BME Design-Fall 2021 - Mitchell Josvai
Complete Notebook

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KATE EICHSTAEDT

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Team contact Information

KATE EICHSTAEDT - Oct 19, 2021, 8:13 PM CDT

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Lall	Avani	BPAG	""		

Project description

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:00 PM CDT

Course Number: BME 400

Project Name: Thyroid Retractor

Short Name: Thyrotractor

Project description/problem statement:

The goal of the design team this semester is to create a device to aid in thyroid retraction during thyroidectomies, as well as allow access below the thyroid. In these operations, endocrine surgeons must retract the thyroid gland medially in order to gain access to the recurrent laryngeal nerve, dissect the thyroid gland from vascular attachments, and find parathyroid glands. Surgeons use either one or two Rochester-Pean forceps with a piece of gauze clamped at the tip, referred to as a “peanut.” This can often be arduous for the surgeon, as one point of contact makes the dissection difficult, and handling two forceps at once is cumbersome. The client requests a surgical instrument that has two prongs to retract the thyroid gland from multiple points of contact.

About the client:

Our client is Dr. Amanda Doubleday. She is an endocrine surgeon. Last year she was working at the University of Wisconsin School of Medicine and Public Health. This year she is working at a hospital in Waukesha but still has her surgery privileges at UW-Madison hospitals.

Client Meeting 2/5

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.

Client Meeting 3/10

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.

Client Meeting 3/19

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.

Client Meeting 4/16

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

Title: Client Meeting

Date: 4/16

Content by: Kate Eichstaedt

Present: Whole group, Dr. Doubleday

Goals: 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.

Advisor Meeting 2/5

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.

Advisor Meeting 2/12

KATE EICHSTAEDT - Feb 12, 2021, 12:39 PM CST

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.

Advisor Meeting 2/19

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.

Advisor Meeting 3/5

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:

Advisor Meeting 3/12

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.

Advisor Meeting 3/19

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

2/18/21: Design Matrix

AVANI LALL (aklall@wisc.edu) - Mar 03, 2021, 12:52 PM CST

Title: Design Matrix

Date: 2/18/21

Content by: Avani

Present: Avani, Ashlee, Mitchell, Kate

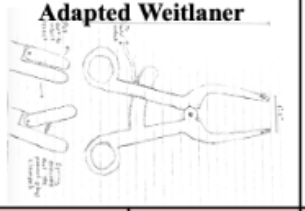
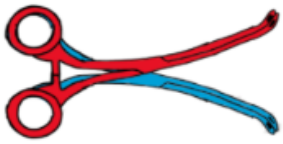
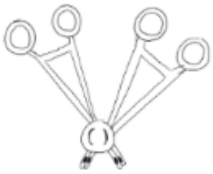
Goals: To each present our design ideas and choose three to move forward with as our preliminary designs. Come up with criteria to evaluate the designs on and create the design matrix.

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.

4/19/21: Final Design Choice

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

Title: Final Design Choice

Date: 4/19/21

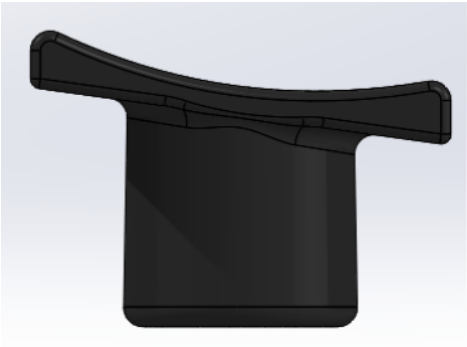
Content by: Avani

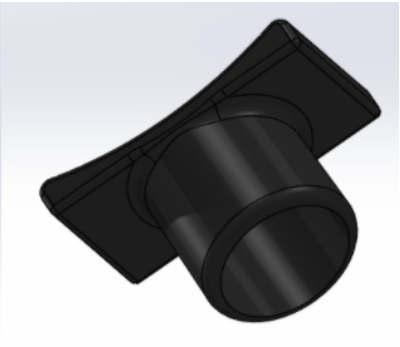
Present: Avani, Kate, Mitchell, Ashlee

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.

4/25/21: Materials and Expenses

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.

4/20/21: Methods

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!

4/19/21: Solidworks Testing

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

Title: Solidworks Testing

Date: 4/19/21

Content by: Mitchell

Present: Avani, Mitchell, Kate, Ashlee

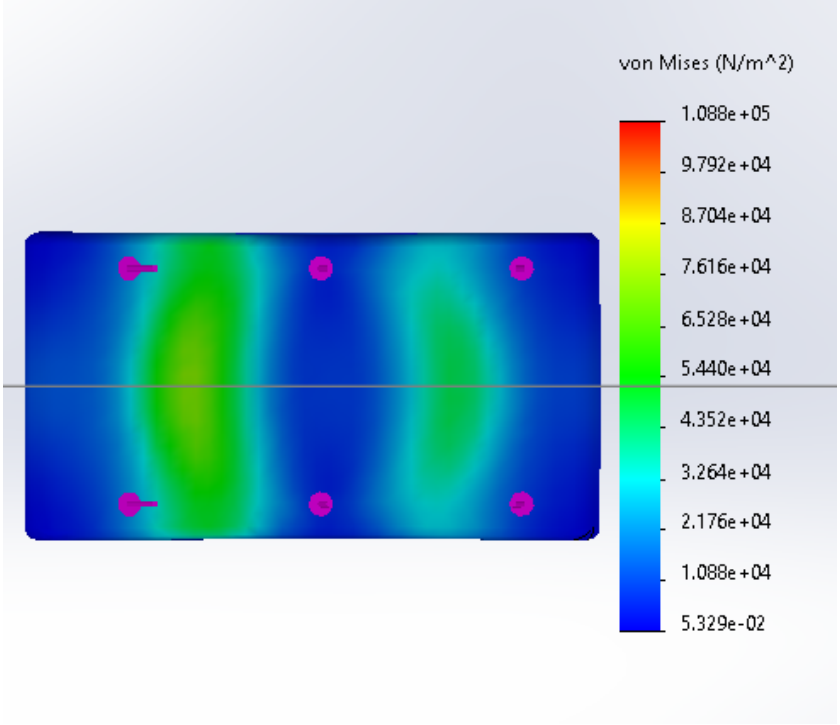
Goals: To conduct mechanical testing on Solidworks model of the rubber shods.

Content:

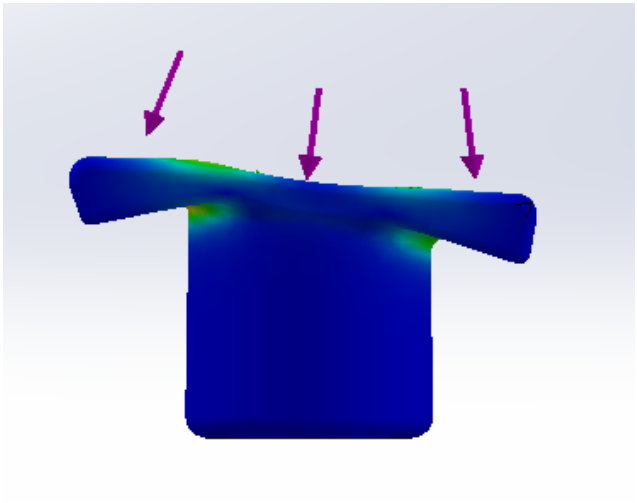
Initial testing was done in SolidWorks. A 1 N distributed load was applied to the surface of the part, and the stress and displacements were analyzed. The interior surface of the hollow cylinder was designated as the fixed surface, because this would be around the retractor, and thus not moving in relation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

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

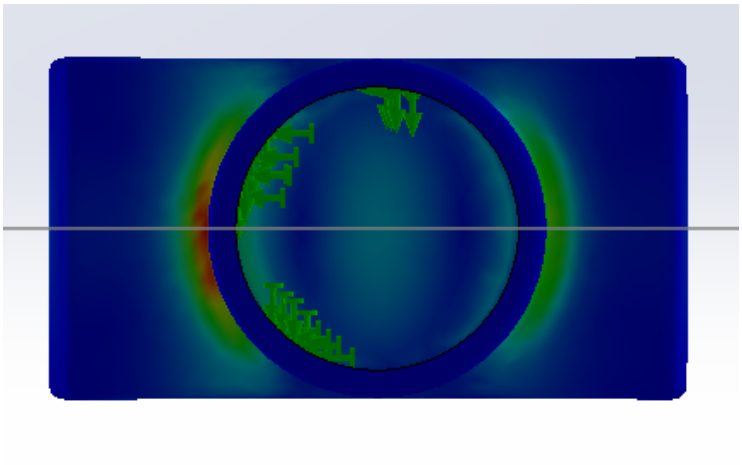
Top view:



Side view:

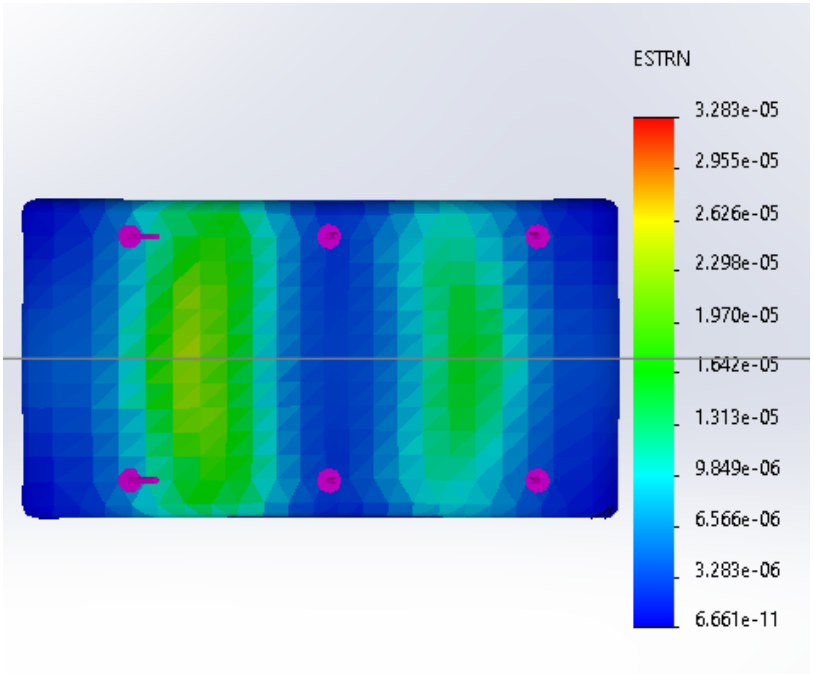


Bottom view:

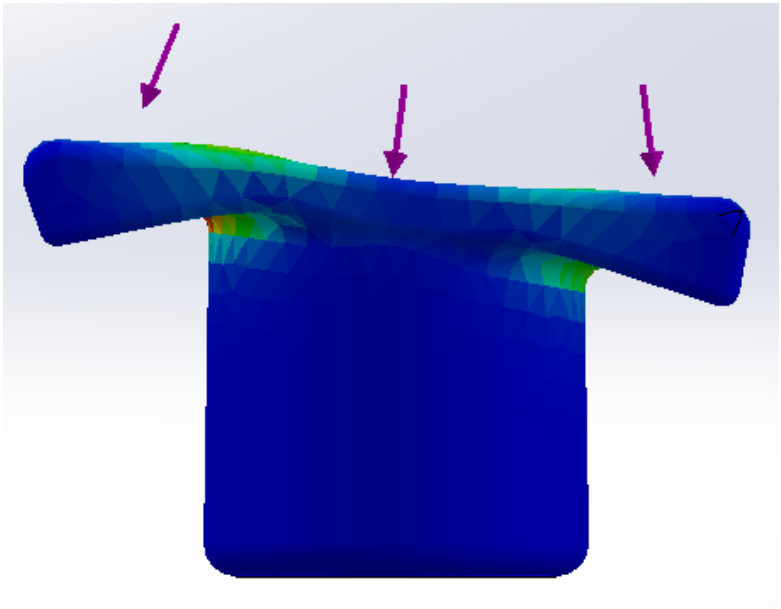


Strain testing: (Scale remained the same for each image, Engineering strain was calculated)

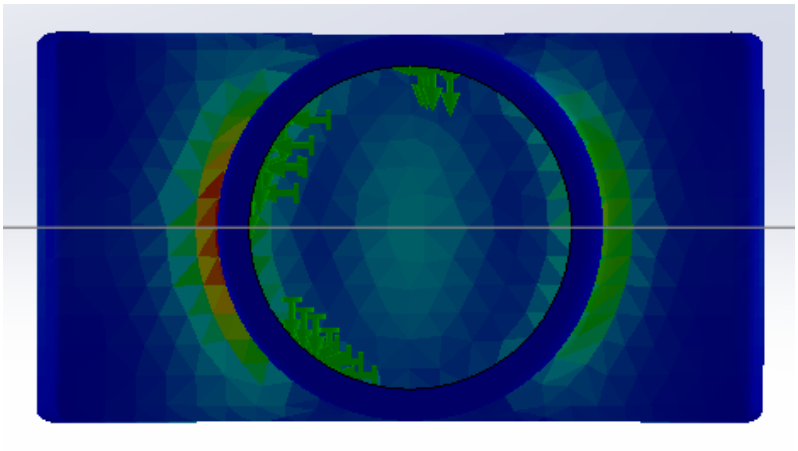
Top view:



Side view:

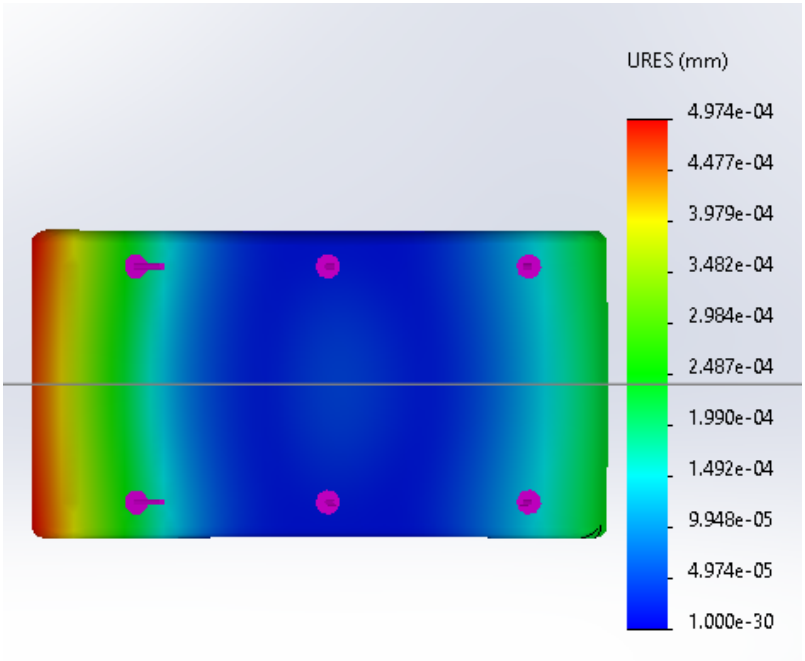


Bottom view:

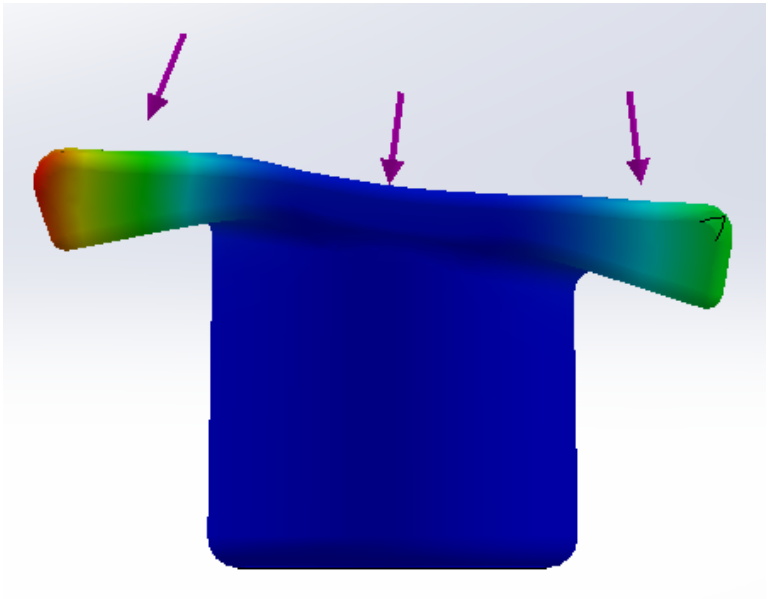


Displacement testing: (Scale remained the same for each image)

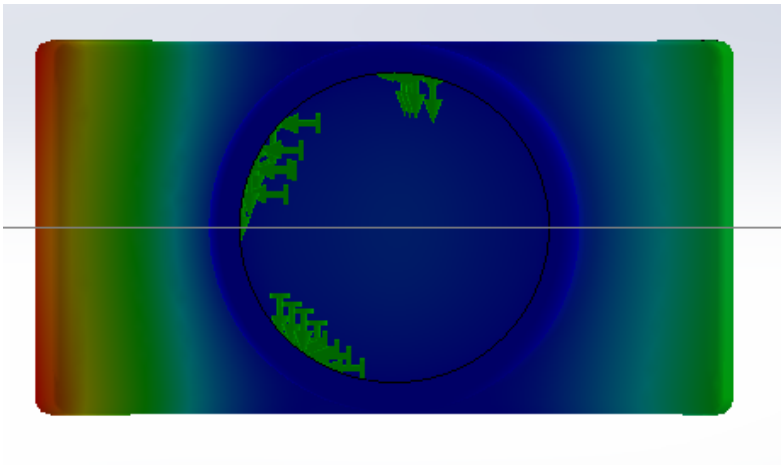
Top view:



Side view:



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.

First Client Meeting 10/1/21

ASHLEE HART - Oct 19, 2021, 8:02 PM CDT

Title: First Client Meeting

Date: 10/1/21

Content by: Ashlee

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

Goals: Record all that we spoke about in our client meeting

Content:

- Dr. Doubleday can order the team a 4.5 inch sized weitlaner

- A meeting can be arranged to do an anatomy lab demonstration where she could either use a peanut to retract the thyroid, or a current prototype we have to retract the thyroid. She has the ability to contact the anatomy lab for availability

- Understand that the parathyroid is not retracted, so the thyroid retractor will not be used for parathyroid retraction but will allow access to the parathyroids by retracting the thyroid

- Using shods for the adapted weitlaner raises a slipping concern. The peanuts don't really have a slipping concern because they're made of gauze

- Whatever tips made for the end of the team's design should be textured to maintain grip

- Dr. Doubleday found a medical device that has two ends of textured metal circles facing each other. She's requested we have an ending that is similar, but the ends will have to rotate 90 degrees in order to lay flat against the thyroid. The prongs should also angle inwards to get the best grip on the thyroid.

Conclusions/action items:

The team had a successful meeting with Dr. Doubleday. We were able to learn about the specific items Dr. Doubleday has requested from us in the thyroid retractor, and come up with some concrete plans to look forward to.

Client Meeting 11/30

ASHLEE HART - Dec 07, 2021, 6:40 PM CST

Title: Client Meeting

Date: 11/30

Content by: Kate Eichstaedt

Present: Entire team and Dr. Doubleday

Goals: Discuss the 3D printed device. Set up testing dates.

Content:

Comments: difficulty on getting the screws out, maybe its the version of Weitlaner we got

General thoughts:

- Good minus ratcheting system of Weitlaner
- Paddle shaped ends; questions on tissue contacting design
    - wider surface area is good
    - little bit of a curvature may be beneficial
        - curve down and towards you to follow contour of thyroid gland
            - add serrations; may be difficult with 3D printing. May have to do after printing
- Chicken breast testing idea sounds like a good idea
- mimic trachea with a paper towel roll; there would be size discrepency but we could use tape to change size of 'trachea'
- include survey in future work; Dr. Doubleday may not be able to get to Madison before presentations
- Found frictional coefficients; could do stimulations
- Ask anatomy lab, test on a cadaver
    - email Dr. Bersu
- Dr. Doubleday could ask too
- Texture on both sides or just one?
    - only on front side \
- Circle or ellipse?
    - maybe do both, see what works better
- Squishy with cyctic nodules; easy to rupture, but not very common. Usually diseased thyroids are firmer than normal healthy thyroids
- Hot glue gun; hot glue will resemble ligament that holds trachea to thyroid
    - is ligament main connective tissue?
        - attachments at superior pole where blood vessels are; usually those are moved before pulling the thyroid.
          Not as robust as ligament on trachea connecting to thyroid

Conclusions/action items:

An email will be sent out to Dr. Bersu to see if he can get us into an anatomy lab with Dr. Doubleday to either watch her perfom a retraction on a cadaver, or test using our device. When it comes to tissue analog testing that is to be conducted this week, using a paper towel was suggested, so we will plan on using those but cut down to approx. 2 cm in diamater to resemble the actual trachea. To prepare for the chicken breast testing, we will need to acquire a food scale that can weigh in grams, a pack of chicken breasts, a hot glue gun to glue the chicken breast pieces to, and ethanol for cleaning down the areas when we're done.

Advisor Meeting 10/1

KATE EICHSTAEDT - Dec 08, 2021, 8:32 PM CST

Title: Advisor Meeting

Date: 10/1

Content by: Kate Eichstaedt

Present: Whole team and advisor

Goals: Discuss edits that need to be made to the PDS

Content:

- Include more details on FDA classification
- Be more specific with what trauma is
  - excessive bleeding? Tissue damage?
- Use explicit temperatures when discussing autoclave details
- Maybe disregard using the word "peanut" because we will no longer be using it in our designs moving forward
- Be more specific in regards to life in service
  - possibly find a manufacturing guide that gives specific guidelines
- Make sure to specify between parts that will be single use and parts that will be sterilized and used again
- Do research on different types of stainless steel and the processing mechanism to create the stainless steel
- Discuss concern of biocontaminants rather than being concerned about the mirror finish
- Compare prices to other competing designs, how much more expensive will our design be?

Conclusions/action items:

To conclude, in this meeting we went over our first version of the PDS and our advisor pointed out things we should change. For action items, we are going to make the necessary changes to our PDS and update our client and advisor with the new version.

10/8/21 Advisor Meeting

ASHLEE HART - Oct 19, 2021, 8:13 PM CDT

Title: 10/8/21 Advisor Meeting

Date: 10/8/21

Content by: Ashlee

Present: Ashlee, Kate, Avani, Mitchell, Professor Tyler

Goals: Lay out what was discussed at our advisor meeting on 10/8

Content:

- Fabrication and testing should now be at the forefront. For testing, if there is a clear opportunity to use a cadaver, that may be ideal. Otherwise, using multiple cuts of a raw chicken breast to mimic multiple sizes/weights of a thyroid could be used. It's definitely important to be able to mimic fluid that the retractor may come into contact like blood or interstitial fluid and such.

- Make sure to insert a screenshot or full video of Dr. Doubleday's thyroid retraction example

- Will need a CAD model of the devices

- Will need to consider the intellectual property situation. We are modifying an existing device, so tinkering with someone else's devices may cause some issues. Also make sure to mention this in the preliminary presentation

- Don't be nit picky when talking about the matrix

- Mention that we'll be in touch with WARF

- The weitlaner retractor is a class 2 medical device that is cleared for use in procedures

Conclusions/action items:

The team had a great meeting with Professor Tyler and definitely feel confident in the content we will be presenting at the preliminary presentations next week.

10/21 Advisor Meeting

KATE EICHSTAEDT - Oct 21, 2021, 5:10 PM CDT

Title: Advisor Meeting

Date: 10/21

Content by: Kate Eichstaedt

Present: Whole team and advisor

Goals: Discuss preliminary presentations

Content:

Notes from preliminary presentation:

- Characterize market size
  - WARF business arm of university
  - Characterize marketability of product
  - How relevant is market, how important is our modification to the device
- Texturing end of gripper - concerns about being able to create texture in a formal stainless steel device
- Presentation:
  - umms when speaking
  - not all changes in slide set showed up, make sure changes are present in final presentations
- Problem statement - do not include long paragraph
  - bullets, key talking points
  - not a lot of words
- Make sure to understand audience's knowledge base, do not assume people know what you are talking about
- Make everything in presentation 'bite size' - easily understandable
- include diagrams, easy to understand charts
- Make sure to include annotations and clear markings
- Make sure diagrams are solidworks by end of semester
  - dimensions in drawings
- Maybe animate video?
- Point audiences attention to the points of interests
  - what's they key thing we want to audience to pay attention to
- no time line
  - lay out timeline with bench marks, use certain dates
    - gant chart

Coordination with client?

- maybe set up meeting with client to make sure that client likes design
- come up with first generation prototype
  - print, do testing
  - we need data

Send word doc of preliminary report to advisor

Questions/concerns for advisor:

- Place notebook entries from last semester into lab archives for this semester?
    - yes, important to journal from start to beginning
        - upload last semesters lab archives and this years into a box or onto microsoft one drive

Unless there is an enormous market, WARF will probably not take on product, do not need to share WARF's decision with manufacturers

Testing protocol

Find most recent patent

Conclusions/action items:

To conclude, this meeting was very helpful to go over changes that need to be made to our preliminary presentations and what we need to complete before our final presentations in December. For action items, we need to make the necessary changes to our report and create plans for fabrication and testing.

10/28 Advisor Meeting

ASHLEE HART - Dec 07, 2021, 6:09 PM CST

Title: 10/28 Advisor Meeting

Date: 10/28/21

Content by: Ashlee

Present: Ashlee, Kate, Avani, Mitchell, Professor Tyler

Goals: List out information discussed and learned at the 10/28 meeting

Content:

- Generate a gantt chart for tasks just to keep all of us on the same page
- While having a concrete plan is great, make plan B's, C's etc. just to avoid problems when issues arise
- Quantitative test to conduct: stress test in solidworks
- Qualitative test to conduct: chicken breast testing
- Show and tell is next week - TBD for if it's in person or not
    - At show and tell, make sure to talk about previous devices, videos, and show why we continued with the design we chose
- Update on our rapid prototype:
    - Slow progress
    - Measurements have been made
- Create a testing protocol ASAP, but by 11/11
    - Testing is proof of us making a good device
- Preliminary Report will be handed back shortly

Conclusions/action items:

The team must create a gantt chart that includes due dates for testing and prototyping. The team also must create a testing protocol that includes both qualitative and quantitative testing procedures. When the report is given back with Professor Tyler's comments, be sure to start making edits ASAP to make editing the final report easier on the team.

11/12 Advisor Meeting

ASHLEE HART - Dec 07, 2021, 6:25 PM CST

Title: Advisor Meeting 11/12

Date: 11/12

Content by: Ashlee

Present: Ashlee, Kate, Avani, Mitchell, Professor Tyler

Goals: List out information discussed and learned at the 11/12 advising meeting

Content:

1. Instead of trying to find data on the thyroid specifically, do some generalizations
    1. The thyroid may be underrepresented in research, so we can use other organs and justify why we chose them
    2. Oncocytoma - happens to a lot of organs
2. Sintered stainless steel may cost around $75
    1. In a past team of Prof. Tyler, they sent out very detailed xml files, fabrication methods, and assembly instructions
    2. Remind Mitch to get specific details on this transaction
3. Notebook:
    1. Can be better
    2. Images are missing on pages 20 and 21
    3. The notebook doesn't give a clear reference to the prior semester
    4. Needs to be thorough
    5. Copy and paste the old notebook into the new one, or make an appropriate reference to the old notebook (either choice, doesn't really matter which)
    6. Having a link to the old notebook at the end is counter intuitive
    7. Be able to walk naive readers through this process
    8. Have more rigor in the conclusions/action items. They are fine, but what do we need to do with these new insights
    9. Remember that this notebook isn't necessarily for us or Mitch, but is for someone to read later in the patent process
    10. Make sure all of the advisor meetings are in the notebook
    11. You want to make sure that the device can be reproduced from the notebook
    12. If something isn't reported in the notebook, it didn't happen. Make sure everything is documented

Conclusions/action items:

There is a fairly serious plan to get a stainless steel rendering of our prototype. This will need to be looked into over winter break, because this process is expected to take about a month. The discussion about the notebooks will definitely be applied to all of our individual entries to be put in the next few weeks before the last notebook check. The main takeaway is that we need to make sure there is as much detail as possible in our following entries.

11/18 Advisor Meeting

ASHLEE HART - Dec 07, 2021, 6:02 PM CST

Title: 11/18 Advising Meeting

Date: 11/18

Content by: Ashlee

Present: Ashlee, Kate, Mitchell, Avani, Professor Tyler

Goals: Write out the discussions held and information learned at the advisor meeting for this week

Content:

- Mitch is getting measurements from the Weitlaner retractor we now have in our posession
- A google form survey has been created for ergonomic testing with clinicians
- Look into the elastography of benign as well as cancerous tumors of the thyroid
- Make sure to send out progress reports out either the morning or middle of the day of our meetings
- Send over the testing protocol draft and receive notes from Mitch
- Start testing in two weeks
- ibid: as went before; in reference to previous comments
- There is a concern about getting enough clinicians to feel out the retractor in the time we have, so start arranging for testing availability now
- Have Dr. Doubelday recommend contacts to reach out to for ergonomic testing

Conclusions/action items:

The team has a pretty solid plan for testing, we just need to get revise the protocol based on comments made by professor Tyler. The team plans to reach out to Dr. Bersu to see if he has any connections to the anatomy lab, and hope to get in before the semester ends. If we cannot get time in a gross anatomy lab before the end of the semester, we will be able to do it at the beginning of next semester with, hopefully, a stainless steel prototype. Organ analog tissue is also to be conducted starting the weekend of 12/4

12/8 Advisor Meeting

KATE EICHSTAEDT - Dec 08, 2021, 8:39 PM CST

Title: Advisor Meeting

Date: 12/8

Content by: Kate

Present: Whole team and advisor

Goals: Go over the draft of the poster for poster presentations and receive feedback

Content:

- Poster looks good in general; but there are too many words
  - for the abstract; cut out any unimportant or redundant details
    - also increase the size of the text, consider changing the font to a sans type fond
  - for the problem statement, cut out mention of 'the client wants/needs'
  - for figure 1, move to background, move figure 2 up to the problem statement
    - possibly annotate this image just so the viewer knows they are looking at a neck
  - for design process, increase the font size of the pie chart labels
  - for the final design section
    - change bullet list into a, b , c... then annotate the image with those so the viewer knows what to look at
    - also, make sure the viewer knows what the blown up right image is of the retractor tip
  - for testing and results
    - include a graph
    - in figure caption, explain left most image is raw image, middle image is image in Kinovea(decreases resolution)
  - for conclusion - change title to discussion, that would be more fitting
  - for future items, possibly include changing locking mechanism to be a little better?

Conclusions/action items:

To conclude, the team had a very good meeting with Prof. Tyler today in the MakerSpace. We went over our first draft of the poster for Friday and things to change so our presentation will be better. For action items, we are going to make the necessary changes to our poster and print our poster. Also, we are going to meet as a team on Thursday to run through the presentation a couple times.

Design Matrix 10/1/21

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:40 PM CDT

Title: Design Matrix

Date: 10/1/2021

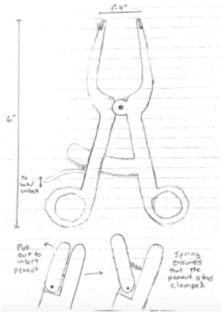
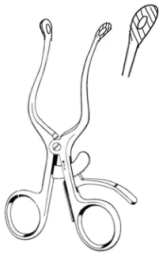
Content by: Avani

Present: Avani, Ashlee, Kate, Mitchell

Goals: Explain the criteria used to evaluate the designs on and create the design matrix.

Content:

- 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.
- Grip on the thyroid. How well the design will be able to grip the thyroid.
- 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		**Shods**		**Springs**		**Treads**	
Criteria	**Weight**						
Safety	25	4/5	20	5/5	25	5/5	25
Ease of Use	20	3/5	12	3/5	12	5/5	20
Grip on the Thyroid	20	4/5	16	4/5	16	3/5	12
Adaptability	15	5/5	15	1/5	3	4/5	12
Ease of Fabrication	10	3/5	6	4/5	8	5/5	10
Cost	10	3/5	6	4/5	8	5/5	10
Total	**100.0**	**75**		**72**		**89**	

Conclusions/action items: The treads design scored the highest and after discussion as a team, with our client and advisor, is the design we will be moving forward with as our final design.

Final Design: 12/1/21

AVANI LALL (aklall@wisc.edu) - Dec 14, 2021, 10:31 PM CST

Title: Final Design

Date: 12/1/21

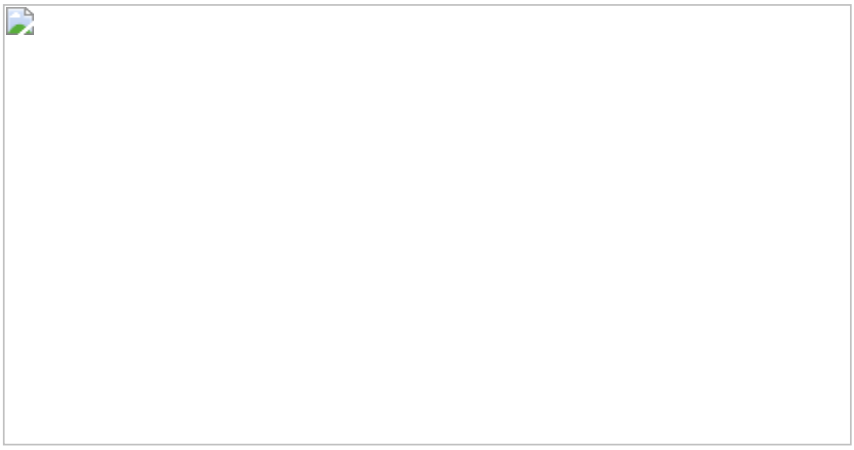
Content by: Avani

Present: Everyone

Goals: The team created a SolidWorks model of the final design.

Content:

After evaluating each design using the design criteria of the design matrix, the Treads design will be used as the proposed final design. This design scored highly in almost every category of the matrix.



- All-in-one reusable design with no disposable components
- Consists of the original Weitlaner retractor ratcheting system
- Ergonomic handle allows for single-handed use
- Tips on this design are modified into circular metal rings.
- Tips will have an inward angle which will aid in the retraction of the thyroid from multiple points.

Conclusions/action items: Print the device using the Makerspace 3D printer.

Expenses

KATE EICHSTAEDT - Dec 08, 2021, 8:50 PM CST

Title: Expenses

Date: 12/8

Content by: Kate

Present: Kate

Goals: Upload a screenshot of the expenses from the google sheet

Content:

Below is a screenshot from the google sheet where we have been keeping track of our expenses. So far, we have purchased two weitlaner retractors from amazon. Both of these were 7.99 USD. Additionally, we have 3-D printed roughly 5 models of our device which are approximately a dollar each time. Our semester total expenses are roughly 20.98 USD

Items	Quantity	Cost	Link	Total
Weitlaner retract	2	7.99	https://www.ama	15.98
3D printing	5	1	N/A	5
				20.98

Here is the link to the amazon weitlaner: https://www.amazon.com/G-S-WEITLANER-RETRACTOR-INCHES-QUALITY/dp/B077TP8R8R/ref=pd_lpo_2?pd_rd_i=B077TP8R8R&psc=1

Conclusions/action items:
To conclude, keeping track of our expenses throughout the semester is very important so we know we do not exceed any budget and so that we may be reimbursed for any necessary expenses. For action items, we will continue updating this google sheet through the rest of the semester incase anything else is purchased. For next semester; we will likely make a new google sheet for new expenses then.

Testing Protocol

KATE EICHSTAEDT - Dec 08, 2021, 8:54 PM CST

Title: Testing protocol

Date: 12/8

Content by: Kate

Present: Whole team

Goals: Upload a copy of the testing protocol we created in google drive

Content:

Thyroid Retractor Team Testing Protocol

A. Organ Tissue Analog Test

The organ tissue analog test will serve as a qualitative test that will allow insight into the effectiveness of the team's thyroid retractor. A raw chicken breast will be used in this test, as it has the ability to mimic the weight and shape of a thyroid gland with modification.

1. All participants of this testing must put on a pair of disposable latex, nitrile, or vinyl gloves to protect themselves while working with raw meat.
2. Obtain 0.5 kg (approx.) raw chicken breast
3. Since thyroids weigh between 10 and 20 grams, cut one 10g, 15g, and 20g, pieces from the chicken breast to serve as mock thyroid glands
4. Set up a video camera to record the tests conducted on each piece
5. Superglue a line down the center of the 10g piece to a paper towel roll that has a diameter of approximately 0.8 inches, as this is the typical diameter of the trachea.
6. If the mock thyroid is dry or sticky, spray with a small amount of water to mimic in body fluid conditions
7. Using the Adapted Weitlaner prototype, adjust the prongs to a width (approx. 5-7 cm, to account for normal and larger sized thyroids) where both prongs have direct contact with the chicken breast piece.
8. Begin to retract the chicken piece and end once the piece has been retracted past the middle of the paper towel roll. While thyroidectomies take approximately 1-2 hours, the thyroid retraction itself should only take approximately 2-5 minutes.
9. Through the retraction, note any slippage and any unideal occurrences. Unideal occurrences include the retractor losing grip of the chicken breast, as well as the chicken breast folding over the retractor.
10. Repeat steps 3-6 for the 15g and 20g chicken pieces
11. Use a surface cleaner across any items that have come into contact with the raw chicken breast
12. Once the testing has been conducted, note any changes that may need to be made to the device

B. Computational-Aided Testing

Use quantitative frictional constants and Young's modulus values for healthy and diseased thyroids to computationally model the possible interactions between the device and thyroid tissue. Possible tests will include:

- Maximal normal force to rupture healthy and diseased tissues
- Maximal shear force to rupture healthy and diseased tissues
- Stress distributions on the device and tissue to determine possible failure points and optimize the interactions between the two

C. Ergonomics Client Test

- Allow the client and other clinicians to experiment with and handle the device to improve the ergonomics and efficiency.
- Assess the functionality of the locking mechanism and the ease of adjusting the distance between the distal ends of the device
- Iterate additional prototypes using clinical advice until the client is satisfied with the ergonomics of the proximal non-tissue contacting portion
- Have the client and any other clinicians fill out an ergonomics satisfaction survey

Other possible tests:

- Biosafety and bio contamination testing. Because of the small grooves on the tissue contacting portion of the device, biocontamination is a possibility if the device is not properly sterilized. A possible test of the ability of autoclaving to sterilize the device includes: Submerging the device in a non-newtonian fluid representative of blood that contains proteins from a manufacturer. The device is then stained with autofluorescent antibodies and autoclaved. The device could then be viewed using an epifluorescence microscope to assess sterilization.
- Simulated thyroidectomy surgery on a cadaver with the client or

Conclusions/action items:

Above is a list of all the possible tests we are going to perform in order to show proof of concept for our device. This semester for our proof of concept; we pursued the mock thyroid retraction using a chicken breast cut into a butterfly shape to resemble a thyroid. For action items, we are going to upload some of our files and images from experimentation to lab archives.

Ergonomics Testing Survey

AVANI LALL (aklall@wisc.edu) - Dec 14, 2021, 10:36 PM CST

Title: Ergonomics Testing Survey

Date: 11/29/21

Content by: Avani

Present: Everyone

Goals: The team wants to create a survey using Google Forms for use when we have a physical device.

Content:

Here is the link to the Google Forms:

https://forms.gle/ksr18a8NLRE5XUtf7

Conclusions/action items: With a physical prototype, we want this survey to be filled out by the client and eventually more physicians and then we can evaluate the results and make any changes necessary.

Chicken Testing

KATE EICHSTAEDT - Dec 08, 2021, 8:56 PM CST

Title: Chicken testing

Date: 12/5/21

Content by: Kate Eichstaedt

Present: Whole team

Goals: Conduct the chicken breast testing

Content:

Steps:

1. Acquired necessary equipment
    1. two chicken breasts
    2. two cardboard paper towel rolls
    3. tape
    4. hot glue gun and glue
    5. scale
    6. 3-D printed retractor
    7. Pin or thumb tac
    8. Video recording device
2. cut paper towel roll to appropriate diameter; this creates the mock trachea
3. Cut chicken breast into appropriate size to represent thyroid shape and weight; this creates the mock thyroid
4. Using hot glue, glue the mock thyroid to the mock trachea
    1. Make sure to record the length and weight of the mock thyroid
5. Create a motion capture marker using the thumb tac
6. Insert the thumb tac into the center of the mock thyroid
7. Set up recording device in a stable position
8. Record thyroid retraction; make sure that the thumb tac is visible
9. The rest of the experimental protocol involves uploading the video to kinovea and doing motion capture analysis

Conclusions/action items:

To conclude; the mock thyroid retraction testing went very well. The device was able to retract the 'thyroid' with minimal slippage or folding; which is the intent of our device. For action items, I am going to upload some of the images from our testing procedure to lab archives.

Chicken Testing Images

KATE EICHSTAEDT - Dec 13, 2021, 11:17 PM CST

Title: Chicken testing images

Date: 12/13

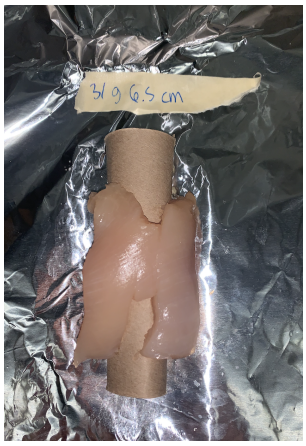
Content by: Kate

Present: Whole team

Goals: Upload some of the images that were taken during the mock thyroidectomy with chicken breast used as a mock thyroid.

Content:

First, there are three images below of the set up of the mock thyroid on the mock trachea. Above each model are tags that indicate the dimensions of each sample. Each mock thyroid was trimmed to be within the standard range for an adult thyroid in regards to weight and length. In the right most image, we attempted to trim the chicken breast to look like a native thyroid; which is typically butterfly shaped.



Images 1, 2, & 3 respectively. Each image above shows a chicken breast that was cut into a mock thyroid and then glued to a cardboard roll that was cut down into the dimensions of a trachea. Above each model is a tag that denotes the weight and length. The model in image 3 shows the full thyroid in the typical butterfly shape.

The image below shows the full testing set up. A phone was placed in a secure stand. We used a cardboard back drop for simplicity of kinovea analysis.

Image 4: Testing set up

Conclusions/action items:

To conclude; the testing for the device went very well. We had slim options for testing due to availability issues and problems getting into an anatomy lab due to final exams and covid. For action items, I am going to use some of these images in our final report.

PDS

ASHLEE HART - Oct 19, 2021, 8:16 PM CDT

BME 400:
Preliminary Product Design Specification

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

Advisor: Dr. Mitchell Tyler

Client: Dr. Amanda Doubleday

Date: September 24, 2021

Function:

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

Client Requirements

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

Design Requirements

1. Physical and Operational Characteristics

a. *Performance Requirements:*

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

b. *Safety:*

The only people allowed to operate with and use the device on a live patient will be trained medical professionals, as to keep the safety of the patient at the utmost importance. Operating on patients when untrained in a device/procedure would be medical malpractice, that could result in a range of injuries surrounding the thyroid. People using any type of medical device they are not trained in have the ability to cause Computational and physical testing of the device's ability to endure forces of the hand applying pressure during surgery will be conducted. These tests laid out will ensure the safety of the surgeons using the device, as the device will be tested to make sure it won't break while in use. The device is not required to be permanently biocompatible, because it will only be in contact with the patient temporarily. However, the device must not be toxic, or susceptible to leaching of potentially harmful chemicals into the body. Finally, blunt edges and ends should be preferred over sharp edges, so as to avoid any unintended perforation or trauma caused by the device.

c. *Accuracy and Reliability:*

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

d. *Life in Service:*

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

e. Shelf Life:

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

f. Operating Environment:

The device will be used in a surgical setting. The likely temperature that the device will be in is somewhere between room and body temperature, depending on the point in the procedure. This gives an operating temperature between 22° C and 37° C [5]. For pressure, the likely pressure the device will be experiencing is around 1 atmosphere [5]. From a biochemical standpoint, this device must be able to withstand corrosion of blood and fluid. The device will be used by surgical staff so it is important for the staff to receive adequate device training. Increased temperature and pressure will occur during autoclave sterilization. Autoclaving is a physical method of disinfectant and sterilization that uses steam, pressure, and time. Under autoclaving procedures, the temperature can reach up to 121° C, and 1 atmosphere, which the device must be able to withstand [6]. Autoclaving will only be for the reusable portion of the device, manufactured from a material capable of withstanding the conditions.

g. Ergonomics:

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

h. Size:

The current device being used is a clamping forceps with a small "peanut" sponge to contact the tissue and reduce surface forces. This device is approximately 8" in length [7]. Typical forceps and retractors used in surgery range from 8 to 12 cm. The device should be similar in length to these devices currently in use, so as to be easily adopted by surgeons utilizing other methods of thyroid retraction. Thyroids are anywhere from 4-6 cm and the device should have the two prongs 2-3 cm apart on average, with an adjustable range spanning from 1-4 cm, so that it may be used on a variety of patients and thyroid sizes. Measurements will be taken on current surgical forceps and retractors to determine accurate dimensions. Adult human hand anthropometry will be taken into account when designing the device, as well as when testing the device for ergonomics with surgeons.

i. *Weight:*

The weight of the device should be close to that of the weight of the forceps used with the peanut currently, or typical surgical forceps and retractors, at around 40.82 grams [8]. A small increase of weight will be allowed due to the addition of the second prong and tissue-contacting area, although the device should not be sufficiently heavy as to be difficult to operate by a surgeon. Measurements will be taken of a standard Weitlaner retractor to determine an accurate target weight for the device.

j. Materials:

The device will be made of stainless steel, as the current device and most modern surgical instruments are. In the medical device industry, stainless steel grade 316 is commonly used for medical grade surgical devices due to their high levels of nickel and chromium [9]. These levels of nickel and chromium allow for endurance through sterilization procedures, as well as tolerance of corrosive material like bodily fluids. Stainless steel provides greater durability because it is anti-bacterial, non-corrosive and rust-resistant. It is also autoclavable, which allows it to be sterilized quickly and repeatedly. The durable stainless steel construction means the device will last and remain dependable for medical use [8].

k. Aesthetics, Appearance, and Finish:

The medical device should have the appearance of a typical surgical instrument. The device should have a highly polished, or mirror finish in order to prevent potential staining [10]. Also, the device should have a satin finish to prevent any bio-contaminants from residing in any ridges that may be present without a satin finish. Other than this requirement, aesthetics are less critical to the design than other relevant criteria.

2. Production Characteristics

a. *Quantity:*

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

b. Target Product Cost:

The target cost of this device should be comparable to typical surgical forceps, although this cost varies greatly. Depending on the supplier and website, retail prices for surgical forceps and retractors can range from $5.00 to around $50 from medical supply companies [11]. For this design, the target cost of production will be between $5.00 and $10.00 per single thyroid retractor. Flexibility of cost will be taken into account to accommodate for the extra forceps incorporated into the device. Additionally, this is the final target cost of production, without development or prototyping taken into account.

3. Miscellaneous

a. *Standards and Specifications:*

The device falls under the category of a Class II medical device as it is substantially equivalent to another similar legally marketed device that already has FDA clearance [12]. This product will need to be FDA cleared in order for surgeon and patient use and is protected under FDA regulation 21 CFR Part 807. The device and the surgery must comply with CDC regulation regarding sterile procedures. During testing and clinical trials, the device must be tested under IRB regulations at the university level, and FDA regulation at the federal level.

b. *Customer:*

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

c. *Patient-related concerns:*

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

d. *Competition:*

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

References

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

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

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Gantt Timeline

AVANI LALL (aklall@wisc.edu) - Dec 14, 2021, 10:39 PM CST

Title: Gantt Timeline

Date: 12/14/21

Content by: Avani

Present: Everyone

Goals: Include the updated Gantt chart as a final timeline for the project.

Content:

Here is the link to the Gantt chart:

https://docs.google.com/spreadsheets/d/1RCWLwGdQ6AsNwlBMC2M6E7sAFcZWpX8aC4e33-Ts0Sk/edit?usp=sharing

Conclusions/action items: Come up with goals for next semester and update.

Thyroidectomy

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)

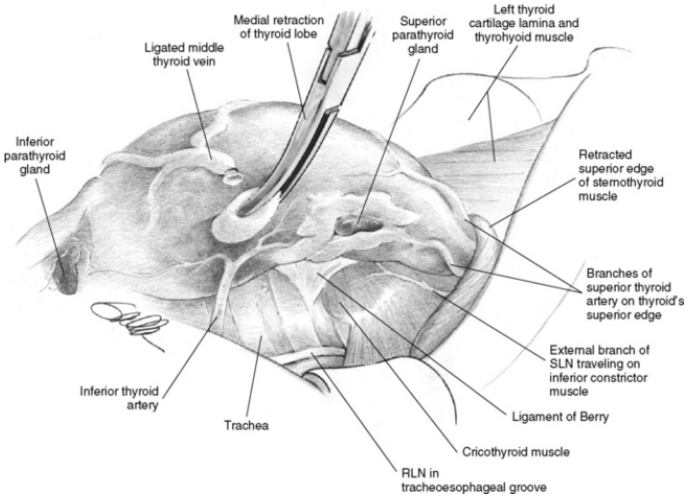


Figure: Medial retraction of one lobe of the thyroid during surgery with a peanut, showing the relevant anatomy near the gland (Randolph, G.W., Clark, O, Principles of Surgery, Chapter 30)

References:

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

Conclusions/action items:

Use the recorded information to inform design choices in the future

Thyroid Anatomy and Physiology

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

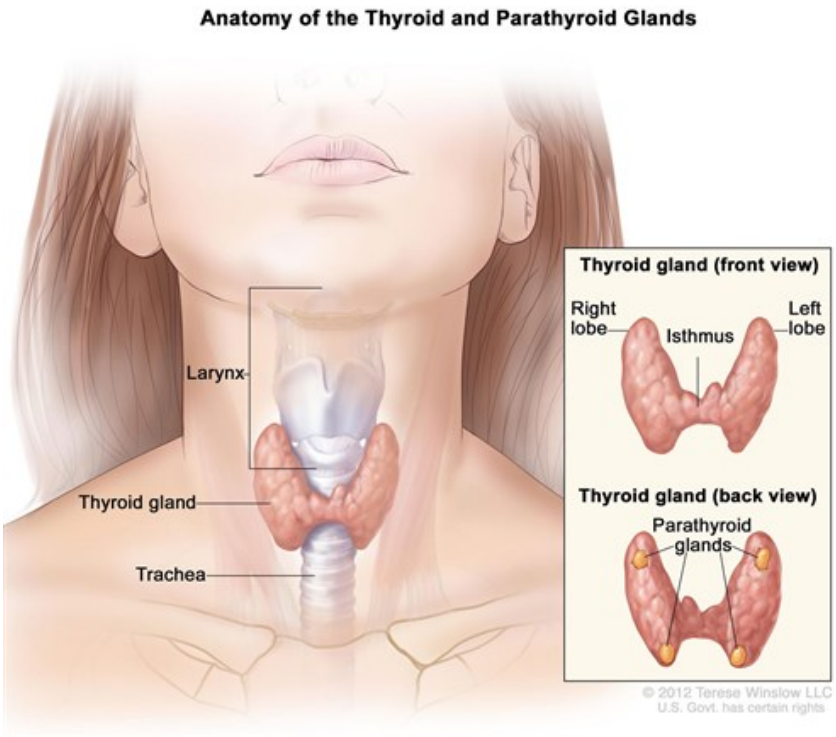


Figure: Anatomy of the thyroid and parathyroid glands (Endocrinesurgery.ucsf.edu. 2020. *Endocrine Surgery - Thyroidectomy*. [online] Available at: <https://endocrinesurgery.ucsf.edu/conditions--procedures/thyroidectomy.aspx> [Accessed 5 February 2021].)

References:

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

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

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.

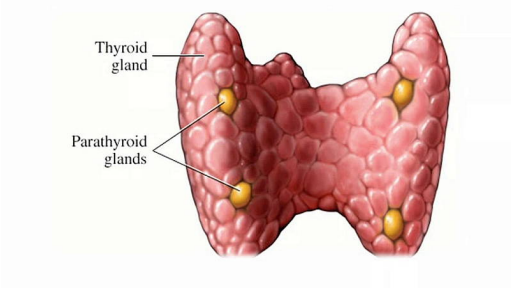


Figure: Location of the parathyroid glands on the posterior of the thyroid gland. Image source: Thyroid Clinic Sydney,

References:

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

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

Conclusions/action items:

Human Grip Strength

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.

Thyroid Mechanical Properties

Mitchell Josvai - Oct 20, 2021, 1:09 PM CDT

Title: Thyroid Mechanical Properties

Date: 9/15/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

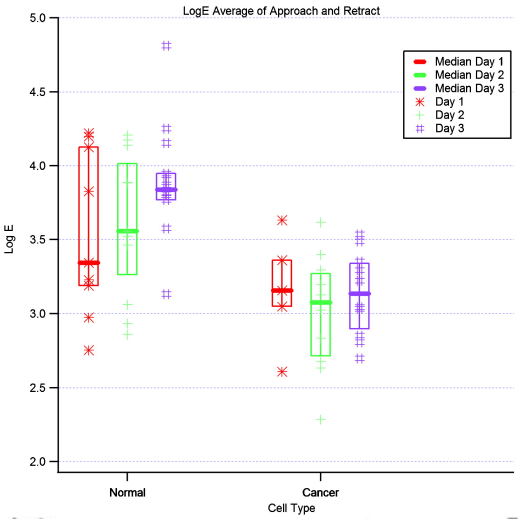
Goals: Research and record data on the mechanical properties of healthy and diseased thyroids

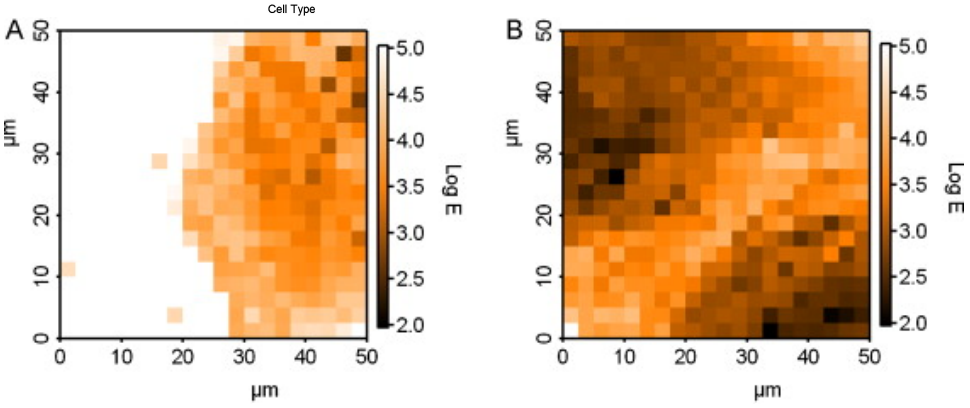
Content:

Because the device we are engineering is a soft tissue-contacting device, the mechanical properties of the tissue in question are important to the design criteria. If we fail to take these properties into account, there is a possibility of damage or harm to the thyroid or surrounding tissues through slippage or rupture.

Additionally, thyroid surgeries and retractions have many root causes, and can occur with both healthy and damaged thyroids. Because of this, both the properties of healthy and diseased thyroid tissue are relevant.

Prabhune, et al. investigated the mechanical properties of both healthy and malignant thyroids using atomic force microscopy. They found a significantly lower modulus of elasticity in cancerous thyroid cells than in healthy cells. The reported median elastic modulus values of normal cells are in a range of 2211–6879 Pa, and those of cancer cells are in a lower range of 1189–1365 Pa.





The device must be efficacious and prevent harm to cancerous and other diseased cells, which have a modulus that is an order of magnitude lower than healthy cells. For this work, we will assume that diseased tissues may have a modulus as low as 1 kPa.

References:

M. Prabhune, G. Belge, A. Dotzauer, J. Bullerdiek, and M. Radmacher, “Comparison of mechanical properties of normal and malignant thyroid cells,” Micron, vol. 43, no. 12, pp. 1267–1272, 2012.

Conclusions/action items:

Hand Anthropometry

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
(13) Breadth at second joint of digit 3	17.72	20.96	17.09	20.46	15.60	17.84	15.03	17.27
(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	47.62
(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	41.27
(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	51.91	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	42.69
(30) Handbreadth at metacarpals	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.

Mitchell Josvai - Feb 18, 2021, 4:21 PM CST

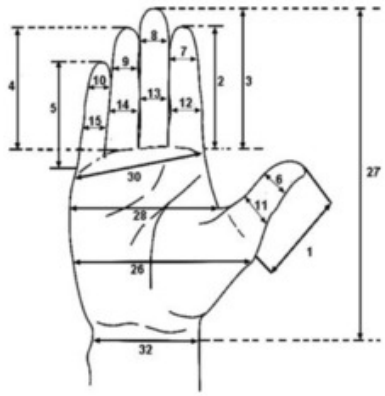


Figure 2 Hand measurements as a diagram.

Figure 3 Hand depth.

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.

Elastic Moduli of Healthy and Diseased Thyroid Tissue

Mitchell Josvai - Nov 29, 2021, 1:52 PM CST

Title: Elastic Moduli of Healthy and Diseased Thyroid Tissue

Date: 11/20/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record information on the elastic moduli of both healthy and diseased thyroid tissues for use in computational modeling and testing

Content:

In order to perform computationally aided analysis and testing of the device in contact with thyroid tissue, the mechanical properties and elastic moduli of the tissue must be quantified for use in the software. The dataset below was acquired to be used to more accurately interpret tissue elastograms of thyroid samples.

Thyroid diseases may present themselves in a multitude of pathologies, and the paper cited analyzed both 24 healthy tissue samples as well as:

1. 2 samples of thyroid tissue with chronic thyroiditis
2. 12 samples of adenomatous goiter lesions
3. 7 samples of follicular adenoma
4. 19 samples of papillary adenocarcinoma (PAC)
5. 3 samples of follicular adenocarcinoma (FAC)

The samples were tested in uniaxial compression within 3 hours of surgical removal. Each sample was tested at precompression strains of 5%, 10% and 20% and applied strains of 1%, 2%, 5% and 10%. The modulus of elasticity exhibited some heterogeneity dependent on the precompression and applied strains, but displayed significantly significant ($p < 0.01$) increases in stiffness at all levels, for all pathologies besides FAC.

Large deformations are common in soft tissues, and this is made more likely with the use of surgical instruments involved in a total or partial thyroidectomy. Because of this, the larger precompression and applied strain values will be used, which demonstrated increased stiffness in comparison to healthy tissue. At 10% precompression and 10% applied strain, the experimental moduli of the sample groups were found to be (in kPa):

1. Normal thyroid tissue = 15.9 ± 5.6
2. Chronic thyroiditis = 114.4 ± 90.2
3. Benign thyroid tumors = 32.3 ± 13.0
4. Papillary adenocarcinoma (PAC) = 213.4 ± 118.2
5. Follicular adenocarcinoma (FAC) = 12.2 ± 2.6

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

Conclusions/action items:

Use the values of healthy and diseased thyroid tissues to computationally model the interaction between the device and thyroid tissue. Attempt to find reported values for the shear moduli and frictional coefficients of healthy and pathologic tissues to improve the model.

Retractors

Mitchell Josvai - Feb 14, 2021, 1:30 PM CST

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	Tip to Jaw	Max spread	Comments	Link
Weitlaner	Stainless	135 mm	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	200 mm	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	More common in abdominal wall procedures. Self-retaining	https://medical-tools.com/shop/balfour-retractors-18cm.html
Golligher	Stainless	102 mm	N/A	51 mm	More common in abdominal operations in the superior region of peritoneal cavity	https://surtex-instruments.com/product/golligher-self-retaining-retractor/

Conclusions/action items:

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

Surgical Sponges

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: <https://www.deroyal.com/docs/default-source/product-literature/surgical-sponges_towels-web.pdf?sfvrsn=f5c00dbd_12> [Accessed 14 February 2021].

Conclusions/action items:

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

Forceps

Mitchell Josvai - Feb 14, 2021, 2:01 PM CST

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 jaw	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	Straight, 3mm OD	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.

Surgical Instrument Materials

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: <https://www.facs.org/-/media/files/education/medicalstudents/common_surgical_instruments_module.ashx>.

Conclusions/action items:

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

Weitlaner Retractor

Mitchell Josvai - Oct 20, 2021, 1:17 PM CDT

Title: Weitlaner Retractor

Date: 9/20/21

Content by: Mitchell Josvai

Present:

Goals: Record information on the Weitlaner retractor

Content:

Each of our final design options has a proximal end based on the Weitlaner self-retaining retractor.

The Weitlaner retractor was first invented by Hans Weitlaner, an Austrian physician. Further research will be conducted on the patent and other relevant intellectual property concerns. The retractor is manufactured from AISI 420 German stainless steel and conforms to ISO 9001, CE-Quality Mark, ISO 13485, FDA and other Quality Standards.

Corrosion resistant and comes in a range of sizes from 11.4 cm (4.5") to 19.05 cm (7.5"). The spread between the jaws of the retractor range from 47 mm to 100 mm, which is greater than the size of the average thyroid, and should be sufficient for our device.

https://www.integralife.com/weitlaner-retractor/product/surgical-instruments-hospitals-surgery-centers-tissue-banks-ruggles-redmond-retractors-weitlaner-retractor

Conclusions/action items:

Model the proximal end of the Weitlaner in a CAD software.

Patents involving Weitlaner

Mitchell Josvai - Oct 20, 2021, 1:28 PM CDT

Title: Weitlaner Patents

Date: 9/30/21

Content by: Mitchell Josvai

Present:

Goals: Research the Weitlaner patent and any other intellectual property concerns involved

Content:

In order to adapt the Weitlaner retractor for our purposes, we must ensure that there are no intellectual property concerns involving the patent that would prevent the manufacturing of our device. I am unable to find an original patent for the Weitlaner through the US patent office, Google patents, or other similar patent search engines. This may be because it was not invented domestically, or because it was first used almost 100 years ago.

There are many patents for adapted Weitlaner retractors with specialized functions, such as:

- Self-retaining retractor with integrated suction and light source (2014): https://patents.google.com/patent/US20170042526A1/en
- Organic Light Emitting Diode Illuminated Surgical Retractor (2011): https://patents.justia.com/patent/20120149992
- Surgical instrument for implanting leads for baroreceptor stimulation therapy (2017): https://patents.google.com/patent/US9839785B2/en?q=weitlaner+retractor&oq=weitlaner+retractor&page=1
- Intermuscular guide for retractor insertion and method of use (2003): https://patents.google.com/patent/US8262571B2/en?q=weitlaner+retractor&oq=weitlaner+retractor&page=1

There are additional current applications or patents granted involving Weitlaner retractors that are adapted for specific purposes. To me, this indicates that if a patent can be filed for an adapted design of the retractor, as long as our device does not infringe on any of these current patents, it will have no intellectual property concerns. Further research and discussion with our advisor and WARF will be required to confirm this.

Conclusions/action items:

Speak with Professor Tyler and eventually WARF to confirm that our design does not infringe on any current patents.

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.

Preliminary Design

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

Title: Preliminary Design

Date: 2/18/21

Content by: Mitchell Josvai

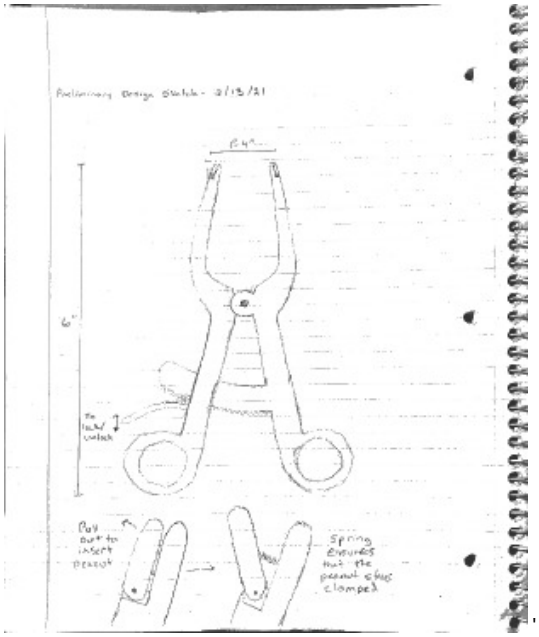
Present:

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

Updated Tip Design Ideas

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

Title: Updated Tip Design Ideas

Date: 3/12/20

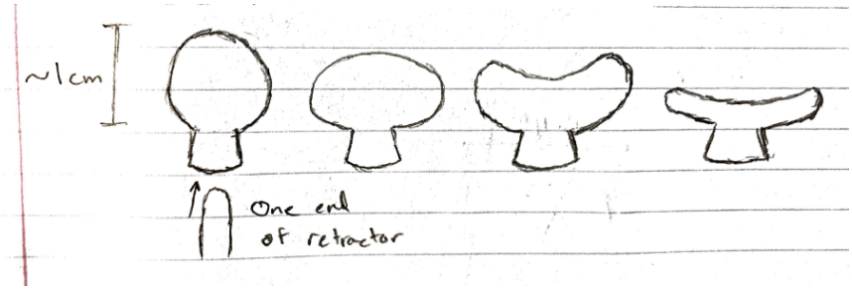
Content by: Mitchell Josvai

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

Updated Final Design Spring 21

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

Title: Updated Final Design

Date: 4/19/21

Content by: Mitchell Josvai

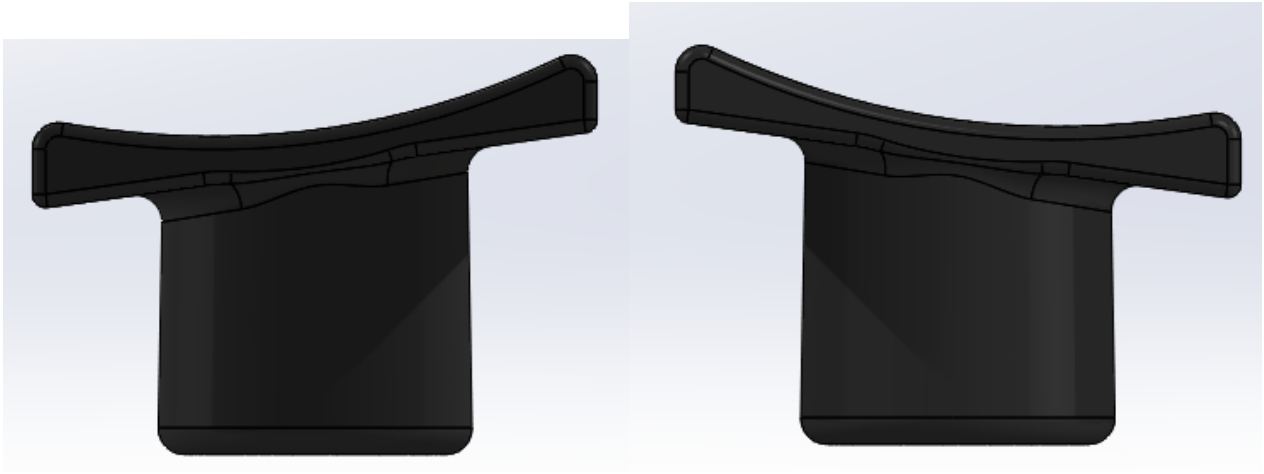
Present: Mitchell Josvai

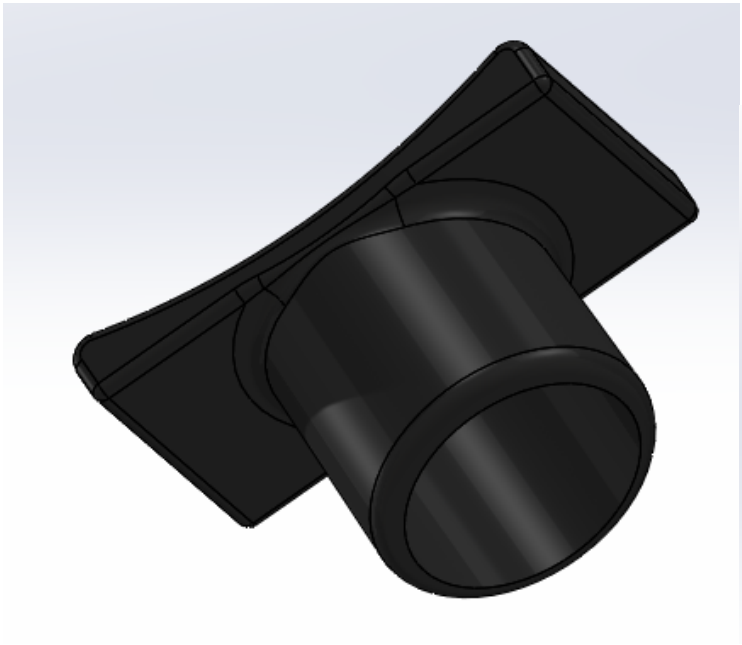
Goals: Record the updated final design

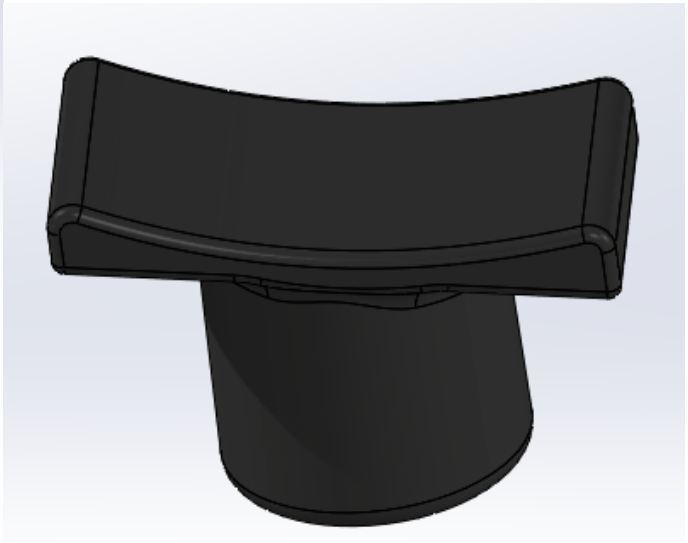
Content:

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.

Rapid Prototyping Polymers

Mitchell Josvai - Oct 19, 2021, 11:30 AM CDT

Title: 3D Printing Materials

Date: 9/12/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Research materials available for 3D printing

Content:

Because our initial prototype will likely be rapid prototyped 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)

High modulus polymers will be considered to best mimic the mechanical properties and density of 420 grade stainless steel, although the material properties will not be fully representative of the final material.

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.

Final Design v1

Mitchell Josvai - Dec 14, 2021, 3:30 PM CST

Title: Final Design v1

Date: 11/20/21

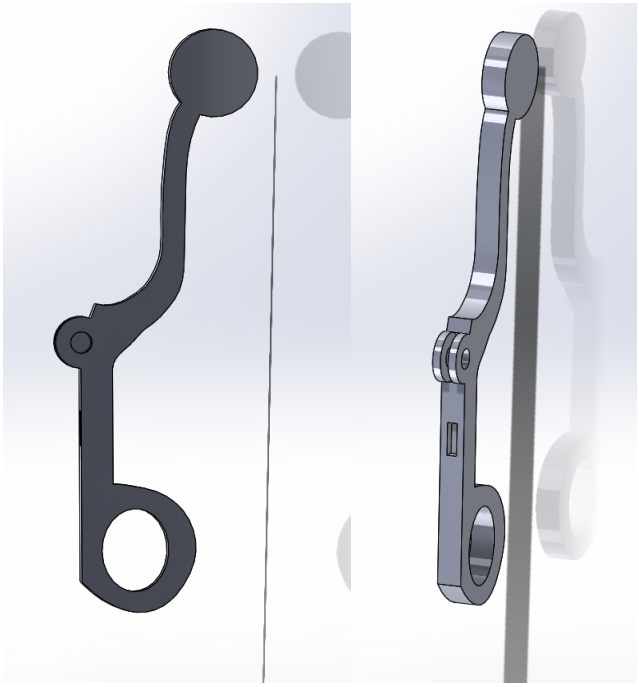
Content by: Mitchell Josvai

Present: Mitchell Josvai

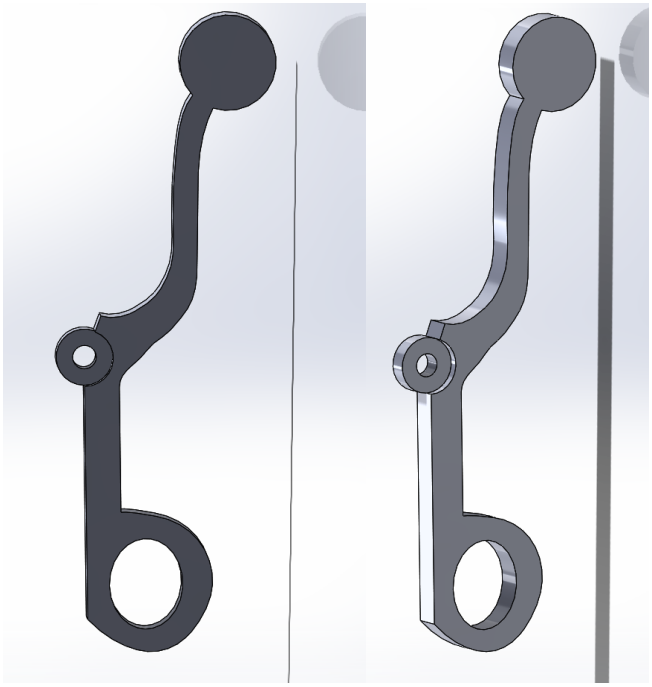
Goals: Record the first iteration of the final design

Content:

File: 'RetractorHalfLeft_v1_NoFillet.SLDPRT"



File: 'RetractorHalfRight_v1_NoFillet.SLDPRT"



Reflection after printing v1:

Tolerance on the 3D printers is poor, the two halves do not fit together well. The corners are too sharp to be used in the OR. The arms have a part near the connection where the design isn't fully smooth.

Conclusions/action items:

Update the model to include the pin that connects the two halves. Add a fillet to smooth the corners. Finalize distal end geometry with the team and Dr. Doubleday.

Final Design v2 and v3

Mitchell Josvai - Dec 14, 2021, 3:42 PM CST

Title: Final Design v2 and v3

Date: 11/ 29/21

Content by: Mitchell Josvai

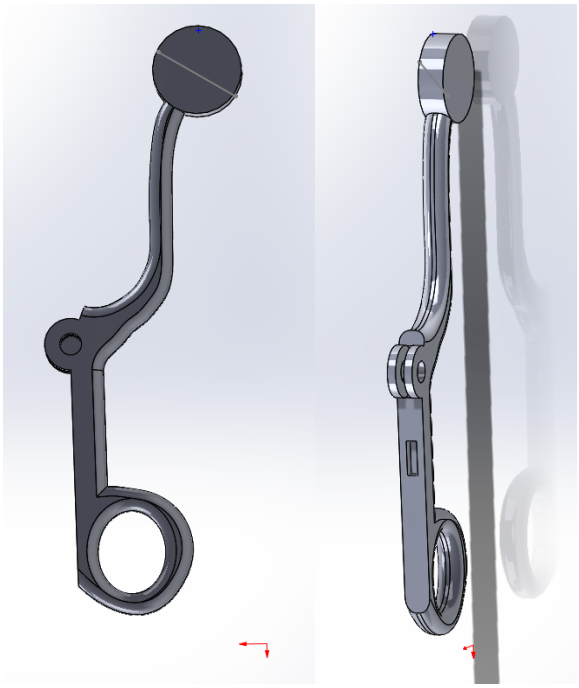
Present: Mitchell Josvai

Goals: Recorded the second iteration of the final design

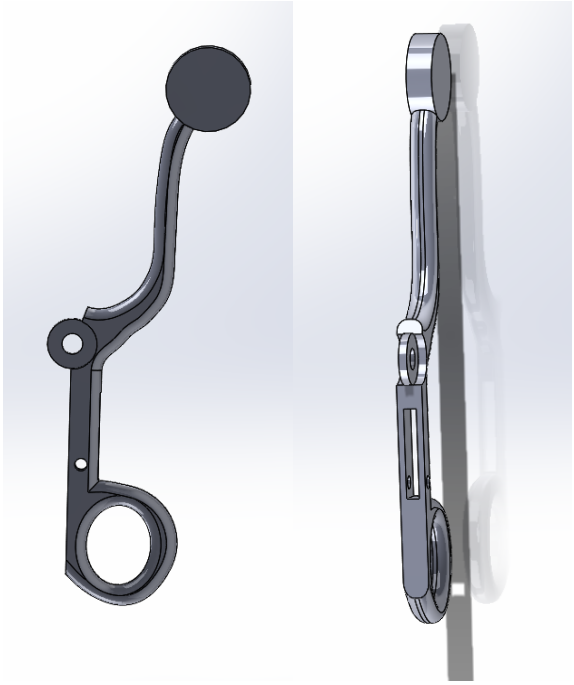
Content:

The only difference between the second and third version of the design was adding a fillet around the distal end geometry. A meeting with Dr. Doubleday is required to decide on the distal end geometry that best suits the procedure.

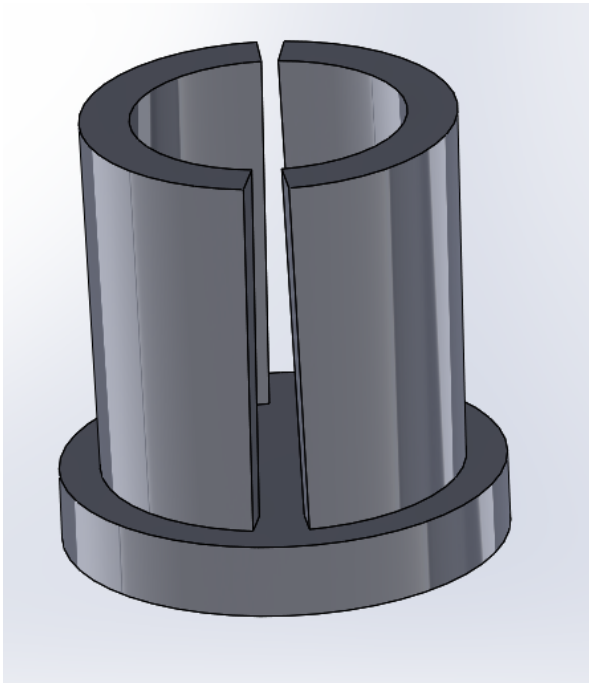
File: 'RetractorLeft_v2_FilletNoEndGeom.SLDPRT'



File: 'RetractorRight_v2_FilletNoEndGeom.SLDPRT'

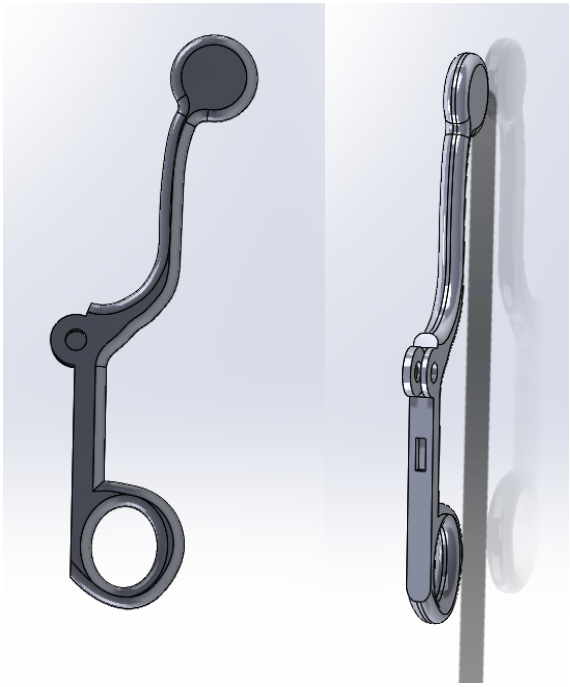


File: 'RetractorCenterPin_5mm.SLDPRT'

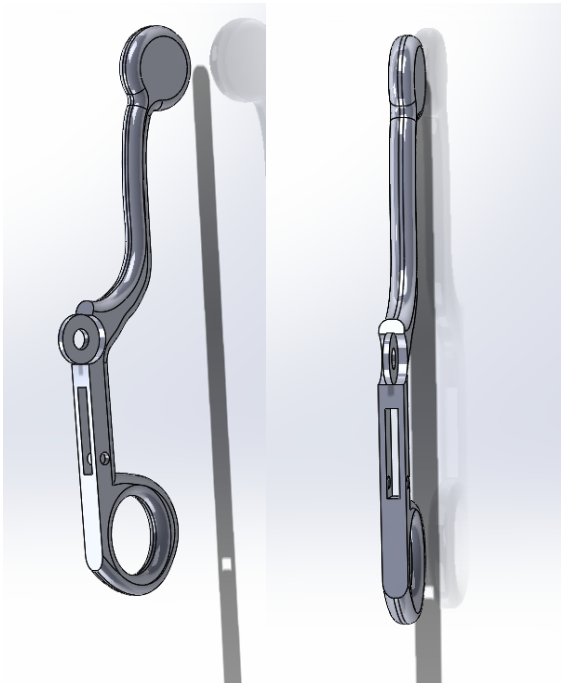


Other versions of the pin were printed with diameters of 4.7, 4.5, 4.3 mm to accomodate the poor tolerance of the 3D printers. The 4.5 mm pin fitsand holds the retractor together the best.

File: 'RetractorLeft_v3_FullFillet.SLDPRT'



File: 'RetractorRight_v3_FullFillet.SLDPRT'



Qualatative reflection after printing:

Pin holds together the retractor but needs to be updated to a standardized screw eventually. Finger holes are slightly small.

Conclusions/action items:

Increase size of finger holes. Make the connecting pin into a screw and get the locking mechanism to work

Final Design v4

Mitchell Josvai - Dec 14, 2021, 3:48 PM CST

Title: Final Design v4

Date: 12/2/21

Content by: Mitchell Josvai

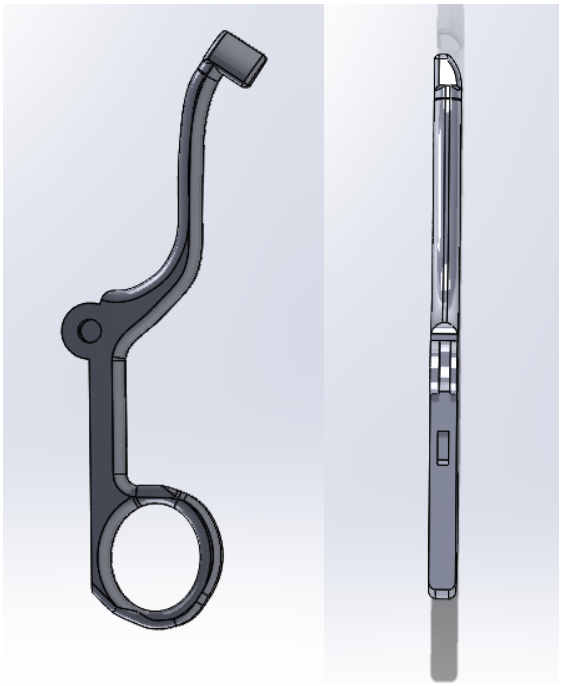
Present: Mitchell Josvai

Goals: Record the 4th iteration of the final design with updated end geometry

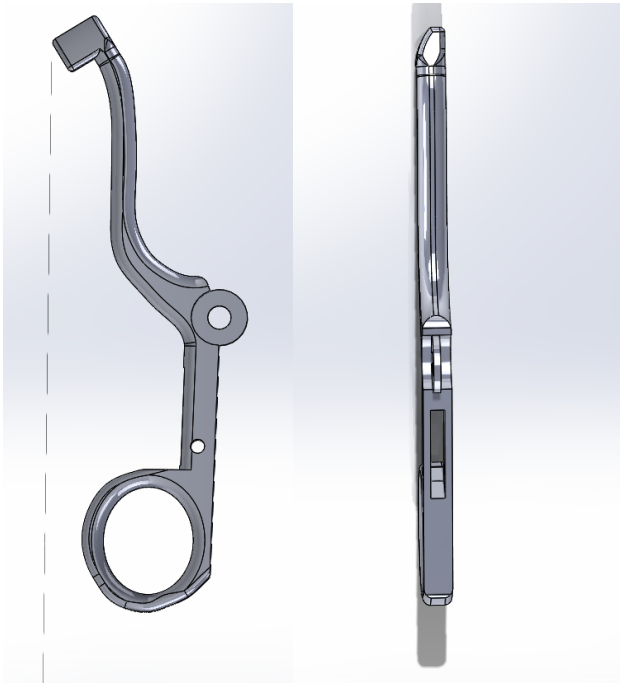
Content:

The 4th iteration of the final design updated the end geometry of the device after our meeting with Dr. Doubleday. Also cleaned up the original sketch to smoothen some of the surfaces of the design. Increased the size of the finger holes to make it more ergonomic.

File: 'RetractorLeft_v4_FullFillet.SLDPRT'



File: 'RetractorRight_v4_FullFillet.SLDPRT'



All fits together well with the 4.5 mm pin well. Still need to update the pins to screws and find a locking mechanism geometry that works

Conclusions/action items:

Finish locking mechanism and make a full assembly in Solidworks and rapid prototyped.

Final Design v5

Mitchell Josvai - Dec 14, 2021, 3:57 PM CST

Title: Final Design v5

Date: 12/6/21

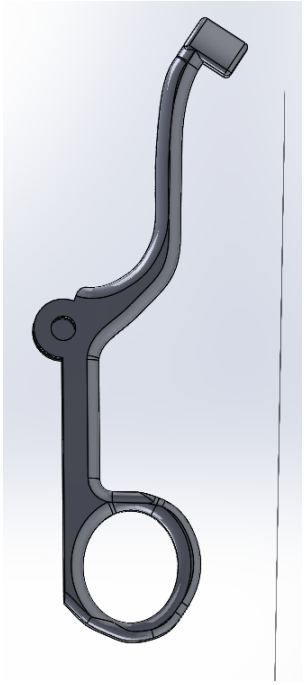
Content by: Mitchell Josvai

Present: Mitchell Josvai

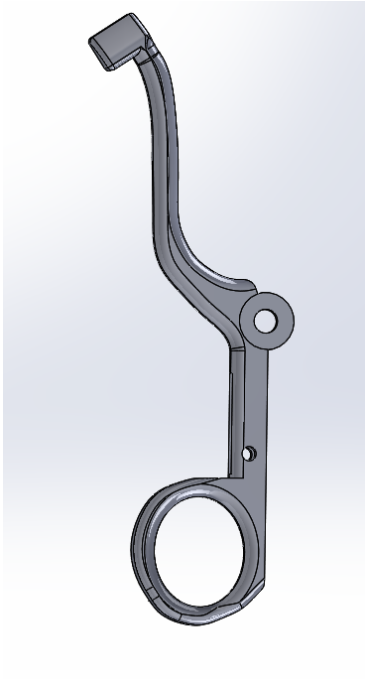
Goals: Record all the compenents of the 5th iteration of the design and the full assembly

Content:

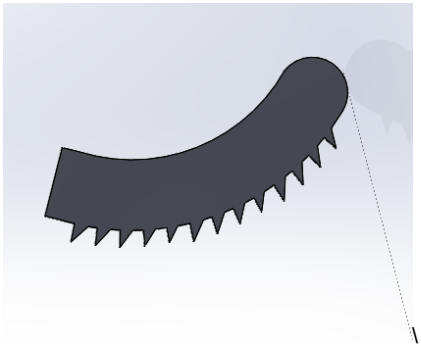
File: 'RetractorLeft_v5_FullFillet.SLDPRT'



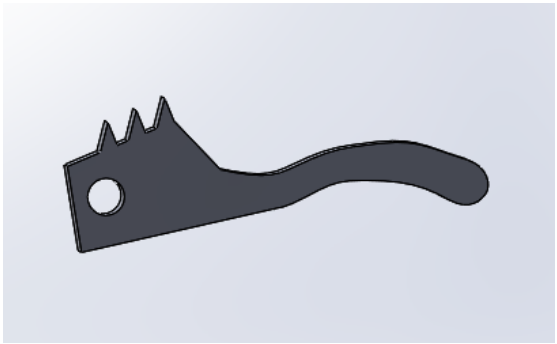
File: 'RetractorRight_v5_FullFillet.SLDPRT'



File: 'LockMechMale_v2.SLDPRT' (Male component of the locking mechanism)

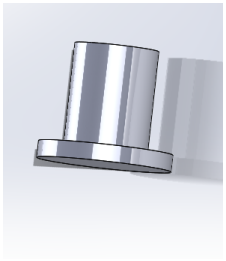


File: 'LockMechFemale_v1.SLDPRT' (Female component of the locking mechanism)

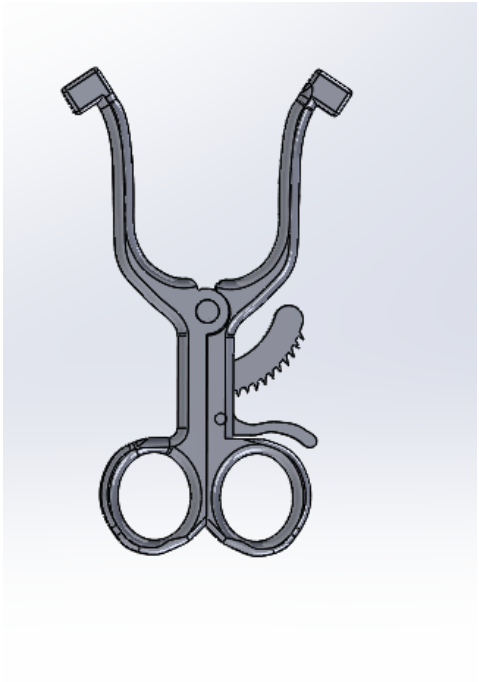


File: 'PinLong_v2.SLDPRT' (5 mm length, 3 mm diameter, connects Female component of locking mechanism to the right half of retractor)

File: 'PinShort_v2.SLDPRT' (5 mm length, 3 mm diameter, connects spring steel to the right half of retractor)



File: 'FullAssembly_v5.SLDASM'



Conclusions/action items:

Print the full assembly for final presentations. Get the final assembly to clinicians to participate in the ergonomics survery. Update as needed in the future.

Biosafety Training

Mitchell Josvai - Oct 20, 2021, 1:03 PM CDT

Title: Biosafety Training

Date: 9/10/21

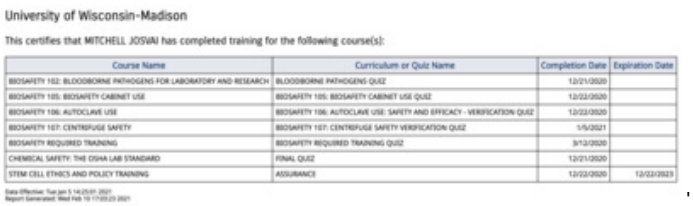
Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Document completion of biosafety lab trainings

Content:

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



University of Wisconsin-Madison

This certifies that MITCHELL JOSVAI has completed training for the following course(s):

Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date
BIOSAFETY 102: BLOODBORNE PATHOGENS FOR LABORATORY AND RESEARCH	BLOODBORNE PATHOGENS QUIZ	12/21/2020	
BIOSAFETY 105: BIOSAFETY CABINET USE	BIOSAFETY 105: BIOSAFETY CABINET USE QUIZ	12/22/2020	
BIOSAFETY 106: AUTOCLAVE USE	BIOSAFETY 106: AUTOCLAVE USE: SAFETY AND EFFICACY - VERIFICATION QUIZ	12/22/2020	
BIOSAFETY 107: CENTRIFUGE SAFETY	BIOSAFETY 107: CENTRIFUGE SAFETY VERIFICATION QUIZ	1/5/2021	
BIOSAFETY REQUIRED TRAINING	BIOSAFETY REQUIRED TRAINING QUIZ	9/12/2020	
CHEMICAL SAFETY: THE OSHA LAB STANDARD	FINAL QUIZ	12/21/2020	
STEM CELL ETHICS AND POLICY TRAINING	ASSURANCE	12/22/2020	12/22/2023

Date Effective: Tue Jan 5 14:25:01 2021
Report Generated: Wed Feb 10 17:03:23 2021

Screen_Shot_2021-02-10_at_5.03.59_PM.png(167.8 KB) - download

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.

Green Permit Documentation

Mitchell Josvai - Oct 20, 2021, 1:02 PM CDT

Title: Green Permit Documentation

Date: 9/10/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record documentation of green permit

Content:

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

IMG_7341_1_.JPG(3.1 MB) - download Green Permit for Mitchell Josvai. Received 1/27/20

Solidworks Testing of Spring Design

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

Title: SolidWorks Testing

Date: 4/19/20

Content by: Mitchell Josvai

Present: Mitchell Josvai

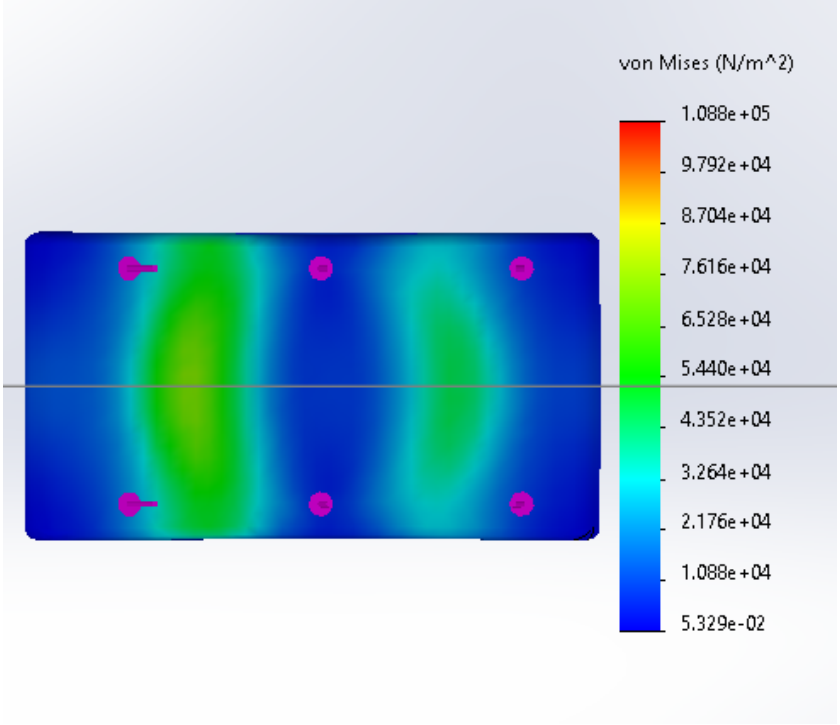
Goals: Record testing done in SolidWorks

Content:

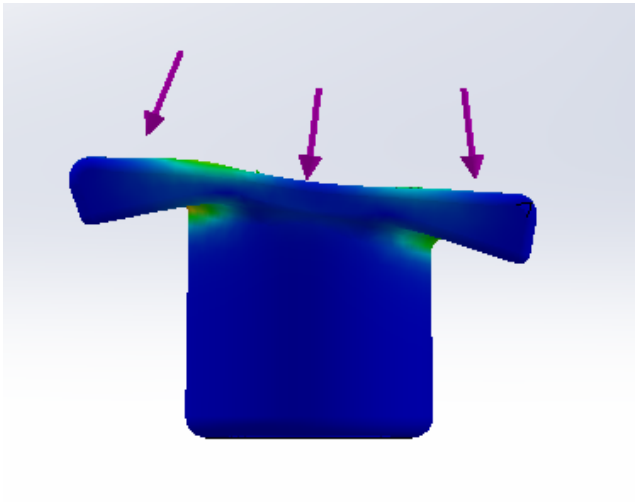
Initial testing was done in SolidWorks. A 1 N distributed load was applied to the surface of the part, and the stress and displacements were analyzed. The interior surface of the hollow cylinder was designated as the fixed surface, because this would be around the retractor, and thus not moving in relation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

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

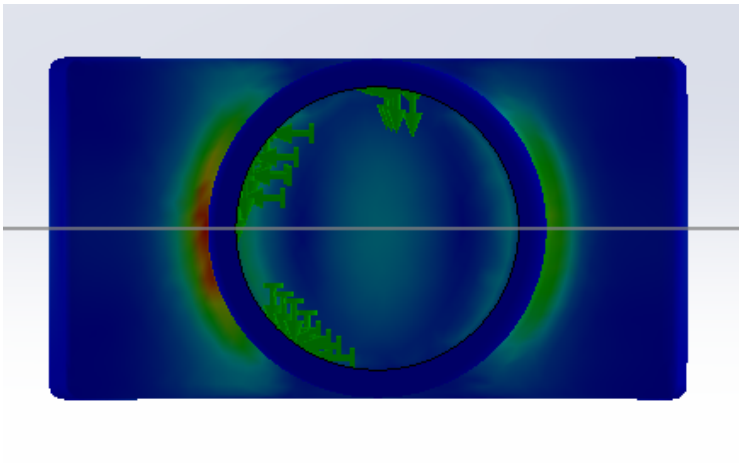
Top view:



Side view:

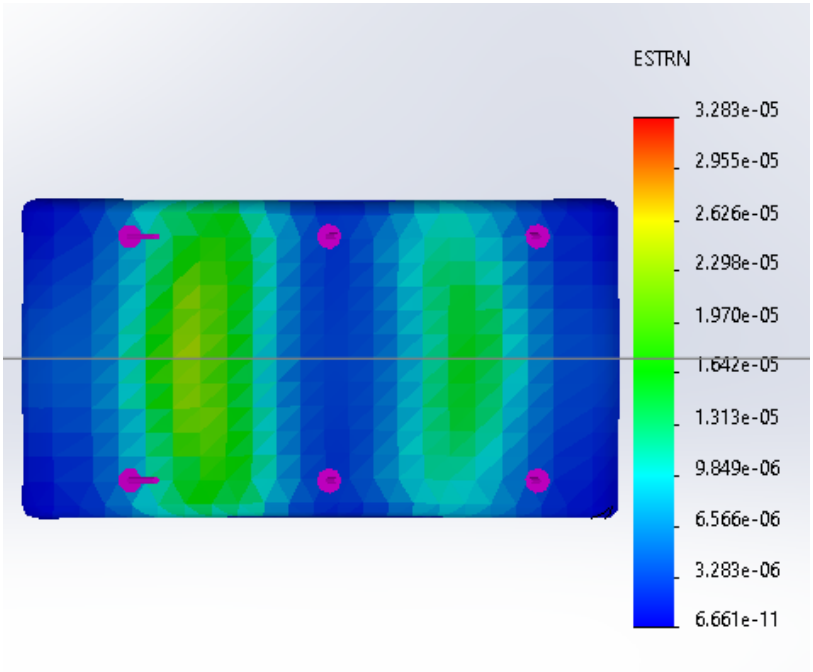


Bottom view:

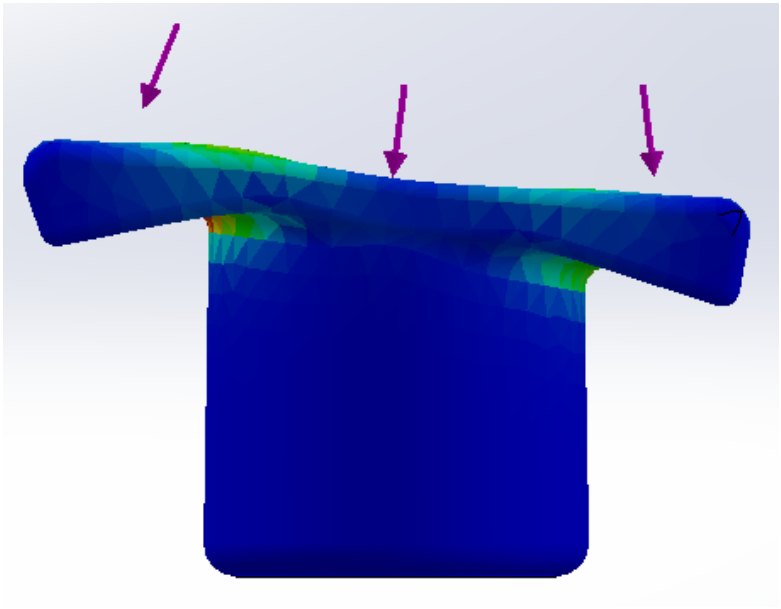


Strain testing: (Scale remained the same for each image, Engineering strain was calculated)

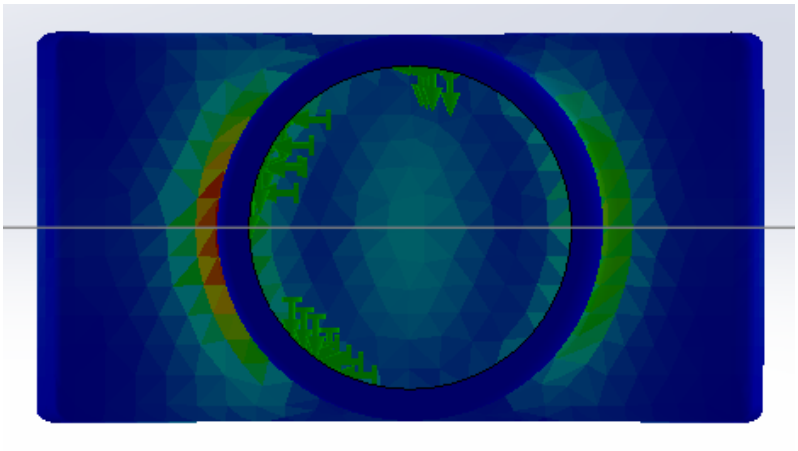
Top view:



Side view:

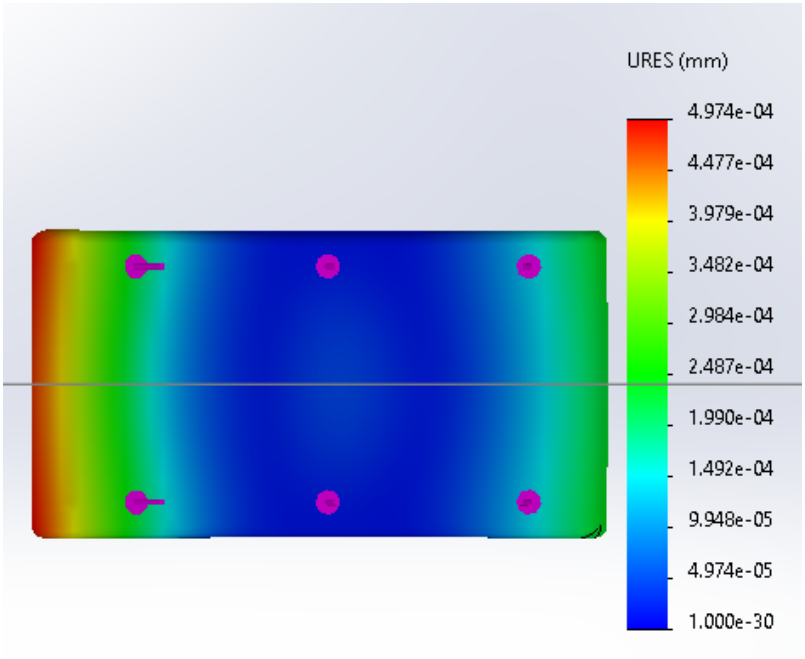


Bottom view:

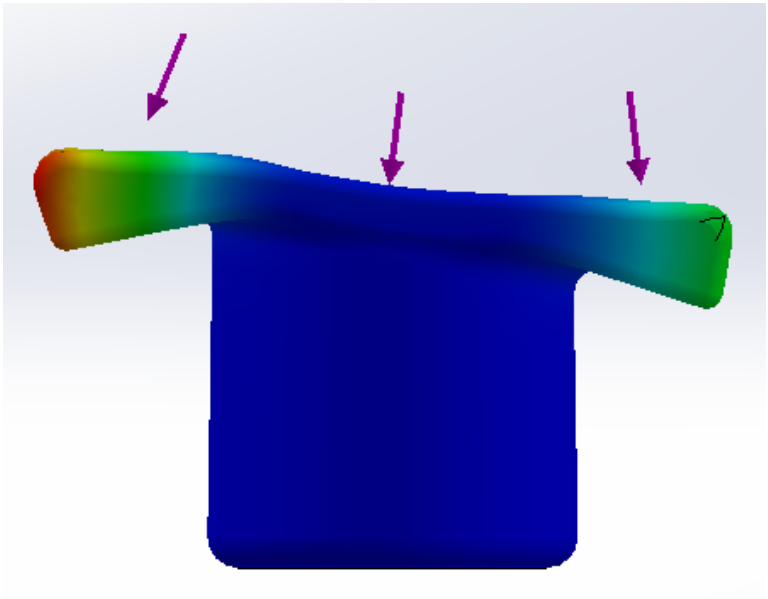


Displacement testing: (Scale remained the same for each image)

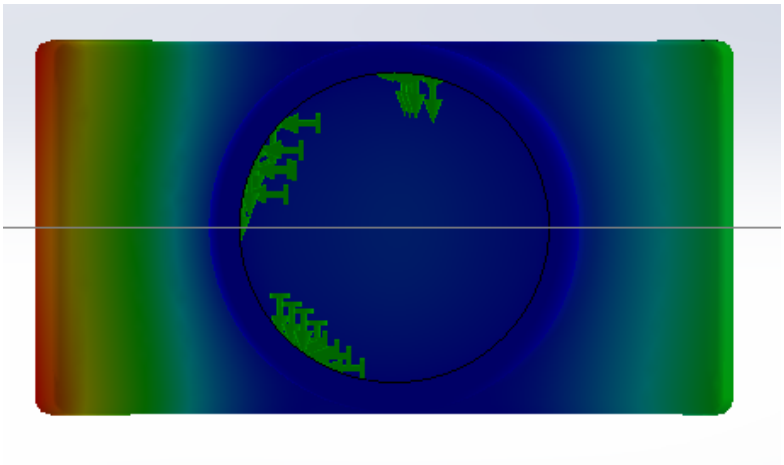
Top view:



Side 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

Analyzing the Tissue Analog Testing

Mitchell Josvai - Dec 14, 2021, 5:11 PM CST

Title: Analyzing the Tissue Analog Testing

Date: 12/3/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record methods for analyzing the tissue analog testing

Content:

The team recorded videos of tissue analog testing in simulated surgery. In order to analyze the video file, I start by uploading it to the free software kinovea.

The software flips the video and lowers the quality, but allows for tracking of the 'optical marker', which is really a thumbtack with a pattern drawn onto it. After it has tracked the marker through the entire video, I can export the data as an .xlsx file to Matlab and analyze it there using the following code for one spreadsheet file:

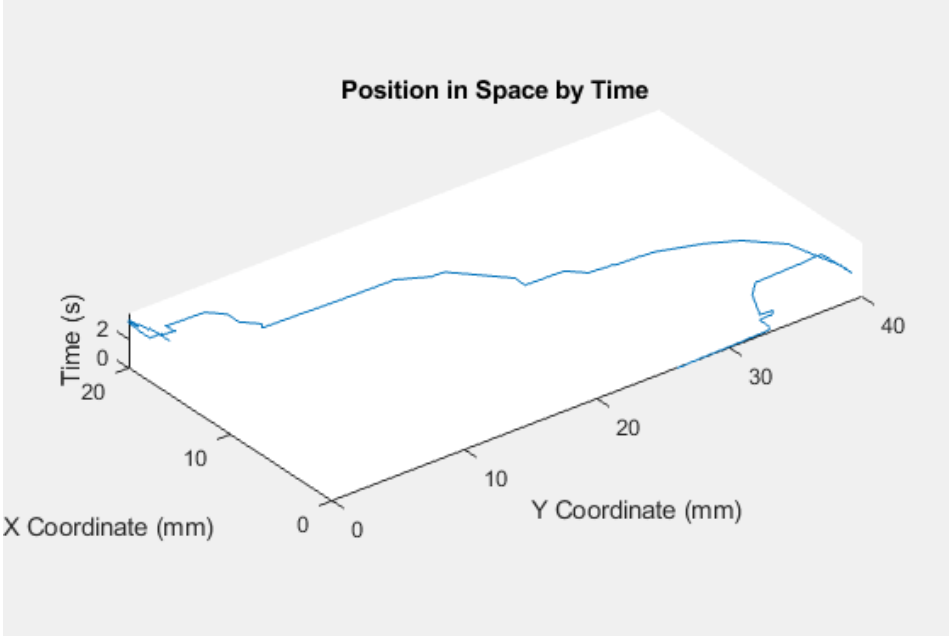
```
clc; clear;
data = readmatrix('IMG_0808.xml.xlsx');

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

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

```
for i = 2:115
    inst_velox(i-1) = (xcoord(i) - xcoord(i-1))/0.033;
    inst_veloy(i-1) = (ycoord(i) - ycoord(i-1))/0.033;
end
for i = 2:114
    inst_accx(i-1) = (inst_velox(i) - inst_velox(i-1))/0.033;
    inst_accy(i-1) = (inst_veloy(i) - inst_veloy(i-1))/0.033;
end

inst_acc_net = sqrt(inst_accx.^2 + inst_accy.^2);
force = 0.02 .* inst_acc_net;
maxacc = max(inst_acc_net); disp(maxacc);
maxforce = max(force); disp(maxforce);
```



The code outputs the above plot of position in the xy plane vs. time, as well as the maximum force of 0.58 N and maximum acceleration of 2.9038 m/s^2.

Conclusions/action items:

I can now use this data to finish filling out the computational model of the interactions between the thyroid and the device.

Developing the Computational Model

Mitchell Josvai - Dec 14, 2021, 5:38 PM CST

Title: Developing the Computational Model

Date: 12/6/21

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record the assumptions and parameters used to develop the computational testing model

Content:

To computationally analyze the ineractions of the thyroid and the device, I will use Solidworks. I begin by tracing a sketch of a thyroid that has been removed from the body, and then making it 3 dimensional to match the dimensions of the human thyroid.

Next, I changed the material constants of the model thyroid to match the constants from the simulation run in Mowlavi, et al. Elastic modulus = 22.3 kPa, density = 1.05 g/cm^3

After, I secure the locations of Berry's ligament and the connective tissue so that they do not move in the model. I then applied the force found in the Matlab analysis of the tissue analog video to the model as a distributed load split between 2 areas that are the shape of the distal geometry of the device. The forces include the 0.196 N of gravitational force on the tissue analog (20g, 9.8 m/s^2) as well as the maximum 0.58 N from the device, for a total of 0.776 N. To add in a extra degree of safety, the distrubuted forces are rounded up to 0.5 N each, for a total force on the model of 1 N.

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

Conclusions/action items:

Record the data and results of the model, optimize the model if new information is found

Computational Model Results

Mitchell Josvai - Dec 14, 2021, 5:33 PM CST

Title: Computational Model Results

Date: 12/14/21

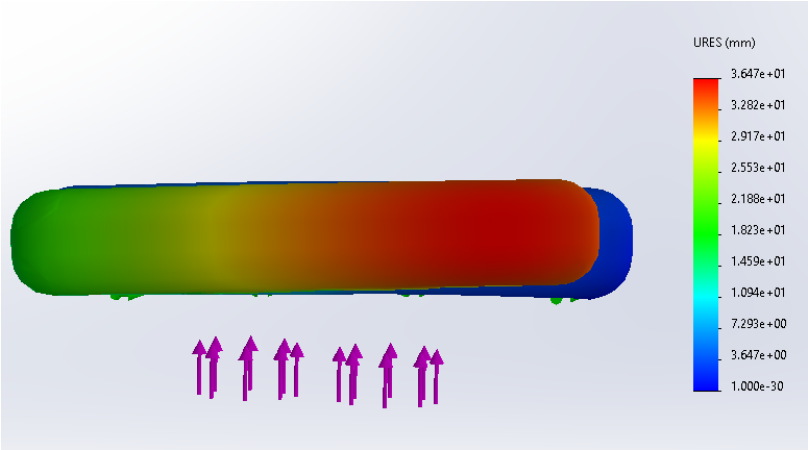
Content by: Mitchell Josvai

Present: Mitchell Josvai

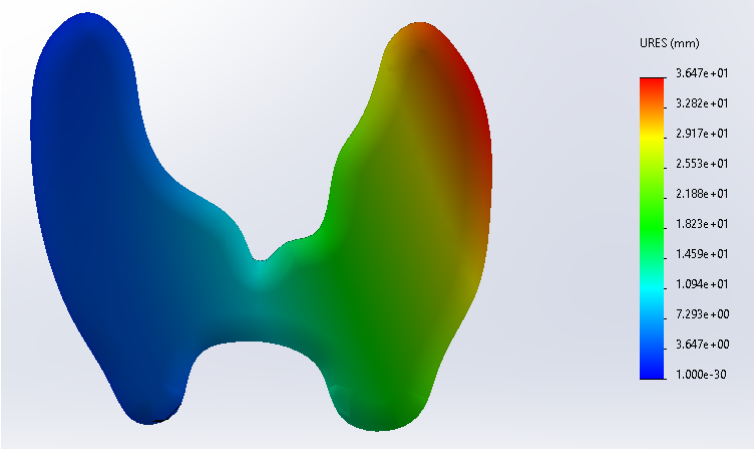
Goals: Record the results of the computational model

Content:

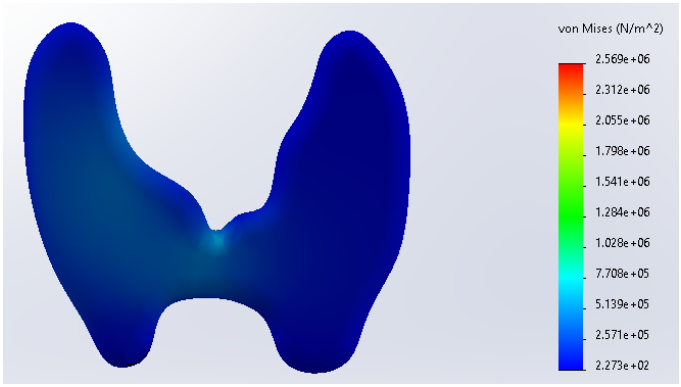
Out of plan geometry change: (1 N of force lifts the thyroid model over 3.5 mm, enough to sever the connective tissue posterior to it)



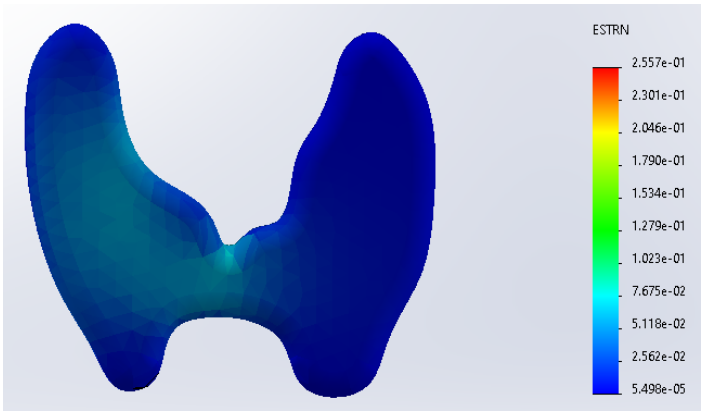
In plane geometry change:



Von Mises Stress: (Based on principal stress orientations in tension, compression and shear)



Engineering Strain:



Conclusions/action items:

Use the data and information in the report and future IDR/patent proposal to justify the use of the device in thyroid surgeries.

Thyroid Physiology

KATE EICHSTAEDT - Dec 13, 2021, 10:27 PM CST

Title: Thyroid Physiology

Date: 10/15

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

Figure A: Control of thyroid secretion

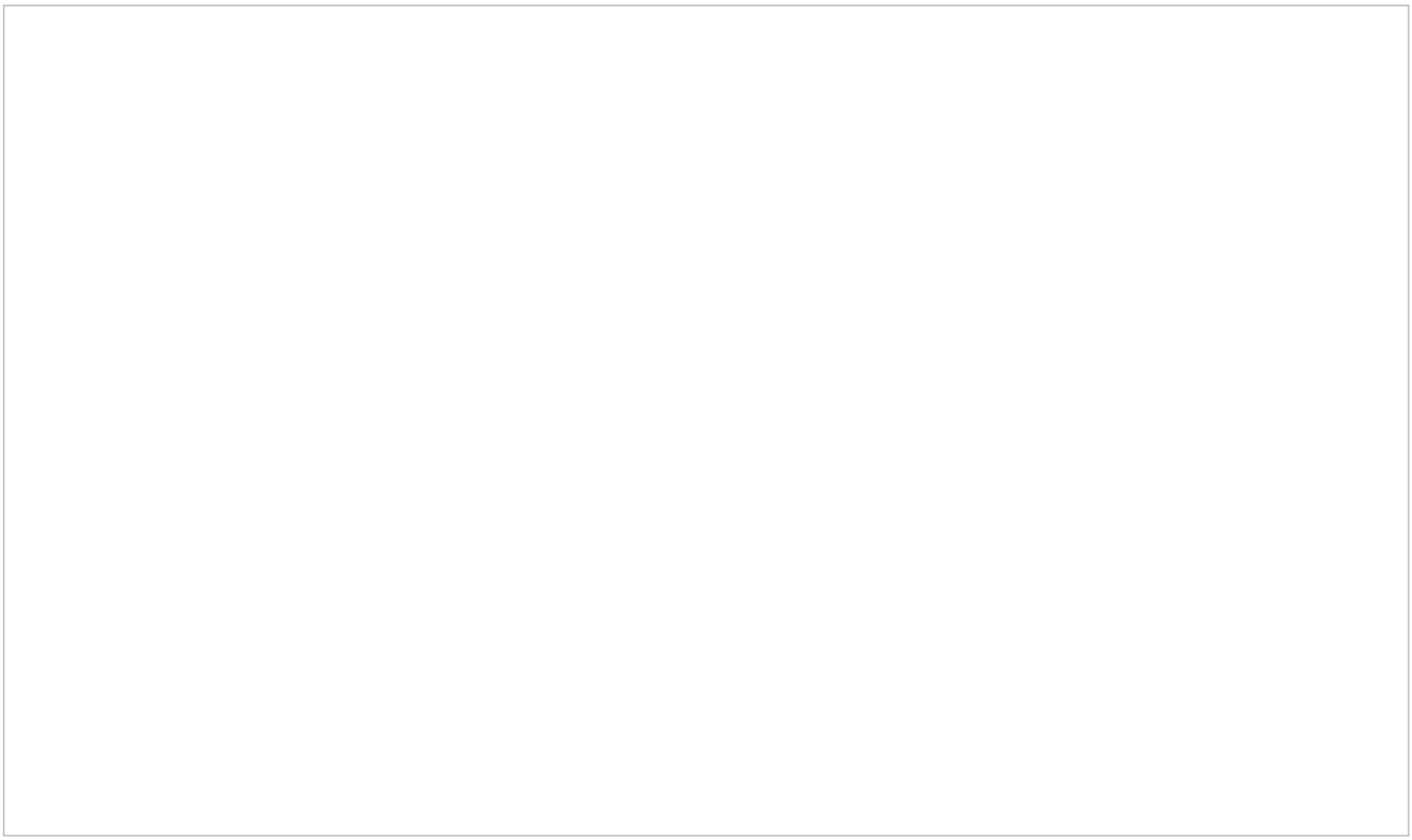


Figure B: Position of thyroid gland in reference to relevant anatomical structures [2]

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:

To conclude, I am uploading some of my research I conducted last semester along with new research just so everything is in the same spot and easily accessible for myself. For action items, I am going to look into any intellectual property issues we may have with the Weitlaner retractor.

Clinical Relevance

KATE EICHSTAEDT - Oct 15, 2021, 5:04 PM CDT

Title: Clinical Relevance

Date: 10/15

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload some of the research I have conducted on why this product is marketable and the clinical relevance it has.

Content:

Problems brought up by our client:

- Often types with larger thyroids, our client will have to use both hands in order to properly retract the thyroid
  - this is problematic because if both hands are occupied with retraction, she will no longer be able to assist in the rest of the surgery
- Also, not every operating room has a full staff or space for extra people to just hold the retractors in place while she operates

On a broader scale, around 130,000 thyroidectomies are performed each year. This does not account for the surgeries that are done where the thyroid just needs to be retracted so the number of surgeries performed where thyroid retraction is necessary is probably greater than this number[1].

Due to this, our product is marketable and hopefully by the end of this project its marketability will be able to extend outside of just our client's operating room.

References:

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

Conclusions/action items:

To conclude, I think performing this type of research when designing a product is very important because if no one needs a certain product, there is really no point in making it. For action items, I am going to continue to work on our preliminary deliverable.

Trachea dimensions

KATE EICHSTAEDT - Nov 30, 2021, 12:57 PM CST

Title: Trachea dimensions

Date: 11/30

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Look up average trachea sizes so we can create a mock trachea that has the correct dimensions.

Content:

In men the average trachea diameter ranges from 15 to 25 mm. In women, it ranges from 10 to 21 mm[1].

In the mock surgical testing set up, our client recommended to use to use a paper towel roll to represent the trachea. The average paper towel roll diameter is around 1.5 inches, which is 38.1 mm[2]. In order to accurately model a trachea, our mock trachea should have a diameter of about 18 mm. This is the average found between the average of men's trachea diameters and women's trachea diameters. In order to change the dimensions of the paper towel roll, we should fold in a section of the roll until the adequate size is obtained.

References:

[1] “Radiology of the Trachea,” *UpToDate*. [Online]. Available: https://www.uptodate.com/contents/radiology-of-the-trachea. [Accessed: 30-Nov-2021].

[2] C. K.-12 Foundation, “8.8 Modeling in Three Dimensions,” *CK*. [Online]. Available: https://flexbooks.ck12.org/cbook/ck-12-interactive-middle-school-math-8-for-ccss/section/8.8/related/lesson/modeling-in-three-dimensions-geom-hnrs/#:~:text=An%2011%20inch%20tall%20roll,towel%20is%200.015%20inches%20thick. [Accessed: 30-Nov-2021].

Conclusions/action items:

To conclude, this was a helpful topic to know in order to accurately model a thyroid surgery. For action items, I am going to update our mock thyroidectomy procedure to include exact dimensions for the trachea.

Thyroid mechanical properties

KATE EICHSTAEDT - Dec 13, 2021, 10:53 PM CST

Title: Thyroid mechanical properties

Date: 12/1

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research thyroid mechanical properties and compare this to chicken breast to see if our mock thyroidectomy is realistic.

Content:

This is a link to a website that has a list of found densities of different human tissues: https://itis.swiss/virtual-population/tissue-properties/database/density/

* 1000 kg/m^3 = 1 g/cm^3

According to this source, the density of a human thyroid gland is typically around 1.05 g/cm^3.

Raw chicken breast prior to cooking is typically around 1.15 g/cm^3.

Comparing these two values, the percent difference is around 9%. For now, using the chicken breast is probably our best option. If we had to do this test again, the research paper from source [2] found that the density decreased as the chicken breast was deep fried for longer. It may be beneficial to cook the chicken prior to testing to try and achieve a more similar density to that of a thyroid gland.

Sources:

[1] “Density,” *Density " IT'IS Foundation*. [Online]. Available: https://itis.swiss/virtual-population/tissue-properties/database/density/. [Accessed: 14-Dec-2021].

[2] L. Kassama and M. Ngadi, “Shrinkage and Density Change of De-Boned Chicken Breast during Deep-Fat Frying,” 28-Jun-2016. [Online]. Available: https://www.scirp.org/pdf/FNS_2016083017004401.pdf. [Accessed: 14-Dec-2021].

Conclusions/action items:

To conclude, this research was very important to conduct in order to determine if our mock thyroidectomy is comparing to comparable things. I found that these two items, thyroid gland, and chicken breast, have a similar enough density to perform similarly during the testing. For action items, I am going to upload some of the images I took during testing.

Rochester pean

KATE EICHSTAEDT - Oct 18, 2021, 10:40 PM CDT

Title: Rochester Pean

Date: 10/18

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research the current device that our client uses, the rochester pean.

Content:

The rochester pean is a commonly used pair of surgical forceps. It is manufactured out of German stainless steel and features serrated jaws[1]. The overall design of this device is similar to a pair of scissors. Our client currently uses this device, along with peanut gauze tips, to retract the thyroid when necessary during surgery. The device can be seen below in figure A.

Figure A: A standard pair of Rochester pean forceps

During retraction, she places a peanut gauze tip in between the jaws of the device, then she retracts the thyroid medially. The peanut tips help with the traction of the device. However, when using this method there is only one point of contact on the thyroid, which may make it difficult to retract large or abnormally shaped thyroids.

When our client encounters a case like this, she uses two rochester pean forceps to retract the thyroid from two points of contact instead of just one.

References:

[1] “Rochester-Pean FORCEP, 6.25,” *Rochester-Pean Surgical Forcep 6.25" Curved*. [Online]. Available: https://www.sterisanimalhealth.com/shop/rochester-pean-surgical-forcep-6-25-curved.html. [Accessed: 19-Oct-2021].

Conclusions/action items:

To conclude, when doing our preliminary presentations and reports, it is important to have a good background on the existing system that our client uses. For action items, I am going to upload a lab archives entry discussing the Weitlaner retractor, which served as inspiration for all three of our preliminary designs.

Weitlaner

KATE EICHSTAEDT - Oct 18, 2021, 10:50 PM CDT

Title: Weitlaner Retractor

Date: 10/18

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload information about the Weitlaner retractor, which is occasionally used to retract the thyroid by our client.

Content:

The weitlaner retractor is a surgical device that is used for retraction. It features a ratcheting system which allows for the handles to be adjusted to a certain distance apart. Additionally, it is self-retaining, so the ratcheting system locks into place once adjusted. It is 16.5 cm long and is made of stainless steel[1]. The tips of the device feature blunted prongs. On one prong, there are three prongs and on the other there are four. Figure A below shows a Weitlaner retractor.

Figure A: Weitlaner retractor

All three of our preliminary designs are based off of the Weitlaner retractor due to the ratcheting system of the base.

References:

[1] “Weitlaner retractor, self-retaining,” *world precision instruments*. [Online]. Available: https://www.wpiinc.com/var-501724-weitlaner-retractor-self-retaining. [Accessed: 19-Oct-2021].

Conclusions/action items:

To conclude, it is very important to research this device because it is what all three of our preliminary designs are based on. For action items, I am going to research piercing prongs, which serve as the inspiration for the tips of the tread device.

Piercing Device

KATE EICHSTAEDT - Oct 18, 2021, 10:56 PM CDT

Title: Piercing Device

Date: 10/15

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Show the piercing device that is the tip inspiration for the tread design.

Content:

Although piercing devices are not used for surgery, they are still typically made out of stainless steel. The inspiration of the grooved circles at the end of the tread design actually come from a common piercing clamp.

When receiving a piercing, the piercer will use this clamp that features the grooved circular ends to pull the skin of the area being pierced taught to that the needle gauge is able to glide cleanly through the tissue[1].

As seen in the figure below, the device features metal treads, which help to provide traction.

Figure A: Piercing forceps, round closed with teeth

The tips of the preliminary tread design feature these grooved tips. However, in the tread design, the grooves are on the opposite side of the metal circles, so they can aid in lifting up the thyroid during retraction.

References:

[1] “Forceps PT1106 round closed,” *Unimax Supply Co Online Store*. [Online]. Available: https://store.unimaxshop.com/forceps-pt1106-round-closed-p476.aspx. [Accessed: 19-Oct-2021].

Conclusions/action items:

To conclude, it is important to feature this device as a lab archives entry because the tips of this device serve as the inspiration for our proposed final design, the tread design. For action items, I am going to research what FDA class our device falls into.

What class is our device?

KATE EICHSTAEDT - Oct 18, 2021, 11:33 PM CDT

Title: FDA Device Classification

Date: 10/18

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Determine what class our device would be in according to FDA regulations.

Content:

There are three device classifications:

1. Class I: General Controls
2. Class II: General Controls and Special Controls
3. Class III: General Controls and Premarket Approval

After researching what classification the Weitlaner retractor has, I found that it has the FDA code 'FFO' and its code name is 'ratcheting, self-retaining.[1]' After looking up the code FFO in the FDA device classification data base, I found that this device is a Class I and is exempt from 510(k) approval, which is a premarket approval that ensures that the device is safe and effective[2].

Due to this, it is likely that our device would be a class I because like the retractor, it does not provide sustained support inside of the body as it is only used temporarily during retraction. I believe this device would also be exempt from premarket approval because the majority of devices that are class I are exempt from this as they are not used long term.

References:

[1] “Medical Device Brand Name : Ambler Surgical (model Weitlaner self-retaining retractor),” *HIPAA Space*. [Online]. Available: https://www.hipaaspace.com/medical_billing/coding/global.unique.medical.device.identification/00190660143947. [Accessed: 19-Oct-2021].

[2] “Product Classification,” *U.S. Food and Drug Administration*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=FFO. [Accessed: 19-Oct-2021].

Conclusions/action items:

To conclude, it is important to know what FDA class our device would fall into to know what codes and regulations will apply to it. Additionally, as we get closer to creating a final model, it is important that we have a strong understanding of what class our device is so we could potentially bring it to market. For action items, I am going to continue to work on the preliminary deliverable.

Short Term Fabrication

KATE EICHSTAEDT - Oct 04, 2021, 8:18 PM CDT

Title: Short Term Fabrication Plans

Date: 10/4/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Create a short term fabrication plan

Content:

Goals to accomplish with short term fabrication:

- Model in solid works
  - either use parts of existing models if possible
    - use to model handle
  - or start model from scratch
    - will need to do research on anthropometric data regarding average hand sizes, finger lengths etc.
- 3-D print
  - obviously will not be made out of final material, may take a couple tries to find the right working printer material
  - want to be as hard and as not ductile as possible to resemble how an actual surgical device would be
  - possible to ergonomics testing with this device
  - could use one of the resin materials
    - formalabs durable, rigid, tough
- once these steps have been completed, we will be able to make a plan for how we are going to fabricate this in the long term with the material the device will actually be made out of (medical grade stainless steel)

Conclusions/action items:

To conclude, I created this short plan as a guide for myself and my team this semester. By working through this checklist, we will hopefully create a 3D printed model that we can do basic testing with and be able to solidify our design with. For action items, I am going to look into the mechanical properties of the different 3D printed materials options and see how they compare to the mechanical properties of stainless steel.

Long Term Fabrication

KATE EICHSTAEDT - Oct 15, 2021, 5:08 PM CDT

Title: Long Term Fabrication plans

Date: 10/15

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Create a long term fabrication plan for device

Content:

There is a short term fabrication plan listed also in this folder.

Once we have 3D printed our device and ergonomically tested it, we will want to manufacture another prototype out of the final material this device will be made in. As this is a surgical device, it should be manufactured out of surgical grade stainless steel such as AiSI 420. The satin finish from this material will help with the sterility of the device and the properties of stainless steel will help give this device a long life of use and protect against degradation.

Once this prototype is created, we will continue to do further testing with the device and continue to reiterate the design as needed to our client's needs.

Conclusions/action items:

To conclude, I made this plan because when I have plans written out it helps me stay on track. For action items, I am going to continue to work on our preliminary deliverable.

Stainless Steel Types

KATE EICHSTAEDT - Oct 04, 2021, 8:48 PM CDT

Title: Stainless Steel Fabrication

Date: 10/4

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research the fabrication process of medical grade stainless steel

Content:

Austenitic 316: surgical steel

- an alloy composed of nickel, chromium and molybdenum
- highly resistant to corrosion
- adequate for biomedical implants

Martensitic 440 and 420

- used for cutlery production but also used for surgical-grade applications
- high-carbon steels alloyed with chromium
    - less resistant to corrosion than 316 but still very resistant
- much harder than 316
- Often used to manufacture surgical implements and medical cutting tools

Surgical devices need to have a satin finish so they will not harbor bacteria and other biocontaminants. Austenitic 316 steel is referred to as 'surgical steel.' Tough and resistant to corrosion.

References:

“Quality Guidelines for Surgical Steel in medical manufacturing,” *Multisource Manufacturing*, 19-Jun-2019. [Online]. Available: https://multisourcemfg.com/2019/07/08/guidelines-surgical-steel-medical-manufacturing/. [Accessed: 05-Oct-2021].

J. Stokes, M. Johnsson, J. Paulos, M. Ashfaq, A. Mishra, R. Chandra, and R. Singh, “Which metals are commonly used for surgical instruments?,” *Matmatch*, 27-Jul-2021. [Online]. Available: https://matmatch.com/blog/metals-commonly-used-surgical-instruments/. [Accessed: 05-Oct-2021].

Conclusions/action items:

To conclude, by identifying the types of stainless steel that are commonly used for medical devices, we will be able to better plan for our long term fabrication of our device. As this is a medical device, we will have to use a medical grade material. For action items, I am going to look into the fabrication methods that are used to produce different types of medical grade stainless steel.

Mechanical Properties Evaluation

KATE EICHSTAEDT - Oct 04, 2021, 8:35 PM CDT

Title: Mechanical Properties Evaluation

Date: 10/4

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Compare the mechanical properties of the different 3D printed materials to stainless steel

Content:

* will use post-cured values for resins

Material	Elastic Modulus
Medical Grade Stainless Steel	187.5 GPa
FormLabs Durable	1.26 GPa
FormLabs Rigid	4.1 GPa
FormLabs Tough	2.7 GPa

References:

"3D printers," *UW Makerspace*. [Online]. Available: https://making.engr.wisc.edu/3d-printers-2/. [Accessed: 05-Oct-2021].

"The Online Materials Information Resource," *MatWeb*. [Online]. Available: http://www.matweb.com/search/datasheet.aspx?matguid=29a84d10fada4e4fa3ebe3986e52d848&ckck=1. [Accessed: 05-Oct-2021].

Conclusions/action items:

To conclude, I made this comparison chart to help chose what material we want to 3D print our device out of initially. When doing this, we want the material to be as close as possible to resembling stainless steel. Of course the mechanical properties of steel are much stronger than the 3D printer options, however, by choosing a device with the closest characteristics, we will hopefully be able to do some ergonomics testing with our device. For action items, I am going to look into the fabrication process and make up of medical grade stainless steel.

Testing model: Chicken

KATE EICHSTAEDT - Nov 30, 2021, 12:30 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

Updated testing goals for end of fall semester

KATE EICHSTAEDT - Nov 30, 2021, 1:04 PM CST

Title: Testing goals for poster presentations

Date: 11/30

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: List out what tests we need to complete before poster presentations and what are plans are for after this semester has finished.

Content:

After meeting with our client, what we planned to have completed before the end of the semester testing wise has slightly changed. Originally, we were planning on doing a mock thyroid surgery using a chicken breast, as well as an ergonomics testing survey.

After meeting with the client, we have decided to postpone the use of the survey as it is unlikely our client will be in Madison before next Friday and we would likely not have enough data yet to do any sort of significant statistical tests.

We are going to move forward with the mock surgery and use that qualitative data on our poster. In addition, we are going to do some quantitative analysis using simulated mathematical models using the coefficient of friction of thyroid tissues against our device, which will be eventually manufactured out of stainless steel.

Those are the two main proof of concepts ideas we will have on our poster in regards to testing.

After this semester, we are going to email our old advisor, Dr. Bersu, and ask if there is any way we could have access to the anatomy labs to possibly use our device on a cadaver. This will likely occur sometime over winter break as our client will be present in Madison for a short while as she is having a surgical case.

Conclusions/action items:

To conclude, listing the testing items we need to accomplish before next Friday is very helpful for myself to maintain organization and have a clear thought process on what needs to be done at what time. For action items, I am going to research the mechanical properties of normal thyroid tissues to hopefully begin to set up a mathematical model of the thyroid being retracted for proof of concept.

Surgical grade stainless steel

KATE EICHSTAEDT - Dec 13, 2021, 10:38 PM CST

Title: Surgical grade stainless steel manufacturing

Date: 12/13/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Research different manufacturers that manufacture surgical grade stainless steel

Content:

In a meeting with our advisor, it was brought up that one of his past groups manufactured a device out of stainless steel using a manufacturing company in east Germany. He also mentioned that it was rather cheap compared to stainless steel manufacturing in the states.

The goal for this entry is to try and find that company to possibly manufacture our device and look up different US manufacturers.

US:

Bergson metals

- located in California - probably pretty expensive
- makes 304 stainless steel
    - used for a lot of medical applications
    - also makes 316
    - website: https://bergsen.com/medical-surgical-stainless-steel

This is a link to a directory that lists a bunch of medical grade stainless steel manufacturers, this may be beneficial for future work when we start to narrow stuff down in regards to manufacturing.

https://directory.qmed.com/stainless-steel-code006396.html

Conclusions/action items:

To conclude; some of these resources will be very helpful for next semester. Over winter break, I am planning on continuing this research. I do not believe I found the manufacturing facility in east Germany that our advisor was referring to so for action items I am going to ask him for the name in our next meeting.

Original Design 1: re-upload from spring 2021

KATE EICHSTAEDT - Oct 15, 2021, 4:47 PM CDT

Title: Design 1: In-line Curved

Date: 10/15

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload previous designs from Spring 2021 so they are all in one place

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.

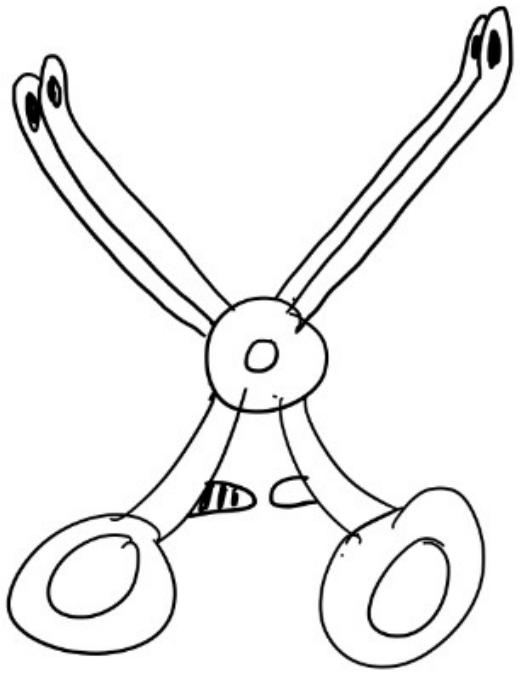


Figure 1: Preliminary Sketch of the In-line curved design. Note: This is not to scale.

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.

Reupload of fused model from Spring 2021

KATE EICHSTAEDT - Oct 15, 2021, 4:48 PM CDT

Title: Fused Model Drawings

Date: 10/15

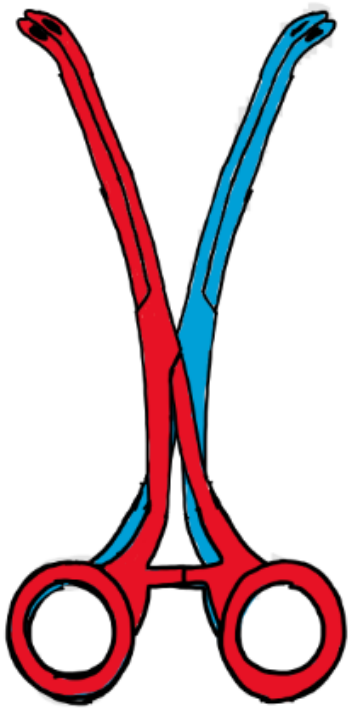
Content by: Kate Eichstaedt

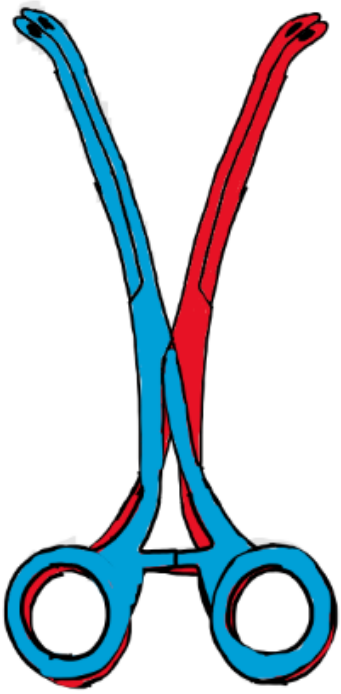
Present: Kate Eichstaedt

Goals: Upload designs from previous semester to current lab archives notebook

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.

Tread Design

KATE EICHSTAEDT - Nov 30, 2021, 12:12 PM CST

Title: Tread Design

Date: 10/15

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload drawing and description of tread design. This is our proposed final design.

Content:

The tread design features the ratcheting system of the original Weitlaner retractor. At the ends, there are curved metal circles. These metal circles will be grooved to promote gripping ability of the thyroid during retraction. Also, the tips will be angled inwards to aid with retraction.

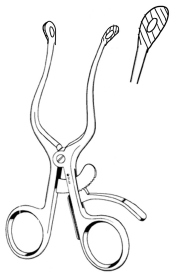


Figure 1: This is a drawing of the tread design. I am not sure how to make the actual image larger in solidworks so it is easier to see but a larger version of the drawing is present in our preliminary presentation slides.

Conclusions/action items:

To conclude, this is the proposed final design. For action items, we need to create a solidworks model of the device and work to 3d print it to do ergonomic and anthroprometric testing.

First Weitlaner ordered

KATE EICHSTAEDT - Nov 30, 2021, 11:25 AM CST

Title: Amazon Weitlaner

Date: 11/30/21

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Upload a image of the weitlaner I ordered from amazon

Content:

Conclusions/action items:

Tissue Analog Testing Thoughts

ASHLEE HART - Dec 14, 2021, 9:49 PM CST

Title: Tissue Analog Testing Thoughts

Date: 12/7/21

Content by: Ashlee

Goals: Give my thoughts and insights on the Tissue Analog Testing we conducted on Sunday, 12/5

Content:

The testing conducted on 12/5 went really well. The mishaps that had prevented testing any earlier included gettimg a food scale to weigh the chicken breasts on and acquiring a glue gun to connect the chicken breast pieces to the paper towel roll. Because of these mishaps, we had to push back testing from 12/3 to 12/5, but that wasn't really a big deal for the group.

I was able to cut three individual chicken breasts weight between 10 and 20 grams, and lengths ranging from roughly 4 cm to 7 cm. All three of these pieces were hot glued onto a paper towel roll (as recommended by Dr. Doubleday), and did really well when it came to retract. I retracted each piece and then used a knife to sever the connection between the chicken breast piece and paper towel roll, mimicking the connection between the thyroid and tissue connections beneath it. One retraction was done with a butterfly shaped thyroid that was a great depiction of the typical thyroid butterfly shape.

Overall, I believe this testing was a success. We have a great proof of concept, as our device was able to adjust to a desirable width based on the size of the chicken breast and retract the chicken breast piece for all sizes. However, there are some changes that will be done in the future of this device. The grooves, or treaded ends, were not very obvious at the distal ends of the device, so those marks may not have provided much extra traction compared to what it could offer. Also, the prongs did not have C-shaped curve to them that would help with retraction. The ratcheting mechanism wasn't functioning due to the tolerances given from the 3D printer we used, but I could still separate the prongs by hand.

Conclusions/action items:

As stated above, the testing conducted was a success. Going into the next semester, it's great we got solid testing conducted to know what changes for sure need to be made to our device before another round of testing is conducted. It was recommended to us at the Poster Session last Friday, 12/10, to use the more expensive 3D printers in the basement of the makerspace to avoid the tolerance issues provided by the more inexpensive 3D printers. Going forward, modifications will be made to the device to make it better, including making the spring adjustability mechanism in the ratcheting mechanism more robust. In terms of testing, in the future we will be able to test with hopefully a stainless steel rendition of our device and get Dr. Doubleday's, as well as other clinicians' thoughts and opinions on the retractor

Thyroid Anatomy and Physiology

ASHLEE HART - Oct 14, 2021, 12:50 PM CDT

Title: Thyroid Anatomy

Date: 9/17/2021

Content by: Ashlee

Present: N/A

Goals: Research basic thyroid anatomy

Content:

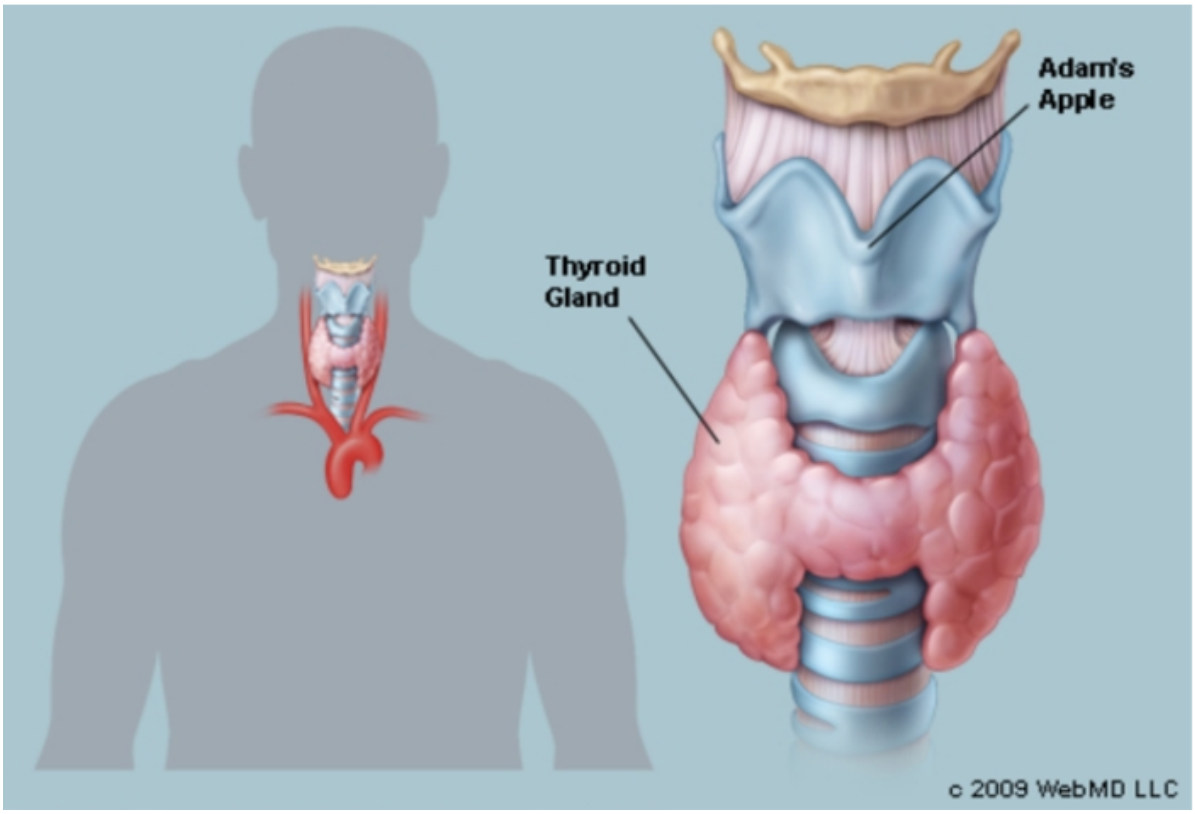


Figure 1: Pictorial representation of the thyroid gland [1]

- 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].

[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 is taken into account for a successful retraction. Knowing the range of weights and sizes of a thyroid will be essential when testing is conducted since we may have to use a mock thyroid to test on.

9/24/21 Other Shod Designs

ASHLEE HART - Oct 19, 2021, 7:25 PM CDT

Title: Shod designs

Date: 9/24/21

Content by: Ashlee

Present: Ashlee

Goals: Brainstorm different shod designs we could 3D print

Content:

The end of a Green thyroid retractor:

Figure 1: Image of a green retractor [1]

The end of the green retractor could possibly be a good option for a shod shape. They're curved in, so that may allow for easier retraction than shapes that would lie flat against the thyroid.

[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].

Conclusions/action items:

At the beginning of this semester we had thought we were continuing with the weitlaner retractor + shods ending, so I wanted to brainstrorm different types of endings we could 3D print. However, after meeting with our client early in the semester, it was decided we would not continue with that design and go a different route.

McBurney Retractor

ASHLEE HART - Oct 14, 2021, 12:56 PM CDT

Title: McBurney Thyroid Retractor

Date: 10/13/2021

Content by: Ashlee

Present: N/A

Goals: Research different types of thyroid retractors

Content:

McBurney Thyroid Retractor:

Figure 1: An image of 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]

[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].

Conclusions/action items:

After doing research on the McBurney Thyroid Retractor, I can see that this retractor would not really compete with the Adapted Weitlaner + Metal circles ending. The McBurney only has one point of contact, so I'm sure Dr. Doubleday would experience similar difficulties with different sized thyroids. Because of this, we have little reason to be concerned with the competition aspect of this design.

Current Retractor in Use

ASHLEE HART - Oct 19, 2021, 6:41 PM CDT

Title: Peanut Thyroid Retractor

Date: 09/17/21

Content by: Ashlee

Present: N/A

Goals: Describe 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:

The image inserted above is a very important representation of what parts of the retractor we need to change. The single point of contact between the device and the thyroid is the main concern, and a self adjusting ratcheting mechanism will be the head of the design.

Weitlaner Retractor

ASHLEE HART - Oct 19, 2021, 7:03 PM CDT

Title: Weitlaner Retractor

Date: 10/19/21

Content by: Ashlee

Present: N/A

Goals: Explain the important features of the weitlaner retractor that will be incorporated into our final design

Content:

The weitlaner retractor is not actually used as a retractor, but is used to hold wounds or openings of the body open for surgery. It is self retaining, with a ratcheting mechanism at the top of the device to allow for adjustability [1]. Since its uses are not for retraction, this device is not exactly a competitor for the thyroid retractor we will create. However, the ratcheting mechanism at the top of the device will be incorporated into our retractor.

Figure 1: Weitlaner Retractor [2]

[1] *The Weitlaner Retractor Innovation & Usage*. Andersen Caledonia. (2021, September 22). Retrieved October 19, 2021, from https://andersencaledonia.com/the-weitlaner-retractor-innovation-usage/.

[2] *Weitlaner retractor, self-retaining*. world precision instruments. (n.d.). Retrieved October 14, 2021, from https://www.wpiinc.com/var-501724-weitlaner-retractor-self-retaining.

Conclusions/action items:

This information about the weitlaner is for sure important due to it being an inspiration for our preliminary designs. Knowing that its purpose is different than the thyroid retractor we're creating is definitely promising, as that should help our case when it comes to filing for a patent.

Rochester Pean Forceps

ASHLEE HART - Oct 19, 2021, 7:16 PM CDT

Title: Rochester Pean Forceps

Date: 10/13/21

Content by: Ashlee

Present: N/A

Goals: Explain a competing thyroid retractor design: rochester pean forceps

Content:

The Rochester Pean Forceps are actually the base of the "peanut" device that Dr. Doubleday uses in her operating room. The peanut is different in that they have a ball of gauze at the tip to aid in retraction. The plain Rochester Pean Forceps are used to clamp vessels in order to control bleeding. They come in 8, 9, and 10 inch lengths [1]. While this design is more related to the currently used retractor versus a competing one, it still doesn't have much competition due to the fact that there is no adjusting mechanism, and it only has one point of contact between the device and thyroid.

Figure 1: Rochester Pean Forceps [1]

[1] *Rochester-Pean FORCEP, 6.25*. Rochester-Pean Surgical Forcep 6.25" Curved. (n.d.). Retrieved October 20, 2021, from https://www.sterisanimalhealth.com/shop/rochester-pean-surgical-forcep-6-25-curved.html.

Conclusions/action items:

This information was just more background on the current retractor that Dr. Doubleday uses. As mentioned before, its features don't make it much of a competition, but any information about the client's current device is still useful.

Weitlaner Retractor FDA Information

ASHLEE HART - Oct 19, 2021, 8:45 PM CDT

Title: Weitlaner Retractor FDA Information

Date: 10/19/21

Content by: Ashlee

Present: N/A

Goals: List information on the Weitlaner Retractor that will be relevant in the patent filing process

Content:

- The weitlaner retractor is a class 2 medical device [1]

- Is in commercial distribution under 21 CFR 807.3(b) [2]

- FDA product code [2]: FFO

- GMDN PT Definition [2]:

> A HAND-OPERATED, SELF-RETAINING, ONE-PIECE SURGICAL INSTRUMENT INTENDED TO BE USED TO SEPARATE/DRAW ASIDE THE MARGINS OF A WOUND/INCISION TO ALLOW ACCESS TO TISSUES/ORGANS DURING OPEN SURGERY; IT IS NOT INTENDED TO RETRACT THE RIBS AND IS NOT DEDICATED TO OPHTHALMIC SURGERY, BUT MAY OTHERWISE BE CLINICALLY DEDICATED. IT IS DESIGNED AS A ONE-PIECE DEVICE (I.E., NOT A MOUNTING RING, OR TABLE-FIXED ASSEMBLY) HAVING TWO LEGS WITH DISTAL HOOKED BLADES AND A SELF-RETAINING MECHANISM TO MAINTAIN THE LEGS IN AN OPEN POSITION FOR RETRACTION. THIS IS A REUSABLE DEVICE.

- Can be sterilized under moist heat or steam sterilization [2]

- Device is intended for more than 1 use [2]

[1] https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

[2] www.hipaaspace.com. (n.d.). *00190660143947 gudid code: Weitlaner Self-retaining retractor model: Ambler Surgical Corp.: Global Unique Device Identification Database Directory: Medical Coding Library: Www.hipaaspace.com © 2021*. www.hipaaspace.com. Retrieved October 20, 2021, from https://www.hipaaspace.com/medical_billing/coding/global.unique.medical.device.identification/00190660143947.

Conclusions/action items:

While the team was aware that the weitlaner retractor was not used to retract the thyroid, it's good to know that the true definition of the medical device reiterates this point. Our team has a goal of getting to file a patent for our device, so having research on FDA regulations and such is very important.

How to Approach WARF

ASHLEE HART - Dec 14, 2021, 11:03 PM CST

Title: How to Approach WARF

Date: 12/14/21

Content by: Ashlee

Goals: Learn about what is needed in order to approach WARF about proceeding with a patent

Content:

Patenting Process:

1. Tell them about our work
    1. Submit an innovation disclosure. We would hear 1-3 business days after submition
2. Go to a disclosure meeting
3. The decision committee makes a determinition
4. The disclosure goes through an equity review
5. If an invitation is accepted, us inventors would enter into a memorandum agreement with WARF
6. WARF applies for the patent

Things that WARF evaluates:

- Patentability
- Market dynamics
- Licensing potential
- Public benefit
- Whether or not WARF can add value

If WARF decides not to move forward with the patent process, it's not a hard no. Additional information and such will always be considered.

Conclusions/action items:

The patent process is definitely one the team has considered, especially considering the unmet need seen in Dr. Doubleday's operating room. However, before this process becomes more serious, I want to do a deep search to make sure all current thyroid retractors have been accounted for in our research to make sure we know why our device outshines the rest of them. I will have to ask professor Tyler if a meeting with WARF is something that should occur before or after we get the stainless steel version of our device.

Future Testing

ASHLEE HART - Dec 15, 2021, 11:40 AM CST

Title: Future Testing

Date: 12/15/21

Content by: Ashlee

Goals: Brainstorm future testing to put into a testing protocol next semester

Content:

- Ergonomic Testing with Dr. Doubleday and other clinicians

  - This has already been included in a testing protocol for the Fall 2021 semester. It consists of letting clinicians get a hand on feel with the thyroid retractor we've created and then rating the device in a google survey. We weren't able to conduct this testing this semester due to timing issues, but we definitely will plan on doing this next semester.
  - Hopefully we'll have a stainless steel rendition of our device for when this testing needs to be completed

- Testing different tread patterns and/or shapes

  - As of right now, the treads are grooved in a slanted way. however, the team could test and see if grip differs when there are vertical grooves, or criss cross grooves, etc.
  - The shapes of the treads are oval as of now. However, we could try different shapes like a rectangle, square, triangle, etc.

- Stainless steel Solidworks and tissue analog testing

  - We've already conducted Solidworks and tissue analog testing with the 3D printed devices, but it would be important to conduct similar, if not the same, tests with the stainless steel version of our device that we hope to get by early next semester

Conclusions/action items:

Make sure the team works to outsource a stainless steel version of our device over winter break. Communicate with Professor Tyler about recommendations about how to get this done over break.

Adapted Weitlaner + Tread Endings

ASHLEE HART - Oct 19, 2021, 8:32 PM CDT

Title: Drawing of Adapted Weitlaner + Endings

Date: 10/01/21

Content by: Ashlee

Present: N/A

Goals: Get an initial drawing of the tread design discussed at our client meeting that we may be pursuing

Content:

The design discussed at the client meeting has the top of a weitlaner retractor: the ratcheting mechanism. The bottoms are like the ends of a treaded forcep but with the ends rotated 90 degrees in order to lay flat against the thyroid.

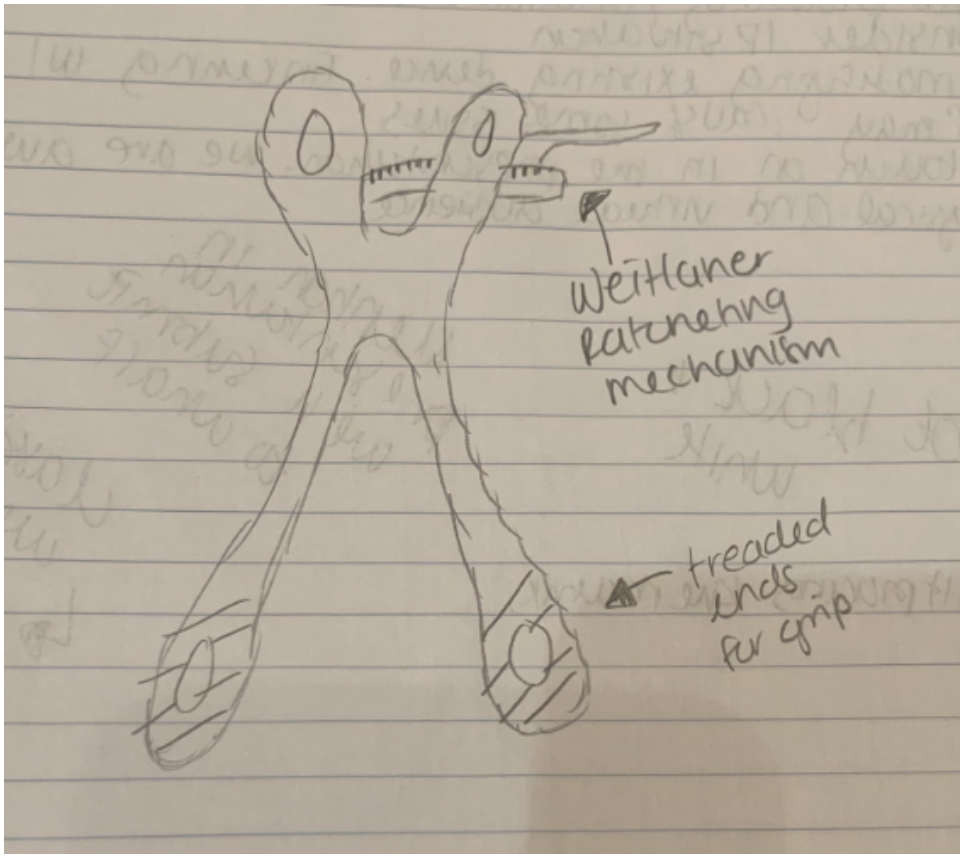


Figure 1: Quick sketch of the adapted weitlaner + tread endings

Conclusions/action items:

This is just a preliminary sketch, a CAD model will be made throughout the semester. However, it seems like a great start and will at least be incorporated into the preliminary presentation.

Stainless Steel Manufacturing

ASHLEE HART - Dec 14, 2021, 10:52 PM CST

Title: Stainless Steel Manufacturing

Date: 12/14/21

Content by: Ashlee

Goals: Research methods on how to manufacture our device in stainless steel

Content:

Information Professor Tyler has given us:

- A company in Europe was able to manufacture an old's team in stainless steel

- The group gave the manufacturer very detailed CAD files and manufacturing protocols

- Winter break is the best time to take some initiative as there may be some delay (~ 1 month) in obtaining the stainless steel rendition

Potential websites to look into:

Kickr Design

- Located in Atlanta, GA

https://www.kickrdesign.com/medical?keyword=medical%20products%20company&camp=kdMED&gclid=Cj0KCQiAnuGNBhCPARIsACbnLzqOK4FzrGo7Be54UKe2TsTiD0gdnPVL_9k8FqolA6AY15M99aa_VdkaAsVcEALw_wcB

Conclusions/action items:

The greatest possibility the team has to outsourcing in stainless steel is getting all the necessary information from Professor Tyler. Since he has direct experience in doing something so similar to what we are trying to do, there is not a doubt that the team will have success with the information provided. At our next meeting, asking about who to contact and what to give to the manufacturing company will be necessary, and will lead to hopefully sending our team's CAD files, manufcaturing protocol, etc. over winter break.

9/12/2021: Thyroid Gland

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:33 PM CDT

Title: Thyroid Gland

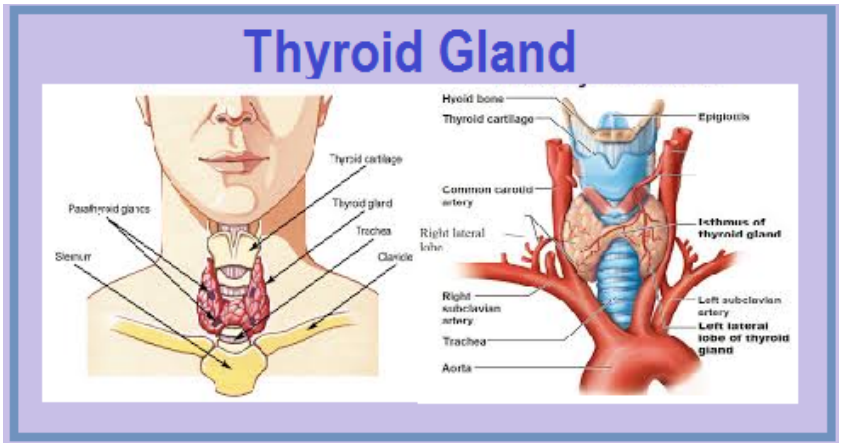
Date: 9/12/21

Content by: Avani

Goals: To gain a better understanding of the procedure and the thyroid in general.

Content:

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



Thyroid Gland.png

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, giving a good background on the anatomy and physiology of the problem.

9/15/2021: Need for Device

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:34 PM CDT

Title: Need for Device

Date: 9/15/21

Content by: Avani

Goals: List reasons for why the device is needed.

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 deliverables and overall project in general.

11/29/21: Stainless Steel Manufacturing

AVANI LALL (aklall@wisc.edu) - Dec 14, 2021, 11:07 PM CST

Title: Stainless Steel Manufacturing

Date: 11/29/21

Content by: Avani

Goals: To get an overview of the process of creating a device in stainless steel.

Content: **https://www.azom.com/article.aspx?ArticleID=20175**

- For parts that must offer excellent strength and stiffness, metals are the preferred choice, particularly in small cross-section
- When indication is given for a metal part to be incorporated into the design of a medical instrument, the usual choice is one of the 300 series stainless steels.
- Stainless steel alloys have the capacity to be cold worked to great tensile and yield strengths while preserving good ductility and toughness.
- 400 series stainless steels, frequently utilized for surgical instruments, are not as corrosion resistant when compared to the 300 series but can be refined through heat treatment to greater strength and hardness levels.
- Stainless steels, hardenable alloys and titanium alloys can be manufactured into different forms as required by the medical industry, including wire, strip, sheet, rod, plate, foil and bar.
- The surface finish on titanium-based and stainless steel strip products is also produced at the reroll stage.

Conclusions/action items: This is something very real and practical to our project as we hope to finalize our 3D printed device before/during winter break and eventually create a stainless steel device.

12/13/21: Max Forces and Bending Moments

AVANI LALL (aklall@wisc.edu) - Dec 14, 2021, 10:49 PM CST

Title: Max Forces and Bending Moments

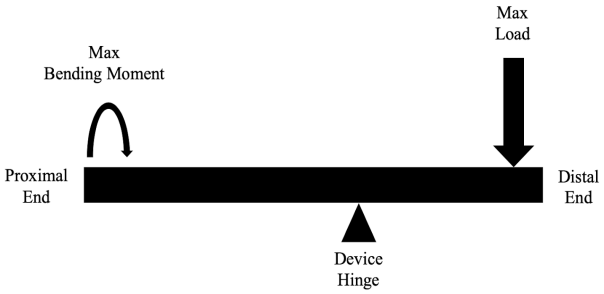
Date: 12/13/21

Content by: Avani

Goals: Create a FBD depicting the maximum forces and bending moments with the device.

Content:

- Device can be simplified as a Class I lever system.
- Maximum bending moment would occur at the proximal end of the device, where the finger holes and hand is.
- Applied maximal forces would occur at the distal end of the device.



Conclusions/action items: Add a safety factor of at least 2 to determine the appropriate cross-sections of both ends.

9/12/2021: Peanut Sponge Forceps

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:21 PM CDT

Title: Peanut Sponge Forceps

Date: 9/12/2021

Content by: Avani

Goals: To learn more about the current device Dr. Doubleday and see what aspects we will be keeping for our design.

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, and 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.

9/26/2021: Ratchet Locking Mechanism for Surgical Instruments

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:23 PM CDT

Title: Ratchet Locking Mechanism for Surgical Instruments

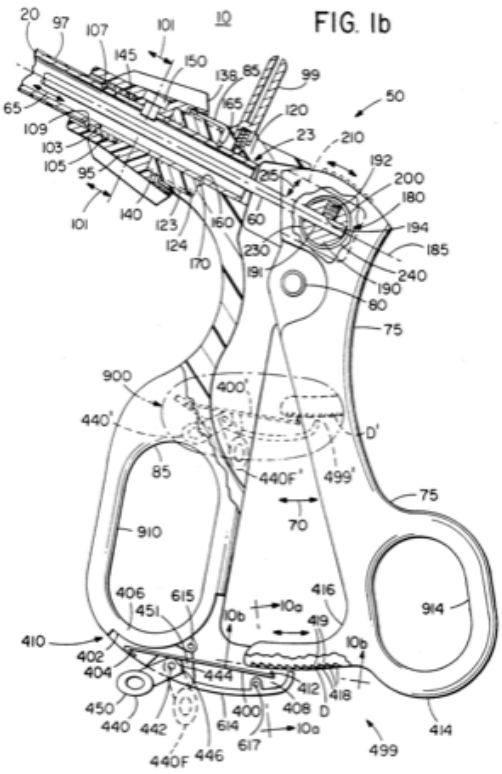
Date: 9/26/2021

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.

10/8/2021: FDA Medical Device Classification

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:29 PM CDT

Title: FDA Medical Device Classification

Date: 10/8/2021

Content by: Avani

Goals: To consider appropriate codes and standards.

Content: https://medevis.test.evidenceprime.com/devices/CSD_339

- The device falls under the category of a Class II medical device as it is substantially equivalent to another similar legally marketed device that already has FDA clearance.
    - Weitlaner retractor is Class II

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

- 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: These standards need to be kept in mind when looking for FDA approval.

10/11/2021: Rochester Pean Forceps

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:19 PM CDT

Title: Rochester Pean Forceps

Date: 10/11/2021

Content by: Avani

Goals: To understand the features of the Rochester Pean Forceps which is the current device our client uses.

Content: https://www.medcareproducts.com/Kelly-Forceps-Stainless/productinfo/IMK/

- The Rochester Pean Forceps are a hemostatic surgical forcep made of grade 420 stainless steel.
- They resemble a pair of scissors with the blade replaced by a blunted grip.
- In surgery, they are used for holding the thyroid tissue out of the way.
- Client's current instrument.

https://www.anthonyproducts.com/store/rochester-pean-forceps-5

Conclusions/action items: The main areas the retractor falls short is that it can only reach a single contact point and doesn't have adjustability for different thyroid sizes.

10/11/2021: Allis Tissue Forceps

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:14 PM CDT

Title: Allis Tissue Forceps

Date: 10/11/2021

Content by: Avani

Goals: To understand the features of the Allis Tissue Forceps and find aspects it falls short to brainstorm ideas for our design.

Content: http://punchout.medline.com/product/Allis-Tissue-Forceps/Tissue-Forceps/Z05-PF13543?question=&index=P8&indexCount=8.

- Commonly used during surgery to firmly grasp the thyroid tissue.
- Forcibly grasps and retracts tissue.
- Made of stainless steel and features a teeth curve to the inside which is designed to help decrease general pressure applied to the area.
    - AISI 420 stainless steel
- Disadvantage: Ends may cause damage to the tissue.

https://www.anthonyproducts.com/store/thoms-allis-tissue-forceps

Conclusions/action items: The device serves as a great comparison and has a lot of areas that we can improve upon.

9/14/2021: Design 1, Shods

AVANI LALL (aklall@wisc.edu) - Oct 19, 2021, 11:54 PM CDT

Title: Design 1, Shods

Date: 9/14/2021

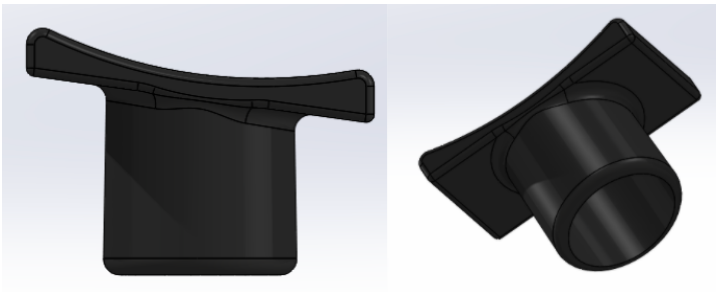
Content by: Avani

Goals: To explain the features of the first design we came up with that was the final design we chose last semester.

Content:

- The top consists of the weitlaner components.
- A handle to hold the device, as well as the ratcheting locking mechanism, which may be set and adjusted with a single hand, in order to facilitate more convenient alterations to the width of the retractor.

- The bottom is the 3D printed rubber shods
- Used to contact the thyroid
- Based on single-use disposable polymer tips used for some surgical clamp applications
- Hollow cylindrical base that allows for tight fit around the tips
- Each consists of a wide, curved surface to maximize contacting area with the thyroid during surgery,
- Rounded edges to minimize that possibility of harm to the patient



Conclusions/action items: As this was our final design from last semester we chose to keep it in the design matrix and evaluate against two more preliminary designs,

9/14/2021: Design 2, Springs

AVANI LALL (aklall@wisc.edu) - Oct 20, 2021, 12:02 AM CDT

Title: Design 2, Springs

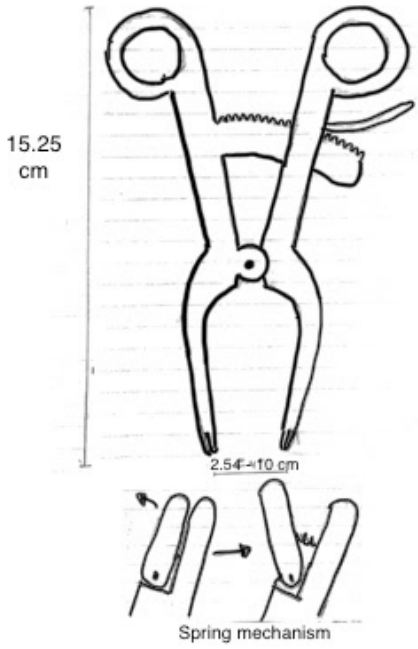
Date: 9/14/2021

Content by: Avani

Goals: To explain the features of the second design.

Content:

- Combination of the Weitlaner retractor and the Peanut.
- Has the ratcheting system and finger holes of the original Weitlaner retract.
- Ability to adjust the width between the two prongs will be able to be maintained.
- Instead of having forked ends like the Weitlaner it has springs that can be pulled apart.
    - Holds the peanut gauze tips in place during thyroid retraction.
- Thyroid will be able to be contacted by two peanuts instead of just one
    - Less slippage or folding of the thyroid



Conclusions/action items: This design also was part of our last semester preliminary designs but may have gotten overlooked which is why we brought it back to the matrix.

10/15/2021: Design 3, Treads

AVANI LALL (aklall@wisc.edu) - Oct 20, 2021, 12:15 AM CDT

Title: Design 3, Treads

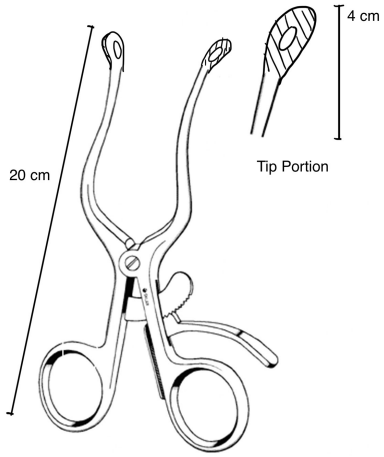
Date: 10/15/2021

Content by: Avani

Goals: Our client showed us pictures of instruments that had specific ends and that was the inspiration for this design.

Content:

- Has the top of Weitlaner retractor.
    - Important for adjustability between the two prongs of the device.
- Metal ring at end of each tip, have an inward angle and are grooved
    - Allows for better retraction of the thyroid.
    - No need to use a peanut or rubber shod for traction on the thyroid because grooves provide traction.



Conclusions/action items: The client expressed a real liking for this design and as a team we believe it is feasible to fabricate and test.

2014/11/03-Entry guidelines

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.

2014/11/03-Template

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

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

BME Design S21 Notebook

Mitchell Josvai - Oct 20, 2021, 12:17 PM CDT

BME Design-Spring 2021 - Mitchell Josvai
Complete Notebook

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