Final Report: Thyroid Retractor

Biomedical Engineering Design

Department of Biomedical Engineering

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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." Working with only one forcep, occasionally there are not enough points of contact on the thyroid which causes the gland to be difficult to retract and hold. The client of this project is Dr. Amanda Doubleday, who is an endocrine surgeon fellow in the department of surgery at the University of Wisconsin School of Medicine and Public Health. 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 design, a two-fused design, and a nut-bolt design. The rest of the report discusses the final design, a modification of the preliminary Adapted Weitlaner, and testing conducted on the shod component of the design. Future work includes more ergonomic testing once a tangible prototype is created. Additional future work includes looking into creating the final design out of stainless steel.

I. Introduction:

A. Motivation

Thyroid surgeries are an extremely relevant procedure. Although these procedures are commonly done, they are still described as tedious [1]. In the United States alone, more than 130,000 thyroidectomies are performed annually [2]. 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. So, 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 extremely advantageous to the client's surgical team specifically, as well as beyond.

Additionally, the design stands to benefit surgeons. Surgeons are highly regarded and compensated for their work, but their job is one of great stress and risk. Surgeons work long and difficult hours, and experience high rates of burnout, among other life stressors. The Bureau of Labor Statistics estimates that to adequately service the entire population, the United States requires 7 surgeons for every 100,000 citizens [3]. The United States currently has around 18,000 general surgeons, or 5.8 per 100,000 people. 60% of physicians who named endocrine surgeons as their first or second speciality had another speciality [4]. As mentioned before, surgeons have a high rate of burnout. Burnout is characterized by emotional exhaustion and a decreased sense of personal accomplishment caused by work-related stress. Burnout rates in surgeons range from 37-53%. It seems that working in surgery is more stressful than ever, with the rate of burnout increasing 10% from 2010 to 2014 [5]. Burnout can lead to many unfortunate consequences including substance abuse, divorce, depression and suicide. If the device created could increase the efficiency of surgeries to require less time in the operating room for surgeons, it could increase their quality of life and lower stress.

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. Examples of different types of thyroid retractors include the McBurney thyroid retractor, which has a single "C" shaped end [6] and the Beckman Thyroid retractor, which has an adjustable ratcheting system as well as two "C" shaped ends [7]. The current thyroid retractor device used on Dr. Doubleday's surgical team is a single peanut sponge held by an auto-locking forceps, (see

Figure 1), or two peanuts and two forceps held with two hands. The purpose of the peanut sponge is to spread the applied force over a larger area and reduce the chance of harm to the gland. Per the client's request, the team's design should gather inspiration from thyroid retractors that have multiple points of contact, and allow for the retraction of different sizes of 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 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 [8].

Figure 1: *Current thyroid retractor used by Dr. Doubleday's team: The Peanut [8]*

C. Problem Statement

The goal of the design team this semester is to create a device to aid in thyroid and parathyroid surgeries. 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 find 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 be arduous for the surgeon, as one point of contact makes the dissection difficult, and handling two forceps at once is cumbersome. The client requests a surgical instrument that has two prongs to retract the thyroid gland from multiple points of contact.

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 2). Typically, the thyroid is about 3 or 4 cm across, and weighs between 10 and 20 grams. The thyroid consists of two lobes located on either side of the trachea, 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 hormones are crucial for brain and somatic development in infants, metabolism of adults, have effects on the majority of organ systems [9], and are extremely important in cell regulation and homeostasis [10]. 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 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 T3/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/T4 in the blood, the pituitary gland increases TSH secretion. An excess of T3/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, thin hair, oligomenorrhea, or increased bone resorption [11]. Conversely, hypothyroidism is the result of too little T3/T4 secretion, resulting in underactivation of cells and cell metabolism. Hypothyroidism is the most common acquired disorder associated with the thyroid, and can result in fatigue, weight gain, poor concentration, and depression among other symptoms [11].

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/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/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; which results in an overproduction of T4/T3, or malignant. Postpartum thyroiditis can be triggered after child birth. This occurs in about 4-9% of women and is usually temporary [12]. 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 for recovery.

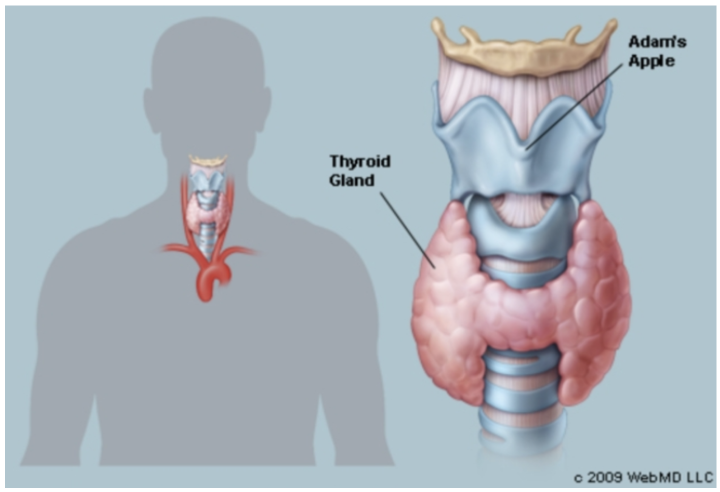


Figure 2: *Anatomical image of the thyroid gland in the human body [10]*

The parathyroid glands are pea-sized glands located near the thyroid in the neck, two of which are superior parathyroid glands and two inferior parathyroid glands. Despite having a similar name, the function of these four glands is entirely separate. 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. Calcium ensures the nervous system runs properly, as it is the means of electrical impulse transduction [13]. 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, the balance between the two is disrupted. This is known as hyperparathyroidism, resulting in a rise of blood calcium levels. 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 [14]. 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 [15].

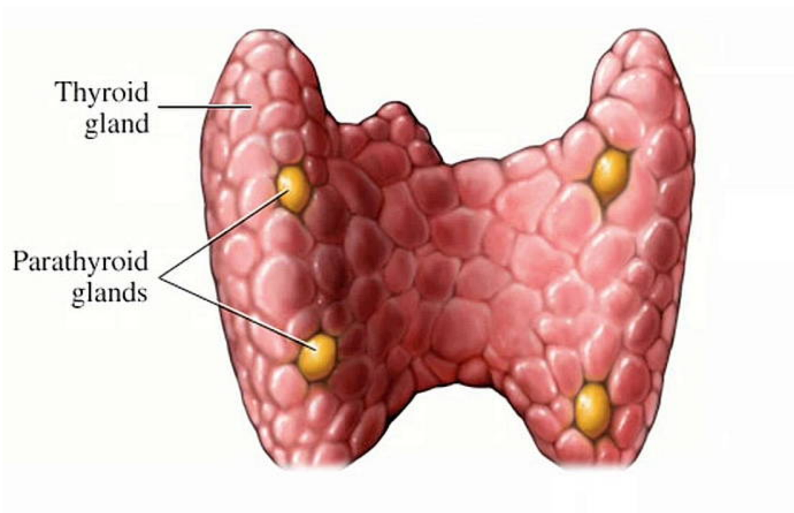


Figure 3: *Anatomical location of the parathyroid glands relative to the thyroid [14]*

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.

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 instrument 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%.

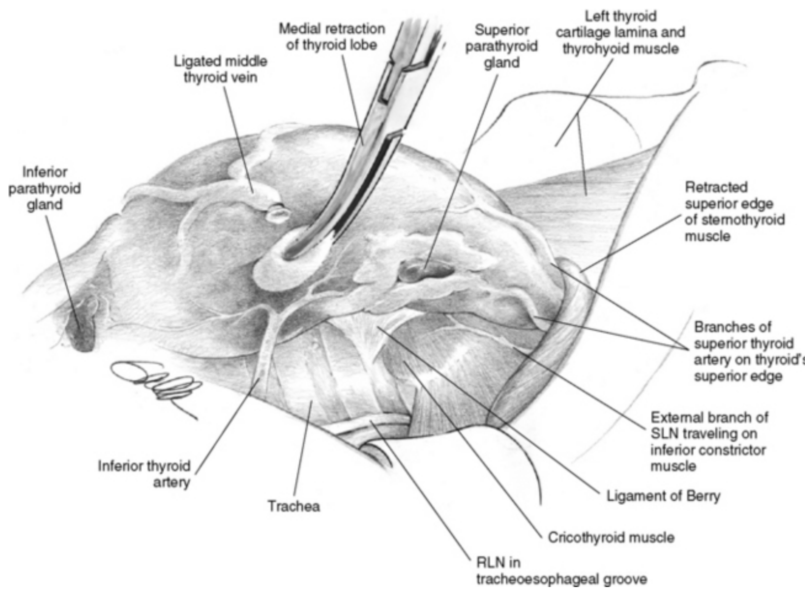


Figure 4: *Depiction of the medial retraction of one lobe of the thyroid during surgery with a peanut sponge, showing the relevant anatomy near the gland [12]*

B. Research Required for Prototype

The main research required for the prototype was research involving the size, materials and dimensions of the device. From research, it was found that most medical forceps are made out of medical grade stainless steel to avoid corrosion and have a length of around 8 inches [16]. Additionally, forceps made from medical grade stainless steel typically have a weight of around 0.09 pounds [16]. 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 so that they can be used multiple times safely. 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 rust resistant [17].

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. As the device is a surgical device that will be manipulated by humans, the device 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 [18]. Because the device should be capable of withstanding extreme forces in the event that the operational requirements call for it, we will use the 95th percentile for men in our 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.

C. Client Information

The client for this design project is Dr. Amanda Doubleday. Dr. Doubleday is an endocrine surgeon fellow in the department of surgery at University of Wisconsin School of Medicine and Public Health. Dr. Doubleday’s inspiration to look into an improved thyroid retractor came from relying on two separate peanuts to successfully retract a single thyroid. While the two peanuts are able to get the job done, retraction would be more efficient and surgeries would run smoother if there was a single, adjustable thyroid retractor capable of retracting thyroids of different shapes and sizes by multiple points of contact.

D. Design Specifications

The most important design specification the team’s thyroid retractor design should accommodate for is the ability to touch multiple parts of the thyroid. Having more than one place of contact makes it so that the thyroid retractor is able to successfully retract the thyroid without worrying about the thyroid slipping, or caving around the single touch point. To be able to effectively retract thyroids of different sizes and shapes, the device must be adjustable in two ways. It should first be adjustable in the width between the two prongs, and it should also be adjustable between the tips of each individual forcep within each prong. This makes it so that ultimate adjustability is accomplished.

For safety and reliability reasons, the device must not have any atypical protrusions that could potentially puncture the thyroid or cause any harm to the patient. The thyroid retractor should follow the same protocol as any typical surgical instrument. The retractor should be made out of stainless steel, have a mirror finish, have a length of about 8 inches [16], and weigh about .09 pounds [16]. The team's complete design specifications can be found in Appendix A.

III. Preliminary Designs:

I. Design 1: Adapted Weitlaner

The Adapted Weitlaner design is a combination of the Weitlaner retractor and the Peanut. Starting with a normal Weitlaner retractor, the main design difference would be the ends of the instrument. The top half of the instrument is the Weitlaner portion and consists of two finger holes and a self-retaining lock. The ratchet system allows for adjustment between the width of the two prongs and that width to be locked into place. Instead of having forked ends, the ends would each be spilt and can be pulled apart. This allows for insertion of a peanut on each side to be secured by a spring. The spring ensures that the peanut stays clamped.

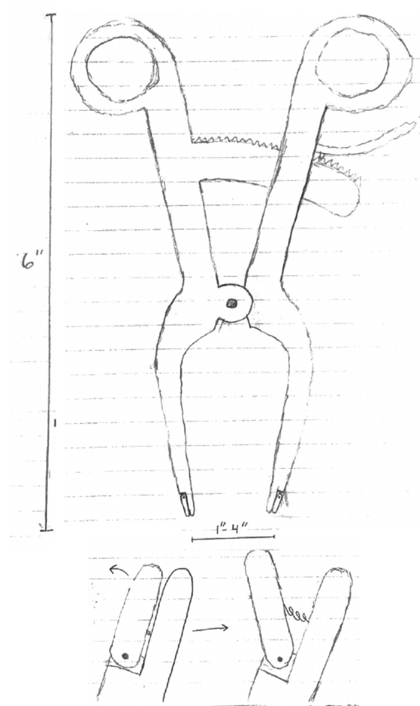


Figure 5: *Adapted Weitlaner design sketch with ratchet system, split tips, and springs.*

II. Design 2: Two Fused

The Two Fused model is simply two Peanut forceps that are tilted at different angles and secured to each other at the midpoint. Each prong has its own ratcheting system so their widths can be adjusted individually. When using the device and moving the finger rings apart, the sliding mechanism that separates them works for both prongs. In figure 4 below, the two different prongs can be seen by the color demarcations of red and blue.

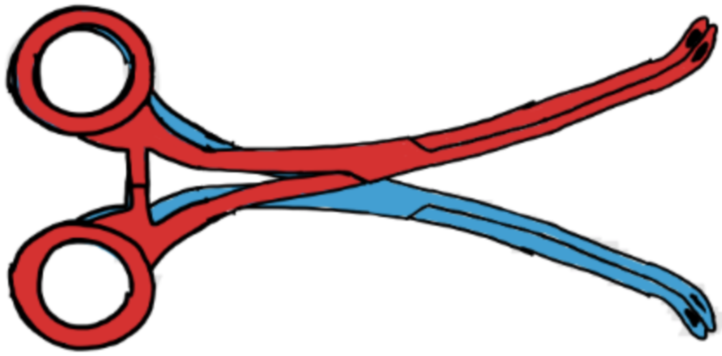


Figure 6: *Two Fused model with top Peanut colored red and bottom Peanut colored blue.*

III. Design 3: Nut and Bolt

The Nut and Bolt Design is the simplest of the three as it only incorporates four things: two Peanuts, a nut, and a bolt. Towards the end of each Peanut, before the instrument splits into two, a hole would be drilled into each clamp. The idea is that the Peanuts can overlap at any desired width and then locked into place using the nut and bolt. The bolt inserts through the hole and is secured on the other end with the nut.

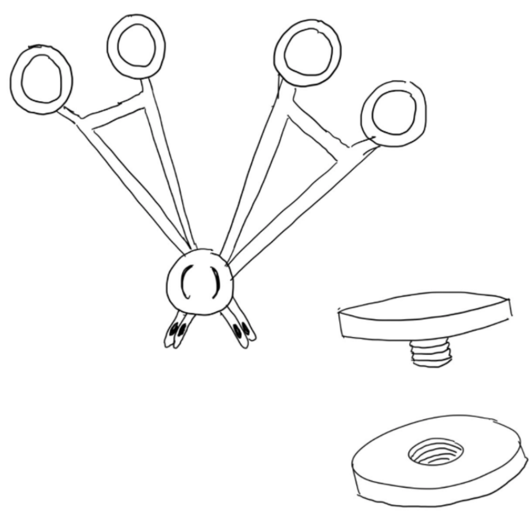


Figure 7: Two Peanuts connected by a nut and bolt.

IV. Preliminary Design Evaluation:

A. Design Matrix Criteria

In order to compare the three preliminary designs, the three designs were evaluated using a design matrix. The design matrix used contained six categories of varying degrees of importance. Each category was given a weight, and then each design was given a score out of 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. Obviously this damage 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, which is ease of use, represents how easily 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 third category is peanut grip strength. In the current system, the forceps used often have a peanut, which is essentially a pad of gauze, at the top of the forcep prong. The peanut helps the surgeon have traction to be able to grip and hold the thyroid during retraction. So, this category represents how well the design will be able to grip the peanut that is currently being used in the existing system. This category was given a weight of 20/100 because it is extremely important that the device can be easily integrated with the current surgical procedure that is currently used at UW-Health University Hospital.

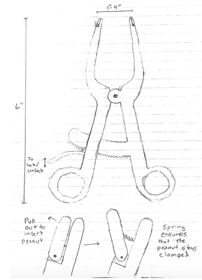
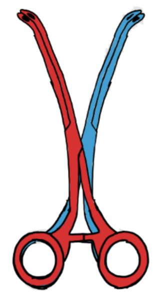
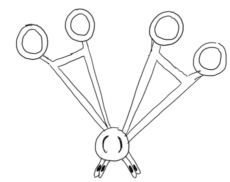
The fourth category is adaptability. This category represents how well the distance between the prongs can be adjusted. During thyroid retraction, this distance may need to be adjusted for a number of reasons, for example if a patient had a smaller or larger thyroid than average. This category was given 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		**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**	

a. Design 1: Adapted Weitlaner

Compared to the other two designs, the adapted weitlaner scored the lowest, with a score of 76. This design scored highly in the category of safety with a 5 out of 5, as it would likely not cause any more damage than any of the other designs. In the ease of use category, it scored lower, with a score of 3 out of 5, this is because the device requires substantial readjustments which may be difficult to do in a surgical setting. In the peanut grip strength category, it scored a 3 out of 5 because this design would not be able to use the peanut tip in the same way that they are currently used. In adaptability, the design scored highly, with a score of 5 out of 5. This is because this design is very adaptable, with the distance between the two main prongs as well as the tips being able to be adjusted. In the ease of fabrication category, it scored a 3 out of 5 because there are many small components of this design which may be difficult to manufacture. Lastly, in cost, the design scored a 3 out of 5. This reasoning is similar to the reasoning of ease of fabrication because the many small parts may be expensive. Overall, this design scored well in the categories of safety and adaptability, but scored lower in the categories of ease of use, peanut grip strength, ease of fabrication and cost.

b. Design 2: Two Fused

After being evaluated in the design matrix, the two-fused design idea received a score of 86. This ranks it in second compared to the other two designs. Similar to the adapted weitlaner, in the category of safety, the two-fused design received a score of 5 out of 5 because it is not likely to cause any more harm to the surrounding tissue than any of the other designs. In the category of ease of use, the two-fused design received a score of 5 out of 5. This high score is because this design is extremely similar to the existing system, so the device could readily be used by surgical staff. Next, in the category of peanut grip strength, the design received a score of 4 out of 5. Similar to the ease of use category, this design is very similar to the existing system so it will be able to maintain a good grasp on the peanut tips that are used. In the category of adaptability, the design scored a 3 out of 5. Due to the fused forceps, the ratcheting system may have limited adjustability for each separate prong, which caused this design to score lower in the adaptability category. Next, in the category of ease of fabrication, this design received a score of 4 out of 5, this is because there would be extra steps involved in order to fuse the two separate forceps. Lastly, in cost the two-fused design scored a 4 out of 5 because the two forceps are required along with the materials needed to fuse them. Overall, the two-fused design scored highly in the categories of safety, ease of use and peanut grip strength but lost points in the categories of adaptability, ease of fabrication and cost.

c. Design 3: Nut-Bolt

After being evaluated in the design matrix, the nut-bolt design received the highest score of the three designs, an 89. Similar to the other two designs, in the category of safety, the nut-bolt 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 ease of use, the design received a score of 4 out of 5, one point was deducted in this category as the surgical staff will have to screw together the pieces of the device before continuing with surgery. In the next category, peanut grip strength, the design scored a 4 out of 5. Similar to the two-fused design, the tips of the nut-bolt design are very similar to the existing system, therefore the nut-bolt design will be able to readily use the peanut tips. Next, in the category of adaptability, the design scored a 4 out of 5 as the nut-bolt portion provides an adjustable system for the device. Next, in the ease of use fabrication category, the nut-bolt design received a score of 5 out of 5 as there are fewer pieces that would need to be manufactured compared to the other designs. Lastly, in the category of cost, the nut-bolt design received a score of 5 out of 5 as there are few design parts that would have to be created, which would result in a lower manufacturing cost. Overall, the nut-bolt design scored highly in the categories of safety, peanut grip strength, ease of fabrication and cost. The nut-bolt design lost points in the categories of ease of use and adaptability. As stated above, this design did receive the highest score of the three designs and will therefore be pursued further as a possible final design.

C. Preliminary Proposed Final Design

After evaluation of each proposed design for the design criteria outlined previously, the nut-bolt design will be continued with as the proposed final design. This design scored well in almost every category, finishing with a final score of 89 out of 100. The design will consist of two Rochester-Pean style forceps with blunt types and serrated jaws, joined with a mechanism that is capable of tightening and loosening. This mechanism will allow for an adjustable width between the tips of the forceps, and therefore an adjustable distance between the peanut sponges to allow for the preferences and needs of a surgeon. The surgeon will attach the peanut sponges prior to use, and tighten the mechanism attaching to forceps at the desired angle and width. The design will allow for two points of contact on the thyroid gland to reduce the difficulty of procedures which require the thyroid to be retracted. Advantages of the nut-bolt design include the ease of fabrication for the device, along with a low cost, and high safety, as there are no sharp edges or other possible methods to puncture the thyroid or cause other injury during the procedure. Additionally, the device can be easily learned and used by endocrine surgeons, as it is an adaption of the current method of thyroid retraction, but requires fewer hands. A possible disadvantage of the design is that it may be arduous for the surgeon to attach both peanuts separately, or to adjust the width between the peanuts during the operation. However, proper training and preparation for surgeons will be useful in mitigating these disadvantages.

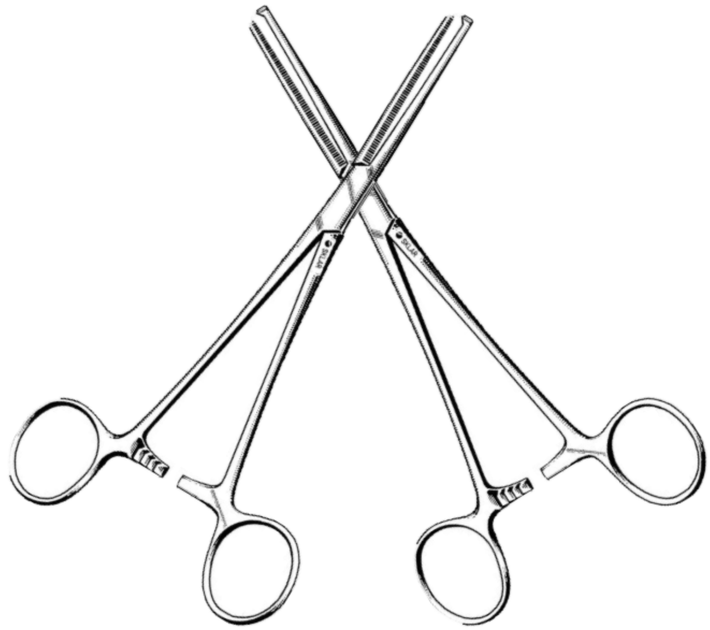


Figure 8*: Rendering of the nut-bolt design.*

D. Design Updates

The preliminary proposed final design was the nut-bolt design. After further discussion with the team's client, the ultimate proposed final design ended up being a modified version of the team's adapted Weitlaner. The nut-bolt design had noted ergonomic drawbacks that would require tedious adjustments each time the width between the two forceps was to be adjusted. It was decided that the adapted Weitlaner design was more of what the team's client was looking for, as it contained a ratcheting system for adjusting its two prongs, and could be used with one hand. The modification to the preliminary design was that the two ends of the Weitlaner would be blunt rather than allow for the insertion of a peanut. On each tip of the retractor, a disposable polymer tip would be used in contact with the thyroid gland, in order to provide additional surface area, as well as two points of contact.

E. Final Design

After consultation with the client, the final design 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 9: *Rendering of the updated adapted Weitlaner design.*

The tips 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.

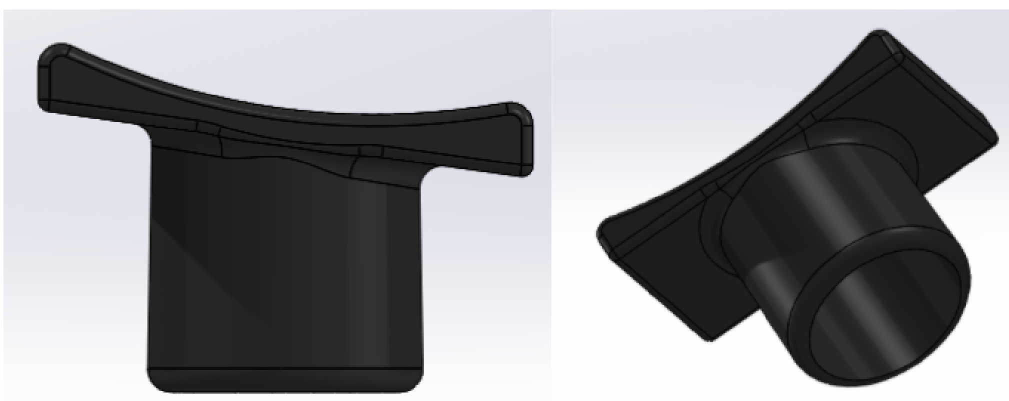


Figure 10: *CAD model of the polymer tips used with the adapted Weitlaner design.*

V. Fabrication/Development Process:

A. Materials

For the purposes of our design, the first prototype iteration will be composed of a 3D-print material. Common materials used in 3D-printing applications include polymers such as polymethyl methacrylate (PMMA), polylactic acid (PLA), polyvinyl alcohol (PVA), and polypropylene (PP) [19]. Future iterations of the design may eventually be manufactured from carbon or stainless steel, depending on the choices made by the team in relation to the reusability of the device. Ideally, the tips will eventually have a component that is detectable through x-ray, similar to many of the smaller surgical devices used currently.

B. Methods

The initial prototype of the design will be manufactured by 3D printing in the Makerspace, located on the University of Wisconsin - Madison campus. This will allow for initial considerations into the ergonomics, size, and other characteristics of the prototype before finalization. Consultation with the client and possibly other surgeons on these important factors will be performed between design iterations, and before any adjustments are made to the design. 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. For the first iteration of the prototype, initial testing will be performed with the applied force simulations within the program.

C. Testing

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.

VI. Results:

Minimal stress, engineering strain, and deformation were observed. 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. Furth confirmation of the results will be provided once a prototype is acquired in the desired material, and physical testing can begin.

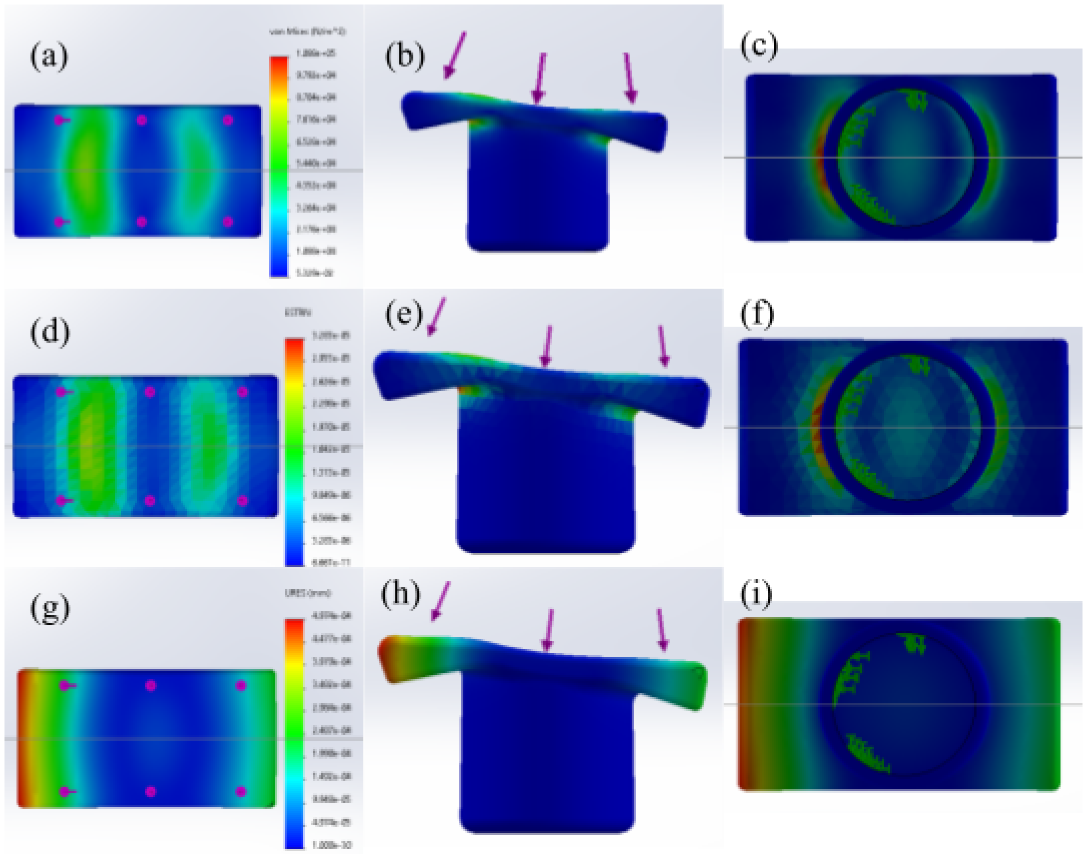


Figure 11: *SolidWorks applied force testing of the polymer tips. Representations of stress (a, b, c), engineering strain (d, e, f), and deformation (g, h, i) of a 2 N applied force are depicted*

VII. Discussion:

The SolidWorks force testing results above indicate that the shod part of the design would be able to withstand the forces that may be applied to it during use. As seen above, there is minimal deformation to the shod when the simulated force is applied. Additionally, because these tips will be single use, the deformation that occurs will not be an obstruction to the product's lifetime as it will simply be discarded after use.

Research that will need to continue specific to the shods is ways to make them detectable by X-rays. Surgical instrument pieces that have the possibility of falling into a patient's surgical site should have the ability to be detected to prevent any damage [20].

For future work, a fully articulating model of the forceps needs to be designed in SolidWorks. Additionally, more testing needs to be completed to ensure that the device will be able to complete its intended purpose. One type of testing that will be performed is qualitative ergonomics testing. In order to do this, a 3D model of the forceps will be printed and given to the client. From there, the client can assess the ergonomics of the model and further adjustments can be made. Lastly, research needs to be done into the process of stainless steel manufacturing as that is what the forceps will be manufactured out of.

VIII. Conclusions:

The main goal of this project was 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. Testing was conducted on one aspect of the final design, the rubber shods, to make sure that force inflicted from the thyroid or surgeon's hand would not cause deformation.

In the next year of Biomedical Engineering Design, a lot of focus will be put on taking the team's current final design and modifying it to fit the characteristics of a common surgical instrument, like being made out of stainless steel. Also, more intensive testing will be conducted to learn more about the ergonomics of the team's final design

References

[1] M. Hoffman, “The Thyroid (Human Anatomy): Picture, Function, Definition, Location in the Body, and More,” *WebMD*, 18-May-2019. [Online]. Available: https://www.webmd.com/women/picture-of-the-thyroid. [Accessed: 05-Feb-2021].

[2] S. M. Kim, A. D. Shu, J. Long, M. E. Montez-Rath, M. B. Leonard, J. A. Norton, and G. M. Chertow, “Declining Rates of Inpatient Parathyroidectomy for Primary Hyperparathyroidism in the US,” *PloS one*, 16-Aug-2016. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4986953/. [Accessed: 23-Feb-2021].

[3] Bls.gov. (2019). Occupational Employment Statistics: Surgeons. [online] Available at: https://www.bls.gov/oes/current/oes291067.htm#(3)

[4] IMS Health, S. (2016). Market Profile of U.S. Orthopedic Surgeons. Market Insights Report. [online] Available at: http://www.coa.org/docs/SKA.pdf

[5] Dimou, F., Eckelbarger, D. and Riall, T., 2016. Surgeon Burnout: A Systematic Review. Journal of the American College of Surgeons, 222(6), pp.1230-1239.

[6]“McBurney Thyroid Retractor,” *integralife.com*. [Online]. Available: https://www.integralife.com/mcburney-thyroid-retractor/product/surgical-instruments-hospitals-surgery-centers-tissue-banks-jarit-general-operating-retractors-mcburney-thyroid-retractor. [Accessed: 05-Feb-2021].

[7]“Beckman Thyroid Retractor,” *integralife.com*. [Online]. Available: https://www.integralife.com/beckman-thyroid-retractor/product/surgical-instruments-hospitals-surgery-centers-tissue-banks-jarit-general-operating-retractors-beckman-thyroid-retractor. [Accessed: 05-Feb-2021].

[8]DeRoyal. n.d. *Surgical Sponges and Towels*. [online] Available at: <https://www.deroyal.com/docs/default-source/product-literature/surgical-sponges_towels-web.pdf?sfvrsn=f5c00dbd_12> [Accessed 14 February 2021].

[9]“Thyroid gland and thyroid hormones,” *myDr*, 05-Apr-2019. [Online]. Available: http://www.mydr.com.au/health-images/thyroid-gland-and-thyroid-hormones/#:~:text=Your%20thyroid%20makes%202%20main,thyroid%20gland%20is%20called%20calcitonin. [Accessed: 05-Feb-2021].

[10]M. Hoffman, “The Thyroid (Human Anatomy): Picture, Function, Definition, Location in the Body, and More,” *WebMD*, 18-May-2019. [Online]. Available: https://www.webmd.com/women/picture-of-the-thyroid. [Accessed: 05-Feb-2021].

[11]Sippel, R.S. Chen, H. 2012. “The Handbook of Endocrine Surgery,” World Scientific Publishing Co. Pte. Ltd.

[12] Randolph, G.W., Clark, O, 2007. *Principles of Surgery*, Chapter 30, p. 414

[13] H., n.d. Parathyroid Disease | Hyperparathyroidism | MedlinePlus. [online] Medlineplus.gov. Available at: <https://medlineplus.gov/parathyroiddisorders.html>.

[14] Thyroid Clinic Sydney. 2014. Parathyroid Facts - Thyroid Clinic Sydney. [online] Available at: <https://www.thyroid.com.au/parathyroid-facts/>.

[15] “Hyperparathyroidism,” *Mayo Clinic*, 18-Jun-2020. [Online]. Available: https://www.mayoclinic.org/diseases-conditions/hyperparathyroidism/symptoms-causes/syc-20356194. [Accessed: 02-Mar-2021].

[16] “Peanut Sponge Forceps: Sklar Instruments 22-9480,” *quickmedical*. [Online]. Available: https://www.quickmedical.com/sklar-instruments-peanut-sponge-forceps.html. [Accessed: 11-Feb-2021].

[17] Visenio, M., 2017. Commonly Used Surgical Instruments and Materials. [online] Facs.org. Available at:<https://www.facs.org/-/media/files/education/medicalstudents/common_surgical_instruments_module.ashx>.

[18] Stokes, J., 1976. NASA - MSFC-STD-512 - MAN/SYSTEM REQUIREMENTS FOR WEIGHTLESS ENVIRONMENTS | Engineering360. [online] https://msis.jsc.nasa.gov/sections/section04.htm. Available at: <https://standards.globalspec.com/std/669461/MSFC-STD-512> [Accessed 9 February 2021].

[19] UW Makerspace. 2021. 3D Printers. [online] Available at: <https://making.engr.wisc.edu/3d-printers-2/>.

[20] X-Ray detectable Surgical Sponges. (n.d.). Retrieved April 27, 2021, from http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8181

Appendix A: Problem Design Specification

BME 301:
Preliminary Product Design Specification

Team:

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Advisor: Dr. Edward Bersu
Client: Dr. Amanda Doubleday
Date: February 12th, 2021

Function:

The function of the device is to aid in the retraction of the thyroid and parathyroid glands during thyroidectomies and related procedures. During surgery, endocrine 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 comfortably by this method. The device should be able to assist surgeons in retractracting and holding the thyroid 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 being traumatic. It should be reusable, auto-clampable and with blunt ends that act as clamps. It must function as one instrument that has two peanut forceps 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 will be trained professionals, as to greatly reduce the risk of injury. In order to ensure the safety of the surgeons using the device, testing of the device's ability to endure forces of the hand, or ability to hold against the typical weight of a thyroid will be conducted. 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 or latching mechanism must not jam or lock or when unintended, but also must lock when intended and avoid releasing until desired. 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:*

The device should have a rather long life in service. The device should be able to be sterilized and reused by autoclaving. The "peanuts" or gauze pads that will be used on the ends of the device however are single use, but are not being designed by the team. 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[3].

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 [4]. For pressure, the likely pressure the device will be experiencing is around 1 atmosphere [4]. The device will be used by surgical staff so it is important for the staff to receive adequate device training.

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.

h. Size:

The current device being used is the Peanut Sponge Forceps and is approximately 8” in length [5]. Typical 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.

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 .09 lbs [6]. A small increase of weight will be allowed due to the addition of the second prong, although the device should not be sufficiently heavy as to be difficult to operate by a surgeon. Measurements will be taken on current surgical forceps and retractors to determine a more accurate target weight.

j. Materials:

The device will be made out of stainless steel such as the current device and most modern surgical instruments are. 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 [5].

k. Aesthetics, Appearance, and Finish:

The medical device should have the appearance that of a typical surgical instrument. The device should have a highly polished, or mirror finish in order to prevent potential staining [7]. 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 [8] from medical supply companies. 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:*

If used during an actual operation, this product will need to be FDA approved because it falls under the category of a medical device which is protected under FDA regulation 21 CFR Part 807. If used during surgery, 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 Peanut 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, the Peanut is used but the one instrument is not enough traction and causes the thyroid to fold. To solve this problem, two Peanut Forceps are being used which is proving to also be problematic because it is difficult to maneuver both with one hand.

PDS References

[1] Stokes, J., 1976. NASA - MSFC-STD-512 - MAN/SYSTEM REQUIREMENTS FOR WEIGHTLESS ENVIRONMENTS | Engineering360. [online] https://msis.jsc.nasa.gov/sections/section04.htm. Available at: <https://standards.globalspec.com/std/669461/MSFC-STD-512> [Accessed 9 February 2021].

[2] Pankow, B., Michalak, J. and McGee, M., 1985. *Adult Human Thyroid Weight*. [online] Pubmed. Available at: <https://pubmed.ncbi.nlm.nih.gov/4077513/> [Accessed 8 February 2021].

[3]"Stainless Steel for a sustainable future," *Team Stainless*. [Online]. Available: https://www.worldstainless.org/Files/ISSF/non-image-files/PDF/Team_Stainless_Stainless_Steel_for_a_Sustainable_Future.pdf. [Accessed: 10-Feb-2021].

[4] Engineeringtoolbox.com. 2020. *STP - Standard Temperature And Pressure & NTP - Normal Temperature And Pressure*. [online] Available at: <https://www.engineeringtoolbox.com/stp-standard-ntp-normal-air-d_772.html> [Accessed 14 September 2020].

[5] "Peanut Sponge Forceps: Sklar Instruments 22-9480," *quickmedical*. [Online]. Available: https://www.quickmedical.com/sklar-instruments-peanut-sponge-forceps.html. [Accessed: 11-Feb-2021].

[6] "ADC® Kelly Hemostatic Forceps, Straight, 5-1/2'L, Stainless Steel," *Global Industrial*. [Online]. Available: https://www.globalindustrial.com/p/medical-lab/medical-equipment/exam-room-supplies/kelly-hemostatic-forceps-straight-5-1-2-l-stainless-steel?infoParam.campaignId=T9F&gclid=Cj0KCQiApY6BBhCsARIsAOI_GjaErxuyu_CezZTVpO3iKXoGy5DLCt760CsGWYqbcB1HmbmZV1jtzcEaApEOEALw_wcB. [Accessed: 10-Feb-2021].

[7] "Metal Finishing for Surgical Instruments," *RP Abrasives*, 15-Sep-2020. [Online]. Available: https://rpabrasives.com/industries/medical-surgical/. [Accessed: 10-Feb-2021].

[8] "MABIS Kelly Forceps, Medical Forceps, Locking Forceps, Silver, 5.5,'" *Amazon*. [Online]. Available: https://www.amazon.com/MABIS-Forceps-Medical-Locking-Silver/dp/B00EKQ7FY4/ref=sr_1_4?dchild=1&keywords=surgical+forceps&qid=1612984299&sr=8-4. [Accessed: 10-Feb-2021].