Final Report: Thyroid Retractor

Biomedical Engineering Design

Department of Biomedical Engineering

University of Wisconsin-Madison

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Client

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Abstract:

There are many procedures that require the retraction of the thyroid gland in order to gain access to relevant anatomical structures. During the operation, the endocrine surgeon must retract the thyroid gland medially in order to gain access to the recurrent laryngeal nerve, to dissect the thyroid gland from vascular attachments, and to find parathyroid glands. When retracting the thyroid gland, surgeons often use one or two Rochester-Pean forceps with a piece of gauze at the tip referred to as a “peanut.” When working with only one forcep, there are at times not enough points of contact on the thyroid which causes the gland to be difficult to retract and hold. The goal presented by the client is to create a device that is similar to standard forceps, but has two prongs that are able to retract the thyroid from multiple points of contact. This report includes the evaluation of three preliminary designs: an adapted Weitlaner with shods, an adapted Weitlaner with spring endings, and an adapted Weitlaner with tread endings. The rest of the report discusses the final design, the adapted Weitlaner with tread endings, and the organ tissue analog and computational-aided testing conducted this fall of 2021. Future work includes conducting ergonomic testing with Dr. Doubleday, as well as a number of different clinicians. Additional future work includes looking into creating the final design out of stainless steel and beginning the patent filing process with the Wisconsin Alumni Research Foundation.

I. Introduction:

A. Motivation

Thyroid surgeries are a relevant procedure, as more than 130,000 thyroidectomies alone are performed every single year [1]. Even though this number is rather high, this does not account for all of the procedures that occur near and around the thyroid gland. Procedures that are performed involving retraction of the thyroid often use different techniques and surgical instruments, such as different types of prongs or forceps. Although procedures surrounding the thyroid are commonly done, they are still described as tedious when it comes to an effective retraction of the thyroid gland [2]. At Waukesha Surgical Specialists, the thyroid retractor used during surgeries surrounding the thyroid does not always provide a complete retraction of the thyroid. The retractor often fails to completely retract thyroids of a larger size, or those with an odd shape. Considering the hardships experienced at Waukesha Surgical Specialists, there is a definite market opportunity for another device. As noted above, thyroid surgeries are very common, so creating a device that helps increase the efficiency of the surgery will be advantageous to the client's surgical team specifically, as well as beyond.

B. Competition

There are multiple medical devices on the market that aid in thyroid retraction. Differences between thyroid retractors come from adjustability, number of points of contact between the retractor and thyroid, as well as the adaptability to different thyroid shapes and sizes. The forcep devices currently being used for thyroidectomies are the Allis Tissues and Rochester Pean forceps. The Allis Tissue Forceps (see Figure 1) are commonly used during surgery to firmly grasp the thyroid tissue. It is made of stainless steel and features a curve towards the midline of the device which is designed to help increase the grip on the tissue. However, one disadvantage to this design is that the ends of the device create force concentrations which may potentially cause tissue damage either via direct trauma or vascular damage [3].

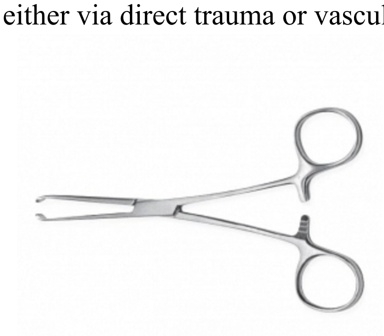


Figure 1: Image of Allis Tissues Forceps [4]

The Rochester Pean Forceps are a hemostatic surgical forcep made of grade 420 stainless steel. They resemble a pair of scissors with the blade replaced by a blunted grip. In surgery, they are used for holding the thyroid tissue out of the way [5]. The Rochester Pean forceps are the current thyroid retractor device used by the client, along with a single peanut sponge held by an auto-locking forceps, (see Figure 2), or two peanuts and two forceps held, one held in each hand. The purpose of the peanut sponge is to distribute the applied force over a larger area thereby reducing the localized pressure on the tissue and the chance of harm to the gland. The fault with this set of forceps is that the prongs allow for one point of contact between the device and the thyroid retractor, which contributes to the current problem of ineffective retraction when it comes to larger thyroids.

Surgical sponges are commonly used in operations and are available in a wide range of shapes, sizes and intended uses. In general, the sponges fall into the categories of ophthalmic, dissecting, gauze, neurology, laparotomy and miscellaneous sponges. Because of the wide range of functions for these sponges, for this design project, only the peanut sponge will be focused on. The peanut sponge falls under dissecting sponges, and is approximately at the midpoint of the sizes of available dissecting sponges at 0.95 cm (3/8"). The peanut sponge is intended for "delicate sponging and soft tissue dissection". They are supplied to hospitals already sterilized, and can be x-ray detectable [6]. With the current method that is used for thyroid retraction, peanut sponges are used in order to decrease the force of the surgical device on the thyroid and help to increase the amount of traction that the surgeon has on the thyroid to avoid any tissue slippage. Tissue sponges will not be kept in the new design to be fabricated, as there is not a current plan to create a mechanism to hold the sponges.

Figure 2: *Current thyroid retractor used by the client: The Peanut [6]*

C. Problem Statement

The project goal of the Fall 2021 term is to create a device to aid in thyroid retraction during thyroidectomies, as well as allow access posterior to the thyroid. In these operations, endocrine surgeons must retract the thyroid gland medially in order to gain access to the recurrent laryngeal nerve, dissect the thyroid gland from vascular attachments, and locate the parathyroid glands. Surgeons use either one or two Rochester-Pean forceps with a piece of gauze clamped at the tip, referred to as a “peanut.” This can often make the procedure challenging because with only one point of contact the dissection is incomplete, whereas handling two forceps at once is cumbersome. The desired design should gather inspiration from the current thyroid retractors, yet have multiple points of contact incorporated into a single device and be adjustable to allow for the retraction of different sized thyroid glands.

II. Background:

A. Background on Relevant Physiology

The thyroid is a very important gland as its hormone production affects virtually every organ system in the human body. It is a butterfly shaped organ that sits anteriorly to the trachea located low in the neck (see Figure 3). The typical thyroid ranges from 3 or 4 cm width, and weighs between 10 and 20 grams. It consists of two lobes located symmetrically on either side of the trachea, and connected by a tissue bridge called the isthmus. It secretes thyroid hormones thyroxine (T4), which accounts for approximately 80% of total hormone production, and triiodothyronine (T3), which accounts for approximately 20%. These two hormones are crucial for brain and somatic development in infants, metabolism in adults [7], and are important in cell regulation and homeostasis [8]. In most cells, T4 is converted to T3, the biologically active hormone which influences cell activity and the rate of metabolism.

The thyroid is regulated by the pituitary gland in the skull, which detects the levels of both T3 and T4 in the blood. The pituitary gland directs the thyroid to secrete these hormones by secreting the thyroid stimulating hormone (TSH). If there is excess of T3 and T4 in the blood, the pituitary decreases or stops secretion of TSH, resulting in the reduction of T3 and T4 secretion. Conversely, if there is too little T3 and T4 in the blood, the pituitary gland increases TSH secretion. An excess of T3 and T4 secretion results in overactivation and metabolism of bodily cells, also known as hyperthyroidism. This can lead to increased heart rate, intestinal overactivity, weight loss, heat intolerance, irritability, hair thinning, or oligomenorrhea, i.e., increased bone resorption [9]. Conversely, hypothyroidism is the result of too little T3 and T4 secretion, resulting in underactivation of cells and cell metabolism. Hypothyroidism is one of the most common disorders associated with the thyroid, and can result in fatigue, weight gain, poor concentration, and depression among other symptoms [9].

Hypothyroidism is most commonly seen in an autoimmune disorder called Hashimoto's thyroiditis resulting from autoantibodies to the thyroid peroxidase (TPO) enzyme, in which the body's innate immune system attacks TPO as if it were a pathogen. This interrupts the natural thyroid cell's ability to manufacture thyroid hormone and thus the thyroid gland secretes less T4 and T3 and is in a constant inflammatory state. Another common autoimmune disorder of the thyroid is Grave's disease. This occurs when the body makes autoantibodies to the thyroid TSH receptor, which results in the overstimulation of the thyroid gland, diffuse growth or goiter, and the over production of T4 and T3. Again, the thyroid gland may be in a constant state of inflammation, but can also be associated with Grave's ophthalmopathy, or bulging eyes which causes dryness, redness and irritation to the eye.

Other thyroid disorders include nodules which can be benign, thyrotoxic, or malignant. Postpartum thyroiditis may occur in approximately 4-9% of women, although it is usually temporary [10]. Viral thyroiditis can be triggered by various infections and again is usually temporary. When diseases like those listed above are present in the human body, endocrine surgery may be necessary in order to remove nodules, biopsy the thyroid, or potentially remove the thyroid.

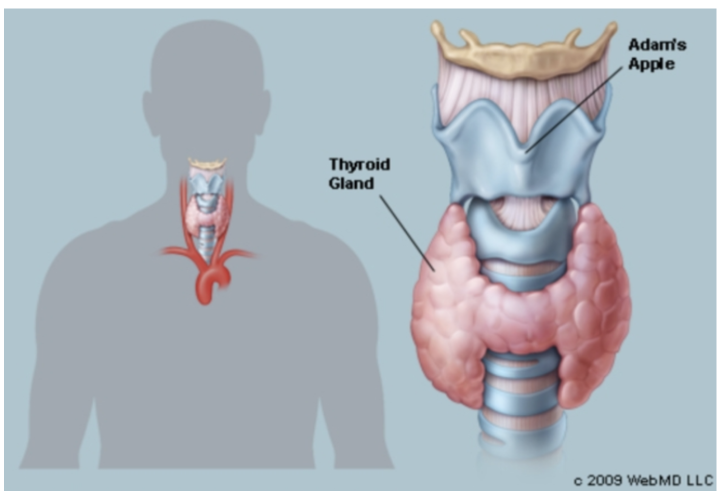


Figure 3: *Anatomical image of the thyroid gland in the human body [10]*

The parathyroid glands are pea-sized glands located adjacent to the thyroid in the neck, two of which are superior parathyroid glands and two inferior parathyroid glands (Figure 4). Despite having a similar name, the function of these glands is entirely separate from that of the thyroid. The parathyroid glands regulate the levels of calcium and phosphorus in the bloodstream by secreting parathyroid hormone (PTH). Calcium controls many functions of the body aside from regulation and maintenance of bones. For example, Calcium ensures that the nervous system runs properly. In the nervous system, Calcium is important for allowing electrical impulses to propagate down axons, and it is also the reason why synaptic terminals transmit neurotransmitters into other synapses [11]. Calcium also regulates energy to the muscular system. Low calcium levels can result in feeling weak or tired, muscle cramps, and other symptoms. PTH regulates calcium levels by releasing calcium from the bones and increasing the amount of calcium absorbed from the small intestine. If calcium is at a sufficient or high level, the parathyroid glands sense this by means of calcium sensing receptors and reduce secretion of PTH. Conversely, if the serum calcium level is low, the parathyroid glands increase the secretion of PTH.

If there is an excess of PTH in the bloodstream, there will be a rise of blood calcium levels, which may be indicative of Hyperparathyroidism. Hyperparathyroidism can be caused by a small, benign tumor on the parathyroid gland, or enlarged parathyroid glands. On rare occasions, the cause of hyperparathyroidism is cancer [12]. Conversely, a lack of PTH in the bloodstream is known as hypoparathyroidism. This also disrupts the balance of calcium and phosphorus in the blood, resulting in calcium deficiency and an excess of phosphorus. Hypothyroidism can be caused by injury to the parathyroid glands, inflammation of the glands or the thyroid, endocrine disorders or inherited disorders. Problems with the parathyroid can also be a reason for endocrine surgery requiring retraction of the thyroid [13].

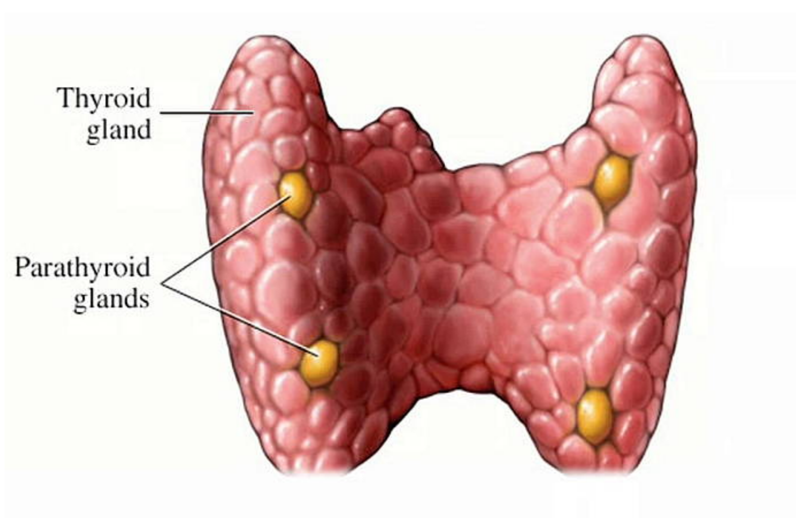


Figure 4: *Anatomical location of the parathyroid glands relative to the thyroid [12]*

B. Current Unmet Need

Endocrine surgeons are routinely faced with thyroid and parathyroid pathology which requires surgical intervention. Thyroidectomies and parathyroidectomies are surgical procedures used to treat a variety of conditions as described above. Thyroidectomies are used to treat various thyroid pathologies including thyroid cancer, hyperthyroidism, hypothyroidism, enlarged thyroid nodules (which may or may not secrete excess thyroid hormone) or multinodular goiters that grow so large that they cause compressive symptoms in the neck. To perform a thyroidectomy, a small horizontal incision is made low in the neck to gain access to the thyroid gland. Once the overlying tissues and muscles are separated and retracted, the thyroid gland is dissected from its muscular and tracheal attachments and retracted medially. This maneuver can be difficult in large or inflamed thyroid glands.

A common occurrence in Dr. Doubleday's operating room is having to retract a thyroid of a larger size. Oftentimes, if a single peanut instrument is used to retract a larger thyroid, there is not enough traction to retract the thyroid completely. Over the duration of the retraction, the thyroid mass may end up folding over the point of retraction, deeming the retraction unsuccessful. In order to combat this problem, two peanut instruments are used (see Figure 5). When two peanuts are used, a surgeon has to use both of their hands, holding one peanut in each hand. This method of retraction, while effective, is also very inefficient. If a surgeon no longer has a free hand to operate, due to using both hands for retraction, another surgeon or staff member may have to enter the operating room to support the surgery. Bringing another person into the operating room is not always possible due to staffing issues, or limited size of the operating space.

Figure 5: *Image during a thyroid retraction surgery done by Dr. Doubleday*

Parathyroidectomies also require medial or superior retraction of the thyroid gland in order to visualize and dissect out parathyroid glands which again, can be difficult in cases of enlarged parathyroid glands. Such maneuvers are currently done with a variety of strategic instruments and surgeon hand placement. Risks of thyroid and parathyroid surgery include postoperative bleeding in the neck, recurrent laryngeal nerve injury, and temporary or permanent hypocalcemia. These risks are all rare, and in the hands of an experienced endocrine surgeon should be less than 5%.

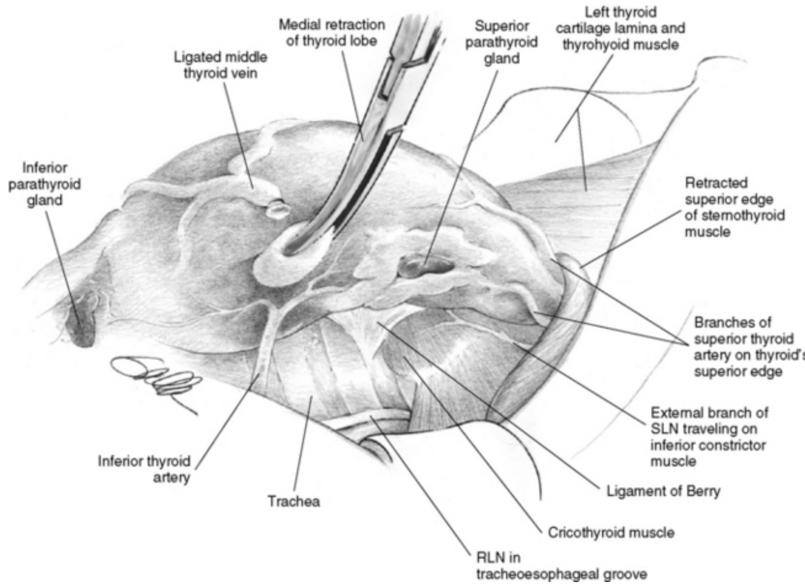


Figure 6: *Depiction of the medial retraction of one lobe of the thyroid during surgery with a peanut sponge, showing the relevant anatomy near the gland [10]*

C. Research Required for Prototype

The main research required for the prototype involved determining the appropriate size, materials and dimensions of the device. It was found that most medical forceps are made out of medical grade stainless steel to avoid corrosion and have a nominal length of 20 cm [14]. Depending on their desired function, surgical forceps and other instruments may be categorized into two distinct subgroups. Disposable forceps and instruments are single use instruments, intended to be disposed of after they are used. They are sterilized once before use in the operating room, but are not required to be sterilized again after use. Because they are not required to be exposed to the intense temperatures and environment of autoclave sterilization, they are often made from lower quality materials and plastics, which would not be capable of repeat sterilization. Materials used for disposable instruments include lower quality stainless steels and alloys, along with strong plastics. Non-disposable instruments are required to withstand repeated steam sterilization at high temperatures, usually around 121°C so that they can be used multiple times safely [15]. These instruments are often made of high-grade carbon steel, but can also consist of other high quality stainless steel, chromium and vanadium alloys that are corrosion resistant [16]. Reusable forceps made from medical grade stainless steel typically weigh approximately 40 grams [14].

In addition to relevant biological, physiological, and logistical information required for the prototype, the ergonomics and applied forces of the design must be taken into consideration. Since it is a surgical device that will be manipulated by humans, it must be capable of withstanding the standard forces that will be encountered in the operating room. One of these important forces is the grip of the surgeon. For that reason, information on the average and extreme values of human grip strength are relevant to the design criteria. Previously, NASA has dedicated research to human performance capabilities for a wide range of quantifiable tests. One such test was for human grip strength among both male and female subjects. The 50th percentile for grip strength in men and women was 452 N and 325 N, respectively [17]. The device should be capable of withstanding applied maximal forces that will occur at the distal ends of the device and bending moments that will be in the most proximal aspect. These occurrences are modeled in Figure 7. Because of this, the team will use the 95th percentile for men in the design criteria. The 95th percentile for male grip strength for the right hand is around 500 N. Although the referenced literature is from 1976, there is no reason to assume that there has been a considerable increase in the force production capabilities of humans in the last 50 years, and thus these values will be used.

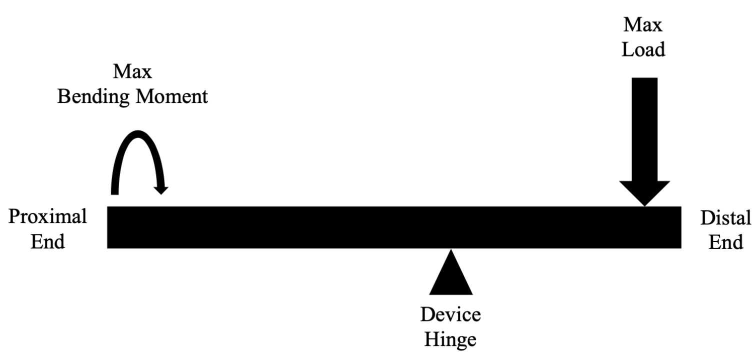


Figure 7: *Free-body diagram depicting the maximum forces and bending moments with the device simplified to a Class I lever system.*

D. Client Information

The client for this design project is Dr. Amanda Doubleday, a surgeon affiliated with the University of Wisconsin School of Medicine and Public Health, and is also a surgeon at a hospital located in Waukesha, WI. Her inspiration to investigate an improved thyroid retractor came from relying on two separate peanuts to successfully retract a single thyroid (Figure 5). While the two peanuts are able to get the job done, retraction and therefore the surgery would be more efficient if there was a single, adjustable retractor capable of accommodating thyroids of different shapes and sizes by making two or more points of contact.

E. Design Specifications

The device the team is fabricating needs to adhere to the following requirements. It should be two pronged, meaning it separates from the head of the instrument into two ends. The distance between the ends needs to be adjustable to accommodate for thyroids of different sizes. The design should accommodate for the ability to contact multiple parts of the thyroid. Having more than one point of contact will allow successful thyroid retraction without slipping, or caving around the single contact point. The device should be intuitive for a trained surgical staff to use and should not interfere with the ergonomics of the device. The device itself should be sterilizable and reusable. Most importantly it should have no atypical protrusions to prevent harm to the patient or surgeon. To be able to effectively retract thyroids of different sizes and shapes, the device must contain prongs where the distance between the two prongs can be adjusted.

The thyroid retractor should have the characteristics of a typical surgical instrument. The retractor should be made out of stainless steel, have a mirror finish, have a length of about 20.32 cm (8 inches) [14], and weigh about 40.8 grams (.09 pounds) [14]. The complete design specifications can be found in Appendix A.

F. Reference Device: The Weitlaner Retractor

The Weitlaner Retractor was an inspiration for the subsequent preliminary designs to be discussed. This device is not actually used for retraction, but is used to hold wounds or cuts open during operation. The retractor features a unique ratcheting mechanism. It is a self-retaining retractor that is set against the edges of the surgical site needed to be held apart. Then ratcheted handles are locked manually by a spring-loaded locking tooth mechanism as denoted by (A), which shows the locking tooth mechanism, and (B) which shows the location of the internal spring in Figure 8 below, while the blades remain apart holding the edges with no assistance [18].

In the review of the initial design from the Spring 2021 semester, the client specified that the retractor should have a ratcheting mechanism, as seen by (A) in Figure 8 below, similar to the Weitlaner retractor. This feature was incorporated into the three preliminary designs in the Fall 2021 semester.

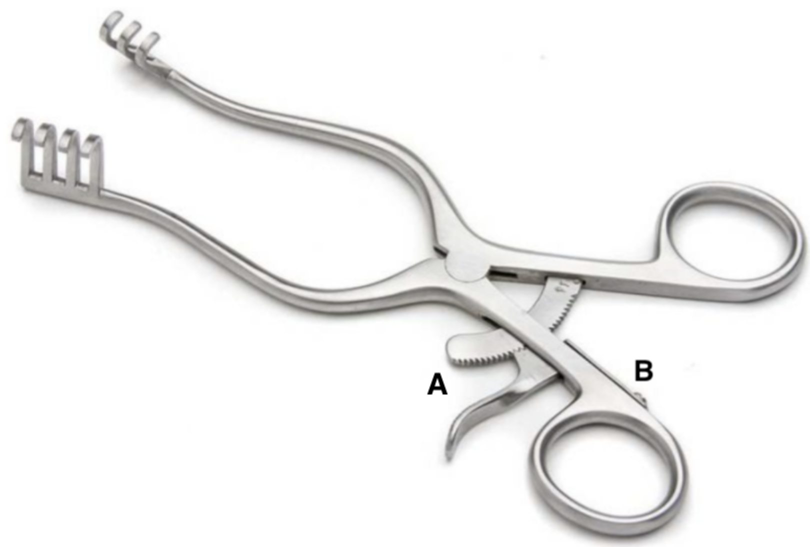


Figure 8: *An image of a Weitlaner Retractor [19]. A denotes the location of the Weitlaner ratcheting and locking mechanism. The spring location is denoted by B*

III. Preliminary Designs:

A. Design 1: Shods

The Shods design is the final design chosen by the team at the end of the Spring 2021 semester. The proximal portion of the device consists of the Weitlaner components. It has a handle to hold the device, as well as the ratcheting locking mechanism, which may be set and adjusted with a single hand, in order to facilitate more convenient alterations to the width of the retractor.

Figure 9: *Adapted Weitlaner with shods*

The distal portion is the 3D printed silicone rubber shods, shown in Figure 10, that contact the thyroid. This approach is based on the single-use disposable polymer tips used for some surgical clamp applications. The shods feature a hollow cylindrical base that allows for insertion over the Weitlaner retractor prong tips. Each polymer tip consists of a wide, curved surface to maximize the contact area with the thyroid during surgery, as well as rounded edges to minimize that possibility of harm to the patient. Solidworks applied force testing was conducted in the 2021 spring semester on the 3D printed rubber shods. The results and details of this testing can be found in Appendix B.

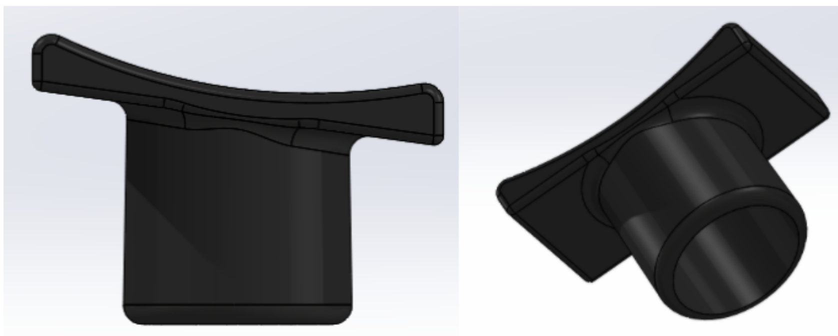


Figure 10*: CAD model of the polymer tips used with the adapted Weitlaner design.*

B. Design 2: Springs

The Springs design is a combination of the Weitlaner retractor and the Peanut. This design features the ratcheting system and finger holes of the original Weitlaner retractor. By using this design, the ability to adjust the width between the two prongs will be maintained. However, instead of having forked ends like the original Weitlaner the ends of the Springs design contain springs that can be pulled apart laterally. The springs in the tips of this design are intended to be spring-loaded in order to hold the peanut tightly in place. The purpose of this feature is to hold the peanut gauze tips in place during thyroid retraction. By adding this design change, during thyroid retraction, the thyroid will be able to be contacted by two peanuts instead of just one, which reduces the likelihood of any slippage or folding of the thyroid occurring.

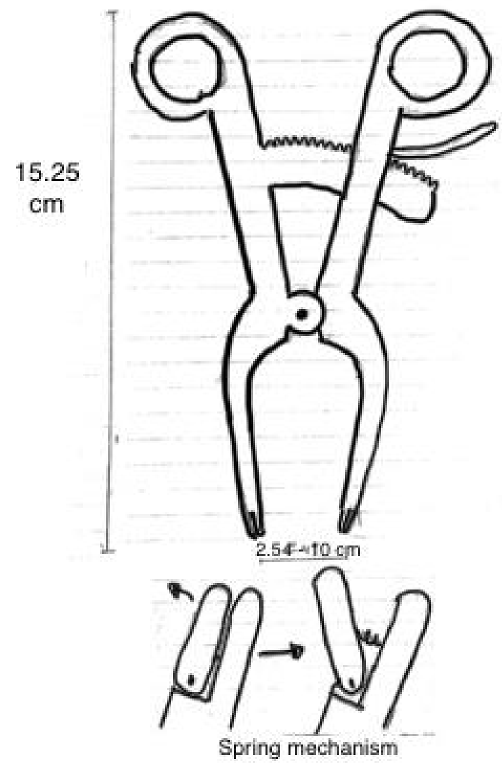


Figure 11: *Springs design sketch with ratchet system, split tips, and springs.*

C. Design 3: Treads

Similar to the Shods and Spring designs, the Tread design also contains features from the original Weitlaner retractor. This allows the Tread design to maintain the adjustability between the two prongs of the device. However, instead of the forked tips of the original Weitlaner, this device will feature a metal ring at the end of each tip. These metal rings will have an inward angle, which will allow for better retraction of the thyroid. Also, the metal rings will be grooved, as seen in Figure 12. By texturizing the metal rings, there will be no need to use a peanut or rubber shod for traction on the thyroid because the grooves of the rings will provide traction.

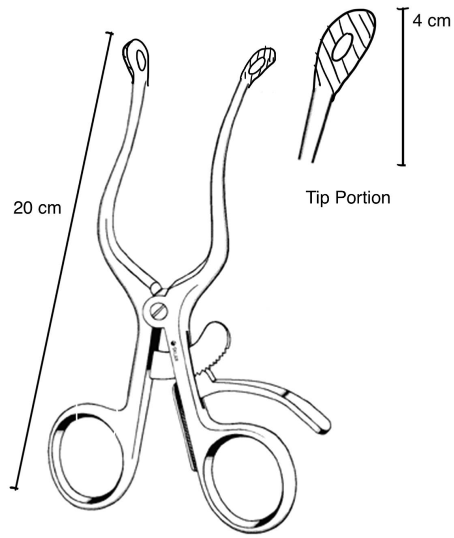


Figure 12: *Treads design sketch featuring a ratcheting mechanism and grooved circular tips.*

IV. Preliminary Design Evaluation:

A. Design Matrix Criteria

In order to compare the three preliminary designs, the designs were evaluated using a design matrix. The design matrix contained six categories with varying degrees of importance. Each category was given a weight, and then each design was given a score of 0-5 in that specific category.

The first category in the design matrix was safety. The measure of safety is determined by the amount of damage the device may create when in use during a surgical procedure. The trauma that may be caused by the device will want to be minimized as much as possible, which is why the category of safety was given the highest weight of 25/100.

The second category is thyroid grip. During surgery, it is important that the retraction device is able to have a firm grip on the thyroid to prevent any slippage from occurring. Also, it is important that the device can contact the thyroid from multiple spots in order to prevent any possible folding of the thyroid. So with these considerations, this category represents how well the device is able to grip the thyroid from multiple points of contact during retraction. This category was given a weight of 20/100 because it is important that the device is able to retract the thyroid efficiently with minimal slippage and folding occurring.

The third category, which is ease of use, represents how efficiently the device can be used by the surgical staff. Specifically for this project, the ease of use represents how fluidly the surgeon can use the device to be able to retract the thyroid medially from multiple points of contact. This category was given a weight of 20/100 because if the device is not able to be used readily to retract the thyroid, then the device will not be able to complete the function it was designed for.

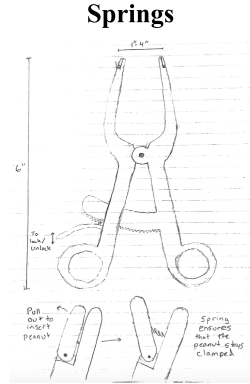
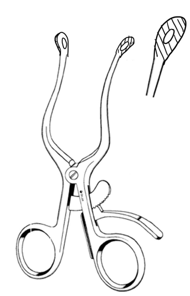
The fourth category is adaptability. This category represents how well the distance between the prongs can be adjusted. During thyroid retraction, this distance may need to be adjusted for a number of reasons. For example if a patient has a smaller or larger thyroid than average, the distance between the prongs of the retractor may need to be adjusted. This category was given a weight of 15/100 because it will be very beneficial if the device will be able to be used on a larger population, additionally, being able to adjust this distance increases the ease of use of the product.

The fifth category is ease of fabrication. This category represents how each design would be manufactured and how difficult that manufacturing process would be. Ease of fabrication was given a weight of 10/100 because most designs will be manufactured using relatively similar methods and materials.

The sixth and last category is cost. This category simply represents how much the device will cost to manufacture and was given a weight of 10/100. This low weight is because cost is not a pressing issue in this design project.

B. Design Matrix

Table 1: *Preliminary Design Matrix. Scores highlighted in red denote a high score in a category.*

Design		**Shods**		**Springs**		**Treads**	
Criteria	**Weight**						
Safety	25	4/5	20	5/5	25	5/5	25
Thyroid Grip	20	4/5	16	4/5	16	3/5	12
Ease of Use	20	3/5	12	3/5	12	5/5	20

Adaptability	15	5/5	15	1/5	3	4/5	12
Ease of Fabrication	10	3/5	6	4/5	8	5/5	10
Cost	10	3/5	6	4/5	8	5/5	10
Total	**100.0**	**75**		**72**		**89**	

a. Design 1: Shod Design

After being evaluated in the design matrix, the Shod design received a score of 75. This gives it the second highest score when compared to the other two designs. In the category of safety, this design received a 4 out of 5, this is because it is unlikely to cause any more harm to the surrounding environment than the other designs. In thyroid grip, it also scored a 4 out of 5 because the device is able to contact the device from multiple points and the rubber shods provide traction for the device against the thyroid. In the category of ease of use, it received a 3 out of 5. This is because it may be time consuming to try and adjust the rubber shods during surgery. In the next category, adaptability, it received a 4 out of 5 because this design still maintains the ratcheting system of the original Weitlaner and the interchangeable rubber shods may be useful for increasing adjustability. In the category of ease of fabrication, the design received a 3 out of 5 because in addition to the retractor being fabricated, the rubber shods will also need to be fabricated. Lastly for cost, it received a 3 out of 5 due to the extra cost of having to fabricate the rubber shods. Overall, the Shod design scored highly in the category of adaptability but lost points in the categories of ease of use, ease of fabrication, and cost.

b. Design 2: Spring Design

After being evaluated in the design matrix, the Spring design received a score of 72. Compared to the other designs, it ranks third. In the category of safety, this design received a 5 out of 5 because this device would not cause any excessive damage to surrounding tissues. Next, in the category of thyroid grip, it received a 4 out of 5. Similar to the Shod design, the Spring design allows for multiple points of contact and the peanut gauze tips used with this design when in action allow for increased thyroid traction. In the category of ease of use, it received a 3 out of 5 because it may be difficult to adjust the spring tips of the design during surgery. In the category of adaptability, this design received a 1 out of 5. It received this score because although it maintains the adjustability of the original Weitlaner, the springs may be challenging to adjust the tips during surgery. In the category of ease of fabrication, it received a 4 out of 5 because there is no additional gauze tip to manufacture because the peanut will be used, however, some of the smaller parts of the spring tip may be difficult to manufacture. Lastly, in the category of cost it received a 4 out of 5 due to the possible extra cost of having to manufacture the spring tip parts. Overall, this design scored highly in the category of safety but lost points in the categories of ease of use and adaptability.

c. Design 3: Tread Design

After being evaluated in the design matrix, the Tread design received the highest score of the three designs, an 89. Similar to the other two designs, in the category of safety, the Tread design received a score of 5 out of 5 as it is unlikely that the design would cause any excessive damage. In the category of thyroid grip, the design received a 3 out of 5 because the design does not utilize any gauze or rubber tip and solely relies on the grooves on the paddles for traction against the thyroid, which may be an issue when operating in a wet environment. In the category of ease of use, the design received a 5 out of 5 because the device does not use any external tips so there will be no need to adjust the device tips during surgery. Next, in the category of adaptability, it received a 4 out of 5. Once again this device retains the adaptable prongs from the Weitlaner retractor, however, the metal circles are unable to be adjusted during surgery. Lastly, in the categories of ease of fabrication and safety, the design scored a 5 out of 5 in both of the categories. For ease of fabrication, the device will be relatively straightforward to produce as it does not require any small or complicated parts for the tip. In cost, the device should be relatively inexpensive because once again there is only a single part that would need to be manufactured. Overall, this design scored highly in the categories of safety, ease of use, ease of fabrication, and cost. However, this design lost points in the categories of thyroid grip and adaptability. As this design scored the highest compared to the other designs, it will move forward as the proposed final design.

C. Proposed Final Design

After evaluating each design using the design criteria of the design matrix, the Treads design will be used as the proposed final design. This design scored highly in almost every category of the matrix. It is an all-in-one reusable design with no disposable components. This design consists of the original Weitlaner retractor ratcheting system with modified prong tips. As seen below in Figure 13, the design contains the Weitlaner ratcheting system. By keeping this portion of the design, the device will be able to maintain the adjustability of the Weitlaner retractor. The ergonomic handle allows for single-handed use. This ratcheting system is self-retaining, which makes it ideal for this scenario. The tips on this design are modified into circular metal rings. These tips will have an inward angle which will aid in the retraction of the thyroid from multiple points. The tissue contacting geometry of the tips allow for increased surface contact and minimal potential for damage. Additionally, the rings will be grooved, which will allow for traction during thyroid retraction. Advantages of this design include the ease of fabrication of this device, cost, safety of the design, and ease of use. Additionally, there will be no need for a gauze tip or a rubber shod to be used.

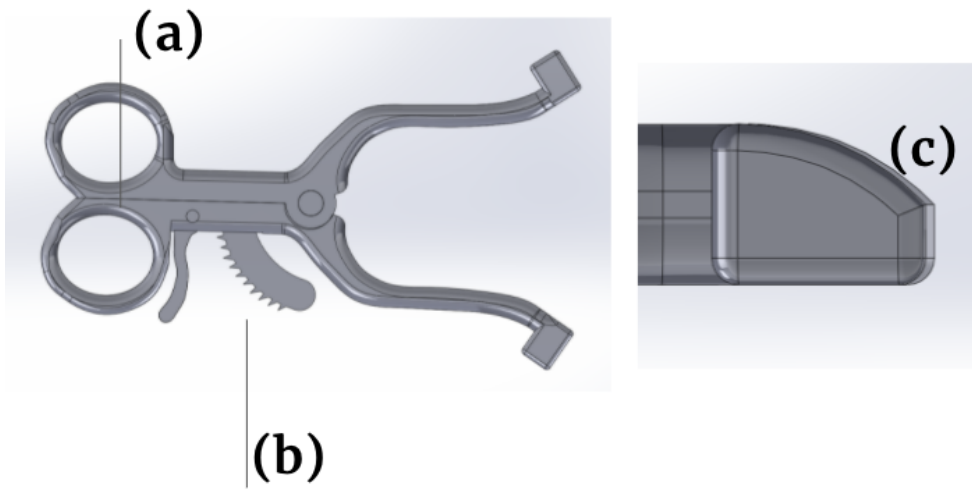


Figure 13: *Treaded Weitlaner design (left) with tissue-contacting geometry (right)*

D. Fabrication/Development Process:

a. Materials

For the purposes of the final design, the first prototype iterations were made by rapid prototyping in a high-modulus polymer representative of the AISI 420 steel used in surgical instruments. Common materials used in 3D-printing applications include polymers such as polymethyl methacrylate (PMMA), polylactic acid (PLA), polyvinyl alcohol (PVA), and polypropylene (PP) [20]. The group decided to rapid-prototype the first five iterations of the design in PLA, due to the reasonable cost and sufficient toughness. Future iterations of the design will eventually be manufactured from a surgical grade stainless steel. The final material will likely be a martensitic stainless steel such as AISI 420 or 430. Because of the harmful effects of nickel on humans, austenitic alloys with high nickel content will be avoided [21].

b. Methods

The initial prototypes of the design were manufactured by rapid prototyping in the Makerspace, located on the University of Wisconsin-Madison campus. Rapid prototyping allowed for initial considerations into the ergonomics, size, and other characteristics of the prototype before finalization and the increased cost of manufacturing a stainless steel prototype. Consultation with the client and other clinical endocrine surgeons on these important factors remain to be performed before the next iteration. Future iterations will continue to be printed in a polymer, until the design is satisfactory to be manufactured in a similar manner as other stainless or carbon steel surgical instruments.

Figure 14: *Five iterations of the device from the earliest (far left) to the most recent (far right). Improvements involved changes to the locking mechanism, distal end geometry, and ergonomics of the handle.*

c. Testing

In order to determine the functionality of the device, a tissue analog was performed. This test mimicked a thyroidectomy by using a mock thyroid and trachea. The mock thyroid was created using raw chicken breast that was trimmed down to match the mass and length of a normal thyroid. The mock trachea was created using a paper towel roll that was cut down to the typical diameter of an adult trachea. The mock thyroid was attached to the trachea using hot glue, which represented the ligaments and connective tissue that attach the thyroid to the trachea. Figure 15 below shows an example of one of the mock thyroids and tracheas that were created. During testing, the mock thyroid was retracted using the printed prototype in order to observe the ability of the prototype to lift the thyroid.

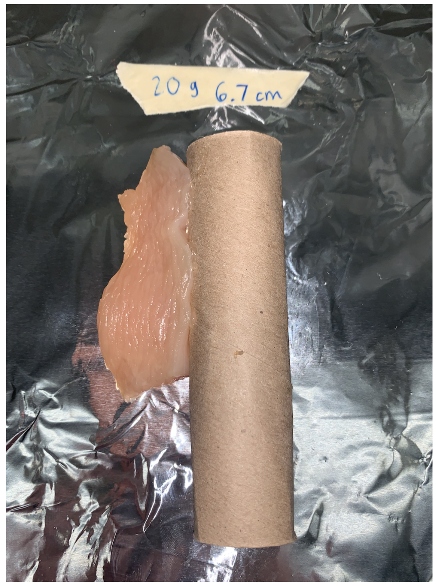


Figure 15: *Mock thyroid and trachea that was created in order to perform a tissue analog test. Above the model is a note that denotes the length and mass of the sample.*

In conjunction with the qualitative testing performed on the tissue analog, optical markers were attached to the analog. The tests were then recorded, and the video file uploaded to the motion capture software Kinovea. Kinovea is a free software capable of tracking the in-plane movement of the optical marker. The data was then exported to Matlab R2018b for further calculations. Using the reference length in the video file and the frames per second of the recording camera, the position in space may be calculated (Figure 16). Using the spatial and temporal data, the instantaneous velocity and instantaneous acceleration may be calculated using Equations 1-5.

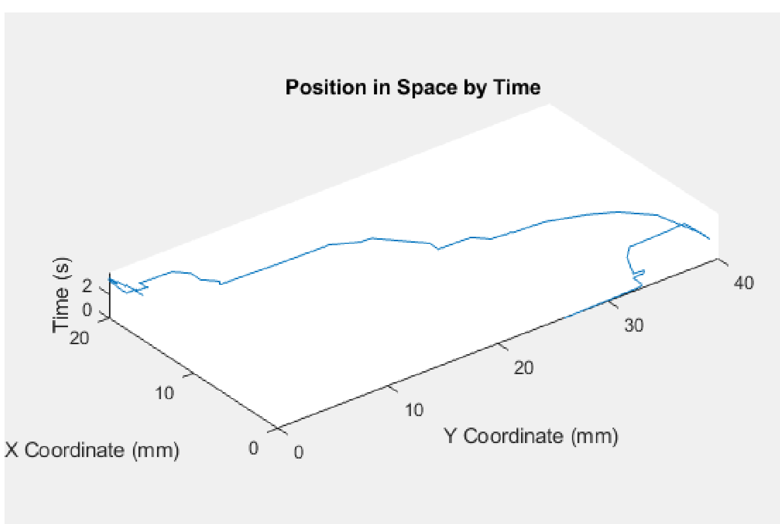


Figure 16: *Calculated position in XY space as a function of time for one experiment of simulated surgery on a tissue analog.*

$$V_{inst,x} = \frac{x_{n+1} - x_n}{t_{n+1} - t_n} \quad (1) \qquad V_{inst,y} = \frac{y_{n+1} - y_n}{t_{n+1} - t_n} \quad (2)$$

$$a_{inst,x} = \frac{v_{inst,x,n+1} - v_{inst,x,n}}{t_{n+1} - t_n} \quad (3) \qquad a_{inst,y} = \frac{v_{inst,y,n+1} - v_{inst,y,n}}{t_{n+1} - t_n} \quad (4)$$

$$a_{net} = \sqrt{a_x^2 + a_y^2} \quad (5)$$

Equations 1-5: *Used for calculating the instantaneous velocity and acceleration, as well as the net acceleration*

With the calculated maximum accelerations, the maximum applied forces are also able to be calculated, by multiplying the acceleration and mass of the tissue analog sample. The maximum calculated acceleration was found to be 2.9038 m/s^2, with a maximum force of 0.58 Newtons. The applied force must be added to the gravitational force of resistance, calculated by multiplying the mass of the tissue analog and the gravitational acceleration constant of 9.81 m/s^2. Subsequently the maximum applied force by the device is the sum of the force values, found to be 0.776 Newtons.

Figure 17: *A 3-dimensional model of the human thyroid in Solidworks 2021, with material properties representative of healthy thyroid tissue*

After acquiring the force and acceleration data from a simulated medial retraction of the thyroid, a computational model was constructed in Solidworks 2021. A 3-dimensional model of the thyroid (Figure 17) was constructed in the software using accurate dimensions for an *in vivo* thyroid. The model was optimized with the clinically reported Young's Modulus and density of a healthy thyroid of 22.3 kPa and 1.05 g/cm³, respectively [22]. Diseased thyroid pathology tends to result in an increase in the elastic modulus and stiffness of the tissue [23], thus the values for the healthy tissues were used. The model assumes that the material is heterogeneous, isotropic and linear elastic. To apply the distributed load representative of the medial retraction by the device, each lobe of the modeled thyroid was held static at the locations of Berry's ligament, a connective tissue between the thyroid and trachea. The force was applied in the simulation as two 0.5 Newton distributed forces in the 2-dimensional geometry of the distal portion of the device, summing to 1 Newton of total force. The force was increased from the value previously reported to aid in the simulation and increase the safety factor allowed.

The maximum displacement in the loading direction (Figure 18A) was found to be 36.47 mm, sufficient to allow access to the posterior anatomy. The out of plane displacement was minimal, with a maximum value of 0.786 mm on the isthmus of the thyroid, and no out of plane displacement on the opposite lobe of the model. Additionally, the stress and strain calculated by the model were nominal. The maximum von Mises stress (Figure 18C) , a common criterion for ductile soft tissue failure [24] [25] based on principal stress orientations, was found to be 2.571 kPa. The maximum engineering strain (Figure 18D) was found to be 0.07181, or 7.181%. Both of these values are well below the reported von Mises stress and engineering strain necessary for soft tissue failure [26] [27].The results of the computational analysis suggest that the device is capable of retracting the thyroid medially, causing a displacement necessary to remove the tissue from its resting anatomy without inducing harmful stress or strain states.

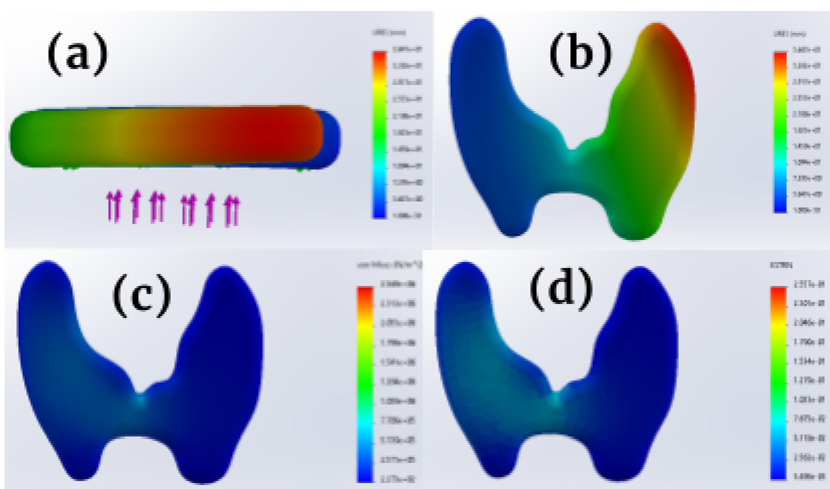


Figure 18: *Results of the computational analysis. (A) In-plane displacement. (B) Out-of-plane displacement. (C) von Mises stresses. (D) Engineering strain. Note: the units and scale of the color-coded values alter between subfigures.*

E. Discussion and Future Work:

In order to evaluate the functionality of the device, two tests were performed, a tissue analog test and a computational-modeling test using data from the tissue analog test. The first test was a tissue analog test followed by motion capture analysis using Kinovea and then further analysis using Matlab R2018b. Based on the observations from the tissue analog test, it was observed that minimal slippage of the mock thyroid occurred, which demonstrates the qualitative ability of the device to retract a thyroid. Using Kinovea, the x and y-coordinates of the optical marker on the mock thyroid was tracked, as seen in Figure 16 above. Using these coordinates, the acceleration of the marker could be calculated and in turn the maximum applied force by the device could be calculated. Further testing was then done using a computational model and the forces found.

Using a force value above the maximum applied force found, a computational test was performed. The force applied was 1 N in total, which is greater than the maximum applied force found in order to increase the factor of safety allowed. In the computational test, the force was applied to a modeled thyroid. From this, the von Mises stress and engineering strain was able to be found. The von Mises stress and engineering strain that were found using the computational model were both far below the threshold for soft tissue failure. This data suggests that the device will not cause excessive damage to the tissue of the thyroid during retraction.

Overall, based on the results found using a tissue analog experiment and a computational test, it can be concluded that the device aids in increasing the tissue contacting area while simultaneously not causing damage to the thyroid. Although further testing will have to be completed to prove the full functionality of the device, based on the results discussed above, the device should function as intended.

For future work, the tissue contacting portion of the device will continue to be modified in order to increase the surface contacting area. Additionally, modifications to the spring mechanism of the ratcheting system of the device will be performed in order to improve reliability. Also, the team will attempt to gain access to an anatomy lab next semester in order to perform a thyroidectomy on a cadaver. Furthermore, more research has to be completed in order to determine a way to manufacture the device in AISI 420 steel. Lastly, the team is planning on approaching the Wisconsin Alumni Research Foundation to inquire about a patent application.

F. Conclusions:

The goal of this project is to create a device that could aid in the tedious, but important procedures involving the retraction of a thyroid. To accomplish this goal, a device able to accommodate for different thyroid shapes and sizes and allow for multiple points of contact was created. Currently, there are no surgical devices available that are designed specifically to retract the thyroid from multiple points of contact, which was the main driving point of this project. As mentioned in the discussion section, the tests that were completed with the current prototype demonstrated proof of concept and function and show that the device should function as intended.

In the next semester of Biomedical Engineering, focus will be put into solidifying the final prototype by continuing to modify the tissue contacting ends and changing the locking mechanism of the device to be more robust. Additionally, more rigorous testing will be completed involving ergonomics and possibly cadavers. Overall, the testing showed that the device should be able to function as intended to in the operating room and more work will be done to ensure that.

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Appendix A: Problem Design Specification

BME 400:
Preliminary Product Design Specification

Team:

Mitchell	Josvai	Leader
Kate	Eichstaedt	Communicator
Avani	Lall	BWIG & BPAG
Ashlee	Hart	BSAC

Advisor: Dr. Mitchell Tyler
Client: Dr. Amanda Doubleday
Date: September 24, 2021

Function:

During endocrine surgery, specifically during thyroidectomies and related procedures, surgeons must retract the thyroid gland medially in order to gain access to the recurrent laryngeal nerve and parathyroid glands. Depending on the procedure, they must then dissect the thyroid gland from vascular attachments, and possibly the parathyroid glands. Surgeons use stainless steel forceps with a piece of gauze clamped at the tip, referred to as a "peanut” to retract and hold the thyroid gland in place, without rupturing it. However, due to the single point of contact, the thyroid gland can often be too large to be held in place by this method. The function of the device is to assist surgeons in retracting and holding the thyroid gland in place from multiple contact points.

Client Requirements

The client requires a surgical instrument to aid in the medial retraction of the thyroid and parathyroid glands during surgery. The device should have a single handle similar to standard forceps, but with two prongs to retract the thyroid gland from multiple contact points. Each prong should be capable of clamping and holding a surgical peanut sponge, a small sponge used to reduce the forces on the thyroid. The handle of the device should have some sort of ratcheting system to be able to adjust the distance between the two prongs. Additionally, the ratchet should allow for the device to be held in place for a period of time without having to manually hold the clamps shut.

Design Requirements

1. **Physical and Operational Characteristics**
   a. *Performance Requirements:*
      The device should be able to assist in completing the tedious dissection of the thyroid without causing harm, such as excessive bleeding, nerve or tissue damage. It should be reusable, auto-clampable and have blunt ends that act as clamps. It must function as one instrument that has tissue-contacting surfaces at the end opposite of the handle. The device must be capable of adjusting the width between the peanuts, and locking into the desired conformation. Finally, the device must be capable of withstanding all forces that are applied to it, both by the surgeon and the areas of the body it is acting on. The 95th percentile for human grip strength in right-handed men is around 500 N [1], and the device handle must be able to withstand this force. As the average adult's thyroid weighs between 20 and 30 grams [2], the forces applied by the thyroid are negligible in comparison to those applied by the surgeon.

   b. *Safety:*
      The only people allowed to operate with and use the device on a live patient will be trained medical professionals, as to keep the safety of the patient at the utmost importance. Computational and physical testing of the device's ability to endure forces of the hand applying pressure during surgery will be conducted. These tests laid out will ensure the safety of the surgeons using the device, as the device will be tested to make sure it won't break while in use. The device is not required to be permanently biocompatible, because it will only be in contact with the patient temporarily. However, the device must not be toxic, or susceptible to leaching of potentially harmful chemicals into the body. Finally, blunt edges and ends should be preferred over sharp edges, so as to avoid any unintended perforation or trauma caused by the device.

   c. *Accuracy and Reliability:*
      The device must reliably be capable of performing the task it is designed for. It must not puncture or cause trauma to the thyroid or other areas of the body when in contact. The ratcheting and latching mechanisms must not jam or lock when unintended. The clamping mechanisms must be capable of holding onto a peanut for the length of surgery without risk of the peanut detaching and entering the body.

   d. *Life in Service:*
      Long service lives should be expected from stainless steel surgical instruments. The client's current device has a shelf life of a few years. The device should be able to last at least a few years with sterilization and being reused by autoclaving [3]. The device should be reusable and autoclavable until wear and tear begins to occur. If there are signs of device damage or material corrosion, the device should be replaced.

e. *Shelf Life:*

The device will be made out of surgical grade stainless steel. Due to the mechanical properties of stainless steel, the shelf life for the device will be rather long. The average lifetime of stainless steel products ranges from 15-25 years[4].

f. *Operating Environment:*

The device will be used in a surgical setting. The likely temperature that the device will be in is somewhere between room and body temperature, depending on the point in the procedure. This gives an operating temperature between 22° C and 37° C [5]. For pressure, the likely pressure the device will be experiencing is around 1 atmosphere [5]. From a biochemical standpoint, this device must be able to withstand corrosion of blood and fluid. The device will be used by surgical staff so it is important for the staff to receive adequate device training. Increased temperature and pressure will occur during autoclave sterilization. Autoclaving is a physical method of disinfectant and sterilization that uses steam, pressure, and time. Under autoclaving procedures, the temperature can reach up to 121° C, and 1 atmosphere, which the device must be able to withstand[AA]. Autoclaving will only be for the reusable portion of the device, manufactured from a material capable of withstanding the conditions.

g. *Ergonomics:*

The device should be relatively simple to use by a trained user in an operational setting. The device should have a handle that is easy and comfortable to grip and is able to be held by one hand. The device should feature a ratchet that can vary the distance between the prongs so it does not have to be manually held to a certain distance. The device should not hinder the surgical staff during the operation, and ideally increases the ease of the procedure. Finally, the device should be able to accommodate 95% of hand sizes.

h. *Size:*

The current device being used is a clamping forceps with a small "peanut" sponge to contact the tissue and reduce surface forces. This device is approximately 8" in length [6]. Typical forceps and retractors used in surgery range from 8 to 12 cm. The device should be similar in length to these devices currently in use, so as to be easily adopted by surgeons utilizing other methods of thyroid retraction. Thyroids are anywhere from 4-6 cm and the device should have the two prongs 2-3 cm apart on average, with an adjustable range spanning from 1-4 cm, so that it may be used on a variety of patients and thyroid sizes. Measurements will be taken on current surgical forceps and retractors to determine accurate dimensions. Adult human hand anthropometry will be taken into account when designing the device, as well as when testing the device for ergonomics with surgeons.

i. *Weight:*

The weight of the device should be close to that of the weight of the forceps used with the peanut currently, or typical surgical forceps and retractors, at around 40.82 grams [7]. A small increase of weight will be allowed due to the addition of the second prong and tissue-contacting area, although the device should not be sufficiently heavy as to be difficult to operate by a surgeon. Measurements will be taken of a standard Weitlaner retractor to determine an accurate target weight for the device.

j. *Materials:*

The device will be made of stainless steel, as the current device and most modern surgical instruments are. In the medical device industry, stainless steel grade 316 is commonly used for medical grade surgical devices due to their high levels of nickel and chromium. These levels of nickel and chromium allow for endurance through sterilization procedures, as well as tolerance of corrosive material like bodily fluids. Stainless steel provides greater durability because it is anti-bacterial, non-corrosive and rust-resistant. It is also autoclavable, which allows it to be sterilized quickly and repeatedly. The durable stainless steel construction means the device will last and remain dependable for medical use [6].

k. *Aesthetics, Appearance, and Finish:*

The medical device should have the appearance of a typical surgical instrument. The device should have a highly polished, or mirror finish in order to prevent potential staining [8]. Also, the device should have a satin finish to prevent any bio-contaminants from residing in any ridges that may be present without a satin finish. Other than this requirement, aesthetics are less critical to the design than other relevant criteria.

2. Production Characteristics

a. *Quantity:*

Only one device will be produced for the full project, but it will be reusable since it is made of stainless steel. In the future, if this kind of device is proved to be beneficial to the procedure, more can be produced.

b. *Target Product Cost:*

The target cost of this device should be comparable to typical surgical forceps, although this cost varies greatly. Depending on the supplier and website, retail prices for surgical forceps and retractors can range from $5.00 to around $50 from medical supply companies [9]. For this design, the target cost of production will be between $5.00 and $10.00 per single thyroid retractor. Flexibility of cost will be taken into account to accommodate for the extra forceps incorporated into the device. Additionally, this is the final target cost of production, without development or prototyping taken into account.

3. Miscellaneous

a. *Standards and Specifications:*

The device falls under the category of a Class II medical device as it is substantially equivalent to another similar legally marketed device that already has FDA clearance [10]. This product will need to be FDA cleared in order for surgeon and patient use and is protected under FDA regulation 21 CFR Part 807. The device and the surgery must comply with CDC regulation regarding sterile procedures. During testing and clinical trials, the device must be tested under IRB regulations at the university level, and FDA regulation at the federal level.

b. *Customer:*

Our client has requested a two pronged, adjustable thyroid retractor. This device should ease common complications endured with just one prong, such as those associated with larger thyroids. Ultimately this device may suit other customers beyond our client, including other surgeons at UW and/or beyond.

c. *Patient-related concerns:*

To ease any patients' concerns, the device will be treated and used like any surgical device in the operating room. The device will be used by a trained professional, and cleaned thoroughly between uses.

d. *Competition:*

Currently, a Rochester-Pean forceps and "peanut" sponge are used to retract the thyroid medially. However, the single tissue-contacting area of the peanut does not provide enough traction or surface area of contact and causes the thyroid to fold. To solve this problem, two Rochester-Pean forceps are sometimes used to increase contact area and traction. This method also proves to be problematic, due to the difficulty of maneuvering two forceps with one hand. Other surgeons may use alternative methods to medially retract the thyroid.

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Appendix B: Matlab Script Used to Calculate Forces and Accelerations

```
%% BME 400 Testing Plotting and Calculation
% Mitchell Josvai, 12/7/21

clc; clear;
data = readmatrix('IMG_0808.xml.xlsx');

% load data
xcoord = flip(abs([0; data(2:115,1)]));
ycoord = abs([0; data(2:115,2)]);
time = (0:0.033070175438596:3.77);
% Plot
plot3(xcoord,ycoord,time);
axis equal
zlabel('Time (s)');
xlabel('Y Coordinate (mm)');
ylabel('X Coordinate (mm)');
title('Position in Space by Time');
hold off

% Calculate instantaneous velocity and acceleration
inst_velox = zeros([114 1]);
inst_veloy = zeros([114 1]);
inst_accx = zeros([114 1]);
```

```
inst_accy = zeros([114 1]);

for i = 2:115
    inst_velox(i-1) = (xcoord(i) - xcoord(i-1))/0.033; %eq1
    inst_veloy(i-1) = (ycoord(i) - ycoord(i-1))/0.033; %eq2
end
for i = 2:114
    inst_accx(i-1) = (inst_velox(i) - inst_velox(i-1))/0.033; %eq3
    inst_accy(i-1) = (inst_veloy(i) - inst_veloy(i-1))/0.033; %eq4
end

inst_acc_net = sqrt(inst_accx.^2 + inst_accy.^2); %eq5
force = 0.02 .* inst_acc_net; %20 g = 0.02 kg, multiply by ag
maxacc = max(inst_acc_net); disp(maxacc);
maxforce = max(force); disp(maxforce);
```