# BME Design-Spring 2021 - Mitchell Josvai Complete Notebook

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# KATE EICHSTAEDT

on

Apr 28, 2021 @02:17 PM CDT

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# Mitchell Josvai - Feb 10, 2021, 4:34 PM CST

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Project Information/Project description



AVANI LALL (aklall@wisc.edu) - Feb 14, 2021, 12:54 PM CST

Course Number: 301

Project Name: Thyroid Retractor

Short Name:

**Project description/problem statement:** 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.

About the client: Dr. Doubleday



KATE EICHSTAEDT - Feb 05, 2021, 8:04 AM CST

**Title: Client Meeting** 

Date: 2/5

Content by: Kate Eichstaedt

Present: Kate, Avani, Ashlee, Mitchell and Dr. Doubleday

Goals: Meet our client and learn more about our project.

#### Content:

Use 'peanut' as a surgical instrument

- · not sure commonality at other institutes
- might be more common at UW
- have to retract the thyroid up towards ourselves off the trachae, usually cant hold thyroid up with hands because it is slippery, peanut with gauze is able to hold up thyroid
  - if the thyroid is large, the singular device is not enough
  - sometimes two peanuts are used to be able to hold up the thyroid with two points of fraction
  - shaped like a V
- want two prongs on end instead of just one
- a way to adjust width between the two prongs?
  - peanut end clamp would work on both ends of the v clamp
  - would have one handle so you have the other hand free to dissect
  - rochester pean forceps is most similar to currently used peanut
  - look up peanut sponges for surgery
- Thyroids are usually 4-6 cm in length, peanuts should be maybe 2-3 cm apart.
  - way to make the distance adjustable?
- reusable
- · sometimes you have to use a fair bit amount of force, nothing strong enough to fracture a surgical device
- · sometimes peanut slips off and can cause some bleeding, especially if there are fragile blood vessels
- Average price per unit? supplier? Covidien. Lots of metal instruments are engraved with 'made in Germany"
- · Might have access to an old clamp so we could use it for prototyping
  - they make disposable ratchets

## Conclusions/action items:

This preliminary meeting was very helpful and cleared up a lot of confusion that we had surrounding the initial project information. Our client showing us pictures of the device was incredibly helpful because now we have a clear image of what is wanted/needed from us. For action items, we are going to conduct preliminary research and begin to draft up our PDS.



KATE EICHSTAEDT - Mar 10, 2021, 6:32 PM CST

Title: Client Meeting
Date: 3/10
Content by: Kate Eichstaedt
Present: Whole team and Dr. Doubleday
Goals: Go over preliminary design
Content:
Concern with nut and bolt- ergonomics of how to hold it, may be too bulky(usually 4-5 centimeters)
Nut-bolt not ideal for adjusting the width quickly
Does not have to necessarily use peanut
Rubber shard? Causes less trauma - instead of peanut
Rubber shard vascular clamp
Some surgeons do not have extra staff to help dissect- allows sufficient retraction that one person can do on their own, no help provided
Add to introduction: requires less staff
Combine best parts of each design- ultimate final design
Likes how two-fused handle is
Weitlaner ratchet mechanism is unreliable after time
Go forward with Weitlaner maybe- maybe change spring? Mentioned with a spring it may be difficult to make fine movements

Conclusions/action items:

This meeting was to go over our preliminary designs. Dr. Doubleday likes the Weitlaner adapted design.



KATE EICHSTAEDT - Mar 19, 2021, 12:56 PM CDT

**Title: Client Meeting** 

Date: 3/19

Content by: Kate Eichstaedt

Present: Whole team and Dr. Doubleday

Goals: Discuss our new revised designs with Dr. Doubleday

#### Content:

Share document with her- fix some stuff about parathyroid and thyroid anatomy and functions

Comments abt- horseness- take out, use nerve finder to protect recurrent laryngeal nerve, usual horseness is from being trached

Less than a 5% injury rate

Use middle right rubber shod from Mitchell's lab archives

Dime size contact is bigger than enough- anything bigger than 2 or 3 cm would be too big, peanut is around 1 x 2 cm

Maybe have options for different shapes and sizes of tips- interchangeable tips would be very useful

- · peanuts are x ray detectable, would this be possible with rubber tips?
  - what if one fell out, would be necessary to have some sort of thread in them to make x ray detectable
  - look into how to make something x ray detectable
- · peanuts have a patch that is radio-opaque, old ones had a blue line sewn into it
- Silicon forcep tips are x ray detectable
- 3D print tips; concave geometry
- 10-20 degree angle on blunt ends

FDA approval process?

Look into IRB, where to begin

## Conclusions/action items:

As a team, we are going to continue to work on modeling our device.



KATE EICHSTAEDT - Apr 16, 2021, 12:44 PM CDT

**Title: Client Meeting** 

Date: 4/16

Content by: Kate Eichstaedt

Present: Whole group, Dr. Doubleday

 $\textbf{Goals:} \ \text{Discuss progress and plans for fall 2021}$ 

# Content:

Few issues with the anatomy part in the intro section-send to Dr. Doubleday so she can make comments

She is interested in continuing this project in the fall semester. She may be at UW, but if she is not she is still interested.

Later today we are going to try and test in lab archives.

Conclusions/action items:

Begin solidworks testing, prepare for meeting with advisor.



KATE EICHSTAEDT - Feb 05, 2021, 4:02 PM CST

# **Title: Advisor Meeting**

Date: 2/5

Content by: Kate Eichstaedt

Present: Dr. Bersu, Mitchell, Kate, Avani, Ashlee

Goals: Meet our advisor. Go over project basics.

## Content:

- Look for surgical procedures/videos
  - not all methods will be the same
- try to get a good lay of the land of the thyroid area
- thyroid is held very firmly in place
  - pull in medial direction
  - have to watch out for arteries, nerves etc.
  - don't want device to compromise area

## Conclusions/action items:

Todays meeting was very helpful. We met our advisor, Dr. Bersu, and he was able to give us a direction to start researching in. For action items, we are going to continue with preliminary research and begin to work on the PDS.



# **Title: Advisor Meeting**

Date: 2/12

Content by: Kate

Present: Kate, Avani, Ashlee, Mitchell and Dr. Bersu

Goals: Discuss the progress that has been made in the past week and where to move forward.

#### Content:

- The Mcburney thyroid retractor is a current system, it would be beneficial to possibly look at this design and add another prong to the end.
- · Looking at grip strength and average hand size will be beneficial when designing this device
- It would be very beneficial to try and find a video of the current system that is being used at UW-hospital systems
   possibly ask if the client has any video recordings or if she would be able to record a surgery for us to observe
- · We should ask our client about reimbursement methods
  - if she would like to collaborate with colleagues and bring them into the project that is more than okay

#### Conclusions/action items:

This meeting was very helpful for rehashing what we have done this week and for providing guidance for our next steps of this project. For action items, we are going to email the client with the questions we have regarding the videos, reimbursement, and collaboration. Additionally, for action items our goal for the next week is for each of us to draft up a deign by mid-next week and then we can use our design matrix to evaluate those designs.



KATE EICHSTAEDT - Feb 19, 2021, 12:17 PM CST

**Title: Advisor Meeting** 

Date: 2/19

Content by: Kate Eichstaedt

Present: Whole team and Dr. Bersu

Goals: Discuss the progress made this past week.

## Content:

If we are able to create the designs in solidworks, we should, but if not that is fine. Does not want us spending hours on a design in solidworks.

Change the problem statement to include the posterior location of the parathyroid glands on the thyroid.

# Conclusions/action items:

We were able to get some questions answered regarding whether or not we need to model our preliminary designs in solidworks. For action items, we are going to begin to work on our preliminary presentation.



KATE EICHSTAEDT - Mar 05, 2021, 12:30 PM CST

**Title: Advisor Meeting** 

Date: 3/5

Content by:

Present: Whole team, Dr. Bersu

Goals:

Content:

Stay on track with our plan and everything should go smoothly.

Testing- more to testing than just statistical analysis

- · force testing-good, would be quantitative
- qualitative- does the individual using this item like it

Do not use black and white thyroid image in poster presentation, okay in report. Look for an image that is a little more clear.

Conclusions/action items:



KATE EICHSTAEDT - Mar 12, 2021, 12:27 PM CST

**Title: Advisor Meeting** 

Date: 3/12

Content by: Kate

Present: Whole team and Dr. Bersu

Goals: Discuss the progress made this past week

Content:

Show and tell is optional

Email him if we have any issues getting into any of the labs for equiptment/misc. stuff

Make sure to keep documenting everything we do- this will be helpful for the future if anyone wants to look at what we did and how we did it. Does not matter if it is in team or individual sections.

Keep next semester in mind.

## Conclusions/action items:

In this meeting we discussed what we did this past week for our project. For action items, we are going to prepare for our meeting on Tuesday with our client.



KATE EICHSTAEDT - Mar 19, 2021, 12:15 PM CDT

**Title: Advisor Meeting** 

Date: 3/19

Content by: Kate Eichstaedt

Present: Whole team and Dr. Bersu

Goals: Discuss the progress made this past week.

## Content:

WARF Lecture

• Add blurb in lab archives

Would rubber tips be slippery?

## Conclusions/action items:

Not much to discuss this week. For action items, we are going to prepare for our meeting with Dr. Doubleday



## Title: Design Matrix

Date: 2/18/21

Content by: Avani

Present: Avani, Ashlee, Mitchell, Kate

**Goals:** To each present our design ideas and choose three to move forward with as our preliminary designs. Come up with criteria to evaluate the designs on and create the design matrix.

#### Content:

The 3 designs we chose to move forward with are the Adapted Weitlaner, Two-Fused, Nut-Bolt.

Criteria we came up with: Safety, ease of use, peanut grip strength, adaptability, ease of fabrication, cost.

- Safety: Determined by the amount of damage the device may create when in use during a surgical procedure. Want safety to be minimized as much as possible, explaining its high weight.
- Ease of Use: How easily the device can be used by the surgical staff. Also, retracting the thyroid medially from multiple points of contact.
- Peanut Grip Strength. How well the design will be able to grip the peanut.
- Adaptability: How well the distance between the prongs can be adjusted.
- Ease of Fabrication: How each design would be manufactured and how difficult that manufacturing process would be.
- Cost: How much the device will cost to manufacture. The low weight is because cost is not pressing.

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		

**Conclusions/action items:** The nut and bolt design scored the highest. Next, we will show our ideas to our advisor and client to see if we should move forward with this design and start thinking about fabrication and testing.



AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:20 PM CDT

#### Title: Final Design Choice

Date: 4/19/21

Content by: Avani

## Present: Avani, Kate, Mitchell, Ashlee

Goals: After meeting with the client and discussing our preliminary designs she suggested some changes to make to our design decision and we came up with our actual final design.

#### Content:

- A novel version of the adapted Weitlaner design.
- 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 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.
- 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.



Conclusions/action items: The team plans to conduct some mechanical testing of the final design in SolidWorks.



AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:23 PM CDT

#### Title: Materials and Expenses

Date: 4/25/21

Content by: Avani

Present: Avani, Mitchell, Kate, Ashlee

Goals: To explain materials we plan to use since no physical fabrication was conducted this semester.

Content:

- 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).
- In the 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.

Conclusions/action items: No expenses were made this semester as most of our work was in SolidWorks and proof of concept. We hope to continue the project and 3D print parts and make a fully functioning device of stainless steel in the future.



AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:31 PM CDT

Title: Methods

Date: 4/20/21

Content by: Avani

Present: Ashlee, Avani, Mitchell, Kate

Goals: To explain our intended fabrication process.

# Content:

- Initial prototype of the design will be 3D printed in the Makerspace.
  - 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.

# Conclusions/action items: We plan to continue this project and make a final prototype!



# **Title: Solidworks Testing**

Date: 4/19/21

Content by: Mitchell

Present: Avani, Mitchell, Kate, Ashlee

Goals: To conduct mechanical testing on Solidworks model of the rubber shods.

## Content:

Initial testing was done in SolidWorks. A 1 N distributed load was applied to the surface of the part, and the stress and displacements were analyzed. The interior surface of the hollow cylinder was designated as the fixed surface, because this would be around the retractor, and thus not moving in relation to the rest of the body.

## Stress Tests: (Scale remained the same for each image)

Top view:



Side view:





## Bottom view:



# Strain testing: (Scale remained the same for each image, Engineering strain was calculated)

Top view:



Team activities/Testing and Results/Experimentation/4/19/21: Solidworks Testing



Bottom view:



Displacement testing: (Scale remained the same for each image)

Top view:



Side view:

Team activities/Testing and Results/Experimentation/4/19/21: Solidworks Testing



Bottom view:



**Conclusions/action items:** 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. More testing needs to be completed to ensure that the device will be able to complete its intended purpose such as qualitative ergonomics testing.



Mitchell Josvai - Feb 10, 2021, 5:28 PM CST

Title: Thyroidectomy

Date: 2/5/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record information on thyroidectomy procedures

#### Content:

As the device we design will be used in thyroidectomy procedures, it is relevant to become familiar with the goals and process of the procedure.

Thyroidectomies are surgical procedures used to treat a variety of conditions. These procedures involve removing part or all of the thyroid gland, located in the neck. Thyroidectomies can treat:

- Thyroid cancer
- Overactive thyroid gland (hyperthyroidism)
- · Enlarged thyroid nodules (which can cause difficulty swallowing or breathing due to obstruction)
- Multi-nodular Goiter (enlarged gland with multiple nodules or bumps

To perform a thyroidectomy, a small horizontal incision is placed in the front of the neck to gain access to the thyroid. The thyroid is then retracted medially and dissected from the body in order to remove the entire thyroid, a single lobe or a smaller portion of the gland.

Risks associated with thyroidectomies include:

- Recurrent laryngeal nerve injuries resulting from dissection of the gland (~5% temporary, ~1% permanent in patients)
- Low blood calcium after removal of parathyroid glands (~5% temporary, ~1% permanent in patients)
- Excessive bleeding (~0.33% of patients, results in a hospital stay)



Figure: Medial retraction of one lobe of the thyroid during surgery with a peanut, showing the relevant anatomy near the gland (Randolph, G.W., Clark, O, Principles of Surgery, Chapter 30)

#### References:

Endocrinesurgery.ucsf.edu. 2020. Endocrine Surgery - Thyroidectomy. [online] Available at: <a href="https://endocrinesurgery.ucsf.edu/conditions--procedures/thyroidectomy.aspx">https://endocrinesurgery.ucsf.edu/conditions--procedures/thyroidectomy.aspx</a>> [Accessed 5 February 2021].

#### Conclusions/action items:

Use the recorded information to inform design choices in the future



Mitchell Josvai - Mar 03, 2021, 10:27 AM CST

Title: Thyroid Gland

Date: 2/7/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research and record information on the thyroid gland

## Content:

The thyroid is a endocrine gland located in the neck, as seen below. 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.

The thyroid is extremely important in cell regulation and homeostasis. It secretes hormones thyroxine (T4, after the four atoms of iodine contained in it) and triiodothyronine (T3, after the three atoms of iodine contained in it) into the bloodstream, which are necessary for proper function of cells in the body. In most cells, T4 is converted to T3 or T3 is taken from the bloodstream. T3 is the biologically active hormone, influencing cell activity. T3 can influence the metabolism of cells in the body.

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 to secrete these hormones by secreting the thyroid stimulating hormone (TSH). If there is excess T3 and T4 in the blood, the pituitary stops secretion of TSH, resulting in the reduction of T3 and T4 secretion.

An excess of T3 secretion results in overactivation and metabolism of bodily cells, also known as hyperthyroidism. This can lead to increased heart rate or intestinal activity. Conversely, hypothyroidism is the result of too little T3 secretion, resulting in underactivation of cells and cell metabolism. Hypothyroidism is the most common disorder associated with the thyroid, and can result in tiredness, weight gain, poor concentration, depression, and other symptoms.

Other diseases associated with the thyroid include:

- · Thyroid eye disease usually affects those with hyperthyroidism
- Nodules or swelling Lumps that can interfere with proper regulation of the thyroid gland or cause irritation
- Thyroid cancer: Rare, but may result in a thyroidectomy or other cancer treatment
- Postpartum thyroiditis triggered after pregnancy, but usually temporary

Common causes of thyroid disorders include:

- Autoimmune thyroid disease the body's immune system attacks thyroid cells as if they were pathogens (can be inherited through generations, Hashimoto's thyroiditis)
- Thyroiditis inflammation fo the thyroid, which can lower the amount of T3 and T4 it is capable of producing and secreting
- Postpartum thyroiditis occurs in 4-9% of women after childbirth, but usually temporary
- Iodine deficiency a lack of iodine can prevent the thyroid from being able to produce adequate T3 and T4
- Non-funcitoning thyroid gland from birth about 1 in 4000 newborns are affected

## Anatomy of the Thyroid and Parathyroid Glands



Figure: Anatomy of the thyroid and parathyroid glands (Endocrinesurgery.ucsf.edu. 2020. *Endocrine Surgery - Thyroidectomy*. [online] Available at: <a href="https://endocrinesurgery.ucsf.edu/conditions--procedures/thyroidectomy.aspx">https://endocrinesurgery.ucsf.edu/conditions--procedures/thyroidectomy.aspx</a>> [Accessed 5 February 2021].)

## References:

Cleveland Clinic. 2020. *Thyroid Disease: Causes, Symptoms, Risk Factors, Testing & Treatment*. [online] Available at: <a href="https://my.clevelandclinic.org/health/diseases/8541-thyroid-disease#symptoms-and-causes">https://my.clevelandclinic.org/health/diseases/8541-thyroid-disease#symptoms-and-causes</a>>.

British Thyroid Foundation. 2019. Your thyroid gland. [online] Available at: < https://www.btf-thyroid.org/what-is-thyroid-disorder>.

#### Conclusions/action items:

Use this information to guide design criteria

Mitchell Josvai/Research Notes/Biology and Physiology/Parathyroid Gland



Mitchell Josvai - Mar 01, 2021, 4:01 PM CST

Title: Parathyroid Gland

Date: 2/20/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research the anatomy and function of the parathyroid glands

## Content:

The parathyroid glands are four pea-sized glands located on the thyroid glands in the neck, two superior parathyroid glands and two inferior parathyroid glands. Despite have a similar name, the functions of the two glands are entirely separate. The parathyroid gland regulates the levels of calcium and phosphorous 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. It also regulates energy to the muscular system. Low calcium levels can result in feeling weak or tired, muscles 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 level, the parathyroid glands reduce 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 caused of hyperparathyroidism is cancer.

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.



Figure: Location of the parathyroid glands on the posterior of the thyroid gland. Image source: Thyroid Clinic Sydney,

#### References:

Topics, H., n.d. *Parathyroid Disease* | *Hyperparathyroidism* | *MedlinePlus*. [online] Medlineplus.gov. Available at: <a href="https://medlineplus.gov/parathyroiddisorders.html">https://medlineplus.gov/parathyroiddisorders.html</a>.

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

# Conclusions/action items:



Mitchell Josvai - Mar 03, 2021, 10:43 AM CST

Title: Human Grip Strength

Date: 2/9/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record information on human grip strength to aid design criteria

#### Content:

As the device is a surgical device that will 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.

NASA has dedicated research to human performance capabilities for a wide 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. 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 the the force production capabilities of humans in the last 50 years, and thus these values will be used.

#### References:

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].

#### Conclusions/action items:

Use the values recorded to ensure that the device will not exceed safe operating parameters when used.



Mitchell Josvai - Feb 18, 2021, 4:18 PM CST

**Title: Hand Anthropometry** 

Date: 2/18/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research relevant anthropometric statistics for human hands

#### Content:

Many studies have been done on the average hand size of humans, mostly by the United States army. Unfortunately, very few of the studies occurred recently, with many dating back almost 50 years. Additionally, many did not include statistics of female hand sizes. Female sizes must be taken into consideration, as this device is considered a "one size fits all" for the handle.

The cited reference is a study on the average hand sizes of dentistry students in 2012, which has been cited numerous times. The authors used 165 total participants, 92 males and 73 females for the study. A table containing relevant measurements, along with a diagram of how the measurements were taken can be found below.

#### Mitchell Josvai - Feb 18, 2021, 4:20 PM CST

TABLE 3. Percentiles Value for Both Hand Dimensions (mm) of Turkish Male and Female Dentistry Students

		Males (	n = 92)		Females (n = 73)				
	Right	Hand	Left Hand		Right Hand		Left Hand		
Hand Dimension	5th	95th	5th	95th	5th	95th	5th	95th	
(1) Fingertip to root digit 1	56.90	73.50	58.79	73.59	53.44	65.63	53.26	65.46	
2) Fingertip to root digit 2	66.58	82.26	66.92	83.49	62.40	75.03	62.05	74.99	
(3) Fingertip to root digit 3	73.00	91.29	72.91	91.89	68.31	81.07	67.90	80.87	
(4) Fingertip to root digit 4	66.65	85.20	66.79	84.72	63.31	74.60	62.06	74.77	
5) Fingertip to root digit 5	53.95	70.79	54.00	70.50	49.58	61.07	50.48	62.08	
6) Breadth at first joint of digit 1	16.28	22.63	15.92	22.19	14.74	19.44	14.04	18.90	
(7) Breadth at first joint of digit 2	14.54	17.83	14.09	17.44	13.13	15.32	12.33	14.75	
(8) Breadth at first joint of digit 3	14.91	18.21	14.40	17.51	13.22	15.19	12.69	14.62	
(9) Breadth at first joint of digit 4	13.90	16.92	13.68	16.54	12.32	14.59	12.05	14.08	
(10) Breadth at first joint of digit 5	12.50	15.23	12.07	15.25	10.90	13.01	10.70	12.74	
11) Breadth at second joint of digit 1	18.26	22.63	18.09	22.26	16.13	19.21	15.77	18.64	
12) Breadth at second joint of digit 2	17.40	21.23	16.85	20.41	15.25	17.93	14.79	17.33	
130 Breadth at second joint of digit 3	17.72	20.96	17.09	20.46	15.60	17.84	15.03	17.23	
14) Breadth at second joint of digit 4	16.39	19.63	16.13	19.40	14.46	16.99	14.18	16.50	
15) Breadth at second joint of digit 5	14.50	17.66	13.89	17.33	12.29	14.82	12.26	14.63	
16) Circumference at first joint of digit 1	53.41	68.26	53.41	68.26	47.62	59.91	45.56	56.03	
17) Circumference at first joint of digit 2	44.44	57.15	44.44	55.56	39.68	49.21	38.09	47.62	
18) Circumference at first joint of digit 3	45.48	57.15	44.44	56.11	39.21	49.68	38.09	47.63	
19) Circumference at first joint of digit 4	42.86	53.97	42.30	52.38	38.09	46.03	36.51	44.44	
20) Circumference at first joint of digit 5	39.13	49.76	38.09	48.18	32.86	43.33	31.75	41.23	
21) Circumference at second joint of digit 1	60.32	73.02	59.76	71.43	53.97	63.97	52.38	61.91	
22) Circumference at second joint of digit 2	58.73	68.81	57.15	67.23	51.91	60.32	50.80	58.73	
23) Circumference at second joint of digit 3	59.76	68.81	57.15	69.85	52.38	59.21	\$1.91	59.21	
24) Circumference at second joint of digit 4	53.97	65.08	53.97	65.08	47.62	57.62	47.14	56.03	
25) Circumference at second joint of digit 5	49.21	58.73	47.62	57.15	42.86	50.80	42.38	49.68	
26) Handbreadth across thumb	172.30	207.40	176.30	208.70	159.00	186.00	160.70	172.00	
27) Hand length	94.05	115.69	95.05	112.04	83.45	99.52	81.41	98.25	
28) Palm breadth	79.95	94.40	78.30	94.94	68.78	84.10	67.98	82.83	
29) Hand depth	36.60	47.82	36.75	49.06	32.62	44.03	30.17	42.65	
30) Handbreadth at metacarpais	71.12	85.54	69.41	86.34	64.90	74.85	63.18	73.97	
31) Wrist circumference	15.19	18.13	14.96	18.03	13.57	16.00	13.37	16.00	
(32) Wrist breadth	51.62	62.34	51.01	62.04	45.49	54.92	45.05	55.04	
(33) Elbow-wrist length	244.60	302.70	249.00	305.35	220.40	275.00	223.00	275.60	

Screen\_Shot\_2021-02-18\_at\_4.14.01\_PM.png(411.1 KB) - download Table: The 5th and 95th percentiles for 29 hand measurements. Our device should be comfortable for all sizes within this range for men and women.



\_

Figure 2 Hand measurements as a diagram.



Screen\_Shot\_2021-02-18\_at\_4.14.08\_PM.png(167.8 KB) - download Figure: The dimensions used to take this measurements. The numbers refer only to the arbitrary number of the measurement, not length or size.

Mitchell Josvai - Feb 18, 2021, 4:19 PM CST

## References:

Cakit, E., Durgun, B., Cetik, O. and Yoldas, O., 2012. A Survey of Hand Anthropometry and Biomechanical Measurements of Dentistry Students in Turkey. *Human Factors and Ergonomics in Manufacturing & Service Industries*, 24(6), pp.739-753.

# Conclusions/action items:

Use these measurements to guide decisions on the dimensions of the device, as it must be comfortable and usable for a range of hand sizes.



Title: Retractors

Date: 2/14/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research and record information on common surgical retractors

Content:

Brand/name	Composition	Length	to I	Max spread	Comments	Link
Weitlaner	Stainless		19 mm	47 mm	Dr. Doubleday mentioned this is brand. Made in Germany	https://www.integralife.com/weitlaner- retractor/product/surgical- instruments-hospitals-surgery- centers-tissue-banks-ruggles- redmond-retractors-weitlaner- retractor
Marina Medical	Stainless		10 mm	N/A	No jaw/spreading. Single pronged	https://orsupply.com/product/7955
Gelpi	Stainless	6.75"	1"	Unlisted	Self-retaining	https://www.alimed.com/gelpi- retractors.html
Balfour	Stainless	63 mm	35 mm	180 mm	wall	https://medical- tools.com/shop/balfour-retractors- 18cm.html
Golligher	Stainless	102 mm	N/A	51 mm	the superior	https://surtex- instruments.com/product/golligher- self-retaining-retractor/

## Conclusions/action items:

Use the dimensional data obtained to guide design decisions for the device.



Mitchell Josvai - Feb 14, 2021, 1:50 PM CST

Title: Surgical sponges

Date: 2/14/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research information on surgical sponges

#### Content:

Currently, to retract the thyroid medially, the client uses an auto-locking forceps, with a "peanut sponge" clamped at the tip to spread the applied force over a larger area and reduce the chance of harm to the gland. Our device should be capable of clamping two of these peanut sponges to increase the ease of the procedure for the surgeon.

Surgical sponges 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, we will only focus on the specific sponge relevant to the project, the peanut sponge.

The peanut sponge falls under dissecting sponges, and is approximately in the middle 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.

Reference:

DeRoyal. n.d. Surgical Sponges and Towels. [online] Available at: <a href="https://www.deroyal.com/docs/default-source/product-literature/surgical-sponges\_towels-web.pdf?sfvrsn=f5c00dbd\_12>">https://www.deroyal.com/docs/default-source/product-literature/surgical-sponges\_towels-web.pdf?sfvrsn=f5c00dbd\_12></a> [Accessed 14 February 2021].

#### Conclusions/action items:

Use this information to guide design decisions, specifically on the clamp mechanism design for the peanut sponge.



Title: Forceps

Date: 2/14/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research and record information on common surgical forceps

## Content:

Brand/name	Composition	Length	Geometry	Locking?	Comments	Link
Kelly Hemostatic Forceps	Stainless	5.5"	Curved	Yes	Serrated iaw	https://www.vitalitymedical.com/adc-kelly- hemostatic-forceps-locking-handle-5-1-2- in-straight-curved.html
McKesson Crile	Stainless	5.5"	Straight	Yes	Rachet lock	https://www.vitalitymedical.com/mckesson- crile-hemostat-forceps-5-1-2-inch-straight- stainless-socking-43-2-447.html
Marina Medical Alligator grasping	Stainless	12 cm	J J ,	At clamp	No scissors-like mechanism, just one tube with a clamp on the end	https://orsupply.com/product/7574
Allis Tissue Forceps	Stainless	15-20 cm	Curved tip	Yes		https://orsupply.com/product/7296

#### Conclusions/action items:

Use the dimensional data obtained to guide design decisions for the device.



Mitchell Josvai - Mar 02, 2021, 4:41 PM CST

Title: Surgical Instrument Materials

Date: 2/25/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research information on the materials used in surgical instruments

#### Content:

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.

#### References:

Visenio, M., 2017. *Commonly Used Surgical Instruments and Materials*. [online] Facs.org. Available at: <a href="https://www.facs.org/-/media/files/education/medicalstudents/common\_surgical\_instruments\_module.ashx"></a>. <a href="https://www.facs.org/-/media/files/education/medicalstudents/common\_surgical\_instruments\_module.ashx">https://www.facs.org/-/media/files/education/medicalstudents/common\_surgical\_instruments\_module.ashx</a>>.

## Conclusions/action items:

Use this information to guide material decisions during the design and fabrication process



Mitchell Josvai - Mar 02, 2021, 4:57 PM CST

# Title: 3D Printing Materials

Date: 2/25/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research materials available for 3D printing

#### Content:

Because our initial prototype will likely be 3D printed rather than stainless steel, it will be beneficial to have a table of materials available for 3D printing in the UW-Madison Makerspace, and their properties and technical data sheets. Source: https://making.engr.wisc.edu/3d-printers-2/ (Under the "Materials" tab)

Brand	Polymer/Name	Cost (\$/mL or \$/g)	Technical Data	Tensile Modulus (GPa)
Ultimaker	PLA	0.08	https://ultimaker.com/download/74599/UM180821%20TDS%20PLA%20RB%20V10.pdf	1.35
Ultimaker	PC	0.12	https://ultimaker.com/download/74975/UM180821%20TDS%20PC%20RB%20V11.pdf	2.20
Ultimaker	PVA	0.19	https://ultimaker.com/download/74607/UM180821%20TDS%20PVA%20RB%20V10.pdf	0.55
Ultimaker	PP	0.13	https://ultimaker.com/download/74977/UM180821%20TDS%20PP%20RB%20V11.pdf	1.325
Formlabs	White	0.24	https://formlabs-media.formlabs.com/datasheets/1801089-TDS-ENUS-0P.pdf	2.8
Formlabs	Elastic	0.29	https://formlabs-media.formlabs.com/datasheets/Elastic_Resin_Technical.pdf	0.75
Formlabs	Tough	0.26	https://formlabs-media.formlabs.com/datasheets/Tough_Technical.pdf	2.7

#### Conclusions/action items:

Use this data in deciding a material to 3D print the initial design. Research specific polymers used in disposable surgical instruments.

Mitchell Josvai/Research Notes/Scope/Surgeon Statistics



Mitchell Josvai - Feb 18, 2021, 4:06 PM CST

**Title: Surgeon Statistics** 

Date: 2/18/21

Content by: Mitchell Josvai

Present:

Goals: Understand how the project may affect surgeons

## Content:

Surgeons are highly regarded and compensated for their work, but their job is one of high stress and risk. Surgeons work long difficult and long hours, and experience high rates of burnout among other life stressors. If the device we create could increase the efficiency of surgeries to require less time in the OR for surgeons, it could increase their quality of life and lower stress.

The Bureau of Labor Statistics estimates that to adequately service the entire population, the United States requires 7 surgeons for every 100,000 citizens [A]. The United States currently has around 18,000 general surgeons, or 5.8 per 100,000 people. 60% of physicians who named endocrine surgeon as their first or second speciality had another speciality [B].

60.7% of orthopedic surgery practices see at least 50 patients a day, though 69.3% of practices are staffed by 10 or fewer surgeons [B].

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%, and general orthopedic surgeons at 50%. It seems that working in surgery is more stressful than ever, with the rate of burnout increasing 10% from 2010 to 2014 [C]. Burnout can lead to many unfortunate consequences including substance abuse, divorce, depression and suicide.

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

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

[C] 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.

# Conclusions/action items:

By making a device to increase the efficiency of endocrine surgery, we can increase the speed with which these operations can be completed. This time saved can allow surgeons to spend less time in the operating room, help more patients, and improve their own quality of life by reducing the risk of burnout.
Mitchell Josvai/Design Ideas/Preliminary Design



Mitchell Josvai - Feb 18, 2021, 5:13 PM CST

Title: Preliminary Design

Date: 2/18/21

Content by: Mitchell Josvai

Present:

Goals: Record my preliminary design

Content:

Conclusions/action items:



Mitchell Josvai - Feb 18, 2021, 5:10 PM CST

2021-02-18\_17-05.pdf(554.3 KB) - download



Mitchell Josvai - Mar 16, 2021, 3:20 PM CDT

#### Title: Updated Tip Design Ideas

Date: 3/12/20

Content by: Mitchell Josvai

### Present:

Goals: Record updated ideas for the ends of the retractor in contact with the thyroid

### Content:

#### Disposable tips:



- · Single-use, disposable tip for the end of the retractor
- · Made from a sterilizable rubber or plastic
- Attaches firmly around each retractor tip to prevent slipping
- · Replaces the need for peanut sponges and a clamping mechanism
- Could be circular, ovular, or many concave geometries
- · Blunt edges to reduce the chance of injury

## Built-In tips



- · Stainless steel tips built on to a retractor with a locking mechanism
- Autoclavable and reusable many times
- · Provides more surface area than a normal retractor to delicately move the thyroid
- · Geometry could be similar to the disposable tip ideas, or to dental mirrors (above)
- No sharp edges, but the harder material may give a greater chance of injury

## Conclusions/action items:

Meet with the team and client to discuss ideas

Mitchell Josvai/Design Ideas/Updated Final Design



Mitchell Josvai - Apr 28, 2021, 12:09 PM CDT

#### **Title: Updated Final Design**

Date: 4/19/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record the updated final design

#### Content:

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.

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.





# Conclusions/action items:

Schedule a appointment at the Makerspace to print so we can show the prototype to Dr. Doubleday, and make adjustments as needed.



Mitchell Josvai - Feb 10, 2021, 5:02 PM CST

Title: Green Permit Documentation

Date: 2/10/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

**Goals:** Record documentation of green permit

Content:



IMG\_7341\_1\_JPG(3.1 MB) - download Green Permit for Mitchell Josvai. Received 1/27/20

Mitchell Josvai - Sep 09, 2020, 2:48 PM CDT



Mitchell Josvai - Feb 10, 2021, 5:05 PM CST

Title: Biosafety Training
Date: 2/10/21
Content by: Mitchell Josvai
Present: Mitchell Josvai
Goals: Document completion of biosafety lab trainings
Content:

Mitchell Josvai - Feb 10, 2021, 5:05 PM CST

This certifies that MITCHELL JOSVAI has completed training for the following course(s):					
Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date		
BIOSAFETY 152: BLOODBORNE PRIVOGENS FOR LABORATORY AND RESEARCH	BLOODBORNE PATHOGENS QUEZ	12/21/2020			
BIOSAFETY 105: BIOSAFETY CABINET USE	BROSAFETY 105: BROSAFETY CABINET USE QUEE	12/23/2020			
BIOSAPETY 106: AUTOCLAVE USB	BROSAFETY 106: AUTOCLAVE USE: SAFETY AND EFFICACY - VERFICATION QUE2	12/23/3020			
BOSAFETY 107: CENTRIPUGE SAFETY	BOSAFETY 107: CENTRIFUGE SAFETY VERIFICATION QUEZ	1/5/3021			
BOSAVETY REQUIRED TRAINING	BROSWETY REQUIRED TRAINING QUIZ	3/13/3020			
CHEMISCAL SAFETY: THE OSHA LAB STANDARD	PINAL QUE2	12/21/3020			
ITTM CILL ETHICS AND POLICY TRAINING	ASSUBANCE	12/23/3020	12/23/2021		

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Mitchell Josvai - Feb 10, 2021, 5:06 PM CST

## Conclusions/action items:

Use relevant information learned in these courses and apply it to the design process this semester.



Mitchell Josvai - Apr 28, 2021, 12:08 PM CDT

### Title: SolidWorks Testing

Date: 4/19/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record testing done in SolidWorks

#### Content:

Initial testing was done in SolidWorks. A 1 N distributed load was applied to the surface of the part, and the stress and displacements were analyzed. The interior surface of the hollow cylinder was designated as the fixed surface, because this would be around the retractor, and thus not moving in relation to the rest of the body.

### Stress Tests: (Scale remained the same for each image)

Top view:



Side view:



### Bottom view:



## Strain testing: (Scale remained the same for each image, Engineering strain was calculated)

Top view:





Bottom view:



# Displacement testing: (Scale remained the same for each image)

Top view:





Bottom view:



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.

## Conclusions/action items:

Create a physical prototype to consult with the client and continue making design adjustments

Thyroid Physiology

Date: 1/30/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research the functions and anatomy of the thyroid.

Content:

- the thyroid is a small gland located at the front of the neck wrapped around the trachea [1]
   it is shaped like a butterfly
- common thyroid disorders are hyperthyroidism(overactive) and hypothyroidism(underactive)
- the thyroid releases thyroid hormones T3 and T4
- The thyroid stimulating hormone(TSH), which is created in the pituitary gland, controls the activity of the thyroid[1]
  - T3 and T4 release is a huge negative feedback loop



a both hyper + hyper thyperism creak a setter

Figure A: Control of thyroid secretion

KATE EICHSTAEDT - Jan 30, 2021, 3:50 PM CST



Figure B: Position of thyroid gland in reference to relevant anatomical structures [2]

#### Sources:

[1] "Thyroid Disease: Causes, Symptoms, Risk Factors, Testing & Treatment," *Cleveland Clinic*. [Online]. Available: https://my.clevelandclinic.org/health/diseases/8541-thyroid-disease. [Accessed: 30-Jan-2021].

[2] U. Ghani, S. Assad, and S. Assad, "Role of Intraoperative Nerve Monitoring During Parathyroidectomy to Prevent Recurrent Laryngeal Nerve Injury," *Cureus*, 15-Nov-2016. [Online]. Available: https://www.cureus.com/articles/5561-role-of-intraoperative-nerve-monitoring-during-parathyroidectomy-to-prevent-recurrent-laryngeal-nerve-injury. [Accessed: 30-Jan-2021].

Conclusions/action items:



#### KATE EICHSTAEDT - Feb 28, 2021, 12:46 PM CST

#### Title: Clinical Relevance and motivation

Date: 2/20/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research the clinical need and motivation for this design.

#### Content:

More than 130,000 thyroidectomies are performed annually in the United States[1]. This number has increased by 30% from 2006 to 2011. This is a significant number and if the device were to work effectively it could help more people than just our client. Additionally, this number is for thyroidectomies alone, so it does not account for the number of operations that were done that just involved retracting the thyroid. Additionally, it is estimated that around 109,000 parathyroidectomies occured between 2002 and 2011 due to primary hyperparathyroidism [2].

#### References:

[1] "For Best Thyroid Surgery Results, Pick Doctor With 25-Plus Cases a Year," *EndocrineWeb*, 11-May-2016. [Online]. Available: https://www.endocrineweb.com/news/thyroid-diseases/20364-best-thyroid-surgery-results-pick-doctor-25-plus-cases-year#:~:text=17%2C000%20Thyroid%20Gland%20Removals,30%25%2C%22%20she%20says. [Accessed: 28-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: 28-Feb-2021].

#### Conclusions/action items:

Looking at the number of thyroidectomies that are performed in the US annually, there is obviously a market that would use this design if it ever becomes functional. For action items, I am going to continue to do relevant research to prepare for preliminary presentations.

Typical Finger/Hand Sizes

KATE EICHSTAEDT - Feb 28, 2021, 3:46 PM CST

#### **Title: Typical Finger Sizes**

Date: 2/17/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research average hand/finger sizes for device dimensions

#### Content:

The hand sizes generally vary with men and women. On average, the average length of a male's hand is 7.6 inches, The average breadth is 3.5 inches, and the average circumference is 8.6 inches[1].

The optimal grip diameter is 19.7% of the users hand length.

## References:

[1] S. Frothingham, "What's the Average Hand Size for Men, Women, and Children?," *Healthline*. [Online]. Available: https://www.healthline.com/health/average-hand-size. [Accessed: 28-Feb-2021].

#### Conclusions/action items:

Knowing the dimensions of the hands and fingers will be helpful for when we model our device in solid works with dimensions. For action items, I am going to continue to work on our preliminary presentation.



KATE EICHSTAEDT - Feb 28, 2021, 3:48 PM CST

Title: Thyroid Dimensions

Date: 2/17/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Determine the typical size of a human thyroid.

Content:

Can range from around 4-4.8 x 1 cm to 1.8 x .8-1.6 cm.

Typically weigh around 10 -20 grams.

References:

M. L. Lyden, T. S. Wang, and J. A. Sosa, "Surgical Anatomy of the Thyroid Gland," *UpToDate*, 09-Sep-2019. [Online]. Available: https://www.uptodate.com/contents/surgical-anatomy-of-the-thyroid-gland#H1. [Accessed: 05-Feb-2021].

#### Conclusions/action items:

Knowing the dimensions of the thyroid will be very helpful for when we add dimensions to our device drawing. Additionally, it is advantageous to have a good idea of the size and structure of the thyroid for this project. Knowing the weight of the thyroid will be helpful for when determining how much force will need to be applied to the device to lift up the thyroid. For action items, I am going to continue to work on the preliminary presentation and report.



### KATE EICHSTAEDT - Apr 25, 2021, 9:21 PM CDT

#### Title: How to make something X-ray detectable

Date: 4/16/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Our client mentioned that it would be advantageous for the rubber tips to be x-ray detectable

Content:

- Engineering plastics do not show up well in x-rays, they need to be modified in someway that makes them more opaque than the surrounding tissue
- Surgical rags and sponges have been modified to be x-ray detectable
- with the surgical rag, x-ray detectable material is sewn into the hem
- by incorporating resin additives into the product, chunks of the product can be x-ray detectable[1]
- Additionally, radiopacifiers(typically dense metal powders) can be added to polymers used to create medical items such as catheters to make them x-ray detectable[2]
- When we make the device, we could possibly mix in one of these radiopacififers to make the tips radiopaque

#### References:

[1] "Metal and X-Ray Detectable Plastics," Kelstream, 01-Jul-2016. [Online]. Available: http://www.kelstream.com/trends-metal-and-x-ray-detectable-plastics-food-processing/#:~:text=Detectable%20PEEK,detectors%20or%20x%2Dray%20machines.&text=Detectable%20additives%20can%20be%20included,and%20x%2Dray%20inspection%20systems [Accessed: 26-Apr-2021].

[2] Tilak M. Shah | Mar 01, "Radiopaque Polymer Formulations for Medical Devices," mddionline.com, 07-Aug-2017. [Online]. Available: https://www.mddionline.com/materials/radiopaque-polymer-formulations-medical-devices. [Accessed: 26-Apr-2021].

#### Conclusions/action items:

When we met with our client, she mentioned it may be beneficial to make the rubber tips we have designed x-ray detectable in case one were to slip off during surgery. She mentioned how most surgical rags have a hem that contains x-ray detectable material. For action items, I am going to work with my team to solid works test our device.



KATE EICHSTAEDT - Feb 28, 2021, 12:48 PM CST

#### **Title: Peanut Sponge Forceps**

Date: 2/8

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research competing design/current device that is used.

#### Content:

The peanut sponge forceps are a pair of specially designed forceps that have a ringed end so it can old the peanut gauze. I am unsure if our client just uses regular forceps that do not have the end, but looking at this pair of forceps will give important insight into what material should be used and also the size and weight of the device.

Q



#### Figure 1: Peanut Sponge Forceps

The peanut sponge forceps are made out of premium OR-grade stainless steel and are reusable[1]. They are 8" in length, and the tip dimensions are 5mm x 8mm. They cost 100 USD.

#### Sources:

[1] "Peanut Sponge Forceps: Sklar Instruments 22-9480," *quickmedical*. [Online]. Available: https://www.quickmedical.com/sklar-instruments-peanut-sponge-forceps.html. [Accessed: 28-Feb-2021].

To conclude, this device is likely very similar to the one we will design. For action items, I am going to continue working on the PDS.



KATE EICHSTAEDT - Feb 28, 2021, 12:49 PM CST

#### **Title: Fletcher Sponge Forceps**

Date: 2/8

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research the fletcher sponge forceps for information about common price ranges, materials, sizes, and weights.

#### Content:

The fletcher sponge forceps are very similar to the peanut sponge forceps. The fletcher sponge forceps are 9-1/2" long and are made of stainless steel[1]. The tip configuration is narrow loops and the curvature is straight. These range anywhere from around 20 USD to 65 USD.



Figure A: A drawing of the fletcher sponge forceps.

Sources:

[1] "Fletcher Sponge Forceps," Novo Surgical Inc. [Online]. Available: http://novosurgical.com/fletcher-sponge-forceps-22148.html. [Accessed: 28-Feb-2021].

## Conclusions/action items:

These are very similar in design to the peanut sponge forceps, except they feature a straight tip instead of a curved one. Looking at the peanut and fletcher forceps design were very helpful for figuring out how the opening mechanism for the forceps works. For action items, I am going to continue to do research for the PDS.



KATE EICHSTAEDT - Feb 20, 2021, 10:08 AM CST

Title: ISO 13485

Date: 2/20

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research the standards set in place by ISO 13485 in regards to safe and quality manufacturing.

#### Content:

If our device were to actually be created and manufactured, there are a set of codes, standards, and regulations that we would have to follow in order to go to market. One of these is the ISO form 13485. The ISO stands for the International Organization for Standardization and they set regulations in place for good manufacturing habits[1].

Code 13485 mainly sets in place quality management regulations. This is important for if the device were to be manufactured to make sure that the quality of the device is being maintained throughout the creation process.

Sources:

[1]ISO.org. 2006. ISO Online Browsing Platform. [online] Available at: <a href="https://www.iso.org/obp/ui/#iso:std:iec:62304:ed-1:v1:en>[Accessed 14 September 2020]">https://www.iso.org/obp/ui/#iso:std:iec:62304:ed-1:v1:en>[Accessed 14 September 2020]</a>.

#### Conclusions/action items:

To conclude, following the standards set in place by the FDA and by the ISO will be extremely important for us if we were to bring this device to market. For action items, I am going to continue my preliminary research.



Title: FDA CFR Title 21

Date: 2/20

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Read about the codes, standards, and regulations that apply to our device.

#### Content:

Title 21 is a comprehensive list of device classifications and regulations that is updated annually by the FDA[1]. The title is public knowledge so while working on a project it is very beneficial to check the code of federal regulations(CFR) to make sure that all regulations are being abided by.

Our device would be in chapter 1(food and drug administration department of health and human services), subchapter H(medical devices), and in part 878, which covers general and surgery devices[1]. Within this part, it is under subpart E and section 878.4800, which includes manual surgical instruments for general use.

Devices in this section are nonpowered and handheld/operated. These devices are in Class I. Devices in this category are also exempt from premarket notification procedures[1].

#### References:

[1] "CFR - Code of Federal Regulations Title 21," *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. [Accessed: 28-Feb-2021].

#### Conclusions/action items:

To conclude, it is very beneficial to know what federal standards and codes our device must abide by. After looking at the CFR, I have a much better understanding of what would be expected of our device if it were to ever go to market. For action items, I am going to continue completing research for our preliminary presentation.



KATE EICHSTAEDT - Mar 19, 2021, 11:30 AM CDT

Title: WARF

Date: 3/19/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Watch the WARF lecture

### Content:

- Founded in 1925
- Supports scientific research
- Copyrights
  - literary works
  - webpages
  - software programs
- Trademarks
  - words and phrases
  - colors
  - pictures and logos
  - sound
- Patents
  - machines and devices
  - compounds
  - processes/methods
  - improvements
- 4th area: trade secret, weakest protection
- In order for a patent to be considered the eligibility, usefulness, novelness, and non-obviousness are considered

#### Conclusions/action items:

Watching this was helpful incase my team or myself in future semesters were to apply for a patent for a design. For action items, I am going to continue to work on what I have to do for my project.



#### KATE EICHSTAEDT - Feb 16, 2021, 11:17 AM CST

#### Title: Design 1: In-line Curved

Date: 2/16/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Present my first design idea sketch.

#### Content:

This was the first design idea I had. Unfortunately, I am unsure about the practicality because I do not think both prongs would be able to move together without some sort of special hinge we would have to create. The design is very similar to many existing forcep designs but it features two prongs so the thyroid would be able to be held by two areas of contact. Additionally, the tips are curved so the device could be used with the existing peanut brand gauze tip. As seen in the figure below, the device still features a ratchet so the device can be held open on its own.



Figure 1: Preliminary Sketch of the In-line curved design. Note: This is not to scale.

### Conclusions/action items:

To conclude, I am pretty happy with how this design sketch turned out. After learning from my errors with the hinge, I think I have figured out a way to troubleshoot that. I will include that idea in my next design sketch. For action items, I am going to research the clinical relevance of this design project and create more sketches.



#### KATE EICHSTAEDT - Feb 16, 2021, 11:25 AM CST

#### Title: Design 2: Fused Model

Date: 2/16/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload the sketch of my second design.

#### Content:

When meeting with our client, she stated that sometimes they hold two forceps to retract the thyroid. This is very bulky and often requires two hands to do. From design 1, I struggled with a way to make sure that both prongs were able to separate by just moving the finger rings apart, like a 4 bladed scissors. The fused model is basically two fused forceps that are both tilted at different angles. Each has its own ratcheting system so they can be adjusted to certain distances individually if needed. As seen in the figure below, when using the device, if one were to move the finger rings apart, the sliding mechanism that separates the tips at the top should still work for both prongs. Obviously the device is not to scale as the prong tips would not be that thick. This design is also meant to be used with the peanut brand gauze tip.



## Figure 1: Fused Forceps sketch. Note: Not to scale.

#### Conclusions/action items:

To conclude, I am pretty satisfied with how this design turned out. Obviously, there needs to be some proportional adjusting that I can work on in the future. For action items, I am going to attempt to redraw this design and make it a little neater.



KATE EICHSTAEDT - Feb 17, 2021, 11:28 AM CST

## **Title: Fused Model Drawings**

Date: 2/16/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload the redrawn sketches of the fused model design.

### Content:

The figures below display the redrawn design of the fused model. There is a picture from the top and bottom, which is why the there are two different colors to help display that to the viewer. Each prong with have its own ratcheting system.





Figures 1 and 2: Display the top and bottom views of the fused model design.

### Conclusions/action items:

To conclude, I think that redrawing the design and adding the different colors helps clarify the concept of the design to the viewer. For action items, I am going to do research regarding dimensions, production, and materials.



Title: Tip design

Date: 4/16

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload the drawings of the rubber tips to lab archives

### Content:

From our meeting with Dr. Doubleday(3/19), she liked the idea of also designing rubber or plastic tips for the retractor as a substitute to using the peanut that is currently being used. The rubber tips would be single use, similar to the peanut. The tips should be x-ray detectable.





#### Conclusions/action items:

To conclude, these tips will serve as a substitute for the peanut tips when using the modified retractor. For action items, I know we will probably not be able to manufacture out of rubber, so I am going to look into possible materials that we could 3-D print out of at the makerspace.

Testing



## Title: Testing Brainstorming

Date: 4/19/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Brainstorm ideas for testing

# Content:

Solidworks testing

- do mechanical force testing in solidworks just to prove the device material will be able to handle the forces applied to it during surgery
- · could do testing for rubber shod and for stainless steel forceps
- Likely both will be able to handle the forces applied
  - good just to show in our presentation for thoroughness

# Qualitative testing

- ergonomics testing
  - print 3D model of forceps when modeled, give to client to assess qualitatively, adjust design as needed
  - possibly have coworkers also evaluate this
- grasping ability tests?
  - just to see if the device is able to pick up objects with multiple points of contacts

# Conclusions/action items:

To conclude, brainstorming these ideas was a good way to get myself organized for what I need to accomplish the rest of this semester. For action items, I am going to try and conduct solidworks testing with my team.

Printing

KATE EICHSTAEDT - Apr 25, 2021, 9:13 PM CDT

## Title: Investigation into 3D printing

Date: 4/19

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Look into the 3D printing resources that are available this semester

## Content:

There are a bunch of different materials we can print out

- for the shods, we will probably need something that is similar to rubber
- for the forceps when we do model them, we will probably need something that is very rigid
   we will also probably want to finish our 3D print so it looks more aesthetically similar to a stainless steel forcep
  - https://www.3dhubs.com/knowledge-base/post-processing-fdm-printed-parts/#polishing use this website for information on how to finish 3D prints whenever the time comes

#### Conclusions/action items:

To conclude, although it may not be necessary for us to 3D print by the end of this semester, it is helpful knowing the resources/3D printing materials that are available to us so we can make as accurate renditions of our product as possible. For action items, I am going to continue to work on solidworks modeling.

KATE EICHSTAEDT - Apr 19, 2021, 10:40 AM CDT

### **Title: Red Pass Training Documentation**

Date: 4/19/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Prove that I have my red pass.

## Content:

Attached below is a picture of my red pass.

Cellege Engi	neering
TEEALDE       Jonation         Detention and Manufacture       Jonation         Permit No:       F.2       T.2.59       R         Issue Date:       2/12/19         Name:       Kate       Eichsten         User Signed:       Manufacture         Display Other Side in Here	Red Permit

Figure A: A picture of my red pass that I earned through the team lab.

#### Conclusions/action items:

To conclude, I have gotten my red pass, this allows me to use basic hand tools, a drill press, a sander, and a drop saw. I was supposed to get my green pass in the spring semester(2020) but then school switched to online and the team lab was damaged due to flooding. For action items, I am not sure when the team lab will be opening again for training, but when it does open back up again I would like to earn my green pass.



ASHLEE HART - Feb 05, 2021, 8:35 AM CST

Title: Thyroid Anatomy

Date: 02/05/2021

Content by: Ashlee

Present: N/A

**Goals:** Research basic thyroid anatomy

#### Content:



representation of the thyroid gland [1]

- The thyroid is a gland that rests on top of the trachea at the low, anterior part of the neck. [1]
- It contains blood vessels as well as nerves that are important for our voices. [1].
- Secretes thyroid hormones such as thyroxine (T4), triiodothyronine (T3) [1], [2]
  - Iodine is required for the thyroid to maintain secreting its hormones [2]
  - Hormones from the thyroid enter the blood stream and go to all parts of the body [2]
  - These hormones are especially important for brain and somatic development in infants, metabolism of adults, and they have an affect on the majority of organ systems
- There are a number of thyroid conditions including a goiter, thyroiditis, hyperthyroidism, hypothyroidism, graves disease, and more. [1]
  - Thyroid disease is most commonly caused from a lack of iodine in the diet but problems can also arise due to autoimmune disorders
- A healthy thyroid is about 4-4.8 x 1 to 1.8 x 0.8-1.6 cm in size. Its volume will be around 7 to 10 mL and have a weight of 10-20 grams [3]
- The thyroid in men is slightly larger than women. The size can fluctuate based on age, weight, and iodine intake

[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] "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].

Ashlee Hart/Research Notes/Biology and Physiology/Thyroid Anatomy and Physiology

[3] M. L. Lyden, T. S. Wang, and J. A. Sosa, "Surgical Anatomy of the Thyroid Gland," *UpToDate*, 09-Sep-2019. [Online]. Available: https://www.uptodate.com/contents/surgical-anatomy-of-the-thyroid-gland#H1. [Accessed: 05-Feb-2021].

### Conclusions/action items:

The anatomy information listed above summarizes the basic, functional anatomy of the thyroid. This information will be relevant with further research on our medical device, as the size and location of the thyroid will no doubt be taken into account. I want to further research the different types of surgical procedures our client may be performing with our device, the different types of medical devices used in thyroid retraction, as well as the current device used in the operating rooms our client works in.



ASHLEE HART - Feb 05, 2021, 8:51 AM CST

Title: Current Thyroid Retractors

Date: 02/05/2021

Content by: Ashlee

Present: N/A

**Goals:** Research different types of thyroid retractors

Content:

McBurney Thyroid Retractor:



a McBurney Retractor [1]

- Made of stainless steel with a satin finish [1]
- 190 mm in length, with the tip/jaw being 16 mm in length [1]
- Reusable [1]
- Right-angled shape [1]

Beckman Thyroid Retractor:



## Figure 2: Image of a Beckman Thyroid Retractor

- Made of stainless steel with a satin finish [2]
- 240 mm in length [2]
- The tip is 27.5 mm [2]
- Has an angle of 90 [2]
- Width of the jaws is 21.6 [2]
- Reusable [2]

## Sklar Mahorner Thyroid Retractor



## Figure 3: Image of Sklar Mahorner Thyroid Retractor [3]

- Manufactured by Sklar [3]
- Has 6 prongs [3]
- spread is 4.4" or 111.76 mm [3]
- Made of Stainless Steel [3]

[1] "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].

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

[3] "Sklar Mahorner Thyroid Retractor," *Medline Industries, Inc.* [Online]. Available: https://www.medline.com/product/Mahorner-Thyroid-Retractorsby-Sklar/Retractor-Hooks/Z05-PF162057?\_8#mrkSpec. [Accessed: 05-Feb-2021].

#### Conclusions/action items:

After research on different types of thyroid retractors, I feel like I have a good overall understanding of what the typical shape is, and what variations the medical device can have. After meeting with our client on 02/05, I plan on researching the specific type of thyroid retractor they use in their operating rooms, as well as research retractors that may have components of the retractor she is looking for.


ASHLEE HART - Feb 07, 2021, 8:57 PM CST

Title: Peanut Thyroid Retractor

Date: 02/07/2021

Content by: Ashlee

Present: N/A

Goals: Find the Peanut thyroid retractor Dr. Doubleday and her surgical colleagues currently use

Content:



## Figure 1: Image of Peanut Sponge found on the DeRoyal website [1]

The image above shows a peanut sponge found on the DeRoyal website on the internet. There is a small wad of gauze that can be inserted into the tip of the device in order to hold the thyroid, and there are finger holes in order to maintain grip.

[1] "Peanut Sponge," *DeRoyal*. [Online]. Available: https://www.deroyal.com/products/search-catalog-item/catalog-item-preview/ac-surgical-peanutsponge. [Accessed: 08-Feb-2021].

## Conclusions/action items:

I was able to find the peanut surgical device that Dr. Doubleday and her colleagues use in thyroid retraction. The concept of combining two peanut instruments together to cover more of the thyroid and help in operating definitely seems doable, and is something that I will continue to research.



## Welded Peanut Forceps Design

Title: Welded Peanut Forceps Design

Date: 02/17/21

Content by: Ashlee

Present: N/A

Goals: List out ideas for a preliminary design that consist of welding two peanuts together

## Content:

The overall idea for this design of a thyroid retractor is to have two peanut forceps connected in order to use two at once. This idea would help hold up the thyroid in an efficient way, make it easier to deal with larger thyroids, and prevent having to hold two peanuts at once.

In a video that Dr. Doubleday sent our team, she held two overlapping peanuts to show how two holds up a thyroid versus just one. This gave me the idea of somehow welding or connecting to peanuts together at the location they overlapped (see Figure 1).



#### Figure 1: Two peanuts overlapping each other, showing the place two peanuts could be connected to each other

One way we could connect the two peanuts is by welding. I personally do not have a welding upgrade, so if someone on our team does, or if we are able to upgrade our permits, we could use some welding tools (plasma torches and/or MIG welders) in order to connect the two metal pieces. A positive thing about being able to use an MIG welder is that it can be used in welding of medical devices. Laser welding is the most ideal form of welding as it holds up to the FDA requirements that medical devices don't contaminate things they come into contact with, don't break when being used, and are made to specified dimensions [1]. While laser welding may be superior, we don't have that option for Teamlab upgrades, so an MIG welding upgrade may be ideal

If the team lab is not able to upgrade permits this semester, we may also be able to purchase soldering kits. Soldering is commonly used in electrical settings, as it's a low temperature type of connection between metals including gold, silver, copper, brass, and iron [2]. The connections between soldered metals are weaker than welded metals, but is a possibility. It's also easy to purchase something like a soldering kit online (see Figure 2) if we were to try it out. There are also probably ways to borrow a soldering kit from a professor like Dr. Nimunkar in the bioinstrumentation field. If we were to solder the two stainless steel pieces of the peanut together, we would need a flux to make it successful. To connect stainless steel, white flux is commonly used [3].

#### Ashlee Hart/Design Ideas/Welded Peanut Forceps Design



Soldering Iron Kit - Soldering Iron 60 W Adjustable Temperature, Solder Wire, Tweezers, Soldering Iron Stand, Soldering Iron Tips Set, Desoldering Pump, Solder Wick, Heatshrink Tubes [110 V, US Plug]

 $\star$   $\star$   $\star$   $\star$   $\star$   $\star$   $\star$  4,611 ratings | 55 answered questions

## 🔒 3 Price Changes

Price: \$16.95 <b>√prime</b>			
Extra Savings Promotion Av	ailable. 1 Applicable Promotion 🐣		
Style	Soldering / Welding		
Brand	Plusivo		
Item Dimensions LxWxH	10.43 x 5.71 x 1.77 inches		
Power Source	Ac		
ltem Weight	15.84 Ounces		

#### Figure 2: Soldering kit that can be purchased on Amazon [4]

[1] "How to Weld Stainless, Titanium, and Steel Medical Devices and Tools: Use High Powered Laser, Tig or Mig Welding?," *Laser Services USA*. [Online]. Available: https://www.accumet.com/updates/laser-welding-titanium-and-stainless-steel-medical-tools-devices/. [Accessed: 17-Feb-2021].

[2] "What's the Difference Between Soldering, Brazing, and Welding?," *StackPath*. [Online]. Available: https://www.machinedesign.com/fastening-joining/article/21831910/whats-the-difference between-soldering-brazing-and-welding#:~:text=Soldering%20is%20a%20low%2Dtemperature,filler%2C%20called%20solder%2C%20melts. [Accessed: 17-Feb-2021].

[3] B. Henson, "Brazing Flux 101," The Harris Products Group. [Online]. Available: https://www.harrisproductsgroup.com/en/blog/2016/january/brazing-flux-101.aspx. [Accessed: 17-Feb-2021].

[4] "Soldering Iron Kit - Soldering Iron 60 W Adjustable Temperature, Solder Wire, Tweezers, Soldering Iron Stand, Soldering Iron Tips Set, Desoldering Pump, Solder Wick, Heatshrink Tubes [1 V, US Plug]," Amazon. [Online]. Available: https://www.amazon.com/Soldering-Kit-Temperature-Desoldering-Electronics/dp/B07GTGGLXN/ref=asc\_df\_B07GTGGLXN/?tag=hyprod-20&linkCode=df0&hvadid=241999416883&hvpos=&hvnetw=g&hvrand=7721003269044261906&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9018948&hvtargid=pla 590653449503&psc=1. [Accessed: 17-Feb-2021].

#### Conclusions/action items:

In this entry I had the goal of brainstorming ways to connect two stainless steel peanut forceps together. I thought of a method including welding, as well as soldering. I think I took a lot of thing into consideration that may be relevant in our design matrix that is to made this week. One thing that could be problematic with welding the forceps together is that the peanut ends would not b adjustable, and so the device may not be as accommodating to multiple thyroid sizes. Next, I want to come up with a design that would be more flexible in terms of adjustment of distance between peanuts.



ASHLEE HART - Feb 17, 2021, 4:44 PM CST

Title: Snap Button Connecting Peanuts Preliminary Design

Date: 02/17/21

Content by: Ashlee

Present: N/A

Goals: Brainstorm ideas relating to a design that would have two peanuts connected to each other by an adjustable snap button

## Content:

I thought of a design that would be easy (in theory) to fabricated without the possible use of machines in the Teamlab, and has materials that can be easily found on websites like Amazon (fast shipping and reliable), or can be gathered from our client.

This design only incorporates three things: two pean/peanut clamps and a snap button.

The idea is that one pean clamp has the bottom of the snap connected to it (by glue, welding, or some other technique). The bottom of the snap is modified, however, so that another pean clamp (more towards the middle of the shaft) can snuggly fit into the snap. The snap, most likely made out of metal, would need some kind of chipping or cutting device in order to modify it. With the second pean clamp in the gap within the bottom of the button, the top of the button would snap on top of the clamp. The top of the button would have the same modification as the bottom of the button to ensure the pean clamp can fit.

I thought of the snap idea so that the forcep laying in the snap button could be in multiple different positions, altering the distance between the ends of the clamps to accommodate for different sized thyroid glands. For ultimate flexibility, there could be multiple notches in the top and bottom snaps (imagine a pattern like a poker chip piece).

A pictorial representation of the materials needed for this are seen in the images below.



Figure 1: Overall idea of a snap button connecting two peanut forceps



Figure 2: Image of general snap metal button fasteners that could be modified to fit a pean clamp [2]

A more straightforward way of connecting the two pean clamps together could be by using a nut and bolt. Ideally, the bolt would be shaved down so that there are not any protrusions that could potentially cut the surgeon using it. Using a nut and bolt would make it so that a hole must be inserted into both pean clamps. This could be done with a drill press, or a different type of machine that make holes directly into stainless steel. Figure 3 shows the type of nut and bolt I believe would work.



## Figure 3: Image of a nut and bolt that has the possibility of connecting two pean clamps [2]

[1] "10sets Metal snap buttons 30mm big large metal brass sew on press button snap button fastener sliver/bronze/black nickle SF023: sew on snap fasteners: button brassbuttons lot," *AliExpress*. [Online]. Available: https://www.aliexpress.com/i/32855141814.html. [Accessed: 17-Feb-2021].

[2] "Nut (hardware)," *Wikipedia*, 11-Jan-2021. [Online]. Available: https://en.wikipedia.org/wiki/Nut\_(hardware)#/media/File:M4\_Inbusschraube\_focusstacked.jpg. [Accessed: 17-Feb-2021].

## Conclusions/action items:

I believe that these ideas for connecting the two pean clamps are feasible and don't require permits that us as a team for sure do not have. I like these two connecting ideas for the ease in purchasing products, and mainly for their ability to alter distances between the two pean clamps - a request of our client. I'm now prepared with preliminary designs to show our group when we meet on 02/18, and then start coming up with a design matrix for our preliminary presentation next Friday 02/26.



#### ASHLEE HART - Mar 02, 2021, 9:47 PM CST

Title: Design Constraints

Date: 03/02/2021

Content by: Ashlee

Present: NA

Goals: Acknowledge design constraints our team may face this semester with prototyping a thyroid retractor

Content:

Throughout this semester, design constraints will be faced due to COVID, as well as more generally.

## Design constraints due to COVID:

- Potentially not being able to see our client in person, which would make seeing/obtaining peanuts to include in our design difficult
   However, our client did express that she may be able to meet in person if we're comfortable
- · Finding it difficult to have all our group members meet up in one spot
- Not be able to rely on fast shipping for materials

## General design constraints

- · The design has to have two or more points of contact to be able to accommodate for different thyroid shapes and sizes
- The retractor should be basically the same as any other surgical instrument
   stainless steel, mirror finish, 8 inches [1], and .09 pounds [2]

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

[2] "ADC® Kelly Hemostatic Forceps, Straight, 5-1/2'L, Stainless Steel," *Global Industrial*. [Online]. Available: https://www.globalindustrial.com/p/medicallab/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].

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

#### Conclusions/action items:

The design constraints I have listed above are fair to have, especially for this type of semester, but our team is doing a great job overcoming any constraints thus far.



ASHLEE HART - Mar 16, 2021, 2:55 PM CDT

Title: Final Design Idea Post Preliminary Designs

Date: 03/16/2021

Content by: Ashlee

Present: N/A

Goals: Explain the final design idea the group talked about in our last meeting with Dr. Doubleday

#### Content:

Dr. Doubleday explained that she liked our Adapted Weitlaner the most because of its adaptability to different sizes of thyroids, as well as the ratcheting system it has.

In the meeting she also mentioned that we don't necessarily have to follow the peanut design. It's what their team is used to using, but it can be an adaptation of any type of retractor seen on the market.

She mentioned having the Adapted Weitlaner, but instead of having spring loaded tips to hold the peanut, just have a blunt end to allow for a rubber cap (see figure 1)



Figure 1: Our Adapted Weitlaner with blunt ends, allowing for a rubber cap

Ashlee Hart/Design Ideas/Final Design Idea Post Prelim. Designs





## Figure 2: The type of rubber caps we may put at the end of our adapted weitlaner

I think this semester we will be able to do a SolidWorks model of the instrument and hopefully 3D print that at the Makerspace. Then if this project carries onto next semester, our team could make a stainless steel version that could actually be used in thyroid retraction.

## Conclusions/action items:

I feel great about where our team is at and I'm excited to see what Dr. Doubleday thinks about where we're at as well.



## ASHLEE HART - Apr 11, 2021, 1:09 PM CDT

Title: Solidworks Pre made Forceps

Date: 04/11/21

Content by: Ashlee

Present: N/A

Goals: Insert all the Solidworks pre-made models of forceps found from the internet

Content:



Figure 1: An image of a Solidworks design

The image shown in figure 1 is a pretty basic forceps design. I think this would be a good set to use for seeing what 3D printed materials would work for our device and what would not. It doesn't include a ratcheting system so we would have to find a way to incorporate that after printing, if a different design is not found/created.



Figure 2: Image of a Gallstone curved forcep

#### Ashlee Hart/Design Ideas/Solidworks pre made Forceps

Figure 2 shows another Solidworks rendering of a pair of forceps that have curved ends, which is what our client had requested with our adapted weitlaner. The image also shows some kind of system for the adjustment of forceps that may be valuable if we decided to test/use this file. We may be able to edit the file to have blunt ends rather than the circular ends it has now.

## Conclusions/action items:

I feel like we found pretty solid Solidworks files we could use going forward. With just two weeks left until our final presentations, our team will have to decide if we have the ability to 3D print or not. We should be able to prove that our forceps will be able to withstand the pressure from the hand of a surgeon by using Solidworks. If this is to be continued next year, we would have a great start.

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



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ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallenzange\_halb\_1.SLDPRT(960.4 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallenzange\_halb\_2.SLDPRT(619.9 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallstone\_forcep\_curved\_L\_001.JPG(424.8 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallstone\_forcep\_curved\_L\_002.JPG(405.4 KB) - download



Gallstone\_forcep\_curved\_L\_003.JPG(406.7 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallstone\_forcep\_curved\_L.SLDASM(717.2 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallstone\_forcep\_curved\_L.STEP(1.8 MB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Gallstone\_forcep\_curved\_L.x\_t(697.8 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



SURGERY\_CLAMP-03.SLDPRT(94.3 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



Clamp1.jpeg(2.7 KB) - download



clamp2.jpeg(5.6 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



SURGERY\_CLAMP\_ASSY.SLDASM(876.3 KB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



SURGERY\_CLAMP\_ASSY.STEP(5.3 MB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



SURGERY\_CLAMP-01.SLDPRT(1.7 MB) - download

ASHLEE HART - Apr 16, 2021, 12:53 PM CDT



SURGERY\_CLAMP-02.SLDPRT(2.3 MB) - download



ASHLEE HART - Apr 27, 2021, 3:04 PM CDT

Title: Final Design

Date: 04/27/21

Content by: Ashlee

Present: N/A

Goals: Document our final design of the semester

Content:



## Figure 1: The Adapted Weitlaner final design



Figure 2: Upclose view of the shods

After meetings with our client and individual brainstorming, our team came to the final design seen in figure 1. The body of the retractor is that of a Weitlaner, with its ratcheting mechanism to allow for the adjustment of space between the two prongs. The end of the adapted Weitlaner includes two blunt ends that allow for the addition of shods. Shods are commonly used with surgical instruments, and can be more a rubbery material. They have the ability to be single use, sterilized, and molded into different designs and shapes for optimal retraction.

Conclusions/action items:

The final design is something our team is proud of. We have a lot more to go until we have a complete final design our client can physically use, but we're at a good spot going into next year.



ASHLEE HART - Mar 02, 2021, 9:56 PM CST

Title: Testing Ideas

Date: 03/02/2021

Content by: Ashlee

Present: NA

Goals: Brainstorm ideas for testing to do later this semester

## Content:

- A more qualitative test our team should do is give our prototype to our client and get her and her surgical team's feedback on it. It would be great if she could use the retractor in a surgery to see how the device holds up, and then give constructive feedback to us after.
  - We could make a document that has ratings for different criteria like:
    - Grip on peanut
    - Adjustability
    - Ease of use
      - All of these criteria could be rated on a scale 1-10 or 1-5
  - I think if we did this type of testing, it would be helpful to document the qualitative things said in a graph to see where our device's strengths and weaknesses are
- While the device should be able to hold up against a human's grip no matter what, we could still inflict a force on the device to document that it does as it should.
- We could make something to resemble a thyroid, like ball up play-dough or something in similar in consistency. Then, use our device in the way that a surgeon would in thyroid retraction to see if our device prevents it from being retracted. To put numbers to the tests, we could see how long the play-dough can stay retracted, or how many times out of 5, for example, the play-dough stays retracted for a certain amount of time.

## Conclusions/action items:

I think I brainstormed a good amount of potential tests our team could perform throughout this upcoming semester. I think it would be important to meet as a group and with our client to see what everyone's ideas are.



Title: Shod Testing

Date: 04/27/21

Content by: Ashlee Hart

Present: N/A

Goals: Document the testing that Mitchell conducted in Solidworks

## Content:



Figure 1: Testing done on the shod component of our final design

The testing images shown above showed that very little strain, stress, and deformation occurred. While going into testing it was assumed by the team that the stress that a surgeon's hand or thyroid could inflict on the thyroid retractor would not damage it, conducting the test through Solidworks proved this point.

## Conclusions/action items:

Our team is confident in the strength of the shods of our final design. Next semester, more ergonomic testing will be conducted to make sure that our client likes the feel and workings of our device.



ASHLEE HART - Mar 02, 2021, 10:05 PM CST

Title: FDA Standards and Codes

Date: 03/02/2021

Content by: Ashlee

Present: NA

Goals: List out relevant things related to the FDA and codes that our team may need to take into consideration when designing a medical device

#### Content:

According to the FDA, the thyroid retractor our team hopes to make is a "manual surgical instrument." This means the following:

- Non-powered
- Hand held
- Reusable or disposable
- Used in various medical procedures

The FDA lists these types of instruments as a Class 1, meaning general controls [1]

[1] "CFR - Code of Federal Regulations Title 21," *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=878.4800. [Accessed: 03-Mar-2021].

## Conclusions/action items:

Based on the information listed above, our device, if commercially sold, would have to be FDA approved. Since our team is starting on a smaller scale, working directly with one client and her surgical team, we have a long ways until we should be immediately concerned with getting FDA approval for our device.



ASHLEE HART - Mar 02, 2021, 10:15 PM CST

Title: Need for Thyroid Retractor

Date: 03/01/2021

Content by: Ashlee

Present: NA

Goals: List the reasons why a thyroid retractor for our client is necessary

## Content:

In our first client meeting, our client detailed the need for an improved thyroid retractor on her team including the following:

- To avoid using two peanuts at one time. Ideally, the peanut that her an her team use would be sufficient in retracting any thyroid despite its shape and size. However, it's most often found in the middle of surgery that the thyroid will need two peanuts in order to retract. This can be a problem because when two peanuts are used in retraction, two hands are needed to ensure stability, and/or more stress is put on the surgeon to make sure that the thyroid remains where it should.
- With the adjustability our device will hopefully have, it will hopefully address our client's need for a retractor that is able to accomodate for multiple shapes and sizes of thyroids. Thyroids can vary in size due to gender, and for other non-specific reasons [1], so it's important to be ready for any size of thyroid that comes a surgeon's way.
- There's a need for a thyroid retractor that has multiple points of contact between the thyroid and retractor. When there's just one point, the thyroid can begin to make its way around the single point, causing not all the thyroid to remain retracted. An image of this can be seen in figure 1. With multiple points of contact, the thyroid should not be able to cave downwards.



Figure 1: Image of thyroid gland and a thyroid retractor with one point of contact

[1] M. L. Lyden, T. S. Wang, and J. A. Sosa, "Surgical Anatomy of the Thyroid Gland," *UpToDate*, 09-Sep-2019. [Online]. Available: https://www.uptodate.com/contents/surgical-anatomy-of-the-thyroid-gland#H1. [Accessed: 05-Feb-2021].

Conclusions/action items:

The need for a new thyroid retractor for Dr. Doubleday's surgical team has been made very apparent. Having this motivation has made this design process go very smoothly.



ASHLEE HART - Mar 02, 2021, 10:28 PM CST

Title: Broader Impact of Thyroid Retractor

Date: 02/28/2021

Content by: Ashlee

Present: NA

Goals: Brainstorm the broader impact of our thyroid retractor design

## Content:

At first, the broader impact of our thyroid retractor will be localized to Dr. Doubleday's surgical team, but has the opportunity to flourish and affect surgeons across the world.

## Surgeon fatigue:

- Fatigue is something that is inevitable for surgeons. Combinations of sleep deprivation, long working hours, and high levels of concentration lead to fatigue [1]. Surgeon fatigue clearly affects the surgeon themselves, but can lead to detrimental effects on the patients they work on if the surgeon makes mistakes due to their fatigue.
- A way to overcome this surgeon fatigue is to plan ways to maximize efficiency [1]. A thyroid retractor that can prevent thyroid retraction issue has great potential to mitigate stress in the operating room, and contribute to lessening fatigue
- When a surgeon has to hold two peanuts to retract a thyroid instead of being able to hold just one device for the job, there's a chance the surgeon may experience muscular fatigue. Muscular fatigue is seen to increase when operating time increases, and so if thyroid retraction is made easier by our device, operating time should be reduced [1].

[1] Washington, "Addressing Surgeon Fatigue: Current Understanding and Strategies for Mitigation," *Plastic and Reconstructive Surgery*. [Online]. Available: https://journals.lww.com/plasreconsurg/Fulltext/2019/10000/Addressing\_Surgeon\_Fatigue\_\_Current\_Understanding.44.aspx. [Accessed: 03-Mar-2021].

## Conclusions/action items:

Similar to how I concluded the need for a thyroid retractor, there's clearly a lot of great motivation for the creation of a new thyroid retractor for Dr. Doubleday. While the impact at first may seem small, it may affect broader things such as surgeon fatigue.



#### ASHLEE HART - Mar 28, 2021, 1:20 PM CDT

Title: 3D Printed Materials

Date: 03/28/21

Content by: Ashlee

Present: N/A

Goals: Learn about the different 3D printed materials offered at the Makerspace and narrow down the materials that will work best for our prototype

#### Content:

- My personal experience with 3D printing at the Makerspace was from freshman year. My design team 3D printed parts for our project that ended up forming cat prosthetics. Our team used TPU, a more sturdy material, for the body and then Elastic for the base to better the traction.
- The 3D printed material(s) we use should most likely allow for a sturdy, close-ish to metal feel, for the forceps/base, and then a more rubbery grip-like material for the caps that will go over the blunt ends of the forceps

Makerspace Notes:

- There are two types of 3D printers at the makerspace. There's the Ultimaker (FFF) that creates efficient, high quality parts, and then the Formlabs (SLA) that are great with small and intricate parts
  - The caps will most likely be printed using the SLA printer. I'm not 100% sure about the forcep body yet
- Below is a table of 3D printed materials our group will most likely choose from. It may be best to choose the type of material in person where we can touch the different types

 Table 1: Makerspace 3D printed materials [1]

# **Ultimaker Filmanet**

Material	Cost (\$/g)	Technical Data	Safety Data Sheet (SDS)
Ultimaker PLA	\$ 0.08	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker Tough PLA	\$ 0.08	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker PC	\$ 0.12	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker PVA	\$ 0.19	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker Breakaway	\$ 0.12	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker Nylon	\$ 0.12	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker PP	\$ 0.13	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>
Ultimaker CPE+	\$ 0.13	Technical Data Sheet	<u>Safety Data Sheet (SDS)</u>

• I also looked into pre-made Solidworks models that are able to be downloaded from the internet and while there aren't any designs with a ratcheting system, there are basic forceps available

[1] https://making.engr.wisc.edu/3d-printers/

## Conclusions/action items:

I did some good basic research on 3D printing resources here on campus. The next step is to go into Solidworks and begin making models of the forcep body and tips. I'm hoping I'll be able to edit basic forcep files to fit our final design description.



ASHLEE HART - Apr 27, 2021, 3:00 PM CDT

Title: Future Work

Date: 04/27/21

Content by: Ashlee

Goals: Discuss what future work needs to be done next year

Content:

- While we were able to have successful testing on the shod component of our design, it's critical that once we have a tangible product we do ergonomic testing to make sure our client is comfortable holding our product.
- We need to do research on how to make the shods detectable by X-ray. Dr. Doubleday mentioned once in a meeting that moving parts in surgeries often have a way to be detected by an X-ray in case they get lost during a surgery. Since the shods have the option to be disposable and/or interchangeable, we will need to look into ways to make sure they can be found if they get lost
- The body of our forcep has not been made in Solidworks, so next semester the team will have to work on creating one, or finding a premade model that follows the Weitlaner body.
  - A potential way to go about creating a Weitlaner body from scratch could possibly be by purchasing a Weitlaner from the internet and cutting the prong-type ends off (seen in Figure 1), and having the blunt end our team is looking for,



Figure 1: Weitlaner retractor

Conclusions/action items:

We're in a good spot to continue our project next semester, and have many things to accomplish before we have a completed final design.



#### ASHLEE HART - Feb 07, 2021, 8:44 PM CST

Title: Client Meeting 02/05 Notes

Date: 02/05/2021

Content by: Ashlee

Present: Ashlee, Avani, Kate, Mitchell, and Dr. Doubleday

**Goals:** Write out the notes taken at our client meeting last Friday, 02/05

## Content:

- The current thyroid retraction process uses a "peanut" (pean clamp with a ball of gauze held between the prongs)
- The thyroid is usually held up towards the one retracting it, which can cause it to roll off to the sides
- A larger thyroid using just one of the peanuts can be difficult to control
  - The potential use of 2 peanuts could help avoid this problem
- · Make the device out of the same material most surgical devices are made of
- Be able to adjust the width between the two prongs
- · The current peanut mechanism works, it would just be beneficial to have two sets connected in the procedure
- Pean clamp
  - Locked by a ratcheting system
  - The ends are blunt and are curved slightly
  - Ball of gauze in the tip
- Two peanuts should be about 2-3 cm apart and adjustable
- Thyroids are about 4-6 cm in length
- Device should be reusable
- · Ratchet system or a spring could be used for the locking mechanism
- · Forces applied to the device would never be enough to fracture the material
- · Part of the procedure involves dissecting out an important nerve from underneath which can be difficult
- A solution a different surgeon uses is holding two peanuts in one hand and crossing them
- · Potential supplier is Covidien, many instruments have a "Made in Germany" stamp

## Conclusions/action items:

Our meeting with Dr. Doubleday was very informative and helpful to get us all started on research and potential brainstorming for prototypes. Based on the information she gave us, I want to look into whether there are other surgeons who have had the same problem with the peanut mechanism, and whether there have been attempts to solve the problem. Dr. Doubleday mentioned a colleague who crossed two peanuts, so welding two peanuts together may be a potential solution. I plan to do further research on the versatility of peanuts and potential solutions.



ASHLEE HART - Feb 17, 2021, 3:13 PM CST

Title: Notes from Dr. Doubleday's Thyroid Retraction Video

Date: 02/17/21

Content by: Ashlee

Present: N/A

Goals: Watch Dr. Doubleday's video and write out notes, techniques, and describe the current technique

## Content:

The video begins with an aerial view of the thyroid retraction (see figure 1). You can see Dr. Doubleday holding the thyroid gland with one of the peanut forceps.



Figure 1: Aerial view of thyroid retraction

She then went on to establish where and what things are. The patient has their chin above the thyroid towards the top of the image, and their chest is below the thyroid location. Within the site of the retraction, she pointed out the thyroid and thyroid artery.

When she began the thyroid retraction, she pulled the gland up and towards herself and exposed a parathyroid, as seen in figure 2.





## Figure 2: Thyroid is retracted up and towards Dr. Doubleday, exposing the parathyroid

Next, she called for a second peanut (figure 3) for more support in holding up the thyroid gland, and described in detail what she was looking for in our project:

• Two prongs crossed over to give better exposure, as using just one peanut tends to have the thyroid gland fold over on itself



Figure 3: Two peanuts holding up the thyroid gland

## Conclusions/action items:

This was an insanely helpful video that helped me understand the logistics of a thyroid retraction, as well as see in action what type of device Dr. Doubleday is looking for. Based on this video, I feel like I have a clear idea of preliminary designs I want to bring up to our team the next time we meet. I'll be doing more research to see what is possible for us in this time, but as of now I could see us welding two peanuts together for the base. If one of us has our welding upgrade that would be ideal, but if not, I'm sure there are other creative ways to connect metal from medical devices together. My plan of action now is to come up with preliminary designs for our next meeting.



#### ASHLEE HART - Mar 10, 2021, 6:48 PM CST

Title: Preliminary Design Client Meeting

Date: 03/10/2021

Content by: Ashlee

Present: Ashlee, Kate, Avani, and Dr. Doubleday

Goals: Write out the notes taken at our client meeting discussing the preliminary designs

#### Content:

- · Does not have to be a peanut
- · Peanuts can slip off with larger thyroids and allow the forcep to puncture the thyroid
- Nut and bolt mechanism can be time consuming
- · A ratcheting system is important
  - Could do two blunt ends with rubber tips
- Weitlander: ratchets can be worn down and may not lock after awhile
- For ergonomics: a thyroid retractor that allows for adaptable retraction makes it so that less staff is needed during an operation, and the surgeon has the ability to hold the retractor in one hand and then do the dissection with the other
- The above ergonomics statement can also be added to the background/introduction section
- · Without good retraction, a surgeon can't get sufficient access to the parathyroid glands
- A spring mechanism could be hard for fine movements/adjustments
- Meeting next Tuesday

## Conclusions/action items:

We had a successful meeting with Dr. Doubleday and are planning to meet next Tuesday.



#### ASHLEE HART - Mar 19, 2021, 1:09 PM CDT

Title: Final design meeting with Dr. Doubleday

Date: 03/19/21

Content by: Ashlee

Present: Ashlee, Kate, Mitchell, Avani, and Dr. Doubleday

Goals: Document notes taken from our meeting with Dr. Doubleday

#### Content:

- · Rubber shods are what can go over the blunt ends of a thyroid retractor
- The tip/end geometry could be at an angle or concave shape for more surface area
- Dime size is bigger than enough
- The tip of a peanut ~1-2 cm, so it doesn't need to be any larger than 2-3 cm
- Peanuts have an x-ray detection that we could look into.
  - Something with the FDA
- We could plan to 3D print tips
- Have a 10-20 degree angle towards the thyroid
- · Retraction used in thyroidectomies as well as parathyroidectomies
- · Hoarseness if not an effect of thyroid retraction

## Conclusions/action items:

We had a really good meeting with Dr. Doubleday today. We've decided on a final design and will make plans this week to get into prototyping. I will look into rubber tip shapes that could be put into Solidworks, as well as Solidworks models of ratcheting designs.



ASHLEE HART - Mar 25, 2021, 9:01 PM CDT

Title: WARF Presentation

Date: 03/19/21

Content by: Ashlee

Present: NA

Goals: List out things I've learned from this lecture about WARF

## Content:

- WARF manages intellectual property, and deals with patenting and innovation.
- WARF supports research at UW-Madison
- Governed by UW-Madison alumni, but completely separate from the university
- WARF is here to support students and those apart of UW-Madison
- Cycle of innovation:
  - UW research and discovery
  - IP protection: protecting ideas of those at UW (international and US patents)
  - Licensing and startups
  - Funding to support research and discovery: give an annual grant between \$60 million and \$100 million to the university every year
- Classes of IP: patents, trademarks, and copyrights
  - These are not mutually exclusive, can have one or more of these classes surrounding an idea
- Prior Art: anything in the world that has been done before your invention
  - What your invention is evaluated against
    - By other people
    - By you yourself
    - There is a grace period: 12 months from the date of your first public disclosure is how long you have to file a patent
      - if someone else has thought of this idea before you, there is no grace period
- Public disclosure: journal publication, talk or poster at a conference, non-confidential department seminar, open thesis defense, cataloged dissertation, some funded grant abstracts
- Requirements for patentability: eligible, useful, enabled, described, novel, non-obvious
  - patent examiners combine other references, so while someone may not have your exact idea, the idea can be rejected if there are multiple references that include parts of your idea
- A single US patent costs about \$30,000
- WARF process:
  - person invents something and bring it to WARF along with an application
  - Take the idea to the disclosure committee and see if it follows the requirements for patenting
  - Get invention down onto paper, and it will pend in the patent office
- US is on a "first to file" process versus "first to think of the idea" process

## Conclusions/action items:

I thought this lecture was really interesting and useful for our current BME project, as well as future projects. Our client in our last meeting mentioned the idea of filing for a patent, or doing something with WARF, and so having this knowledge is great.

2/5/21: Client Meeting Notes

AVANI LALL (aklall@wisc.edu) - Mar 03, 2021, 10:52 AM CST

**Title: Client Meeting Notes** Date: 2/5/21 Content by: Avani Present: Team and Dr. Doubleday Goals: To get an overview of Dr. Doubleday's requirements for the design and get a better understanding of the problem. Content: -peanut surgical instrument currently used for thyroid surgery, very frequently -tedious dissection, have to pull the thyroid up with the peanut (clamp with gaws) without being traumatic -thyroid is big, one instrument isn't enough traction and causes thyroid to fold -current solution: using 2 peanuts -want a handle with 2 prongs shaped like a V -same typical material used for surgical instruments -possibly adjust width between 2 prongs -want one free hand to dissect -looks similar to pean forceps (pean clamp surgery) -has ratchet to lock when its closed -has blunt, not sharped, curved end -thyroids are anywhere from 4-6 cm, about 2-3 cm apart would work -resusable, auto-clampable -similar to weitlaner retractor

**Conclusions/action items:** Ask the client if we could possibly get a recording of the thyroid retraction procedure to better understand the problem. Start thinking about design ideas and use the above specifications for the PDS.



Title: Thyroid

Date: 2/6/21

Content by: Avani

**Goals:** After meeting with the client and her expressing how tedious the dissection is, I wanted to get a better understanding of the procedure and the thyroid in general.

## Content:

The client explained the dissection is tedious because you have to pull the thyroid up with the peanut without being traumatic. She also explained that the thyroid is big and one instrument isn't enough traction and that causes the thyroid to fold.



https://www.mayoclinic.org/tests-procedures/thyroidectomy/about/pac-20385195

- Thyroidectomy: Surgical removal of all of part of the thyroid gland.
- Thyroid: Butterfly gland shaped at the base of the neck.
- Thyroidectomy is used to treat thyroid diseases such as cancer, noncancerous enlargement of the thyroid (goiter) and overactive thyroid (hyperthyroidism).
- Generally a safe procedure.
- Procedure: Surgeon makes a cut low in the center of the neck. All or part of the thyroid gland is then removed.

https://www.elsevier.es/en-revista-cirugia-espanola-english-edition--436-articulo-use-alexis-retractor-in-thyroid-S2173507718302497

- Thyroid and parathyroid surgery requires good exposure of the glands, for which an incision must be made to provide access to the superior and inferior thyroid poles.
- Exposure of the gland during thyroidectomy can be maintained with different methods.

**Conclusions/action items:** This helped better understand the anatomy and procedure. Hopefully, Dr. Doubleday is able to provide the team with a video of her completing the procedure or potentially us seeing it in person to get a better understanding of the procedure and current instrument.

#### AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:41 PM CDT

## **Title: Need for Device**

Date: 3/22/21

## Content by: Avani

Goals: After meeting with the client, Dr. Doubleday gave more reasons for why the device is needed after reading our preliminary report.

## Content:

- The client requires a surgical instrument to aid in the medial retraction of the thyroid and parathyroid glands during surgery.
- Extremely relevant procedure. Can be tedious
- Surgeons working with only one forcep, occasionally run into the problem that there are not enough points of contact on the thyroid which causes the gland to be difficult to retract and hold.
- Procedures that are performed involving retraction of the thyroid often use different techniques and surgical instruments, so, there is a definite
  market opportunity for another device.
- Retraction of the thyroid gland from multiple contact points in order to successfully retract the thyroid without worrying about the thyroid slipping, or caving around the single touch point.
- Advantageous to the client's surgical team
- To be able to effectively retract thyroids of different sizes and shapes.
- · There are many procedures that require the retraction of the thyroid gland in order to gain access to relevant anatomical structures.
- 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.

Conclusions/action items: This information is useful for sections of the final report and overall project in general.



AVANI LALL (aklall@wisc.edu) - Feb 12, 2021, 12:26 PM CST

Title: Peanut Sponge Forceps

Date: 2/10/21

Content by: Avani

**Goals:** To learn more about the current device Dr. Doubleday and see what aspects we will be keeping for our design. Also, think about items to include in the PDS.

Content: https://www.quickmedical.com/sklar-instruments-peanut-sponge-forceps.html



- The current device being used is the Peanut Sponge Forceps and is approximately 8" in length.
- 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 so that it can be used on a variety of patients and thyroid sizes.
- The weight of the device should be close to that of the weight of the forceps used with the peanut currently
- A small increase of weight will be allowed due to the addition of the second prong.
- The device will be made out of stainless steel 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

**Conclusions/action items:** The information from this source is very helpful for sections of the PDS. Also, there are a lot of aspects from the Peanut we will want to keep in our final design and it serves as a great comparison.



2/17/21: Ratchet Locking Mechanism

AVANI LALL (aklall@wisc.edu) - Mar 03, 2021, 10:46 AM CST

## Title: Ratchet Locking Mechanism for Surgical Instruments

Date: 2/17/21

## Content by: Avani

Goals: To explore the ratchet locking mechanism used on surgical instruments like the one used for the Weitlaner retractor.

Content: https://patentimages.storage.googleapis.com/c1/4b/b5/b4970ae1fcf904/US5176702.pdf

- Includes:
  - Leaf spring with a locking barb which is located on a handle of the medical instrument.
  - A ratchet on a lever arm which is pivotally engaged to the handle.
  - A latch on the handle of the medical instrument.
- The latch on the handle engages and resilienty deforms the left spring to cause engagement of the locking barb in a groove of the ratchet when the latch is in a first position.
- When in a secondposition, the latch releases the locking barb from the ratchet groove.



Conclusions/action items: The mechanism is actually patented so I was able to find all the patent information and gain knowledge from there.



AVANI LALL (aklall@wisc.edu) - Mar 03, 2021, 12:39 PM CST

## **Title: Code of Federal Regulations**

Date: 3/1/31

Content by: Avani

Goals: To consider appropriate codes and standards.

Content: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=878.4800

From the FDA Title 21:

- A manual surgical instrument is to be: no powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures.
- The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers.
- A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.
- The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

Conclusions/action items: Keep these standards in mind when fabricating our design.


AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:47 PM CDT

## **Title: Competing Thyroid Retractors**

Date: 3/20/21

Content by: Avani

Goals: Discuss the devices on the market currently that aid in thyroid retraction.

Content:

- 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: McBurney thyroid retractor which has a single "C" shaped end, the Beckman Thyroid retractor which has an adjustable ratcheting system as well as two "C" shaped ends.
- Dr. Doubleday's surgical team currently uses a single peanut sponge held by an auto-locking forceps.
- Weitlaner Retractor
  - Not currently used for thyroid retraction, but is a device that the client expressed she really liked the mechanism it has.

**Conclusions/action items:** It is important to have knowledge of current devices because often there are aspects of certain products that should be kept when coming up with a new design.



# 3/19/21: WARF Patent Lecture Notes

AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 7:45 PM CDT

### Title: WARF Patent Lecture Notes

Date: 3/19/21

Content by: Avani

Goals: To take notes on the pre-recorded patent lecture.

### Content:

- WARF is governed by an independent board of UW-Madison alumni.
- WARF's proceeds support research at UW by providing financial support, managing assets, and moving innovations to the marketplace.
- Cycle of Innovation: UW Research & Discovery --> IP Protection --> Licensing & Startups --> Funding to support research and discovery -->
- Protecting Innovation:
  - Patents: Machines and devices, commands, processes and methods, improvements.
  - Trademarks: Words and phrases, colors, pictures or logos, sound.
  - Copyrights: Library works, webpages, software programs.
- Prior Art: "References" created before a specific date.
  - By inventor: >1 year before the filing date of the patent application.
  - By another: Before the filing date of the patent application.
  - Novelty and non-obviousness are evaluated.
  - Internationally, absolute novelty is usually required.
- Examples of Public Disclosures of an Invention:
  - Journal publication, often available before printing.
  - Talk or poster at a conference/professional meeting, abstracts sometimes published in advance.
  - Non-confidential department seminar.
  - Open thesis defense.
  - Cataloged dissertation.
  - Some funded grant abstracts.
  - Description on an internet site.
- Requirements for Patentability: Eligible, useful, enabled, described, novel and non-obvious.
- Examination: Assessment of invention.
  - Based on statutory requirements and application of prior art.
- WARF'S IP Management Process:
  - Disclose invention to WARF.
  - Disclosure committee meets monthly to review new disclosures.
  - Patent application drafting, filing, and prosecution.
  - Technology marketing.
  - · Licensing.
- Licensing Considerations
  - Chance of Licensing: Potential applications, technology benefits and impact, state of the market, WARF's history in licensing.
  - Timeline for Licensing: Stage of the technology, patent status, position in WARF's portfolio.
  - · Licensing Strategy: Companies (existing or start-up), exclusive vs. non, field limitations.
  - Plan for Next Year: Further technology development, proactive marketing, marketing materials.
  - Revenue Projections: Early revenue, patent reimbursement, lifetime royalty projections.
- Licensing Innovation
  - WARF provides exclusive or non-exclusive rights to make, use, sell, or import.
  - Licensee provides develop and commercialize, reasonable fees (upfront, royalties, milestones, etc), fulfill obligations under Bayh-Dole.
  - Timeline varies form months to years, depends on technology and market readiness.
  - WARF's Accelerator Program: Milestone-based validation funding to speed promising technologies to a commercial license.
    - Goal is to accelerate commercialization prospects for WARF IP.
- Finding a Licensee:
  - Internal: Inventor contacts, meetings, sponsored research.
  - External: Technology descriptions on website, publications, technology portraits and targeted outreach.
  - Inventor startup.
- · Factors to consider in starting a company: Technology, market, management and capital requirements.

# Avani Lall/Research Notes/3/19/21: WARF Patent Lecture Notes

**Conclusions/action items:** I found this lecture super helpful because I didn't have much prior knowledge about any of this kind of stuff. Especially, I feel like it's super relevant information for this course and our project this semester Dr. Doubleday put the idea out there about filling for a patent.



AVANI LALL (aklall@wisc.edu) - Feb 17, 2021, 2:50 PM CST

Title: Weitlaner-Peanut Design

Date: 2/17/21

### Content by: Avani

**Goals:** To come up with a design idea that meets the clients needs: a handle with 2 prongs shaped like a V and able to adjust the width between the 2 prongs.

### Content:

Based of the designs of the Weitlaner Retractor and the Peanut Sponge Forceps:

• Weitlaner Retractor: Has a self-retaining lock.



• Peanut:



The main design difference would be the ends of the instrument. The design would have the top half (handles and lock) of the Weitlaner retractor, but instead of having forked ends, the ends would resemble the end of a peanut on each piece.



**Conclusions/action items:** Meet with the team and present this design idea. Then as a team we will chose 3 of all of the design ideas we came up with and move forward with them as the preliminary design. Conduct research on the ratchet locking mechanism used.



AVANI LALL (aklall@wisc.edu) - Mar 18, 2021, 3:40 PM CDT

### Title: New Design Idea

Date: 3/14/21

### Content by: Avani

**Goals:** After meeting with the client this past Friday, she gave some feedback on our preliminary designs and some more details about the design she wanted both from aspects of our designs and new ones. My goal is to put all of those into one new design.

### Content:

Dr. Doubleday also gave some information we could add to the background/problem statement:

- The device would make less staff be required for the procedure.
- The device would make the procedure more efficient in terms of time.

Dr. Doubleday expressed that the nut and bolt design would be too bulky and she liked our Adapted Weitlaner design the best. She likes the ratcheting system and top of the Weitlaner just wants the bottom to be changed.

From watching the video she sent in the beginning of the semester of her performing the procedure, it is evident that the peanut sponge forceps are not open and closed at the ends, they are more so just used to hold sponges.

My new design idea is to take the Weitlaner retractor pictured below and cut it just above the forked ends. Then create a small sliver at each of the ends to allow for a sponge to be put in between and sort of wedged in similar to how it is in the Peanut Sponge forceps pictured second.





Another approach is to keep the blunt ends of the Weitlaner after cutting off the forked ends and using rubber caps over the ends.

• Atraumatic occlusion.

Conclusions/action items: Meet with the client again and present our new designs.

AVANI LALL (aklall@wisc.edu) - Mar 18, 2021, 4:02 PM CDT

AVANI LALL (aklall@wisc.edu) - Mar 18, 2021, 4:02 PM CDT

# Title: Drawing of Updated Adapted Weitlaner

Date: 3/18/21

Content by: Avani

Goals: To draw out my description for the new design explained in my previous entry.

Content:

Drawing uploaded below.

Conclusions/action items: Show this drawing as well as description from previous entry to Dr. Doubleday and the rest of the team.

11 Ratchching 6" ₩ h ~.scm ship allows for sponge to be wedged in between

IMG\_3006.JPG(890.7 KB) - download

# 4/19/21: Final Design Choice

### AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:50 PM CDT

### **Title: Final Design Choice**

Date: 4/19/21

### Content by: Avani

Goals: We changed our final design decision after meeting with the client, so the plan for our new final design can be documented here.

### Content:

- A novel version of the adapted Weitlaner design.
- 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 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.
- 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.





Conclusions/action items: The team plans to conduct some mechanical testing of the final design in SolidWorks.

AVANI LALL (aklall@wisc.edu) - Apr 27, 2021, 8:55 PM CDT

## Title: SolidWorks Testing

Date: 4/20/21

### Content by: Avani

**Goals:** Mitchell had prior knowledge of the mechanical testing procedure in SolidWorks and was able to complete it, so I am documenting how we tested here to make sure I have a good understanding of what was done and what that means.

### Content:

- A 2 Newton distributed load was applied equivalently across the contacting surface of the device.
  - 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.
- 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.
- The simulation calculated a maximum von Mises stress of 9.871 kPa ,
  - Well below the modulus of most polymers, usually on the scale of MPa to GPa.
- The maximum engineering strain and deformations were 3.254e-05 mm/mm and 48.44 um,
  - 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.

**Conclusions/action items:** 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. More testing needs to be completed to ensure that the device will be able to complete its intended purpose such as qualitative ergonomics testing.



John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

### Content:

Contains clear and organized notes (also includes any references used)

### Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.



John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: