can limit the materials that the item to be sterilized can be made of. Single use devices, such as the modified Alexis® design and the Alexis® with mesh design (see *3.1 Designs*), are produced in sterile environments, and carefully disposed after use in surgery. While the sterile environment is important to those designs, it is a manufacturing concern that only effects the working prototype phase. A reusable design, however, (such as the revised metal spring retractor, see *3.1 Designs*) requires sterilization between uses.

There are two main categories of sterilization: high temperature and low temperature. Within these categories are many different types. High temperature sterilization includes steam, (often referred to as auto-clave) and dry heat sterilization. According to the CDC, "if items are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality"[9]. The steam carries thermal energy quickly throughout the surface being sterilized and helps destroy bacteria and other microorganisms by softening their outer layers. Steam is also the quickest and most common, as well as being relatively safe for the environment as no harsh chemicals need to be used. However, anything that cannot handle water or high temperatures, such as anything that might rust or melt, cannot undergo steam sterilization. The other common high temperature sterilization method is dry heat. This is good for anything that cannot handle water, but still does not work with plastics or anything that could melt. While dry heat is still effective at killing microorganisms, it is not quite as effective as steam, and requires higher temperatures and longer times to sterilize.[9]

The category of low temperature sterilization is rapidly growing, since it can be used on plastics and other materials that might melt or be damaged in high temperature sterilization. Within the category of low temperature sterilization, there are several subcategories, including liquid chemical sterilization and gas sterilization. The most common gas used in sterilization is ethylene oxide (ETO)[9]. ETO is difficult to use, however, because it can irritate tissue (including lungs), so a long aeration is necessary as well as protection for the staff doing the sterilizing. The other common low-temperature sterilization technique is liquid chemical sterilization, such as glutaraldehydes or formaldehyde[10]. These require a long soaking time for the items to be properly sterilized, and need a sterile water rinse as they are possibly carcinogenic. However, since the chemicals are in liquid form, they are less likely to be inhaled by staff, and therefore less dangerous. ETO is still more common than liquid chemicals, however, because glutaraldehydes and formaldehyde are more expensive[10].

For our purposes, with a modified metal spring retractor, the best form of sterilization is Steam Sterilization, or auto-clave. This type of sterilization is recommended by the CDC and is relatively environmentally friendly and cost

effective. As it is also the most common type of sterilization, the hospitals likely to use our device would already have the equipment for this type of sterilization.

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 (see section *2.6 Sterilization*). Therefore, focus was shifted to designing a metal retractor. Many different devices were considered. These designs, however, were not pursued dues 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.

An ideal device provides all of the visual and protective features of the Alexis® device (see section *2.3 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.

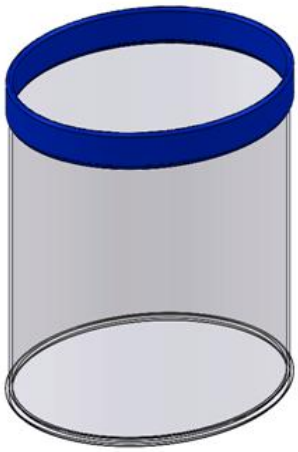

Figure 4: Design 1 is a revised Alexis® device with oval rings and a shorter tube.

The first design, as seen in Figure 4, 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 four 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.

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 5 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 5: 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.

The third design, as seen in Figure 6, is a metal spring retractor designed to provide a more even distribution of force which reduces trauma. As compared to the existing model (see Figure 7) the plates have a larger surface area to better delocalize 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.

Figure 6: Design 3 is a revised metal spring retractor with larger, angled plates and reduced spring constant.

3.2 Design Matrix

All three designs were evaluated based upon their pressure distribution, compatibility with varying anatomies, safety features, ease of production, ease of use (ergonomics), and environmental impact. The categories were weighted based upon perceived importance to the client (see Table 1).

Categories	Weight	Revised Alexis® Device + Oval Rings	Revised Alexis® Device + Wire Mesh	Revised Metal Spring Retractor
Pressure Distribution	0.20	10	10	4
Compatible with varying anatomies	0.20	9	8	6
Safety Features	0.20	9	10	5
Ease of Production	0.15	8	6	5
Ease of Use (Ergonomics)	0.15	9	8	5
Environmental Impact	0.10	4	3	10
Total:	**1.00**	**8.55**	**8.00**	**5.50**

Table 1: The design options were evaluated based upon weighted categories implicitly stated by the clients. The first design, the revised Alexis® device with oval rings, ranked the highest and is therefore our final design.

The first design ranked the highest due to its universal shape, burn and electrocautery protection, simplicity and ergonomics. Tensile forces are distributed over all surfaces in which the polyurethane tubing remains taught. Since the design is very similar to the existing Alexis® device, one can assume that the tube will remain taught over all portions of the incision except for the corners regardless of the shape of the incision. This simple, universal design also alludes to the high compatibility with varying anatomies. The device, however, will not function well in extreme cases in which there is a large amount of tissue that creates a depth of the incision larger than 4 centimeters. In addition, polyurethane is an antimicrobial and insulating material which can be used to prevent burns from the electrocautery or harmonic scalpel. Production is dependent upon the fabrication of the oval rings and the attachment of the polyurethane tube. Both processes could be done on a large scale with an assembly of machines in a sterile environment; production by hand, however, involves the tedious process of sealing the polyurethane tube uniformly around the rings. The design is also very easy to insert and can be inserted in any manner without readjusting later (see *3.1 Design Options*). Due to the single use nature of the device, it has a negative environmental impact, and thus ranked very low in this category.

The second design is supported by a wire mesh; the universal compatibility of the device, however, is limited by this mesh. This design has equal force distribution over a larger portion of the incision possibly even over more area near the corners than the first device. The double layer of polyurethane makes this device safer than the first device. The mesh, however, prevents it from being used with all incision sizes. The mesh must be in contact with skin to exert outward pressure necessary for retraction. For this reason, the device is less ergonomic than the first device. The added mesh also adds to the environmental impact. An addition method must also be devised to attach the mesh securely to the

polyurethane tubing or the rings; this is dependent upon the material chosen for the mesh (see *3.1 Design Options*).

The third design is ranked the lowest because it lacks the even force distribution and safety features associated with the polyurethane in the Alexis® device. Force is directed to the area covered by the plates; it is not localized over the large surface area of the rings like first and second designs. This also reduces the compatibility with varying anatomies. It is not compatible with very large incisions that exceed the maximum position. Also, if the incision is larger than the plates, the surgical view especially nearest the thyroid will be obscured. The device will need to be repositioned throughout the case to achieve the desired view (less ergonomic). Device production will be very tedious as it will need to be assembled in pieces – bend wire handle to achieve desired spring constant, coat plates – and weld or braise them together. On the other hand, the device is metal and can withstand repeated sterilization and is therefore environmentally friendly.

4. Future work

For the rest of the semester, we will be focusing on the revised Alexis® device, since it is the best option for our clients' needs. We will research the best options for materials for both the rings and the tube. Then prototypes will be constructed for testing. We will research and perform a test of the pressure distribution of our design, to prove that it is less likely to damage tissue than current designs. A test will be conducted using chicken breast or some other widely available animal tissue to see how the device works under realistic surgical conditions. This will determine how well the design works at pulling back the tissue from the surgical site as well as show how easy it is to use. If the proper paperwork and permission are able to be received, there is also the possibility of testing in a live animal lab, such as a pig. This will provide additional data on how well the design works in a surgical setting.

As marketing is an important concern for any product, the team will continue to research the potential client base. Other possible surgeries where this device could be used will be considered. In addition, a survey will be sent out to surgeons in the area to see what their needs are for a new retractor for thyroid surgery. This will give an idea of what surgeons other than our clients desire in a retractor.

5. Conclusion

There is a need for an improved device to retract the incision during thyroid surgery. Our clients request a device similar to the Alexis® O Wound retractor or spring metal retractor that will provide even pressure distribution and eliminate scarring. A prototype will be fabricated of the final design, the revised Alexis® device with oval rings. Pressure distribution will be determined in an animal tissue model. In addition, a questionnaire will be distributed to other endocrine surgeons to verify need for a new device.

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7. Appendix

7.1 Images of Metal Retractors Currently In Use

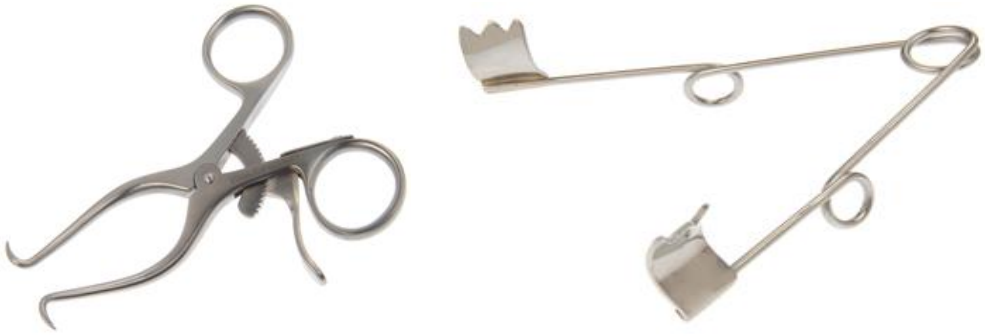

Figure 7: Gelpi Retractor (left) and a Spring Retractor (right) are shown above. Each provide a great amount of force for a small surface area. The small, sharp edges may puncture skin or dig into skin further causing damage[11].

7.2 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 round, flexible wound retractors 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). Ideally the device should be used more than once with sterilization (see *1.f. Operating Environment*). The device also should be easily insterted 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: If designed for one-time use (ie revised Alexis designs), the retractor must last length of surgery (approximately 60 to 90 minutes). If designed for multiple uses (ie metal spring retractor design), it must be able to withstand sterilization processes (see *1f. Operating Environment)*.

e. Shelf Life: The retractor must be durable enough to withstand room temperature and sterilization conditions (see 1*f. Operating Environment)* between uses (ie metal spring retractor design).

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. While being sterilized, the device will be exposed to a pressure of 15 psi and a temperature of 121oC for 15 to 20 minutes in a steam autoclave or exposure to 5 to10 percent of ethylene oxide (alkylating agent) and hydrogen peroxide and ozone (oxidizing agents) for inert chemical sterilization.

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. The rings for the revised Alexis designs must be 5 by 6 centimeters. The spring constant of the metal spring retractor design must be minimized to cause the least amount of trauma.

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. If reusable (ie revised Alexis designs), the retractor must handle sterilization conditions (see *1.f. Operating Environment)*. 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. A revised metal retractor is a last resort as countless other similar devices already exist.

c. Patient-related concerns: The retractor needs to be sterilized between uses (see *1.f. Operating Environment)* and 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.