A Novel Device to Assist in the Medial Retraction of the Thyroid During Endocrine Surgery

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ABSTRACT

Thyroidectomies, parathyroidectomies and other endocrine procedures require the medial retraction of the thyroid gland in order to gain access to relevant anatomical structures anterior to the gland. The device currently used in these procedures makes only one point of contact with the thyroid and does not account for varying sizes and morphologies of the gland, making it difficult to retract and stabilize. This paper introduces a novel adjustable medical device to address the aforementioned problems and aid in the retraction of the thyroid from multiple contact points. The proposed device consists of two finger rings, a self-retaining ratcheting mechanism, two legs positioned at an inward angle, and grooved circular tips. The performance of the thyroid retractor was assessed through an ergonomics survey administered to clinical endocrine surgeons, tissue analog testing and computational modeling of the device's interactions with the thyroid. This new device was determined to be a valuable tool for the safe and efficient retraction of the thyroid and suggests further commercial development of the design to provide a more effective thyroid retraction.

1 INTRODUCTION

Motivation

Procedures involving the manipulation of the thyroid are common – more than 130,000 thyroidectomies alone are performed every single year [1]. Although 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 varying prongs or forceps. Because of the ubiquity of these procedures, they are often described as tedious when it comes to an effective retraction of the thyroid gland [2]. At Waukesha Surgical Specialists and University of Wisconsin Health hospitals, 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 of an unusual shape. Considering the difficulties experienced during surgeries involving thyroid retraction, there is a definite market opportunity for another device. Creating a device that helps increase the efficiency of the surgery will be advantageous.

Competition

There are multiple medical devices on the market that aid in thyroid retraction. Differences between thyroid retractors are the adjustability, number of points of contact between the retractor and thyroid, and 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 features a curve near 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 distal ends of the device generate stress concentrations in the tissue which may potentially cause damage either via direct trauma or vascular harm [3].

The Rochester Pean Forceps are hemostatic surgical forceps that resemble a pair of scissors with the blade replaced by a blunted grip [4]. 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 limitation of this set of forceps is that the legs allow for only one point of contact between the device and the thyroid retractor which contributes to the current problem of ineffective retraction of abnormal or hypertrophied 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. The peanut sponge is a form of dissecting sponge, 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 modulate the force of the surgical device on the thyroid and help to increase the degree of traction to avoid any tissue slippage. While effective the peanut sponge method includes multiple limitations. The sponges are single-use and must be sterilized and disposed of after each procedure. Additionally, a postoperative x-ray must be performed to ensure they do not remain within the patient. A fully reusable and sterilizable device capable of retracting the thyroid independently of other equipment presents both a financial and clinical benefit.

Problem Statement

The goal of this project was 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 frequently 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 one point of contact can result in an incomplete dissection, whereas handling two forceps at once is cumbersome. The desired design should gather inspiration from the current thyroid retractors, while having multiple points of contact incorporated into a single device that is adjustable to allow for the retraction of different sized thyroid glands.

2 BACKGROUND

Thyroid 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 bilaterally symmetric lobes located on either side of the trachea, and connected by a tissue bridge termed 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].

The thyroid, and indirectly the levels T3 and T4, are regulated by thyroid stimulating hormone (TSH) secreted by the pituitary gland. Excess or lack in T3 and T4 in the blood result in hyperthyroidism and hypothyroidism, respectively [9]. 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 the effects are generally transient. In instances that such pathologies present in humans, endocrine surgery may be necessary in order to remove nodules, biopsy the thyroid, or potentially remove the thyroid.

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). The parathyroid glands regulate the levels of calcium and phosphorus in the bloodstream by secreting parathyroid hormone (PTH). In the nervous system, calcium is important for the propagation of electrical impulses down axons and the regulation of neurotransmitters [11]. PTH regulates calcium levels by inducing calcium release from the bones and increasing the amount of calcium absorbed from the small intestine. An excess of PTH in the bloodstream will cause a rise in blood calcium levels, which may be indicative of hyperparathyroidism. 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. Pathologies of the parathyroid can also be a reason for endocrine surgery requiring retraction of the thyroid [13].

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 on the neck to gain access to the thyroid anatomy. 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 during thyroid surgery 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 inadequate traction to completely retract the thyroid. Over the duration of the retraction, the thyroid mass may end up folding over the point of retraction, increasing the difficulty of dissection. To mitigate this problem, two peanut instruments are used (Figure 5). When two peanuts are used, however, a surgeon must use both 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, 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.

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 enlargement. Such maneuvers are currently done with a variety of strategic instruments and surgeon hand placement.

Prototype Research

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 tolerate repeated 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 the device 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. NASA human performance capabilities analysis for human grip strength at the 50th percentile for 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 6. Because of this, the device was designed to the 95th percentile for men which is approximately 500 N.

3 FABRICATION AND DEVELOPMENT

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. Iterations of the design were printed in PLA 3D printing material, due to the reasonable cost and sufficient toughness. The final material will be a martensitic stainless steel such as AISI 420 or 430, both commonly used in surgical applications.

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.

Testing

In order to evaluate the functionality of the device, two main tests were performed along with a qualitative assessment conducted in a cadaver lab. The two tests performed were: (1) a tissue analog test with a subsequent computational-modeling test using the data from the analog test and (2) an ergonomics survey. The tissue analog test was performed to ensure the device is able to retract a modeled thyroid. The computational test was performed to prove that the device does not apply enough force to damage the thyroid tissue. The ergonomics survey was conducted in order to gauge medical professional's opinions on the device and if they would feel comfortable using the device during a thyroid retraction. Qualitative testing was also performed in a gross anatomy lab at the University of Wisconsin - Madison. During this test, the device was used to retract the thyroid of a medical cadaver.

The tissue analog test mimicked a thyroidectomy by using a mock thyroid, trachea, and skin. The thyroid analog was created using raw chicken breast cut to match the mass and dimensions of a normal thyroid. The mock trachea was a PVC tube with a diameter of 20 mm, the average tracheal diameter in humans. The skin analog used was 4 MPa PDMS laid across the thyroid analog and trachea. The thyroid analog was attached to the tube by an adhesive mimetic of the ligaments and connective tissue that attach the thyroid to the trachea. During testing, an incision with a scalpel was made through the polymer and the mock thyroid was retracted using the printed prototype device in order to observe the ability of the prototype to lift the thyroid.

As part of the quantitative testing performed on the tissue analog, optical markers were attached to the analog. The mock thyroid retraction tests were recorded and the video file was uploaded to the motion capture software Kinovea, a free software capable of tracking the in-plane movement of the optical marker. The movement data was then exported to Matlab R2018b to calculate instantaneous acceleration and body forces applied to the tissue. Using the reference length in the video file and the frame rate of the recording camera, the position in space may be calculated (Figure 7). Using the spatial and temporal data, the instantaneous velocity and instantaneous acceleration may be calculated using Equations 1-5. With the calculated maximum accelerations, the maximum applied forces were calculated, by multiplying the acceleration and mass of the tissue analog sample.

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 8) 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/cm^3, respectively [18]. Diseased thyroid pathology results in an increase in the elastic modulus and stiffness of the tissue [19], thus the values for the healthy tissues were used. The model assumes that the material is heterogeneous, isotropic and linear elastic. In cases of small deformations occurring at a slow rate, these assumptions are fair for soft tissue. 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 3-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. Engineering strain and von Mises stress values were then calculated from the computational model to ensure an absence of soft tissue trauma due to the device.

An ergonomics survey was also used to receive feedback from endocrine surgeons regarding the comfortability of the device. The survey was conducted using Google Forms and featured both quantitative and qualitative open response queries. The survey was sent to three different groups of specialists in Wisconsin and Illinois along with a 3-D printed, assembled prototype. The data from this test provided useful insight regarding the practical functionality of the device.

Results

The maximum displacement in the loading direction 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 0.589 mm at 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, a common criterion for ductile soft tissue failure [24] [25] based on principal stress orientations, was found to be 2.621 kPa. The maximum engineering strain was found to be 0.07211, or 7.211%. 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.

The results from the ergonomics survey were somewhat variable. Of those the survey was sent to, five responses were sent back via Google Forms. Although the data collected from this survey is not considered statistically significant, there were still qualitative comments from clinicians that helped direct the formation of the final design. Specifically, comments were made about how it would be beneficial to increase the length of the device to accommodate for the small surgical area. Additionally, comments were made that recommended adding an inward contour angle to the legs to aid further in retraction. Lastly, the qualitative observations from the cadaveric testing indicated that the legs of the device should be increased in length.

4 DISCUSSION

In order to prove the functionality of the device, two tests were performed. The first test, a tissue analog test and subsequent computational testing was performed in order to ensure the device is able to retract a tissue similar to thyroid tissue. From the tissue analog test, data regarding the amount of force applied to retract the tissue was calculated using an optical tracker and motion capture analysis. From here, the force applied was used in the computational model test to ensure that the thyroid will not face excessive forces from the device that may cause soft tissue damage. Additionally, an ergonomics survey was performed to determine the practical functionality of the device.

Qualitatively, the results from the ergonomics survey helped inform changes made to the design of the device to make it as comfortable in a clinicians hands as possible. It was observed during cadaveric testing as well as the tissue analog that the device was able to successfully retract the cadaver thyroid and mock thyroid from two points of contact. The computational model testing found that the force applied by the device onto the thyroid would not be great enough to cause soft tissue damage. Specifically, the von Mises stress and engineering strain were not great enough to indicate soft tissue failure or rupture.

Overall, the tests that were performed were important to evaluate the functionality of the device. Based on both the quantitative and qualitative results, the device should be able to retract a thyroid successfully from two points of contact.

5 ACKNOWLEDGMENT

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6 FUNDING

The creation of this thyroid retractor was possible through funding from Dr. Amanda Doubleday.

7 CONCLUSION

The overall goal of this design project was to create a device to increase the efficiency of procedures that involve thyroid retraction. 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.

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EQUATIONS

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

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

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

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

FIGURES

Fig. 1 Image of Allis Tissue Forceps [2]

Fig. 2 Current thyroid retractor used by the client: The ‘Peanut’ consists of a dissection sponge and a Rochester Pean forceps [4]

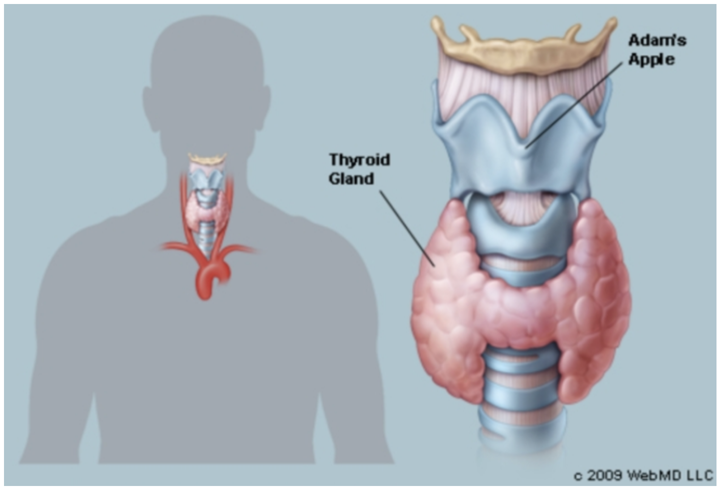


Fig. 3 Anatomical image of the thyroid gland in the human body [10]

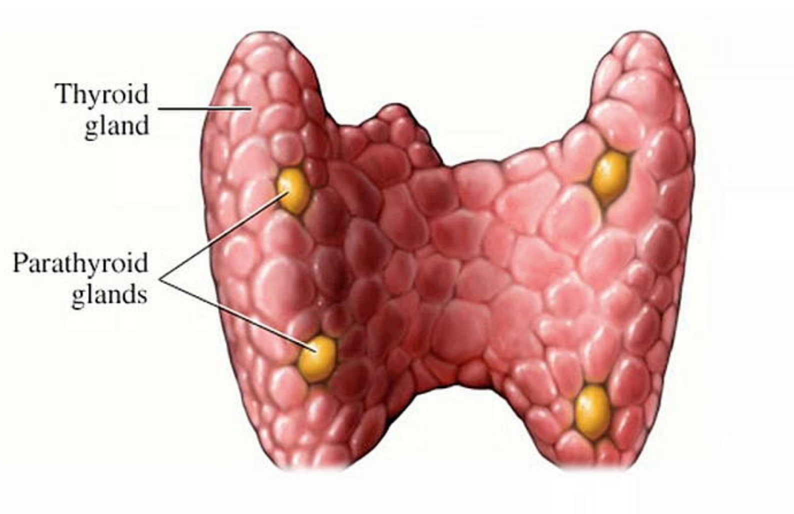


Fig. 4 Anatomical image of the parathyroid glands relative to the thyroid [12]

Fig. 5 Image during a thyroid retraction done by Dr. Doubleday

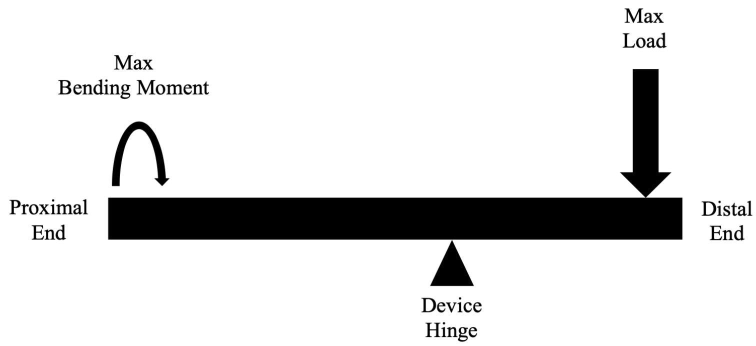


Fig. 6 Free-body diagram depicting the maximum forces and bending moments with the device simplified to a Class I lever system

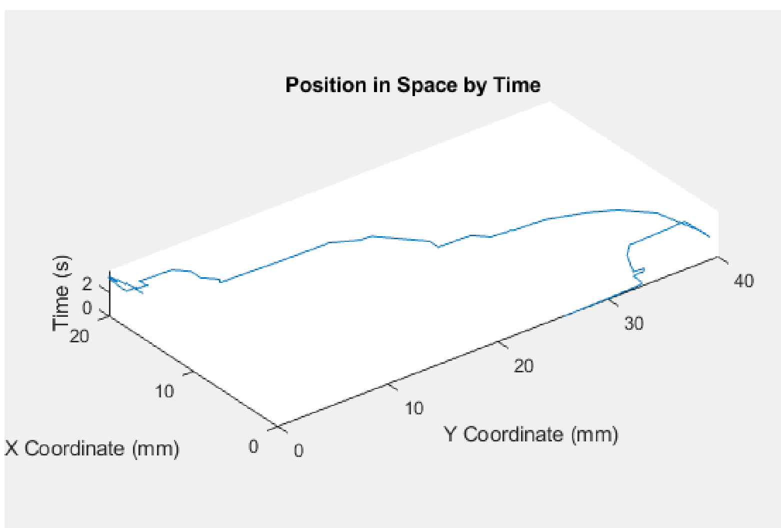


Fig. 7 Calculated position in XY space as a function of time for one experiment of simulated surgery on a tissue analog

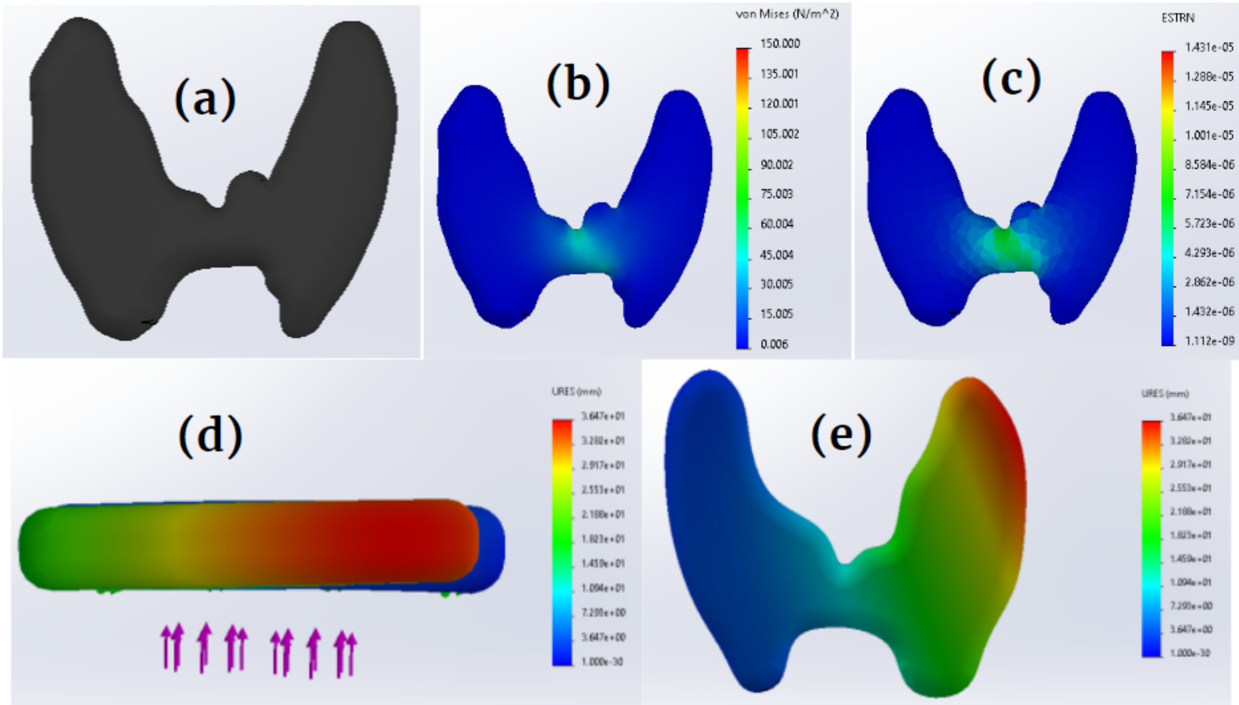


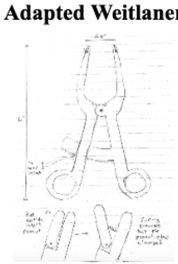
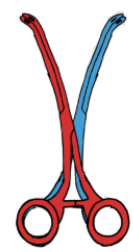
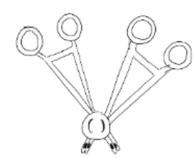
Fig. 8 (a) A 3-dimensional model of the human thyroid in Solidworks 2021, with material properties representative of healthy thyroid tissue. (b) The von Mises stresses applied to the tissue in the model. (c) The engineering strain applied in the model. (d) The in-plane displacement applied to the model tissue. Sufficient displacement was observed to access the anterior anatomy. (e) Alternate view of in plane displacement.

APPENDIX: DESIGN PROCESS

<u>Spring 2021</u>

The team began this project in the spring of 2021. Three preliminary designs were created: the Adapted Weitlaner, Two-Fused, and Nut-Bolt. In order to compare the three preliminary designs, the designs were evaluated using the design matrix shown in Table 1. 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 Nut-Bolt design scored the highest and was the proposed final design.

Table 1: *Preliminary Design Matrix of spring 2021 scores highlighted in red denote a high score in a category.*

Design		**Adapted Weitlaner**		**Two-Fused**		**Nut-Bolt**	
Criteria	**Weight**						
Safety	25	5/5	25	5/5	25	5/5	25
Ease of Use	20	3/5	12	5/5	20	4/5	16
Peanut Grip Strength	20	3/5	12	4/5	16	4/5	16
Adaptability	15	5/5	15	3/5	9	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**	**76**		**86**		**89**	

Upon further consultation and evaluation with the team's client, the Nut-Bolt design would have to be modified before fabrication. The final design seen in Figure 1 was updated to a novel version of the adapted Weitlaner design. The mechanism of the device remained, while the thyroid-contacting portion was updated. The proximal portion of the device consists of a handle to hold the device, as well as a 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. The distal portion of the updated design now uses disposable polymer tips to contact the thyroid. The tips are single-use, and based on the disposable rubber shods used for some surgical clamp applications.

***Figure 1**: Rendering of the updated spring 2021 adapted Weitlaner design.*

The tips seen in Figure 2 have a hollow cylindrical base, intended to insert the retractor. The tips will fit tightly around each arm of the retractor, to prevent unintended rotation around the retractor or other movement. Each polymer tip consists of a curved surface to maximize contacting area with the intended surface, as well as rounded edges to minimize that possibility of harm to the patient.

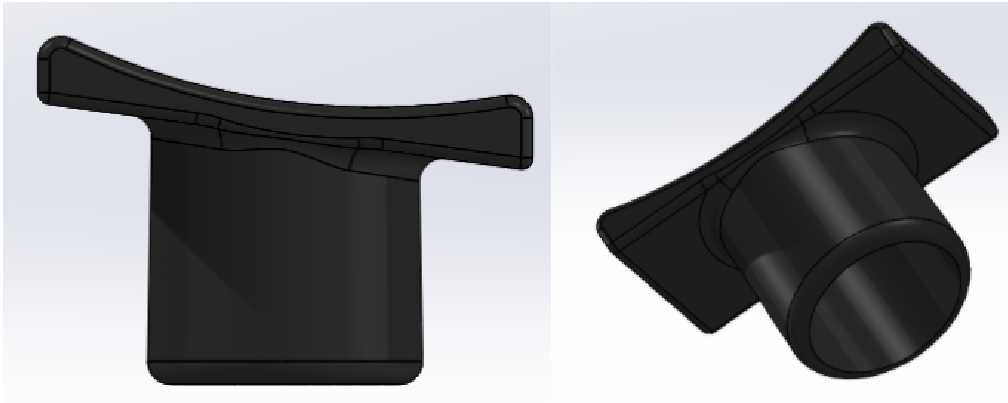


***Figure 2**: CAD model of the polymer tips used with the adapted Weitlaner design.*

Applied force testing was performed in SolidWorks CAD and simulation software. The mass of the thyroid is usually between 10 to 20 g, but can exceed this value in an enlarged thyroid. Because of this, and the delicate nature of endocrine surgery, the tips are not expected to have great forces applied during an operation. A 2 Newton distributed load was applied equivalently across the contacting surface of the device. The interior wall of the hollow cylindrical base was chosen as the fixed surface, as this would be fixed in relation to the retractor.

Minimal stress, engineering strain, and deformation were observed, and the results can be seen in Figure 3. The simulation calculated a maximum von Mises stress of 9.871 kPa , well below the modulus of most polymers, which is on the scale of MPa to GPa. The maximum engineering strain and deformations were 3.254e-05 mm/mm and 48.44 um, respectively. These values would likely be inadequate to cause any form of damage to the device, especially because it is a single-use device fabricated from a non-brittle material.

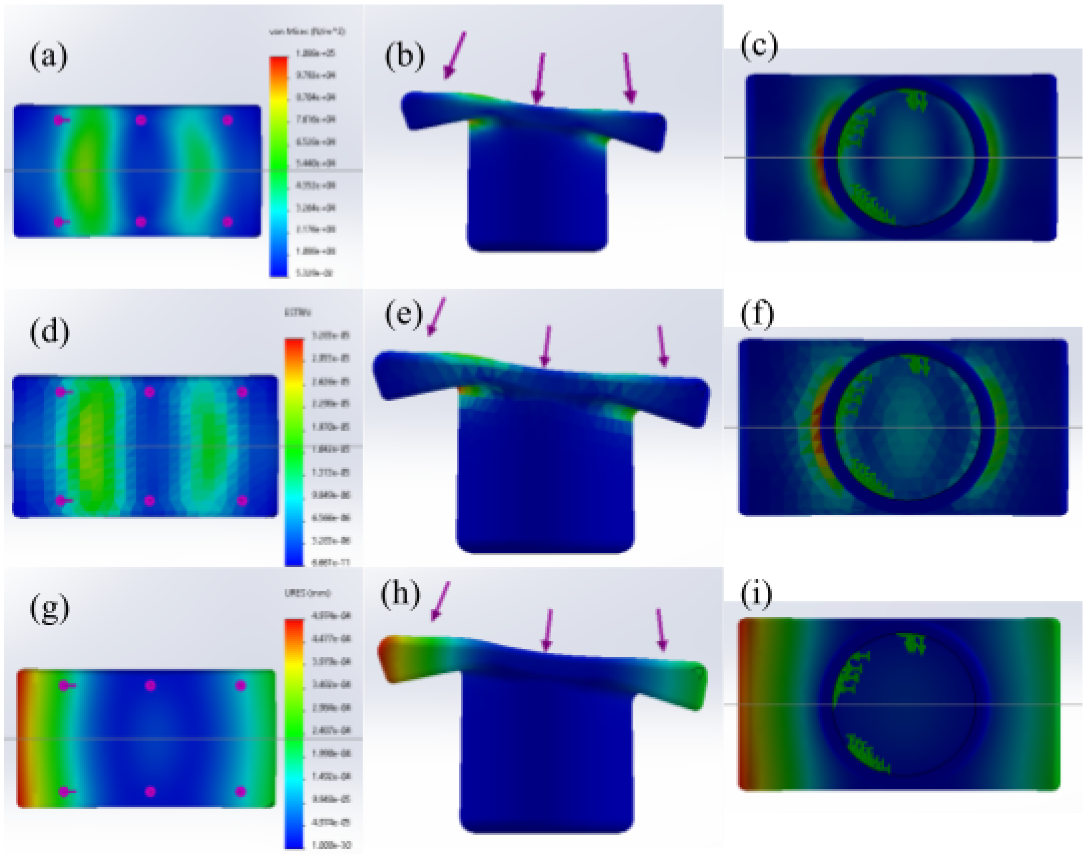
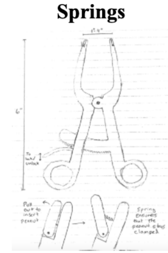


Figure 3*: SolidWorks applied force testing of the polymer tips. Representations of stress (a, b, c), engineering strain (d, e, f), and deformation (g, h, i) of a 2 N applied force are depicted*

<u>Fall 2021</u>

In the fall of 2021, three preliminary designs that met the product design specifications and client needs were created. The first, the Shods design was the final design chosen at the end of the Spring 2021 semester. The other two designs are different from those of the previous semester, Spring and Tread designs. All three designs featured the finger rings and self-retaining ratcheting mechanism of the Weitlaner Retractor. These designs were evaluated using the design matrix seen in Table 2.

Table 2: *Preliminary Design Matrix of fall 2021 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	
Thyroid Grip	20	4/5	16	4/5	16	3/5	
Ease of Use	20	3/5	12	3/5	12	5/5	
Adaptability	15	5/5	15	1/5	3	4/5	
Ease of Fabrication	10	3/5	6	4/5	8	5/5	
Cost	10	3/5	6	4/5	8	5/5	
Total	**100.0**	**75**		**72**		**89**	

After evaluating each design using the design criteria of the design matrix, the Treads design was selected as the final design. This design consisted of an adjustable ratcheting system and two legs. It is an all-in-one reusable design with no disposable components. The ergonomic handle allows for single-handed use by the operator. The tips on this design are modified into circular metal rings and will have an inward angle to aid in the retraction of the thyroid from multiple contact points. Additionally, the tissue contacting geometry of the grooved tips allow for increased surface contact and traction with the thyroid, and minimal potential for damage.

For the purposes of the final design, the first prototype iterations 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.

Figure 4: *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.*

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. Further testing was then done using a computational model and the forces 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. Although further testing and device alterations will have to be completed to prove the full functionality of the device, based on the results discussed, the device should function as intended.