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

M.B. Josvai[1], K. Eichstaedt[1], A. Hart[1], A. Lall[1], M. Tyler[1], A. Doubleday[2]

[1] Department of Biomedical Engineering, University of Wisconsin-Madison, Madison, WI, USA
[2] Department of Endocrine Surgery, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA

Corresponding Authors:
Kate Eichstaedt
Department of Biomedical Engineering,
University of Wisconsin-Madison College of Engineering
1415 Engineering Drive
Madison, WI 53706
e-mail: kreichstaedt@wisc.edu

Ashlee Hart
Department of Biomedical Engineering,
University of Wisconsin-Madison College of Engineering
1415 Engineering Drive
Madison, WI 53706
e-mail: arhart3@wisc.edu

Mitchell Josavi
Department of Biomedical Engineering,
University of Wisconsin-Madison College of Engineering
1415 Engineering Drive
Madison, WI 53706
e-mail: mjosavi@wisc.edu

Avani Lall
Department of Biomedical Engineering,
University of Wisconsin-Madison College of Engineering
1415 Engineering Drive
Madison, WI 53706
e-mail: aklall@wisc.edu

ABSTRACT

Many procedures require the retraction of the thyroid gland in order to gain access to relevant anatomical structures. However, the current retractor only makes one point of contact with the thyroid, and does not account for thyroids of different sizes which make it difficult to retract and hold. This paper introduces an 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 circular grooved tips. The performance of the thyroid retractor was tested through an ergonomics survey administered to experienced surgeons, computational tissue analog testing, and bio-contamination testing. The designed device was verified as a valuable tool and suggests further development of the design into stainless steel could open doors to more effective thyroid retraction.

1 INTRODUCTION

Motivation

Thyroid surgeries are ubiquitous – 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.

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].

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 legs 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.

Problem Statement

The goal of this project 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.

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 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.

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].

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 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 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.

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%.

Prototype Research

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 6. 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.

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. Common materials used in 3D-printing applications include polymers such as polymethyl methacrylate (PMMA), polylactic acid (PLA), polyvinyl alcohol (PVA), and polypropylene (PP) [18]. The first five iterations of the design were printed out of 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 [19].

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. 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. Additionally, future prototypes will be 3-D printed using the Form3 printer once that device is available for use at the University of Wisconsin-Madison Makerspace. This printer will be used due to the higher accuracy of the device.

Testing

In order to evaluate the functionality of the device, three main tests were performed along with qualitative testing done in a cadaver lab. The three tests performed were a tissue analog test with a subsequent computational-modeling test using the data from the analog test, an ergonomics survey, and a bio-contamination test. 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. Lastly, the bio-contamination test was performed to ensure that the device is reusable. 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 donated cadaver.

The tissue analog 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. During testing, the mock thyroid was retracted using the printed prototype in order to observe the ability of the prototype to lift the thyroid.

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 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 able to be 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 [20]. Diseased thyroid pathology tends to result in an increase in the elastic modulus and stiffness of the tissue [21], 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. Engineering stress and von Mises stress values were then found from this computational test in order to ensure there would be no soft tissue failure due to the device.

An ergonomics survey was also used to receive feedback from medical professionals regarding how comfortable they are using the device. This survey was conducted using Google

Forms and featured questions where the survey taker could rank aspects of the device on a scale of one through seven. Additionally, there were optional questions where the survey taker could choose to elaborate on their rankings. The survey was sent to different endocrine surgeons in the states of Wisconsin and Illinois along with a 3-D printed, assembled prototype. The data from this test gave information regarding the practical functionality of the device.

Lastly, a bio-contamination test was performed to demonstrate that the device is reusable and does not feature any parts that may harbor bio-contaminants. This test was performed using a total protein assay and results were viewed using a fluorescence microscope.

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 0.786 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, 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 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.

Additionally, cadaveric testing demonstrated that the device is able to retract the thyroid medially from multiple points of contact.

4 DISCUSSION

In order to prove the functionality of the device, three 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 testing to ensure that the thyroid will not face excessive von Mises stresses or engineering strain. Additionally, an ergonomics survey was performed to determine the practical functionality of the device. Additionally, a bio-contamination test was used to prove that the device is reusable.

5 ACKNOWLEDGMENT

The team would like to acknowledge their client, Dr. Amanda Doubleday, for her guidance and motivation throughout this project. The team would also like to acknowledge their former Biomedical Engineering Design advisor, Dr. Ed Bersu, as well as their current advisor Professor Mitchell Tyler. Finally, the team acknowledges the University of Wisconsin - Madison Biomedical Engineering Design program.

6 FUNDING

The creation of this thyroid retractor is possible thanks to the funding by the team's client, 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.

REFERENCES

[1] 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].

[2] 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].

[3]"Allis tissue forceps," *Medline Industries, Inc.* [Online]. Available: http://punchout.medline.com/product/Allis-Tissue-Forceps/Tissue-Forceps/Z05-PF13543?question=&index=P8&indexCount=8. [Accessed: 11-Oct-2021].

[4] "Allis tissue forceps," *Medline Industries, Inc.* [Online]. Available: https://www.medline.com/jump/product/x/Z05-PF13543. [Accessed: 14-Dec-2021].

[5] "Kelly forceps - stainless," *medcareproducts.com*. [Online]. Available: https://www.medcareproducts.com/Kelly-Forceps-Stainless/productinfo/IMK/. [Accessed: 11-Oct-2021].

[6] 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].

[7]"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].

[8]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].

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

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

[11] C. Wood, “Neurons run on calcium,” *BrainFacts.org*. [Online]. Available: https://www.brainfacts.org/brain-anatomy-and-function/genes-and-molecules/2020/neurons-run-on-calcium-022020#:~:text=In%20neurons%2C%20calcium%20is%20the,%2C%20metabolism%2C%20and%20cell%20growth. [Accessed: 14-Dec-2021].

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

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

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

[15] Centers for Disease Control and Prevention. (2016, September 18). *Steam sterilization*. Centers for Disease Control and Prevention. Retrieved October 19, 2021, from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html.

[16] 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>.

[17] 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].

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

[19] K. Yang and Y. Ren, “Nickel-free austenitic stainless steels for medical applications,” Science and Technology of Advanced Materials, vol. 11, no. 1, p. 014105, 2010.

[20] A. Mowlavi, M. Fornasier, and M. de Denaro, “Thyroid Volume's influence on Energy Deposition from 131i calculated by Monte Carlo (MC) simulation,” Radiology and Oncology, vol. 45, no. 2, 2011.

[21] A. Lyshchik, T. Higashi, R. Asato, S. Tanaka, J. Ito, M. Hiraoka, A. B. Brill, T. Saga, and K. Togashi, “Elastic Moduli of thyroid tissues under compression,” Ultrasonic Imaging, vol. 27, no. 2, pp. 101–110, 2005.

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 Tissues Forceps [4]

Fig. 2 Current thyroid retractor used by the client: The Peanut

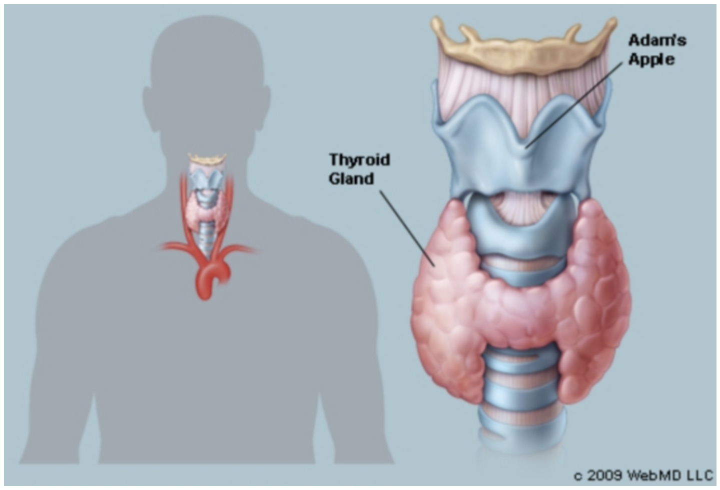


Fig. 3 Anatomical image of the thyroid gland in the human body [10]

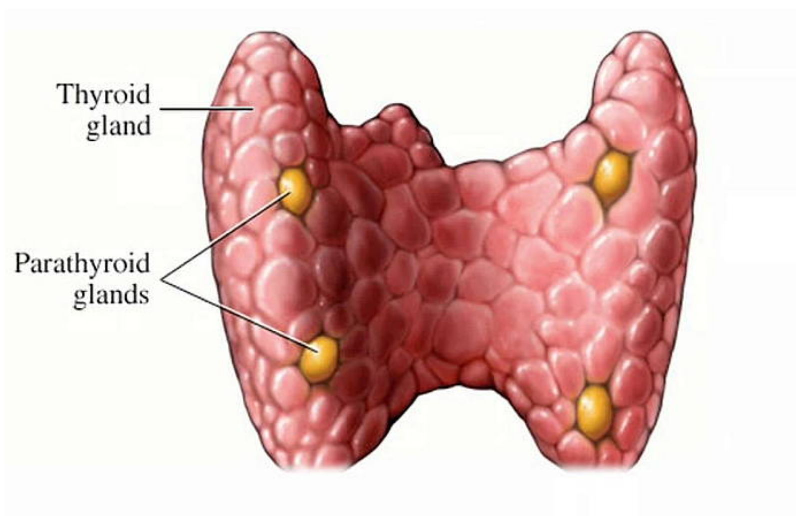


Fig. 4 Anatomical image of the parathyroid glands relative to the thyroid [12]

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

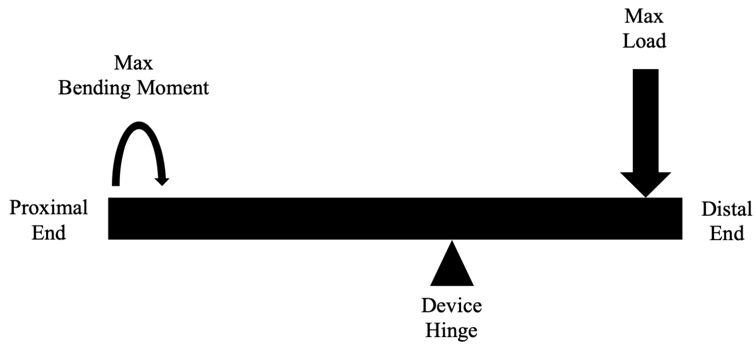


Fig. 6 Free-body diagram depicting the maximum forces and bending moments with the device simplified to a Class I lever system

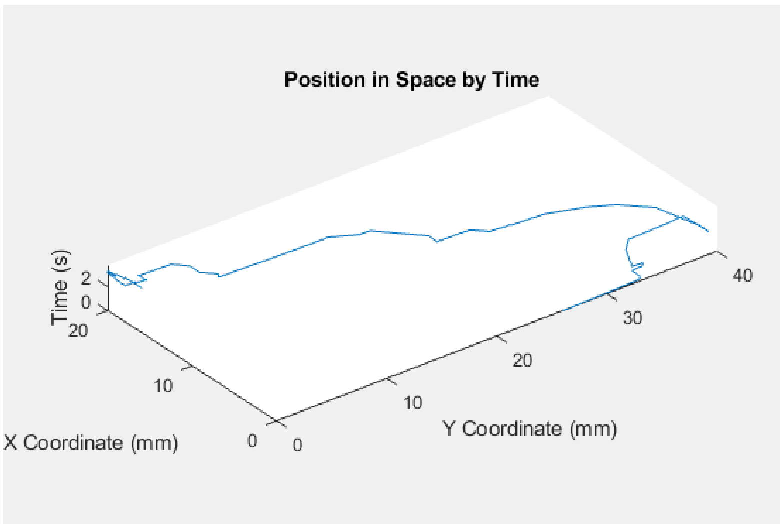


Fig. 7 Calculated position in XY space as a function of time for one experiment of simulated surgery on a tissue analog

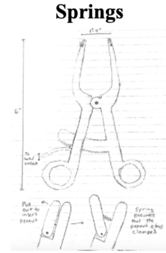
Fig. 8 A 3-dimensional model of the human thyroid in Solidworks 2021, with material properties representative of healthy thyroid tissue

APPENDIX: DESIGN PROCESS

Three preliminary designs that met the product design specifications and client needs were created. All three designs feature the finger rings and self-retaining ratcheting mechanism of the Weitlaner Retractor. The Shods design features 3D printed silicone rubber shods that insert over the Weitlaner 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. The Springs design contains springs that can be pulled apart laterally in order to hold peanut gauzes tightly in place during thyroid retraction. By adding this design change, 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. The Treads design contains a metal ring at the end of each tip. These metal rings have an inward angle, which will allow for better retraction of the thyroid, and are grooved to provide traction.

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.

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	
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 will be used as the final design. This design scored highly in almost every category of the matrix. Advantages of the design include the ease of fabrication of this device, cost, safety of the design, and ease of use. This design consists of an adjustable ratcheting system and has 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.