BME Design-Spring 2022 - KATE EICHSTAEDT
Complete Notebook

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Team contact Information

KATE EICHSTAEDT - Feb 21, 2022, 10:24 AM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
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Lall	Avani	BWIG	aklall@wisc.edu		
Lall	Avani	BPAG			

Project description

KATE EICHSTAEDT - Feb 21, 2022, 10:25 AM CST

Course Number: BME 402

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.

2/23: Client Meeting

AVANI LALL (aklall@wisc.edu) - Feb 23, 2022, 3:39 PM CST

Title: Client Meeting

Date: 2/23/2022

Content by: Avani

Present: Avani, Ashlee, Kate

Goals: Get feedback on our latest 3D printed model of device and on the ergonomics survey.

Content:

- Client held latest model of 3D printed device, client comments:
  - More textured ends, bigger coarser grooves angled up, 4-5 on each end for more grips
  - Curved angles of ends
  - Doesn’t need to be longer, maybe a little longer on the handle part.
- Spoke about ergonomic survey
  - Need at least 12 responses
    - All people in Waukesha are general surgeons, 4-5 responses
    - Could extend to UW endocrine surgeons (5)
    - Could send to Rockford, for the remaining
  - Anon doesn't really matter
- Timeline:
  - However long client needs to get adequate number of responses, a few weeks
  - At the same time, we will do tissue analog and biocontamination tests.

Conclusions/action items:

Make updates to SolidWorks model: Longer handle and bigger, coarser grooves on end (may be hard to print).

Reach out to UW endocrine surgeons.

WARF application, think about manufacturing in final material.

4/19: UW Hospital meeting

KATE EICHSTAEDT - Apr 19, 2022, 11:05 AM CDT

Title: UW Hospital presentation

Date: 4/19

Content by: Kate Eichstaedt

Present: Kate, Mitchell, Avani, Dr. Doubleday, various UW hospital endocrine surgeons

Goals: Show the device to the surgeons at UW

Content:

- Overall, I think the presentation went pretty well. They would like us to drop off a couple models at the hospital so they can evaluate them and fill out the ergonomics survey
- They said the ends could be longer and it may be beneficial to have them curved in to follow the contour of the thyroid
- Some concern over grooving the ends of the device as it may cause tissue damage
    - Possibly just put a peanut over the ends or some sort of shod
- Overall consensus was that they have developed their own unique ways of retracting the thyroid, most of them seem to just use their hand but said they would be open to trying something new

Conclusions/action items:

This was a good meeting to have to hear feedback from medical professionals who would actually be using the device. For action items, we are going to print more models to distribute at the UW hospital.

Advisor Meeting 2/7

KATE EICHSTAEDT - Feb 07, 2022, 5:07 PM CST

Title: Advisor Meeting

Date: 2/7/22

Content by: Kate Eichstaedt

Present: Whole team and advisor

Goals: Discuss recent goals, ask questions about journal article, recap last semester

Content:

To do list next coming week:

- Writing draft of peer reviewed journal submission
  - unmet need, what did we do, what did we build, how did we test it, why did we test it, what are the results
  - emphasis on outcome
- Next week:
  - testing plan
    - reflect our intention of using our prototype, showing it completes PDS
    - shows that it works as intended
    - tests will be indicative of outcomes we are trying to demonstrate
      - WARF, future manufacturers, clinicians
    - Emphasis on what we delivered and why it meets our clients requirements
    - Lighter on the technical side
  - Find a model of a peer reviewed journal submission
    - journal that talks about medical device testing
    - write content off of that format
      - abstract, intro, methods, results, discussion
  - Meeting next week is preliminary presentation
    - propose what we are going to do, why, and what it is going to tell us
  - Need to research business viability
  - IDR
    - need to demonstrate business viability for Tong competition anyways
      - kill two birds with one stone
    - better to do it now than later ?
  - Basically find a journal to model our draft after for our next meeting
    - make a couple recommendations for the journal we want to submit to
    - look at journal guidelines; know what is expected from us
  - No impact factor requirements

Conclusions/action items:

This meeting was very helpful for clarifying some of the events of the semester, such as draft journal submission and preliminary presentations.

Advisor Meeting 2/14

ASHLEE HART - Feb 17, 2022, 12:51 PM CST

Title: Preliminary Presentation Meeting

Date: 2/14

Content by: Ashlee

Present: Whole team + Mitch

Goals: Detail what the team discussed and learned in our advisor meeting

Content:

- In our journal article, make sure to include our interaction with a cadaver, and how it influenced our need to modify the design: make the distal ends of the retractor longer
- Ergonomics Survey
    - Make sure to send the ergonomics survey over to Mitch by this weekend to get feedback and make modifications for our client meeting next Wednesday
        - Have in word document format
    - Include an introduction paragraph:
        - who we are
        - what we're doing
        - intention of survey
        - nature of survey
    - Tally the number of responses
    - Don't have a slide bar
    - Encourage Dr. Doubleday to disperse this survey widely
    - Have an open comment box for any questions on the survey
    - Get 12-20 participants
    - Draft using the language Dr. Doubleday would use
    - Post the survey on the team website
    - The negative comments we receive will be much more helpful than the praise
    - Create an ID system so participants remain anonymous
- For future ergonomics testing, we can look into ballistic gel with film to mimic skin
- The ASME Journal of Medical devices sounds good, but look for one other alternative. Make sure we fit the criteria of the journal well.

Conclusions/action items:

We had a lot of discussion in this meeting about the ergonomics survey we will be sending to Dr. Doubleday next week. We have a plan to insert an introduction paragraph to the survey and make any modifications Mitch and recommended before sending it to him. The team plans on sending the word document version of our survey over to Mitch by this weekend, so that we can have a great survey prepared for Dr. Doubleday.

Advisor Meeting 2/21

KATE EICHSTAEDT - Mar 01, 2022, 4:14 PM CST

Title: Advisor Meeting

Date: 2/21

Content by: Kate

Present: Whole team and prof. Tyler

Goals: Record notes from our weekly meeting

Content:

- Questions about WARF
    - Include final report from last semester alongside other CAD files of device
    - Last semester's final poster presentation is our first non-confidential presentation because it was not in a closed setting unlike the one on gather town or over zoom, so list this presentation date in WARF application
    - Think about it more as a sales pitch
- Survey looks good
    - add more specific questions
        - ask about how they tested it, length of legs, size and shape of finger holes
    - Say please when asking for respondent to explain ranking
- No meeting next week, 2/28
- Deliverables due Friday 3/4

Conclusions/action items:

To conclude, this meeting was helpful in order to ask a few questions about our WARF application. For action items, we are going to continue work on the WARF application and make necessary changes to our survey.

Advisor Meeting 3/7

KATE EICHSTAEDT - May 03, 2022, 8:48 PM CDT

Title: Advisor Meeting

Date: 3/7

Content by: Kate

Present: Whole team and advisor

Goals: Listen to verbal feedback on deliverables

Content:

Draft manuscript was due last week Friday.

- People reading this in a medical device journal would be less interesting in the actual medical problem
    - we can probably cut out a lot of the background section
- Really express why the testing we did was important and what it proves
- Try to filter out extraneous information that is not essential to the narrative.

Conclusions/action items:

To conclude, this was very helpful feedback regarding our draft manuscript. I have never written something like this and was not totally sure what sections to all include so the feedback was very helpful for what sections we need to change or omit in the final. For action items, we are going to make the necessary revisions to our manuscript.

Advisor Meeting 4/25

Mitchell Josvai - May 06, 2022, 1:20 PM CDT

Title: Advisor Meeting 4/25

Date: 4/25

Content by: Mitchell Josvai

Present: Mitchell Josvai, Kate Eichstaedt, Ashlee Hart, Avani Lall

Goals: Prepare for final presentations and finalize manuscript

Content:

- Prefer if the abstract is bullet points over paragraph
- Poster is essentially a short version of the paper
    - Focus on 5 finger philosophy
    - Audience has only read the executive summary, must inform them
    - Cut to the chase, be overly brief and allow them to ask questions
    - 5 min
- Emphasizer technical chops, good science, and IP potential
- Short future work, idealized
- Show that testing has informed future iterations of the design
- Future: steps to be ready to commercialize (that we are aware of)
- Name drop possible companies/manufacturers we could target
- How to make it a pre-commercial prototype and pass it to someone capable of manufacturing

Conclusions/action items:

Use our advisors advice and critiques to improve our presentation for the Tong competition

2/15/2022: Past and Future Costs

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 2:58 PM CST

Title: Past and Future Costs

Date: 2/15/22

Content by: Mitchell

Goals: Create a sheet of expenditures spent last year and expected for this upcoming semester.

Content:

- Past Expenditures:

Item	Individual Price	Number	Total
Preliminary Fabrication (PLA)	$1.12 - $1.36	5	$6.00
Testing Materials	$5.00	1	$5.00

- Expected Future Expenditures

Item	Individual Price	Number	Total
Final Fabrication	$10*	3	$30.00*
Final Testing Materials	$75	1	$75

Conclusions/action items: Keep track of costs for the rest of the semester.

3/5/2022: Organ Tissue Analog Testing Protocol

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 8:47 PM CDT

Title: Organ Tissue Analog Testing Protocol

Date: 3/5/2022

Content by: Avani, Mitchell, Kate, Ashlee

Present: Avani, Mitchell, Kate, Ashlee

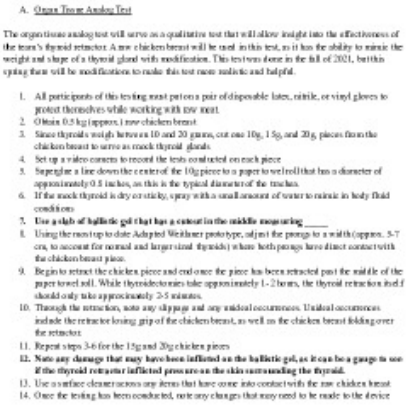
Goals: To provide a walkthrough of the organ tissue analog testing we will perform.

Content:

See attachment.

Conclusions/action items: Conduct organ tissue analog testing as well as other tests with final prototype.

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 8:46 PM CDT



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. This test was done in the fall of 2021, but this spring there will be modifications to make this test more realistic and helpful.

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 0.5 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. **Use a slab of ballistic gel that has a cutout in the middle measuring ____**
8. Using the most up to date Adapted Weidauer 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.
9. 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.
10. 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.
11. Repeat steps 3-6 for the 15g and 20g chicken pieces
12. **Note any damage that may have been inflicted on the ballistic gel, as it can be a gauge to see if the thyroid retractor inflicted pressure on the skin surrounding the thyroid.**
13. Use a surface cleaner to clean any items that have come into contact with the raw chicken breast
14. Once the testing has been conducted, note any changes that may need to be made to the device

Download

Spring_2022_Test_Protocol.pdf (57.3 kB)

1/30/22: Semester Timeline

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 2:54 PM CST

Title: Semester Timeline

Date: 1/30/22

Content by: Avani, Ashlee, Kate, Mitchell

Goals: To create a Gantt Chart with semester goals.

Content:

https://docs.google.com/spreadsheets/d/1LAaQn-xYFA16L-Fg_2QgshOVJ6Vt3G78uWsM9TAEYRo/edit?usp=sharing

Conclusions/action items: Update the Gantt Chart regularly, is a living document

2/14/22: Preliminary Presentations

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 2:32 PM CST

Title: Preliminary Presentations

Date: 2/15/2022

Content by: Avani, Kate, Mitchell, Ashlee

Present: Avani, Kate, Mitchell, Ashlee

Goals: To create a presentation focused on demonstrating how we as a team has moved and will move forward from the work done in the Fall semester to a final device that closely meets the clients needs.

Content:

https://docs.google.com/presentation/d/1H_HRcqo9Af8Am_CDbJTUMZ1XxyGxITl4nTd0L6EE_dg/edit?usp=sharing

Conclusions/action items: Get feedback on our specific goals and timeline for the semester from advisor.

4/29/22: Final Poster

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 8:50 PM CDT

Title: Final Poster

Date: 4/29/2022

Content by: Avani, Kate, Ashlee, Mitchell

Present: Avani, Kate, Ashlee, Mitchell

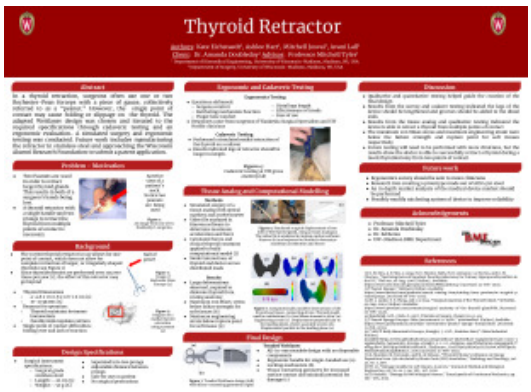
Goals: To create a poster showing our work to date on creating a novel thyroid retractor.

Content:

See attached file.

Conclusions/action items: Work on rest of final deliverables.

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 8:50 PM CDT



Download

Final_Presentation.pdf (1.01 MB)

IJMDAT

KATE EICHSTAEDT - Mar 01, 2022, 4:17 PM CST

Title: IJMDAT Journal

Date: 2/10/22

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Investigate a possible journal to model our paper after

Content:

The international journal of medical device and adjuvant treatments (IJMDAT) is a journal that publishes papers that are related to the development and use of medical devices and adjuvent treatments.

This seems like a pretty good journal to base our paper on because the journal is a medical device journal and we are creating a medical device.

The format guide states that the word limit is 3500 words, which excludes the abstract and references. The abstract needs to be less than 300 words.

The text should start with a abstract that contains the following headings:

INTRODUCTION, MATERIALS AND METHODS, RESULTS, CONCLUSIONS

Double spacing should be used. Tables and figure captions are in separate files. These have to be mentioned in the text of the paper. Uses all SI units.

link to guidelines: https://www.ijmdat.com/instructions-for-authors

References:

“Instructions for authors,” *IJMDAT*, 26-Mar-2021. [Online]. Available: https://www.ijmdat.com/instructions-for-authors. [Accessed: 01-Mar-2022].

Conclusions/action items:

Overall, this seems like a good possible journal to follow the requirements for for our paper. The guidelines were pretty straight forward and the sections required are very reasonable. For action items, I am going to do more research to find other medical device journals.

Journal of Medical Devices

KATE EICHSTAEDT - Mar 01, 2022, 4:19 PM CST

Title: ASME Journal of Medical Devices

Date: 2/10/22

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Investigate a possible journal to model our paper after

Content:

The journal of medical devices is a subset of the ASME (American Society of Mechanical Engineers) Digital collection.

https://asmedigitalcollection.asme.org/medicaldevices/issue/15/4

Our type of paper would be a research paper.

Requires all SI units.

Paper requirements are as follows: title, authors and affiliations, abstract, body(subdivided), equations, acknowledgments, funder information, nomenclature, appendices, references, figures and tables

https://www.asme.org/wwwasmeorg/media/resourcefiles/shop/journals/asme_guide_for_journal_authors_final.pdf

References:

"Issues," *Volume 15 Issue 4 | J. Med. Devices | ASME Digital Collection*. [Online]. Available: https://asmedigitalcollection.asme.org/medicaldevices/issue/15/4. [Accessed: 01-Mar-2022].

"ASME's Guide for Journal Authors Submit Your Manuscript." [Online]. Available: https://www.asme.org/wwwasmeorg/media/resourcefiles/shop/journals/journaladministration/med-cfp-healthtechnologies_final.pdf. [Accessed: 01-Mar-2022].

Conclusions/action items:

This is a possible journal that we could model our paper after. However, the requirements for the body of the paper were somewhat vague. I would prefer a journal that states explicitly what is needed in that section. For action items, I am going to continue trying to find a suitable journal.

Medical Device Market

KATE EICHSTAEDT - Apr 19, 2022, 11:10 AM CDT

Title: Medical Device Market

Date: 4/19

Content by: Kate

Present: Kate

Goals: Upload the notes I took about the medical device market when I was doing research for the Tong essay.

Content:

According to Grand View Research, the global market for surgical devices was estimated to be 12.79 billion USD in 2021. North America accounts for 40% of this market. The market is expected to grow by 9.8% between the years of 2021 and 2028. Factors contributing to this increased number includes the rising geriatric population and increased surgical volumes. This is a very large market and it is not too niche that our device would be wasteful to pursue in my opinion.

Conclusions/action items:

To conclude, I succeeded in uploading the notes I took when researching for the Tong executive summary. The medical device market holds a very large market share which may be appealing in a commercial sense. For action items, I am going to make last changes to the IDR.

Device Costs

KATE EICHSTAEDT - May 03, 2022, 8:52 PM CDT

Title: Device Costs

Date: 4/18

Content by: Kate Eichstaedt

Present: Kate

Goals: Research into the costs associated with manufacturing this device

Content:

The final product will be manufactured out of AISI 420 steel which is a medical grade steel that is often used for medical devices like our own. I found on a whole sale website that a ton of this steel generally costs around 1,000 USD[1]. The device will likely be around 50 grams. 50 grams is roughly 5.5116e-5 much of a ton. So, the amount of steel that would be used per iteration of the device would only cost around 6 cents.

From what I could find from medical device websites, a Weitlaner retractor usually costs around 170 USD depending on the length one would like to order[2]. There would be other costs associated with the actual manufacturing process, but if the price of material for one device is only 6 cents, there is a large potential margin for profit.

Also depending on where the device is manufactured could alter a lot of things. It is much more expensive to manufacture stainless steel goods in the United States or certain European countries than other countries, but we would have to deal with the ethicality of outsourcing if we ever reached the point where we were looking to actually manufacture this device.

Sources:

[1] “420 stainless steel price,” *Source Strong Wholesale 420 stainless steel price Today - Alibaba.com*. [Online]. Available: https://www.alibaba.com/showroom/420-stainless-steel-price.html. [Accessed: 03-May-2022].

[2] “Weitlaner retractor, self-retaining,” *World Precision Instruments*. [Online]. Available: https://www.wpiinc.com/var-501724-weitlaner-retractor-self-retaining. [Accessed: 03-May-2022].

Conclusions/action items:

To conclude, this was beneficial research to conduct and it will be important for our Tong presentation and if we were to eventually submit an IDR. For action items, I am going to continue to edit the executive summary with the things I find regarding the medical device market.

Reflections after gross lab

KATE EICHSTAEDT - Feb 20, 2022, 5:53 PM CST

Title: Reflections after gross lab

Date: 2/20/2022

Content by: Kate Eichstaedt

Present: Kate Eichstaedt

Goals: Discuss realizations that occurred from going to gross lab to test device.

Content:

Recently me and my teammates went to the UW gross anatomy lab to see a cadaver's thyroid and to attempt to lift the thyroid with our 3-D printed prototype. This experience was very helpful. One of the first things I noticed was that the area Dr. Doubleday is operating in is very small. It may be beneficial to increase the length of the device's legs in order to have better access to this area. Additionally, the finger holes in the device should be made slightly larger. I was using the device and have medium sized fingers, about a size 7 ring size, which is 17.35 mm in diameter, and the finger hole edges were brushing my finger on all edges. In order to accommodate to a larger population, the hole sizes should be increased.

When using the device to retract the thyroid medially, it did work as intended. Obviously the environment I was using the device in is different than a surgical environment, but the device operated as intended. For me, it was a little confusing to first operate the device because the Weitlaner retractor works opposite the way a normal scissors would. For example, when using a normal scissors, if you spread the finger holes, the blades separate, the Weitlaner ratcheting system works in the opposite way so it was a little hard to get the hang of at first but I am sure that a trained surgeon would have no issue with this. Below is an image of me using the device to retract the thyroid medially (towards me). I tried to replicate what I saw in Dr. Doubleday's video that she sent us last year as best as possible.

Conclusions/action items:

Overall, attending the anatomy lab was very helpful. While doing background research for this project, I have become familiar with different medical diagrams of the thyroid and adjacent anatomy, however, there is a big difference between seeing a diagram versus actually seeing the anatomy in person. For action items, I am going to continue to work together with my group to make adjustments to the device design.

Ergonomics survey

KATE EICHSTAEDT - Feb 21, 2022, 10:17 AM CST

Title: Ergonomics survey

Date: 2/21/22

Content by: Kate

Present: Kate

Goals: Upload survey questions as well as explain why ergonomics survey will be conducted

Content:

In order to prove the functionality of our device, performing an ergonomics survey is essential. We can do other tests like a tissue analog or biocontamination test to ensure the device works and does not damage the thyroid, but a big part of device performance is if the surgeon using the device is comfortable using it. This is the main reason for performing this test. During our meeting with Dr. Doubleday on Wednesday, we are planning on giving her a couple prototypes to take home with her. We are hoping she will show these to her co workers who will then fill out the survey.

Below are the survey questions:

* the survey will be a google form and sent out using a link

Thyroid Retractor Ergonomics Survey

Our team is a group of undergraduate Biomedical Engineering students currently enrolled in Biomedical Engineering Design 402. This three semester long project has been dedicated to the creation of a thyroid retractor to be used in thyroid related surgeries. This ergonomics survey will be conducted in order to evaluate the effectiveness and the usefulness of our team's thyroid retractor.

1. How comfortable do you feel holding the thyroid retractor? (1 being very uncomfortable, 7 being very comfortable)

Discuss your answer to question #1 and why you gave it the rating you did

2. How well does the ratcheting mechanism function? (1 being functions very poorly, 7 being functions as expected/needed)

Discuss your answer to question #2 and why you gave the rating you did

3. How easy is the retractor to use? (1 being very difficult, 7 being very easy)

Discuss your answer to question #3 and why you gave the rating you did

4. What is your overall satisfaction with the thyroid retractor? (1 being very unsatisfied, 7 being very satisfied)

Discuss your response to question #4 and why you gave the rating you did

Please leave any overall thoughts, comments, advice, etc. on the thyroid retractor. Thank you!

- This last question is optional

Conclusions/action items:

To conclude, I think that this survey will be a good way of receiving feedback on the design of our device. Although our device may technically work, the use of the device really depends on if medical staff like to use the device. For action items, I am going to create lab archives pages for the other testing procedures that will be performed this spring semester.

Tissue analog

KATE EICHSTAEDT - Feb 21, 2022, 10:21 AM CST

Title: Tissue analog

Date: 2/21/22

Content by: Kate

Present: Kate

Goals: Describe what the tissue analog test is and why it will be performed.

Content:

Last semester, a tissue analog test was performed. The tissue analog test was performed in order to obtain data to determine if our device would damage a thyroid based on computational modeling. Last semester, we found that the force applied by the device onto the thyroid was not substantial enough to cause damage.

This test will be conducted again this spring. We are continuing to make small changes to the design of the device, so once we have our final design iteration, an additional tissue analog test should be performed just to ensure that the final design will not cause excessive damage to the thyroid.

Conclusions/action items:

To conclude, I think that describing each test that we are going to perform as well as the purpose behind it is very beneficial. When writing our 'manuscript', we will likely have to explain why we chose the tests we performed and why the results are significant. For action items, I am going to research biocontamination testing.

Biocontamination testing

KATE EICHSTAEDT - Mar 01, 2022, 4:23 PM CST

Title: Biocontamination testing

Date: 2/20

Content by: Kate

Present: Kate

Goals: Explain the reasoning for completing biocontamination testing

Content:

The reason we will perform this is to ensure our device is reusable. Although this test will be performed on our prototype, which will not be made of stainless steel, it will still show where there may be 'problem' areas that could harbor potential biocontaminants.

In order to do this, we will use a total protein assay. Mitchell has a fluorescence microscope at work so we will use that in order to determine the presence and locations of any proteins that are present on the device.

Conclusions/action items:

To conclude, I believe it is very important that we explain and justify each test we are doing to prove that it will actually produce meaningful results that will help us reach our ultimate goal. For action items, I am going to do more research into different types of total protein assays.

Questions for 2/23 meeting

KATE EICHSTAEDT - Feb 20, 2022, 5:59 PM CST

Title: Questions for 2/23 meeting

Date: 2/20/22

Content by: Kate

Present: Kate

Goals: Prepare questions to ask Dr. Doubleday for when we meet with her in person this coming Wednesday.

Content:

- Questions about ergonomics survey
    - basic thoughts, things we should add/remove
    - Concerns about not getting enough responses
        - realistically does she think 12+ people would be willing to take the survey
        - possible connections at UW hospital for people to take the survey there?
- Basic device questions
    - thoughts about prototype
        - changes she thinks may be beneficial
- Possibly discuss WARF application
- Technical questions after seeing gross lab
    - about how many centimeters is the incision you make in the neck?
    - vertical or horizontal?

Conclusions/action items:

I think that creating a list of prepared questions to ask Dr. Doubleday for our meeting will be very helpful for making the meeting go efficiently and to make sure we are not forgetting to ask her something. For action items, I am going to upload a copy of the ergonomics survey to our lab archives.

Ergonomics survey results

KATE EICHSTAEDT - May 03, 2022, 8:39 PM CDT

Title: Ergonomics survey results

Date: 4/18

Content by: Kate Eichstaedt

Present: Kate

Goals: Reflect on some of the feedback from the ergonomics survey.

Content:

Unfortunately we only received 5 responses from the survey, this was kind of expected as I understand that the clinicians were likely very busy and may not have had time to sit down and evaluate the device. Nevertheless, the feedback we received was very helpful.

Overall, it seemed like those who took the survey would be willing to try this device in a surgical setting. There were many comments made about the length of the device, so we will use that feedback to increase the leg length of the device. Additionally, some survey takers were concerned about the ability of the distal portions of the device to have traction on the thyroid, so that would be something we should look into. This feature specifically was difficult to convey because the device actually would have little ridges on the distal portions, but this is very hard to do when 3-D printing.

I think the ergonomics survey was a very important test we did this semester and even though we did not receive the volume of feedback we wanted, I think it was still important to hear some feedback from the people who would actually be using the device.

For the complete survey results, they are in the team google drive and can be displayed in a google spread sheet.

Conclusions/action items:

To conclude, as stated even though we did not have as many responses as we would have liked, the survey was still very helpful in guiding our creation and solidification of the final design. For action items, I am going to write the discussion portion of the draft manuscript regarding the ergonomics survey results.

Spring Testing Schedule

KATE EICHSTAEDT - Feb 20, 2022, 6:15 PM CST

Title: Spring testing schedule

Date: 2/20/22

Content by: Kate

Present: Kate

Goals: Upload the spring testing schedule I created for the preliminary presentations.

Content:

Below is a tentative testing schedule for this semester. It will be very helpful to ensure that we stay on track throughout the semester and make steady progress.

Date	Task
2/15	Adjust SolidWorks model based on feedback from cadaveric observations
2/18	3D Print multiple prototypes using the Form 3 printer at UW Makerspace
2/23	Meet with client and give her prototypes to bring to Waukesha for her and her coworkers to evaluate using ergonomics survey
2/24 - 3/3	Receive feedback from client and coworkers via ergonomics survey and adjust device model as needed
3/10	Tissue analog test and further computational testing
3/17	Biocontamination test with total protein assay using fluorescent microscope

Conclusions/action items:

To conclude, I think that this schedule is manageable. The one thing I am concerned about is the ergonomics survey because I am worried that the responses may take a while to come in. Other than that, there is a lot of wiggle room at the end of the semester which I think will be advantageous if things go wrong or if we run into any obstacles. For action items, I am going to create the preliminary deliverable document so the team can begin to work on it.

IDR-Warf

KATE EICHSTAEDT - Feb 20, 2022, 6:31 PM CST

Title: IDR-WARF

Date: 2/20/22

Content by: Kate

Present: Kate

Goals: List steps we need to complete for filing an IDR with WARF

Content:

https://www.warf.org/invent/patenting-process/

1. First, we will need to submit our innovation disclosure. Submit form online, takes between 1-3 business days to hear back typically. We should do this soon, hopefully before March.

Form basically lists all of our names and affiliations, basic information about the innovation. Why is this innovation needed/how will we implement.

List presentations and publications. I have a question for our next advising meeting because technically I think all of our presentations are considered confidential(?).

'Dates and brief descriptions of any non-confidential presentations, publications or Internet postings'

2. Hear back, schedule 1 hour meeting

Informal, confidential meeting about the details and applications of the design.

3. Committee makes a decision

WARF meetings once a month, so they will decide in their monthly meeting.

4. Disclosure will go through equity review

Ask advisor about this, not really sure what it means

5. Innovators with accepted inventions will enter into a memorandum agreement with WARF

Legal agreement

6. They apply for patent

Conclusions/action items:

To conclude, looking at the steps of an IDR application makes it seem not too difficult. I do have a few questions to ask our advisor during our next meeting though because I am not sure what some of the verbage means. For example, I am not sure what an equity review would entail. For action items, I am going to create a document that lists the questions for the invention disclosure so we can all work together to submit this.

IDR Initial form

KATE EICHSTAEDT - Feb 21, 2022, 10:42 AM CST

Title: IDR Initial form

Date: 2/21

Content by: Kate

Present: Kate

Goals: List the questions that are asked in the initial form for the IDR application and list bullet points on how to answer each one

Content:

1. IP manager - i do not think we have one

2. Innovators

- me, Mitchell, Avani, Ashlee
- Dr. Doubleday
- Prof. Tyler (?)

3. Innovation details

- Title
  - thyrotractor
- Description
  - novel surgical device to aid in the better retraction of the thyroid during surgery
  - explain background in this section?
  - for attachments:
    - include CAD files
    - Photo of prototype
    - Fall 2021 final report?
- Why is this innovation better or needed?
  - no item on market that is able to retract thyroid from multiple points
  - current method is not efficient, pretty clunky and uses both of the surgeons hands
  - makes thyroid retraction more efficient
- How do you envision this innovation being implemented or applied?
  - implemented as a surgical device
    - would be used by Dr. Doubleday and colleagues
  - initially would be marketed as thyroid retraction device
    - however, has more applications in other surgeries that require basic retraction

Presentations and publications -dates and brief descriptions of any non-confidential presentations, publications, or internet postings

- In the past
  - spring preliminary and final presentation
  - spring preliminary and final report
  - fall preliminary and final presentation
  - fall and preliminary final report
- In the future
  - spring manuscript
  - spring final poster presentation
  - Tong competition

Conclusions/action items:

To conclude, this was helpful to complete to organize my thoughts for each section of this form. By having bullet points for each section, I will be able to better write out well written paragraphs for each section. For action items, I am going to ask our advisor about if our class presentations are considered 'non confidential'.

Potential Journal Articles

ASHLEE HART - Feb 12, 2022, 11:42 AM CST

Title: Potential Journal Articles

Date: 2/12/22

Content by: Ashlee

Present: N/A

Goals: Learn and mark down any journal articles that would be good to submit publication to

Content:

1. American Society of Mechanical Engineers, Journal of Medical Devices

- https://asmedigitalcollection.asme.org/medicaldevices
- The thyroid retractor we have is purely a mechanical engineering device, so this may be relevant
- This journal has papers that deal with "improving diagnostic, therapeutic, and interventional treatments." Does look into the development of new medical devices, which our device is
- It may be better to publish to a journal that is more specific

2. World Journal of Endocrine Surgery

- https://www.wjoes.com/journal/WJOES/page/about
- Pathophysiology and pathobiology of endocrine diseases
- Highlights training tools in endocrine surgery - not extremely relevant to our thyroid retractor, but could possibly apply
- Does not highlight the creation of new medical devices

3. Journal of Surgical Endocrinology

- https://scholars.direct/journal.php?jid=surgical-endocrinology
- Covers surgery that treats endocrine surgeries
- Helps surgeons understand advancements in endocrine surgery
- Our thyroid retractor is technically advancing endocrine surgery, so this may be a relevant journal

Conclusions/action items:

I found three solid journal options. I would most likely go with Journal of Surgical Endocrinology because it discusses the advancement of endocrine surgeries, and is more specific than the general Journal of Medical Devices. For what is next, the team will discuss what journals everyone found and decide which is best. If there is no consensus on a journal article to move forward with, I will continue research on other options.

Makerspace 3D Printers

ASHLEE HART - Feb 06, 2022, 10:07 AM CST

Title: Makerspace 3D printers

Date: 02/06/22

Content by: Ashlee

Present: N/A

Goals: Research all the 3D printers available at the Makerspace to see which one may be best for the most accurate rendition of our prototype

Content:

Ultimaker (FFF)

- FFF: Fused Filament Fabrication
- "efficient and economical while producing high-quality parts"
- This is the printer the team has been using, which has produced good parts, but we're looking for higher quality. The ratcheting part of the design especially needs more attention to detail

Formlabs 2 and 3s (SLA)

- Excel in print small and intricate parts in high resolution
- These printers may definitely be something our team looks into. We may be able to keep printing the main body of the device with the Ultimaker, and then print the ratcheting part with the formlabs

Formlabs Fuse 1 (SLS)

- Fuses nylon powder layer by layer
- Creates complex parts with no need for support structure

Stratasys F370

- Prints in carbon fiber
- Makes light tools

Markforged and Dolomite

- Dolomite designed for microfluidics
- Markforged prints in carbon fiber and reinforced nylon

Conclusions/action items:

There is definitely a variety of 3D printers available at the makerspace. Our current prototypes from the Ultimaker are great, but we haven't been able to print one that has a solid ratcheting mechanism. Our team should probably look into using one of the Formlabs (1, 2, or 3) for the ratcheting mechanism specifically, or for the whole device. Those printers are a bit more expensive, but should be worth if it we want to bring the best prototype to WARF.

Post Ergonomic Survey Design Idea

ASHLEE HART - May 06, 2022, 12:27 PM CDT

Title: Post Ergonomics Survey Design Idea

Date: 5/3

Content by: Ashlee

Present: N/a

Goals: Demonstrate a design idea that modifies the device after getting results from the ergonomic survey

Content:

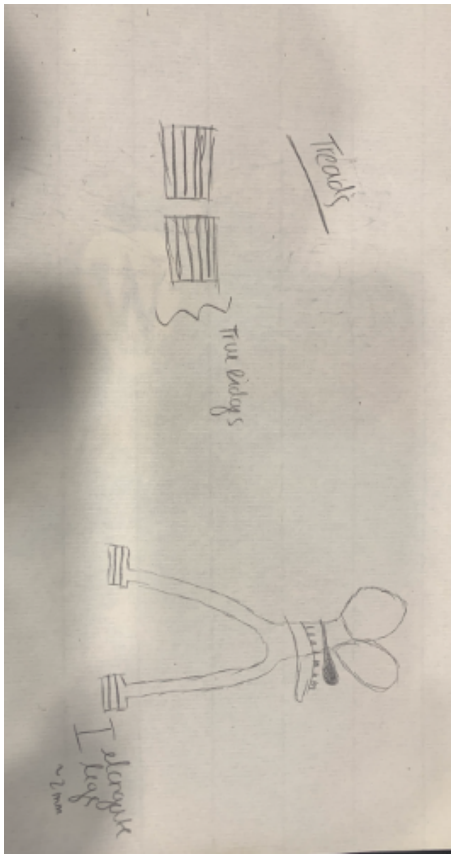


Figure 1: Modifications to be made to the device after the ergonomic survey

Based on the ergonomics survey, the main adjustments to be done to the thyroid retractor have to do with the ratcheting system, length of the legs, and treads. The ratcheting system wasn't very robust due to the nature of 3D printing, which is to be expected. However, it was important for users to get a good feel for how it may look and feel. It was recommended that the legs be extended by 2 mm. Finally, the treads were also not very apparent due to the nature of 3D printing. To combat this with the 3D printing material, we could carve the treads ourselves.

Conclusions/action items:

The ergonomics survey was a success. We learned what modifications would need to be made to make endocrine clinicians content with our device. Unfortunately we only have 5 responses as of May 6, but more responses are anticipated due to Mitchell dropping off more prototypes with Dr. Doubleday Monday, May 2.

Analog Test Ideas

ASHLEE HART - Feb 20, 2022, 3:21 PM CST

Title: Spring semester analog testing ideas

Date: 2/20/22

Content by: Ashlee

Present: N/a

Goals: Explain ideas relating to the analog test we plan to conduct this semester

Content:

- Last semester we conducted a tissue analog test with a chicken breast, paper towel roll, and hot glue. I believe that we should all the same items going forward, but have some modifications to the test
- We definitely need to figure out the typical space dimensions that Dr. Doubleday works with. When we went to the cadaver lab with Dr. Bersu, we had all the space needed to get a great visual of the thyroid. However, Dr. Doubleday works with much smaller dimensions
- In order to designate space for retraction, we most likely will need a skin representation. It was brought up at the show and tell session last semester that ballistic gel can be a good representation of skin. However, Professor Tyler said that with the combination of a film, it could probably work
- Similar to the analog test from last semester, we should plan to cut a minimum of three different shapes/weights of the chicken breast

Conclusions/action items:

The main thing to obtain moving forward are the approximate dimensions of the space Dr. Doubleday works with when performing a thyroid retraction. The team is meeting with Dr. Doubleday this Wednesday, so it will be a good time to get those questions asked. While the ergonomics test is being administered starting next Wednesday, we will be able to conduct the analog test in the meantime. Before this Wednesday, I plan to have a list of questions to ask Dr. Doubleday drafted up, and in the following weeks I plan to do more research on skin mimicking material.

Tissue Analog Test Recap

ASHLEE HART - Apr 16, 2022, 2:13 PM CDT

Title: Tissue Analog Test Recap

Date: 4/16/22

Content by: Ashlee

Present: Ashlee, Avani, Kate, Mitchell

Goals: List what happened during testing on 4/11

Content:

The testing we conducted last Monday was a great success. We were able to provide proof of concept with our thyroid retractor that has been updated since the last tissue analog test we conducted.

Instead of a paper towel/toilet paper roll, we used a PVC tube that had a diameter closer in size to the average human trachea. We used chicken breast pieces to mimic the thyroid and a hot glue gun to mimic the connections between the thyroid and trachea (same as last tissue analog test).

The first three rounds of tests conducted consisted of chicken breast pieces of different lengths: 5.5 cm, 6 cm, and 7 cm. In each round of testing, the chicken breast piece was dried off and then glued to the PVC tube. We used the most recent thyroid retractor prototype to retract the thyroid medially, and then used a scalpel to sever the hot glue gun between the thyroid and PVC tube. We repeated this process for all three chicken breast pieces. The final round we did consisted of using a chicken breast piece along with a polymer that has the same modulus as skin to mimic the skin surrounding the thyroid. We used a scalpel to make an incision through the polymer, and then had a second person hold open the incision with a weitlaner retractor, and then retracted the thyroid through the incision.

Conclusions/action items:

There were conclusions that could be made about the testing right away. We know that our thyroid retractor is successful in its retraction of thyroids of different sizes, and is able to retract thyroids through an incision. Mitchell will be doing some motion tracker analysis on this retractions to make further conclusions. Overall, this was a successful set of tests, and will be a good discussion point in our final poster presentation.

Ergonomics Survey Test Recap

ASHLEE HART - May 03, 2022, 12:56 PM CDT

Title: Ergonomics Survey Test Recap

Date: 5/3/22

Content by: Ashlee Hart

Present: N/a

Goals: Discuss the process and outcome of our ergonomics survey

Content:

Creating our ergonomics survey was a great experience and thinking of questions to ask clinicians wasn't difficult.

The questions asked of our client and clinicians and some of their responses:

1. How comfortable do you feel holding the thyroid retractor?
    1. Majority (3/5) people felt that holding the thyroid retractor was comfortable
    2. Some comments say it fit well into most hands but the ratcheting mechanism was tough to feel comfortable with
2. How well does the ratcheting mechanism work?
    1. Most (3/5) did not believe the ratcheting mechanism worked well
    2. Comments say that the mechanism unlocked when it was bumped and didn't work as well
3. What is the comfort level of the finger holes?
    1. All but 1 survey response felt that the finger holes were appropriately sized
    2. One comment mentioned that the finger holes may not be necessary since clinicians don't necessarily use them in the retraction
4. How comfortable is the length of the retractor?
    1. No one had any issues with the length
    2. The only modification suggested was curving the ends of the device inward to have better retraction. Also lengthening by the slightest amount
5. How are the effectiveness of the treads?
    1. Answers were across the board (1-7 score)
    2. Comments mentioned that it was tough to really see the treads in the PLA form. The ones shown didn't really seem like they would retract well
6. How easy is the retractor to use?
    1. It was agreed that the device was fairly easy to use
    2. Comments mentioned the device being simple and intuitive
7. How likely would you be to use the thyroid retractor?
    1. People would be likely to use the thyroid retractor
    2. People were willing to give the thyroid retractor a try
8. Overall satisfaction of the thyroid retractor?
    1. Ranged in ratings from 1-7
    2. There were concerns about gripping the thyroid

These responses came from 5 different clinicians of Waukesha Surgical Specialists and UW Health. This prototype definitely had many aspects to be modified in order to use it for a true retraction, but the feedback was great. Changes to make to the device moving forward include making the ratcheting mechanism more robust, lengthening the legs by a small amount, and curving the legs inward to help with retraction.

Conclusions/action items:

Ideally the team would have had at least 10-20 responses to our ergonomics survey. Mitchell has dropped off two prototypes with Dr. Doubleday to bring to UW Health for more survey responses, so we'll be able to get more feedback from that. We were overall satisfied with the outcome of our survey.

Updated Tissue Analog Test Protocol

ASHLEE HART - May 03, 2022, 1:05 PM CDT

Title: Tissue Analog Test Protocol Round 2

Date: 4/11

Content by: Ashlee

Present: N/a

Goals: Document our Tissue Analog Test Protocol

Content:

1. 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. This test was done in the fall of 2021, but this spring there will be modifications to make this test more realistic and helpful.

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 PVC tube 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. Lay a polymer mimicking skin over the chicken breast and PVC tube to prepare for cutting through "skin"
8. Using the most up to date 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.
9. Use a scalpel to make an incision along the the polymer mimicking skin
10. Begin to retract the chicken piece and end once the piece has been retracted past the middle of the PVC tube. While thyroidectomies take approximately 1-2 hours, the thyroid retraction itself should only take approximately 2-5 minutes.
11. 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.
12. Repeat steps 3-6 for the 15g and 20g chicken pieces
13. Note any damage that may have been inflicted on the skin mimicking polymer, as it can be a gauge to see if the thyroid retractor inflicted pressure on the skin surrounding the thyroid.
14. Use a surface cleaner across any items that have come into contact with the raw chicken breast
15. Once the testing has been conducted, note any changes that may need to be made to the device

Conclusions/action items:

The main things that were changed from last semester's tissue analog test protocol including using a PVC tube instead of a paper towel roll. We also added the polymer mimicking skin to help replicate the series of events during a thyroid retraction.

Cadaveric Testing Recap

ASHLEE HART - May 03, 2022, 1:35 PM CDT

Title: Cadaveric Testing Recap

Date: 2/9

Content by: Ashlee

Present: N/a

Goals: Discuss the outcome of the cadaveric testing we did in February

Content:

- Kate, Avani, and I went to the gross anatomy lab with the guidance of Dr. Bersu, our former BME design advisor
- Dr. Bersu gave us a "tour" of the thyroid and its features, as well as where the parathyroid glands would be if they were not removed (or too small) from the cadaver
- We were given the opportunity to put our thyroid retractor directly to the cadaver's thyroid to see how a retraction would play out
    - We noticed that with retracting the thyroid gland medially, it may be helpful to elongate the legs of the retractor to reach better
    - We felt that the width in between the legs was good no matter which setting the ratcheting mechanism is at

Conclusions/action items:

We came to good conclusions on the device. The main takeaway was deciding to elongate the device by a bit for a better reach. Moving forward, more tests will be conducted (tissue analog and ergonomics survey test) so more modifications will be made.

Tent. Plan for Spring 2022

ASHLEE HART - Feb 06, 2022, 9:54 AM CST

Title: Tentative Plans for Spring 2022

Date: 02/06/22

Content by: Ashlee Hart

Present: N/A

Goals: List out the goals and plans for this semester

Content:

In these first two weeks of school, we have so far created our complete gantt chart with all updated deadlines. We also have discussed, as a team, how to move forward in prototyping. Mitchell has reached out to Protolabs with our current stl files and are waiting on an estimate for a rapid prototype. From last semester, we were recommended to look into a more accurate 3D printer, so more research will be done on that in the next few weeks. The team also discussed what we want to do with going to see WARF. We may have a more in depth conversation soon, but I recommended we hear from Protolabs and/or get the most accurate prototype we can get with the 3D printers with the makerspace, and then approach WARF.

This upcoming semester, our main focus will be prototyping to the best of our ability, and conducting the human ergonomics test we didn't get the chance to conduct last semester. So far we already have plans to meet with Dr. Cotter in the gross lab on Wednesday 2/9, and will be bringing our most recent prototypes (if allowed to contact the thyroids with them). It will be a great way to see an actual thyroid in a human body.

Conclusions/action items:

I mainly want to do research on all the 3D printers and the Makerspace, and contact the team last semester who recommended a 3D printer for us to use. Our preliminary presentations are next week, so our whole team will need to prepare for that. Finally, prepare for the team's time in the gross lab this Wednesday (have questions, and create an agenda).

Q's for Dr. Doubleday 2/23

ASHLEE HART - Feb 22, 2022, 9:51 PM CST

Title: Questions to ask Dr. Doubleday on 2/23

Date: 2/22/22

Content by: Ashlee

Present: N/a

Goals: Brainstorm questions to ask Dr. Doubleday in our meeting 2/23

Content:

- What are the dimensions of the incision you're working with when retracting the thyroid or performing a surgery where retraction is necessary
    - If these dimensions vary per patient (understandably), what's a general measurement to go off of
- Considering the tissue analog test we conducted in the previous semester, do you have any recommendations or changes you'd like to see?
- What connections do you have to other clinicians that may want to test our retractor?
- What is the contact information of who you know here at Madison that may also want test out the retractor?
- What changes do you want made to the design?
- Do you have other modifications you want made to the device?

Conclusions/action items:

Our team is meeting with Dr. Doubleday here in Madison tomorrow 2/23. We plan on showing her the ergonomics survey that is to be sent out to all the clinicians we can. We should be able to get feedback on the survey and see if we need to edit it before we finally send it out. Mitchell ran into some trouble today (2/22) with 3D printing the prototype to show to Dr. Doubleday, so he plans on going into the Makerspace tomorrow to try another successful print. I believe I have a lot of good questions to ask and will be sure to document the answers to any of my and our questions tomorrow.

Tissue Analog test skin research

ASHLEE HART - Mar 20, 2022, 11:48 AM CDT

Title: Tissue analog test skin research

Date: 3/20/21

Content by: Ashlee Hart

Goals: Research multiple methods of ways to mimic human skin surrounding the thyroid

Content:

In our team's second round of the tissue analog test, we want to make the setting more accurate. One way to do this is to incorporate a material mimicking human skin around the chicken breast. Having a skin barrier will let the team see if the thyroid retractor has enough room to retract given the space provided by the incision.

In the fall of 2021 at the show and tell, one group recommended we use ballistic gel in order to mimic skin. The following information will be research done on this material and if it may be a feasible option.

Ballistic Gel

- Was created to simulate effects of bullets in animal muscle tissue
- Matches pig muscle tissue which matches human muscle tissue
- Does not match tensile strength of muscles or skin and bones
- Can be created with gelatin and water [1]
- May tear easier than skin
- Closest artificial thing to human or animal flesh [2]

Recipe:

Materials: 2 packets of knox gelatin, cooking spray, water

1. Put two packets of gelatin in a container
2. Slowly add 3/4 cup of water and constantly stir
3. Cool mixture for 3-4 hours
4. Place container in a hot water bath for 15 minutes
5. Pour this now liquid substance in a second container that has been sprayed with non stick pray
6. Put the container in the fridge to cool for 12 hours [3]

Ballistic gel thoughts: It seems like ballistic gel is a decent option for mimicking skin. The team is mostly looking for material that can hold its own like skin, so it represents the dimensions of an incision around the thyroid accurately. Since the team has already tested that our thyroid retractor will not inflict damage to the thyroid, ballistic gel ripping easier than skin is not a concern. If a better, easier option is not found, it seems like ballistic gel should be a good option.

Other Materials

- Liquid suspensions, gelatinous substances, elastomers, epoxy resins, metals and textiles [4]

Fake skin

- This is a recipe for creating fake skin which is commonly used to practice tattoos on
- Ingredients needed: plastic bag, cornstarch or flour, warm water, bowl, rolling pin, fork or whisk
- Real skin stretches more than this fake skin [5]

Fake skin thoughts: I think doing a test run on this skin would be very beneficial to see if it's something we should move forward with in testing. It seems promising, and uses ingredients that are very easy to find. I think as long as this skin doesn't "goop", or slide and not maintain its shape, it would be a good contender.

[1] “Ballistic gelatin,” *Wikipedia*, 26-Jan-2022. [Online]. Available: https://en.wikipedia.org/wiki/Ballistic_gelatin. [Accessed: 20-Mar-2022].

[2] “Ballistic gel: Discover strengths and limitations of ballistic gel at wholesale supplier custom collagen,” *customcollagen*, 26-Jan-2021. [Online]. Available: https://www.customcollagen.com/ballistic-gel-test-results/#:~:text=While%20ballistic%20gel%20is%20the,t%20represent%20skin%20or%20bones. [Accessed: 20-Mar-2022].

[3] wikiHow, “How to make ballistics gel,” *wikiHow*, 18-Mar-2021. [Online]. Available: https://www.wikihow.com/Make-Ballistics-Gel. [Accessed: 20-Mar-2022].

[4] Dąbrowska AK;Rotaru GM;Derler S;Spano F;Camenzind M;Annaheim S;Stämpfli R;Schmid M;Rossi RM; “Materials used to simulate physical properties of human skin,” *Skin research and technology : official journal of International Society for Bioengineering and the Skin (ISBS) [and] International Society for Digital Imaging of Skin (ISDIS) [and] International Society for Skin Imaging (ISSI)*. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/26096898/#:~:text=Results%3A%20It%20was%20found%20that,to%20tune%20their%20physical%20properties. [Accessed: 20-Mar-2022].

[5] J. Betts, “How to make fake skin for tattooing practice,” *LoveToKnow*. [Online]. Available: https://tattoos.lovetoknow.com/tattoo-supplies-resources/how-make-fake-skin-tattooing-practice. [Accessed: 20-Mar-2022].

Conclusions/action items:

Ballistic gel and the fake skin recipe are both great contenders for this tissue analog testing. Before actual testing commences, it would probably be a good idea to test make both of these gels and make a decision about which one to use. Based on the team's gantt chart, we want this test to be conducted by March 31st, so I want to create both of these gels by this weekend (March 27th). I'll discuss with the team if they have any opinions on the material and/or suggestions.

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)

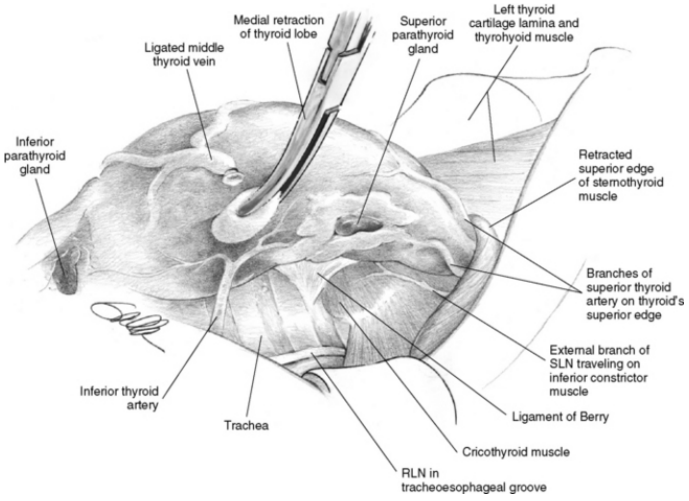


Figure: Medial retraction of one lobe of the thyroid during surgery with a peanut, showing the relevant anatomy near the gland (Randolph, G.W., Clark, O, Principles of Surgery, Chapter 30)

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

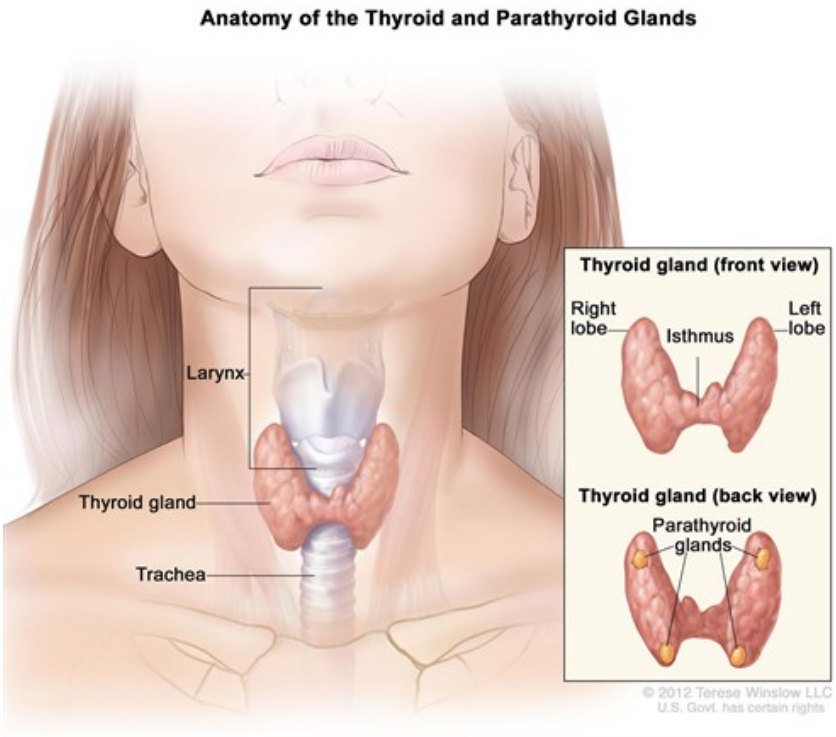


Figure: Anatomy of the thyroid and parathyroid glands (Endocrinesurgery.ucsf.edu. 2020. *Endocrine Surgery - Thyroidectomy*. [online] Available at: <https://endocrinesurgery.ucsf.edu/conditions--procedures/thyroidectomy.aspx> [Accessed 5 February 2021].)

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.

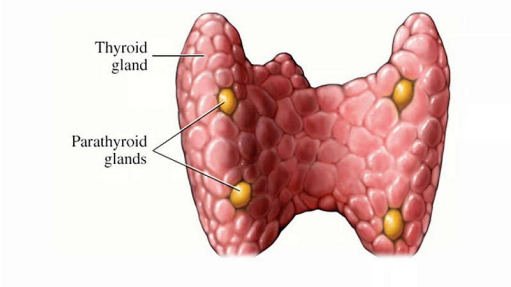


Figure: Location of the parathyroid glands on the posterior of the thyroid gland. Image source: Thyroid Clinic Sydney,

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

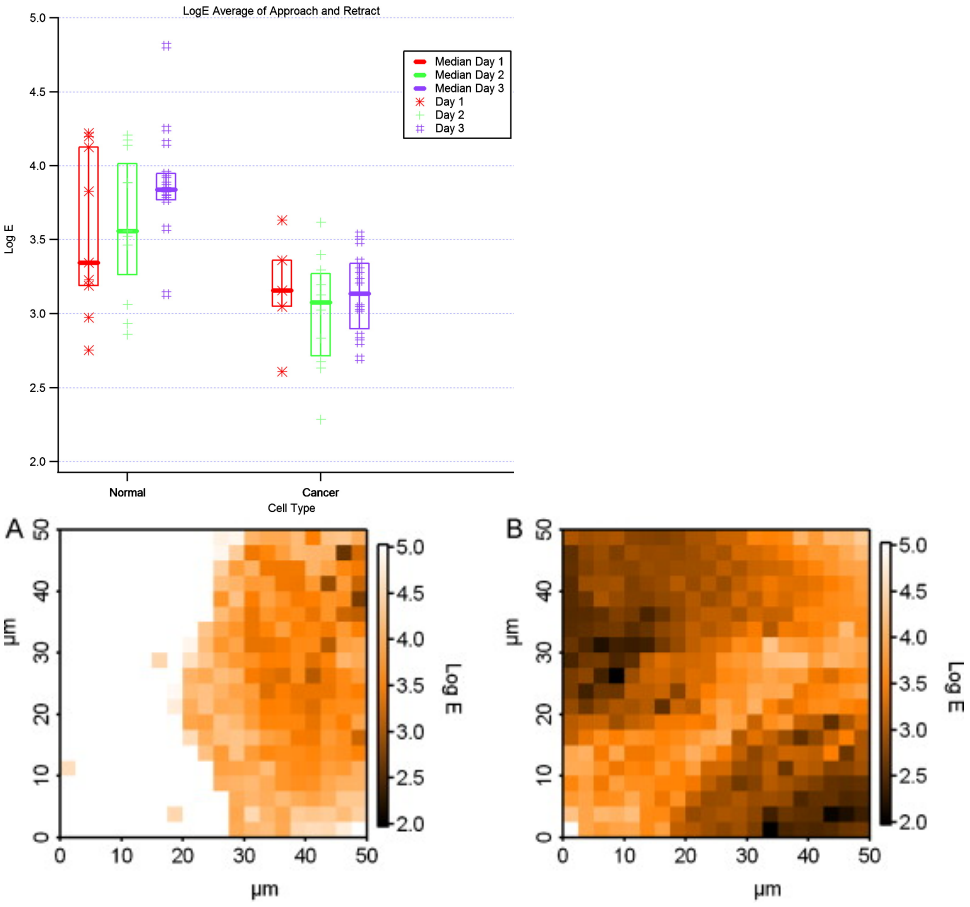
Goals: Research and record data on the mechanical properties of healthy and diseased thyroids

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

Download

Screen_Shot_2021-02-18_at_4.14.01_PM.png (421 kB) 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

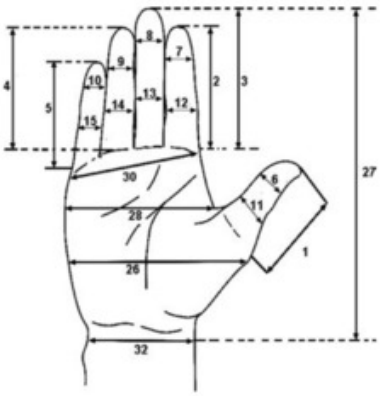


Figure 2 Hand measurements as a diagram.

Figure 3 Hand depth.

Download

Screen_Shot_2021-02-18_at_4.14.08_PM.png (172 kB) 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

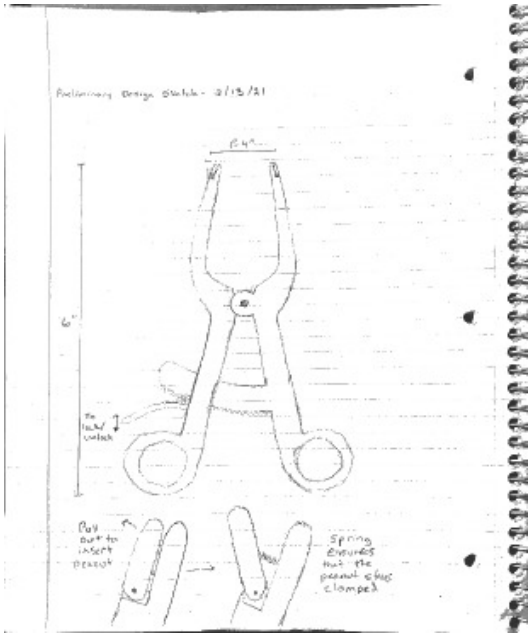
Present:

Goals: Record my preliminary design

Content:

Conclusions/action items:

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



Download

2021-02-18_17-05.pdf (568 kB)

Updated Tip Design Ideas

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

Title: Updated Tip Design Ideas

Date: 3/12/20

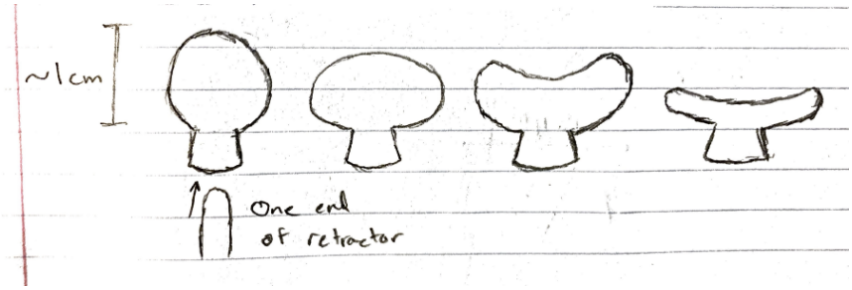
Content by: Mitchell Josvai

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

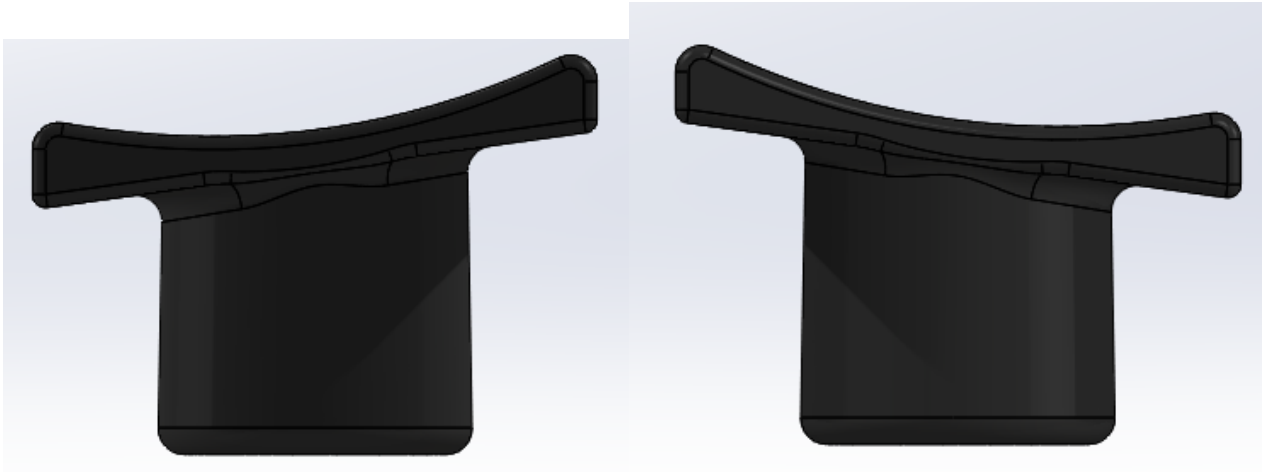
Present: Mitchell Josvai

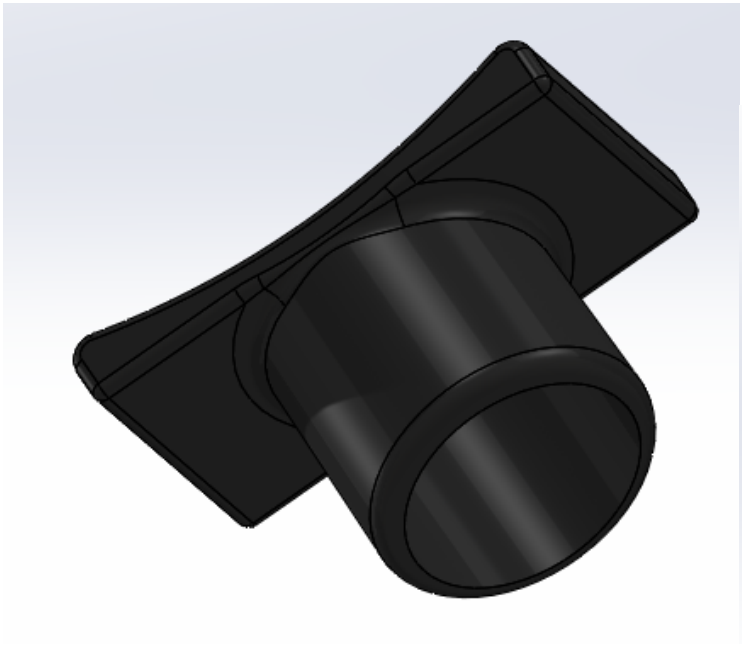
Goals: Record the updated final design

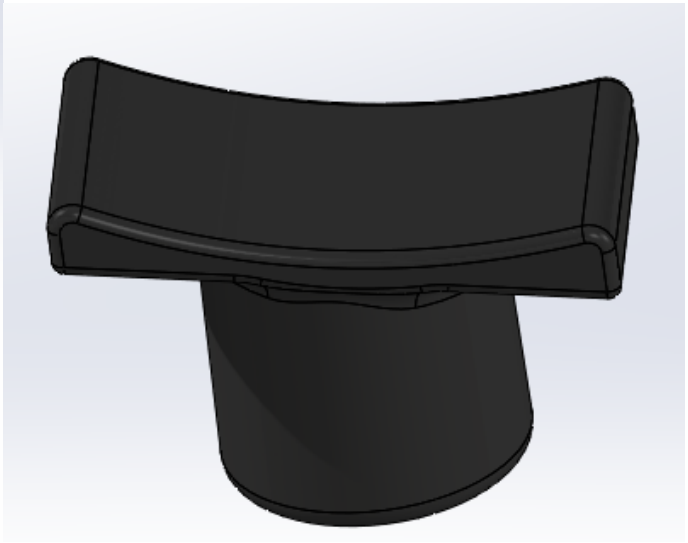
Content:

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

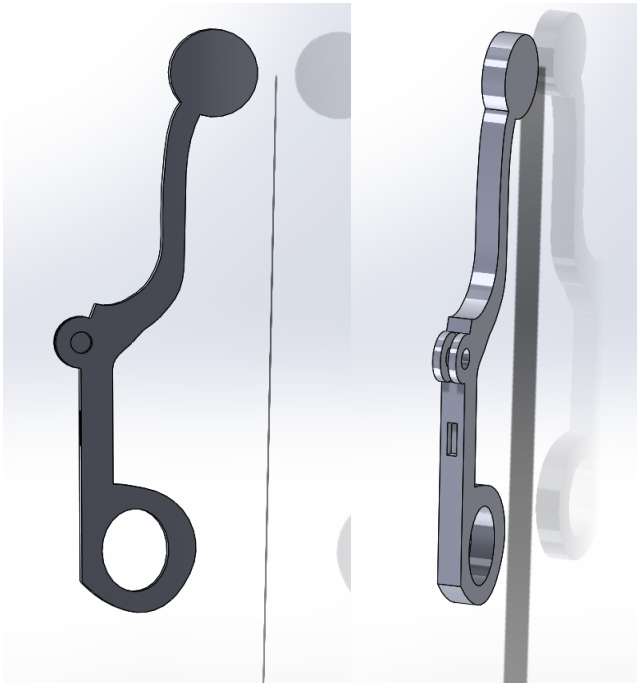
Content by: Mitchell Josvai

Present: Mitchell Josvai

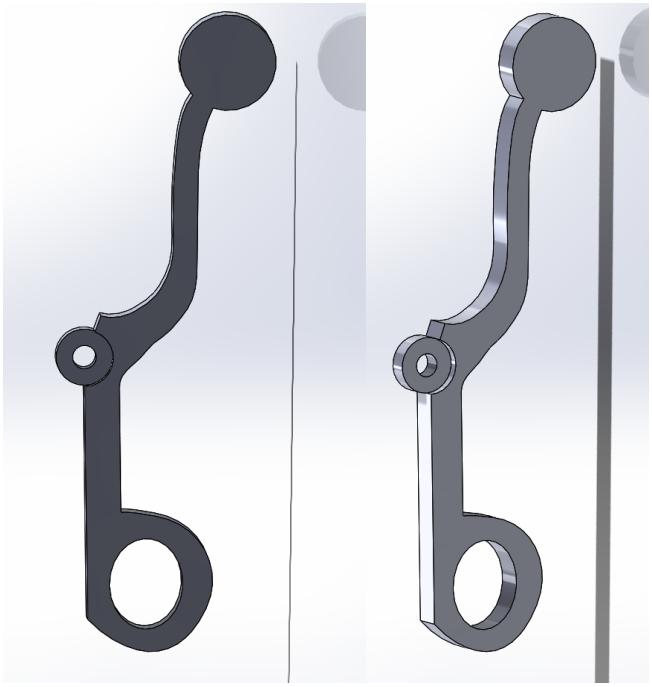
Goals: Record the first iteration of the final design

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

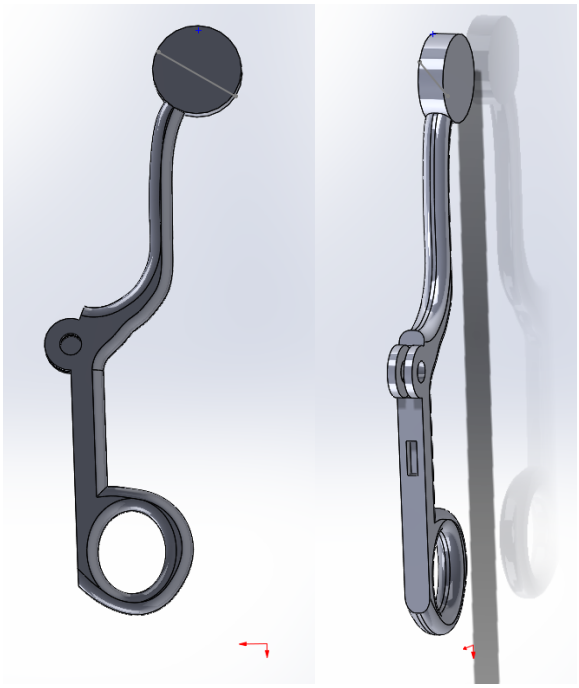
Present: Mitchell Josvai

Goals: Recorded the second iteration of the final design

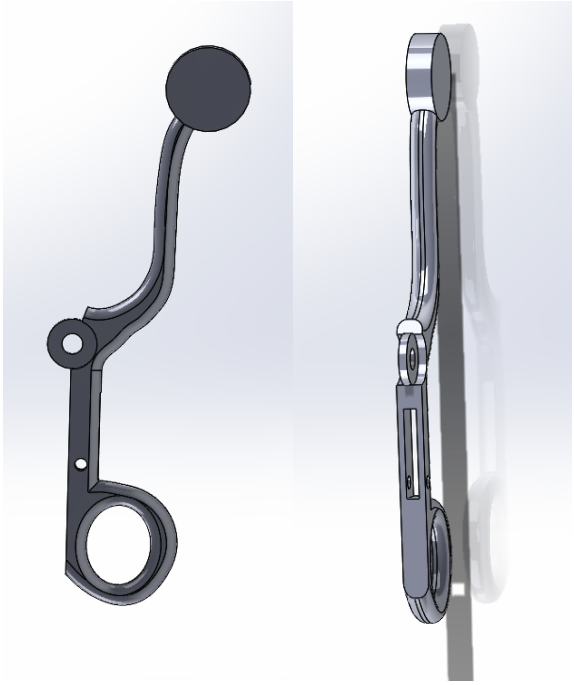
Content:

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.

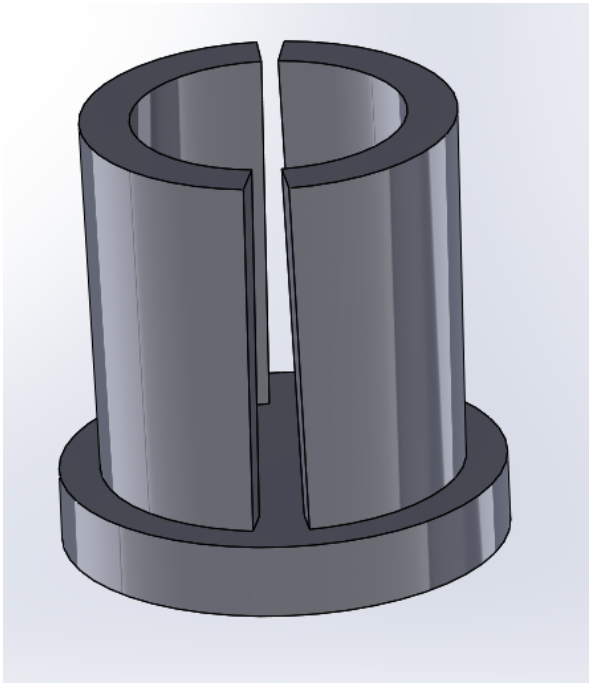
File: 'RetractorLeft_v2_FilletNoEndGeom.SLDPRT'



File: 'RetractorRight_v2_FilletNoEndGeom.SLDPRT'

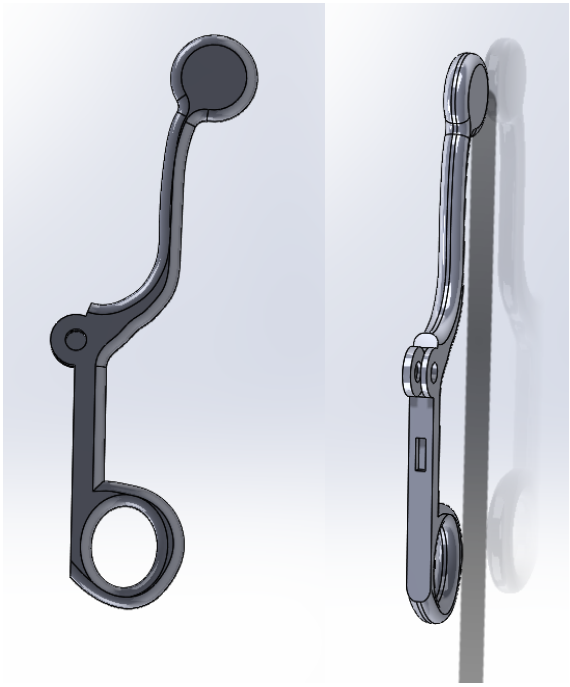


File: 'RetractorCenterPin_5mm.SLDPRT'

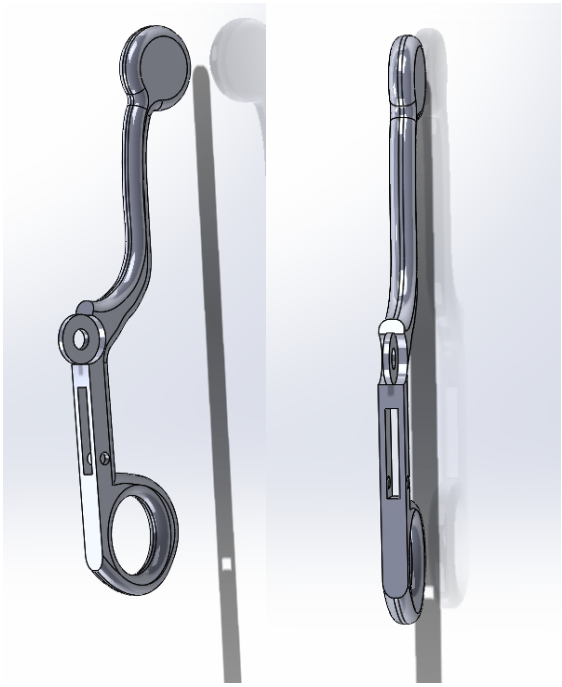


Other versions of the pin were printed with diameters of 4.7, 4.5, 4.3 mm to accomodate the poor tolerance of the 3D printers. The 4.5 mm pin fitsand holds the retractor together the best.

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

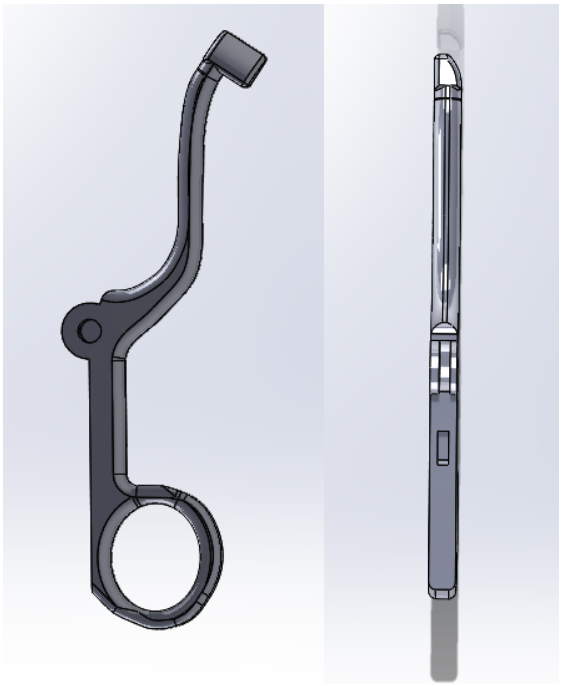
Present: Mitchell Josvai

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

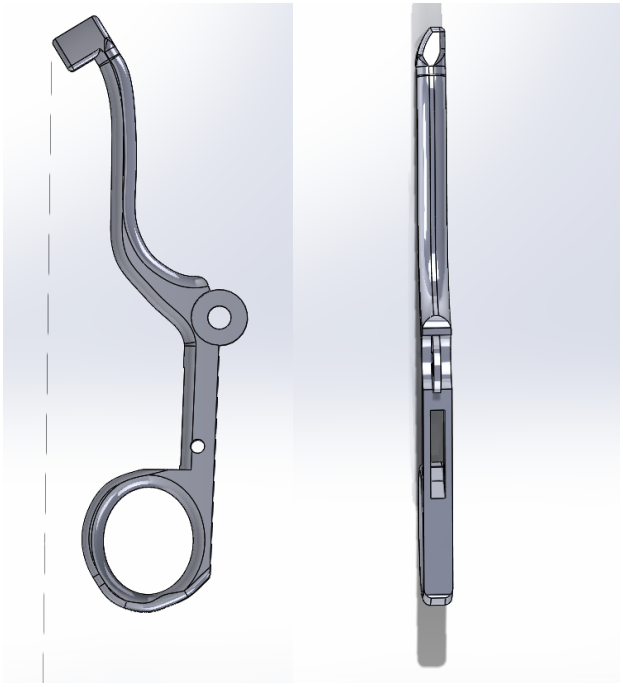
Content:

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

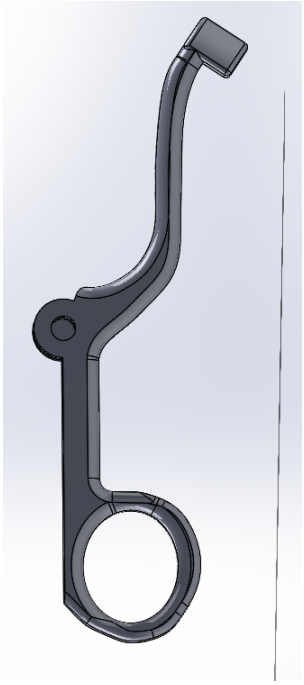
Content by: Mitchell Josvai

Present: Mitchell Josvai

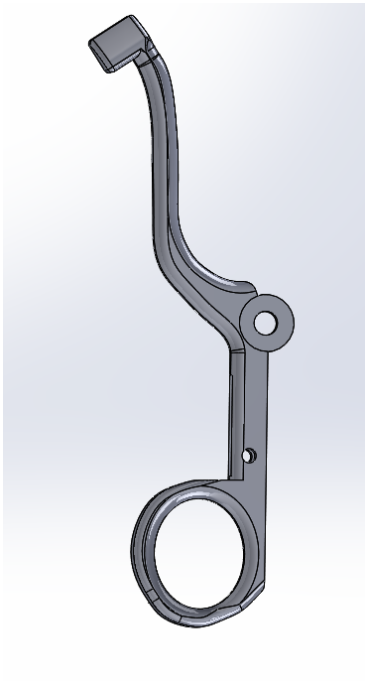
Goals: Record all the compenents of the 5th iteration of the design and the full assembly

Content:

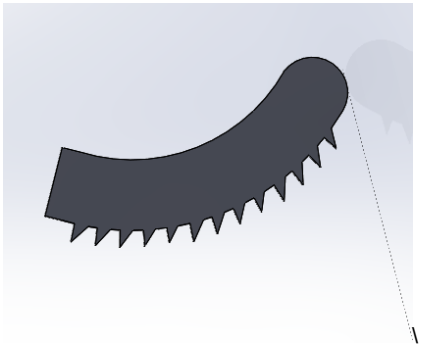
File: 'RetractorLeft_v5_FullFillet.SLDPRT'



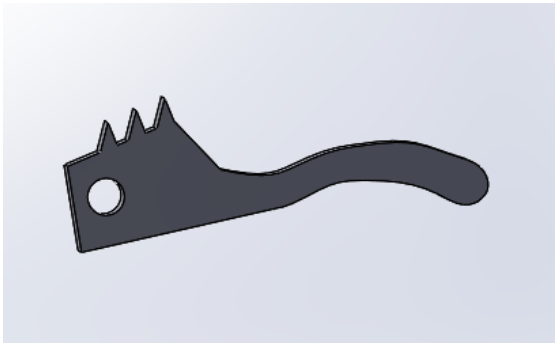
File: 'RetractorRight_v5_FullFillet.SLDPRT'



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

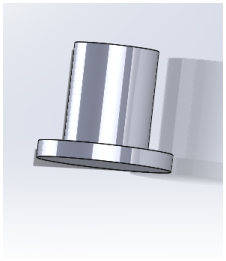


File: 'LockMechFemale_v1.SLDPRT' (Female component of the locking mechanism)

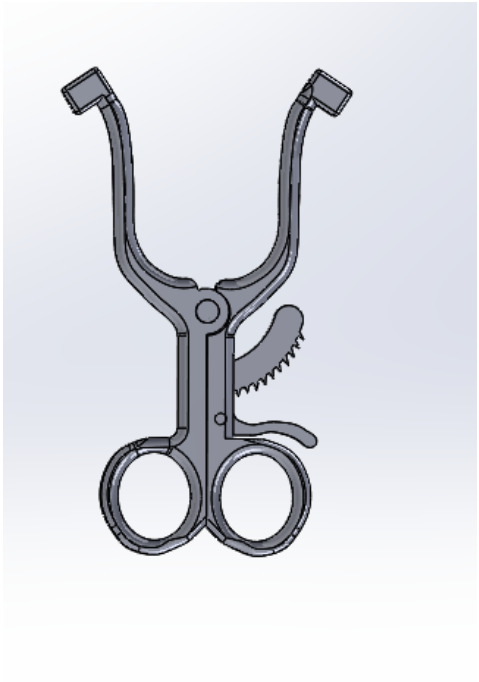


File: 'PinLong_v2.SLDPRT' (5 mm length, 3 mm diameter, connects Female component of locking mechanism to the right half of retractor)

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.

Design v6

Mitchell Josvai - May 06, 2022, 11:24 AM CDT

Title: Design v6

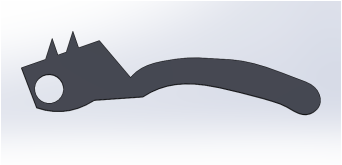
Date: 2/23/22

Content by: Mitchell Josvai

Present: Mitchell Josvai

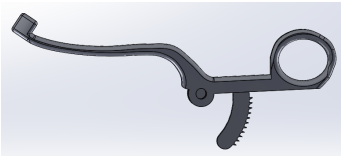
Goals: Record updated design

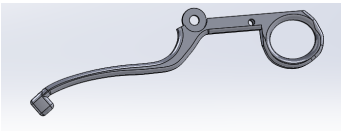
Content:



Locking mechanism part was updated increase the range of motion and prevent it from hitting the base of the retractor finger holes.

'LockMechFemale_v2.SLDPRT'





The left and right pieces of the retractor were modified to increase the length of the legs based on feedback from the ergonomics evaluation and cadaveric assessment. The locking mechanism was added directly to the right piece to increase the ease of assembly and prevent the use of an adhesive in the rapid prototyped models. The final design fabricated in stainless will still have these as separate parts.

'RetractorRightFullFillet_v8.SLDPRT' and 'RetractorKLeftFullFillet_v8.SLDPRT'

Conclusions/action items:

Rapid prototype and assess. Continue to iterate.

Design v7

Mitchell Josvai - May 06, 2022, 11:32 AM CDT

Title: Design v7

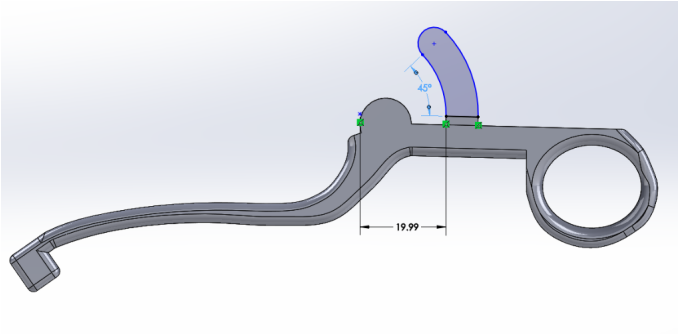
Date: 4/14/22

Content by: Mitchell Josvai

Present: Mitchell Josvai

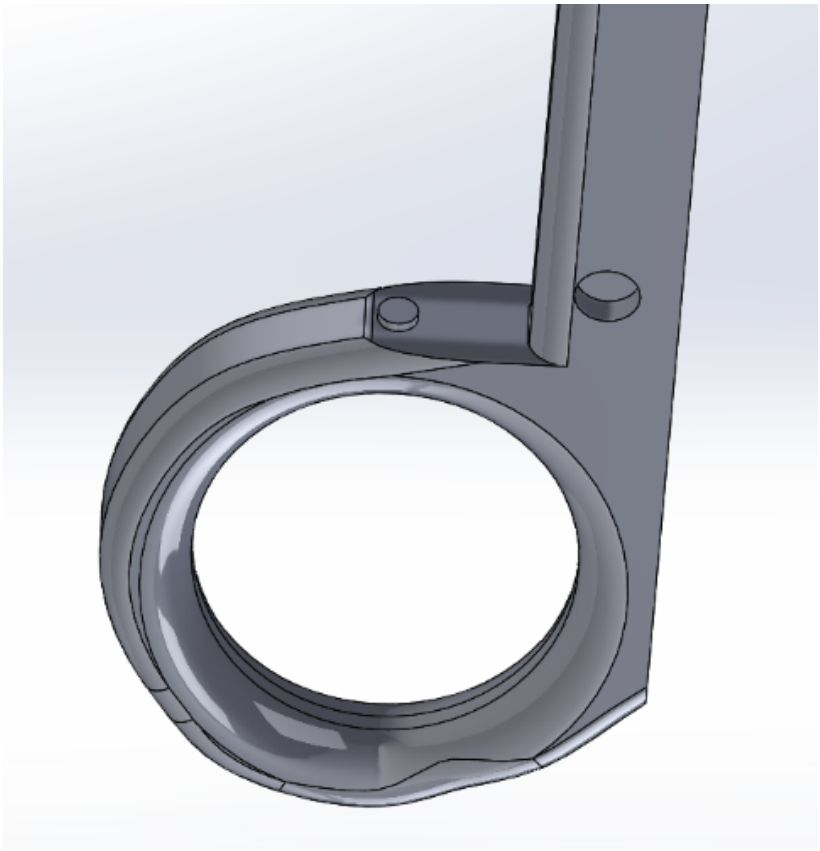
Goals: Record the v7 design updates

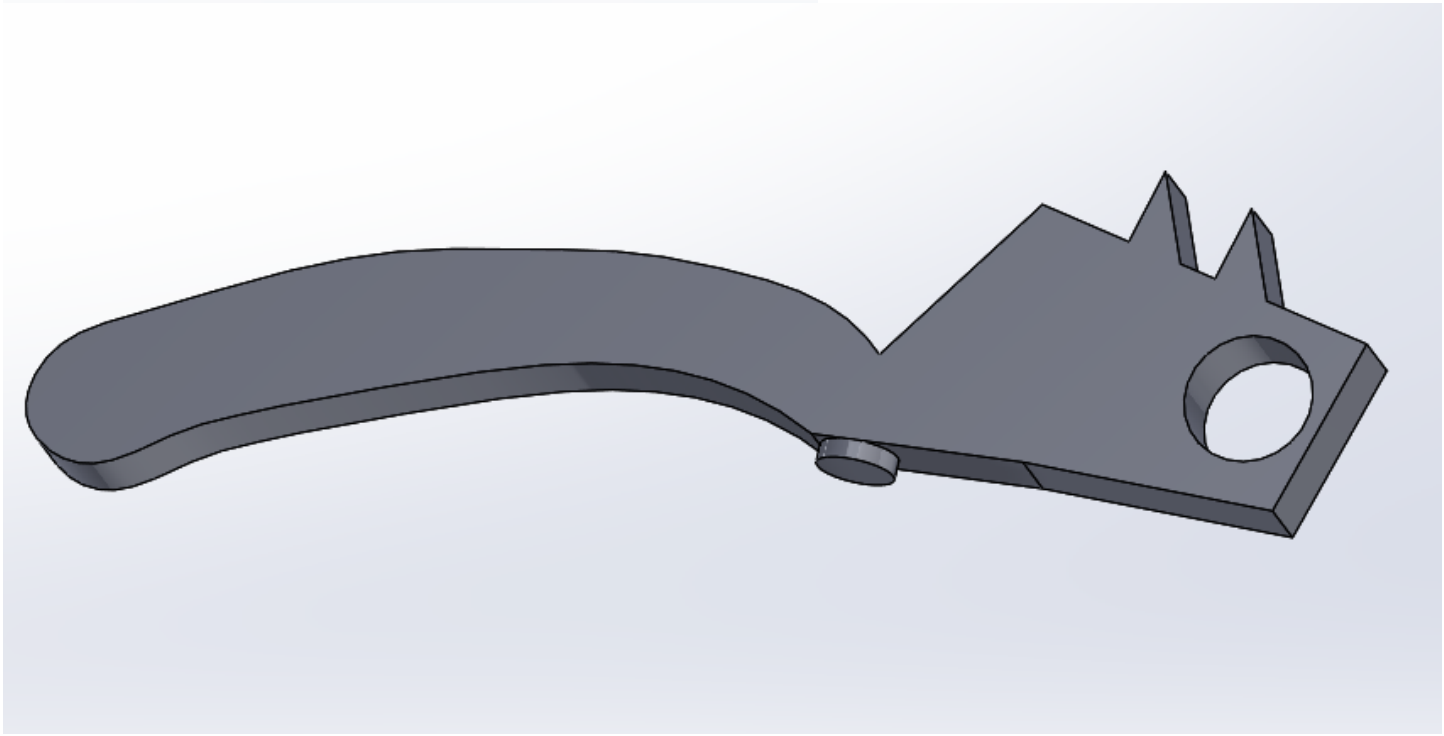
Content:



The left side of the model was updated so that the locking mechanism has a radius of 20 mm and an angle of 45 degrees.

'RetractorLeftFullFillet_v9.SLDPRT'





The right side of the device was modified to add a notch so that a spring may be added. The locking mechanism for the right side was also modified to allow addition of a spring.

'RetractorRightFullFillet_v9.SLDPRT' and 'LockMechFemale_v4.SLDPRT'

Conclusions/action items:

Print and evaluate the locking and racheting mechanism. Improve the reliability by final presentations

Design v8

Mitchell Josvai - May 06, 2022, 11:38 AM CDT

Title: Design v8

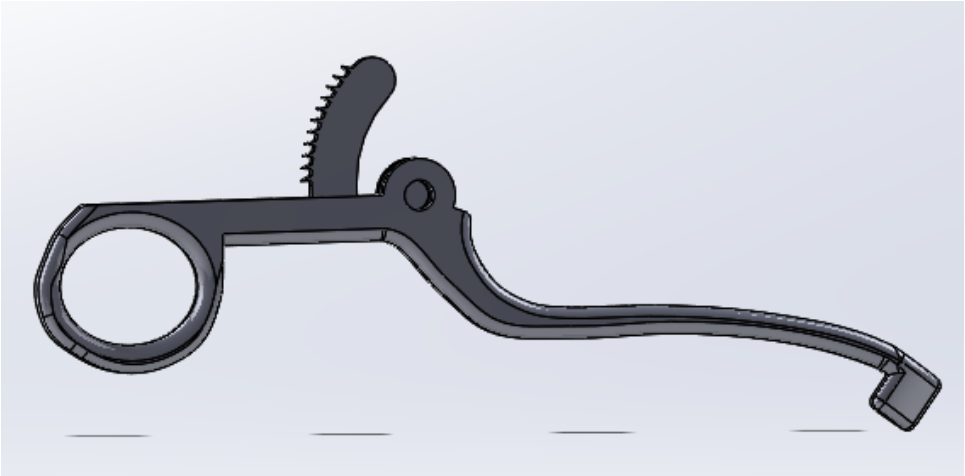
Date: 4/20/22

Content by: Mitchell Josvai

Present: Mitchell Josvai

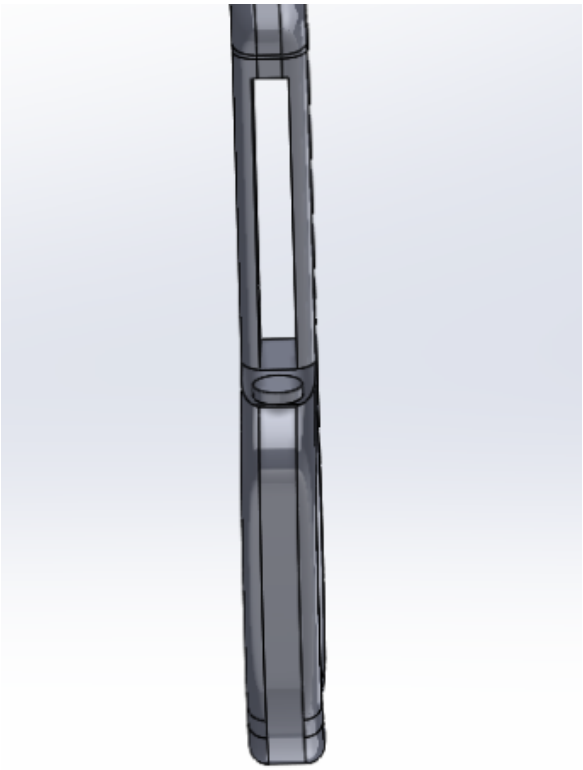
Goals: Record the most recent iteration of the design

Content:



The design was updated to modify the gears to improve the reliability of the locking mechanism.

'RetractorLeftFullFillet_v10.SLDPRT'



The right piece was modified to increase the diameter of the notch to better secure the spring. The length of the opening in the center was increased, to increase the range of motion as the locking mechanism passes through.

Conclusions/action items:

3D print and assess. Iterate once more before final presentations.

Final Design v9

Mitchell Josvai - May 06, 2022, 11:42 AM CDT

Title: Final Design v9

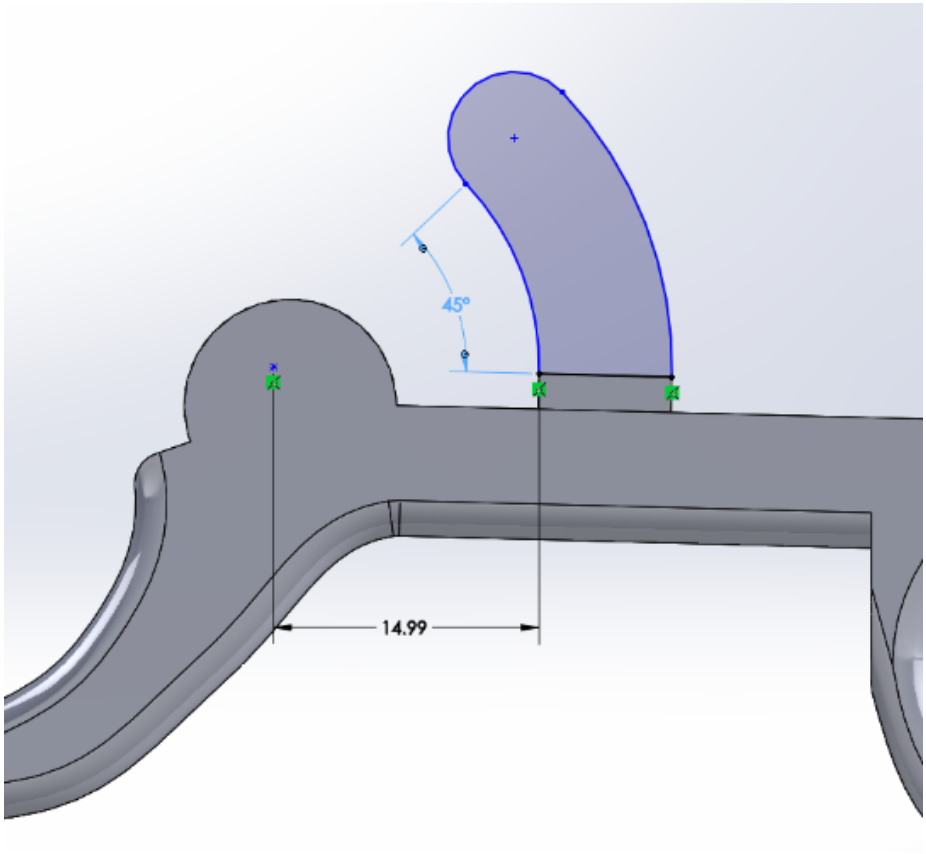
Date: 4/26/22

Content by: Mitchell Josvai

Present: Mitchell Josvai

Goals: Record the updated design

Content:



The locking mechanism on the left side of the model was updated to decrease the radius to 15 mm to increase the range of motion and reliability.

'RetractorLeftFullFillet_v12.SLDPRT'

Conclusions/action items:

Print the final design and present at final presentations.

Biosafety Training

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

Title: Biosafety Training

Date: 9/10/21

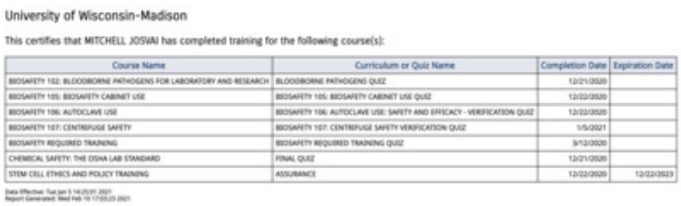
Content by: Mitchell Josvai

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	9/13/2020	
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

Download

Screen_Shot_2021-02-10_at_5.03.59_PM.png (172 kB)

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

Download

IMG_7341_1_.JPG (3.25 MB) 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

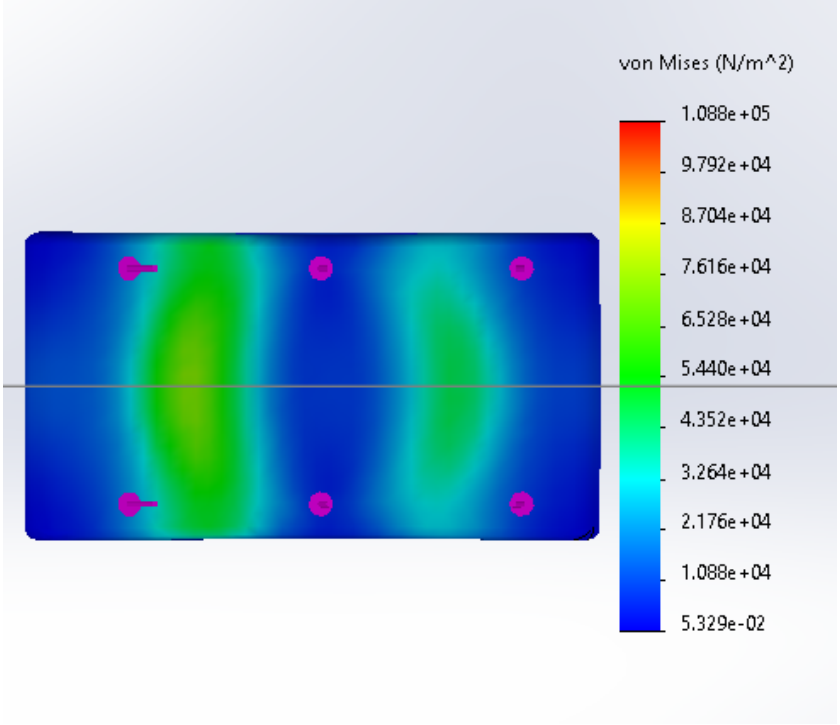
Goals: Record testing done in SolidWorks

Content:

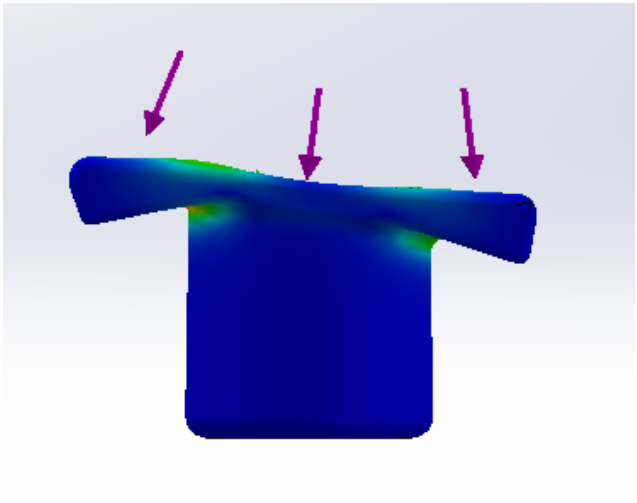
Initial testing was done in SolidWorks. A 1 N distributed load was applied to the surface of the part, and the stress and displacements were analyzed. The interior surface of the hollow cylinder was designated as the fixed surface, because this would be around the retractor, and thus not moving in relation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

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

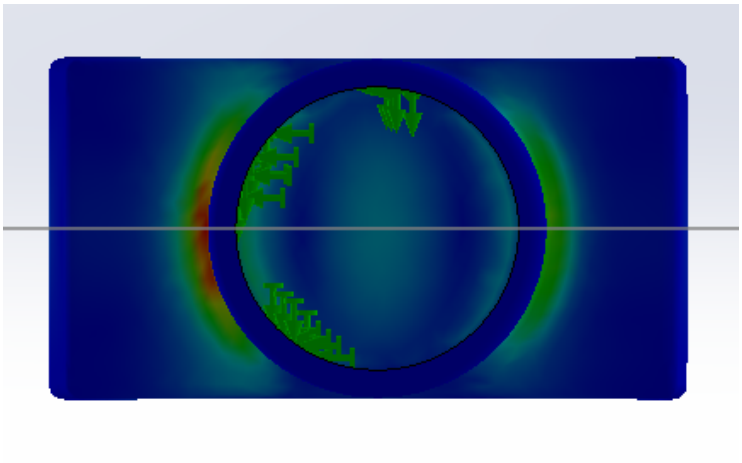
Top view:



Side view:

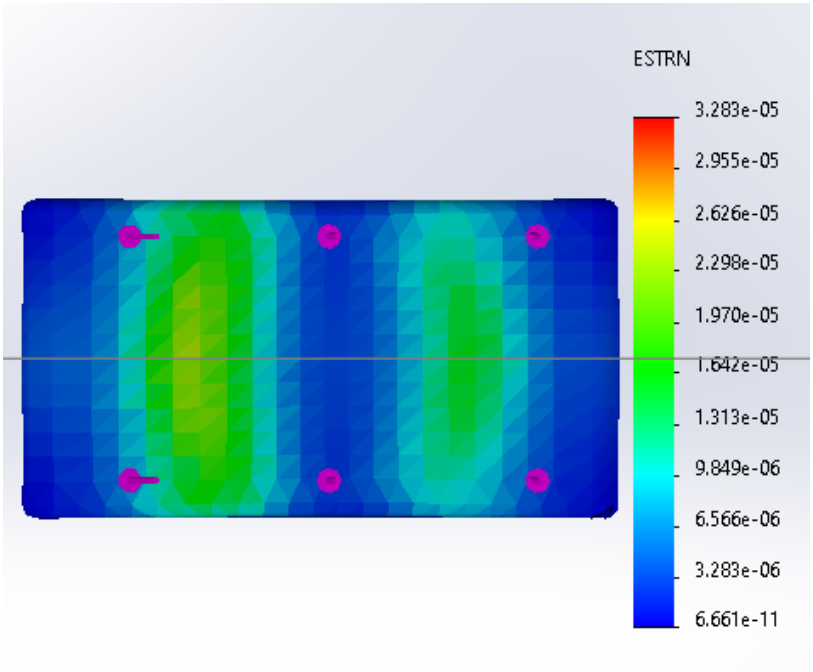


Bottom view:

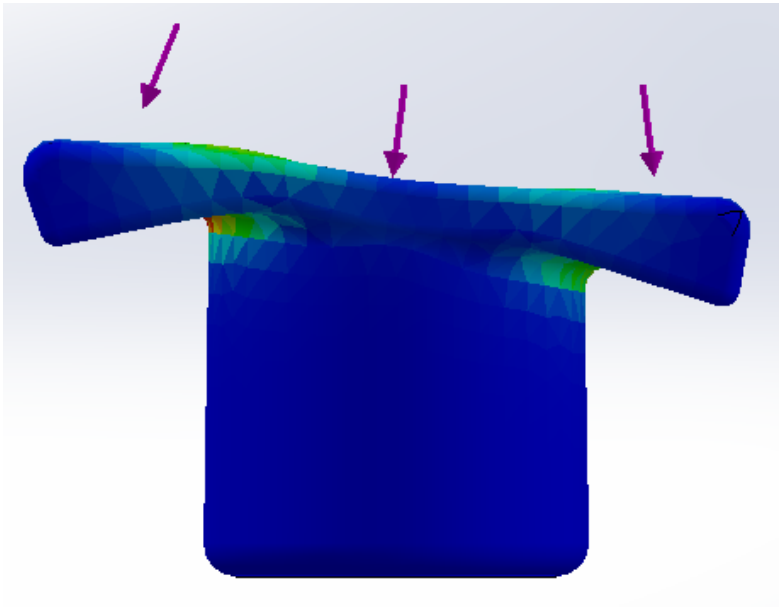


Strain testing: (Scale remained the same for each image, Engineering strain was calculated)

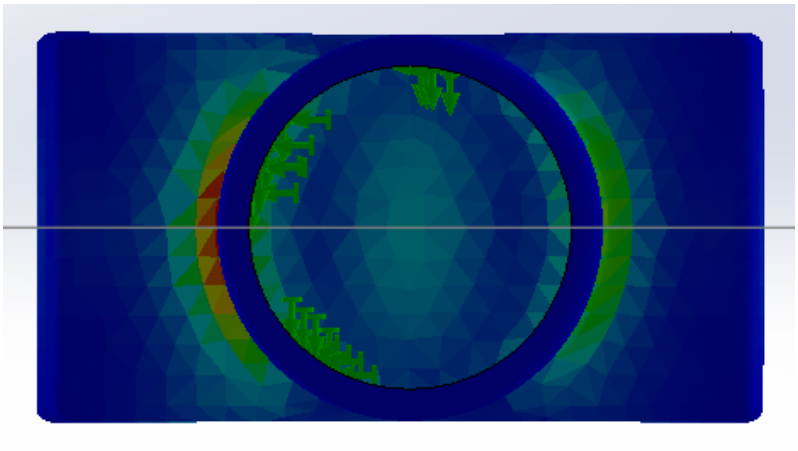
Top view:



Side view:

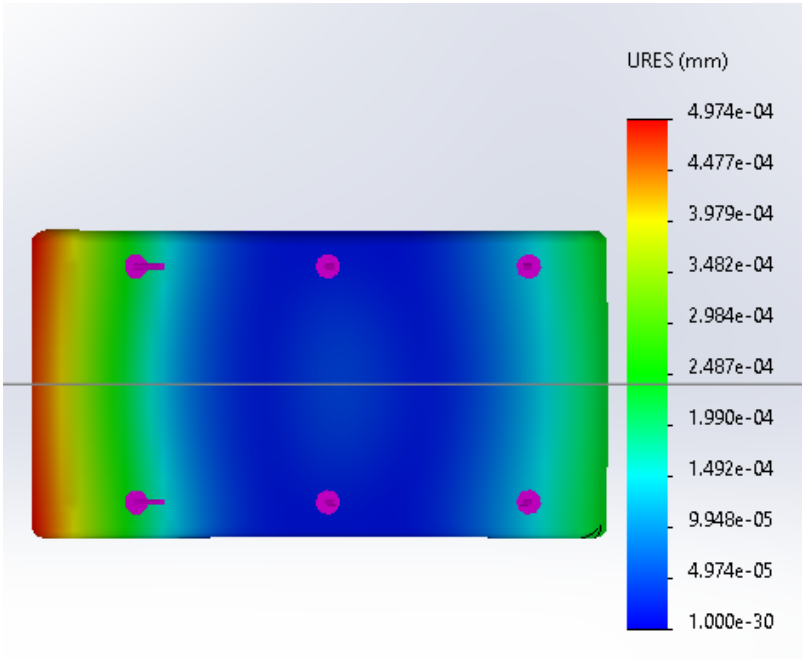


Bottom view:

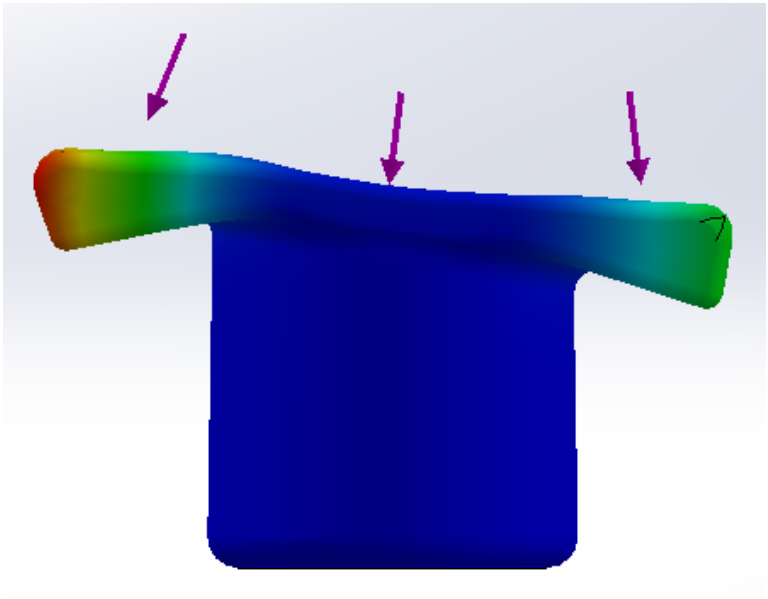


Displacement testing: (Scale remained the same for each image)

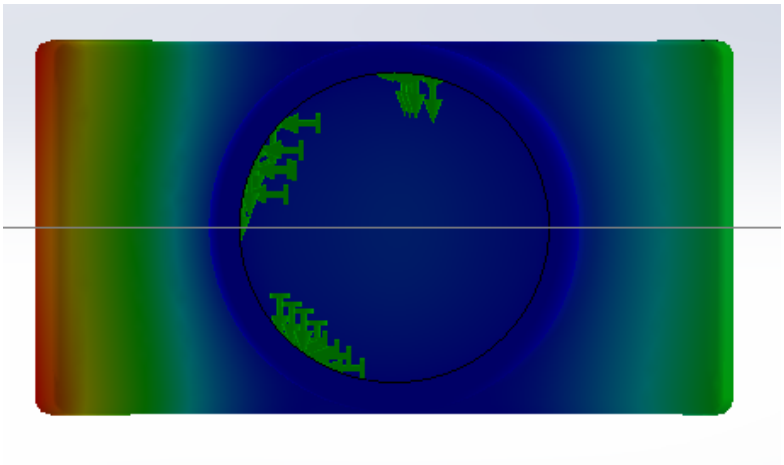
Top view:



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 - May 06, 2022, 11:15 AM CDT

Title: Analyzing the Tissue Analog Testing

Date: 12/3/21, updated 4/22/22

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:

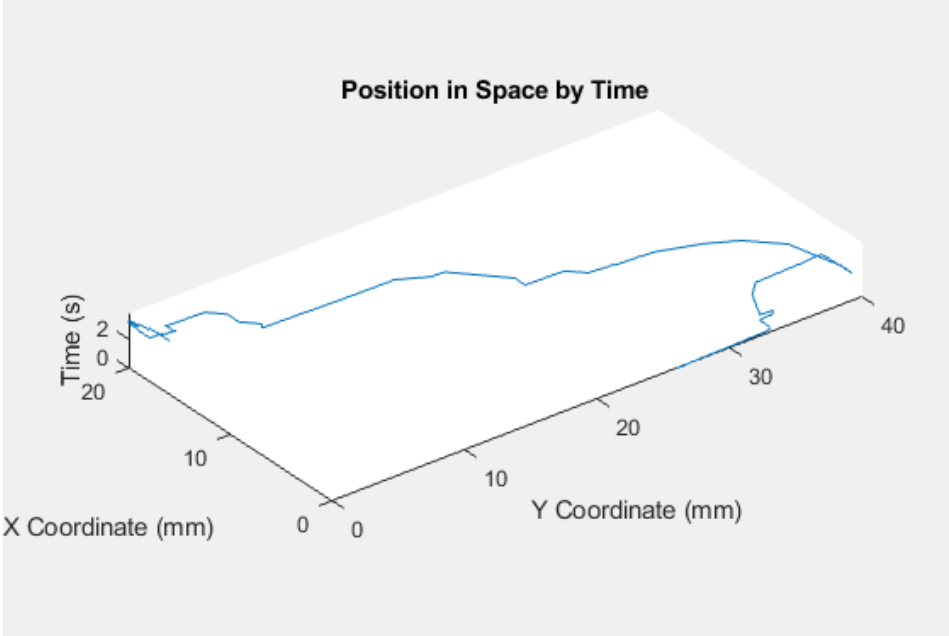
```
clc; clear;
data = readmatrix('IMG_0808.xml.xlsx');

%% 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 - May 06, 2022, 11:15 AM CDT

Title: Computational Model Results

Date: 4/29/22

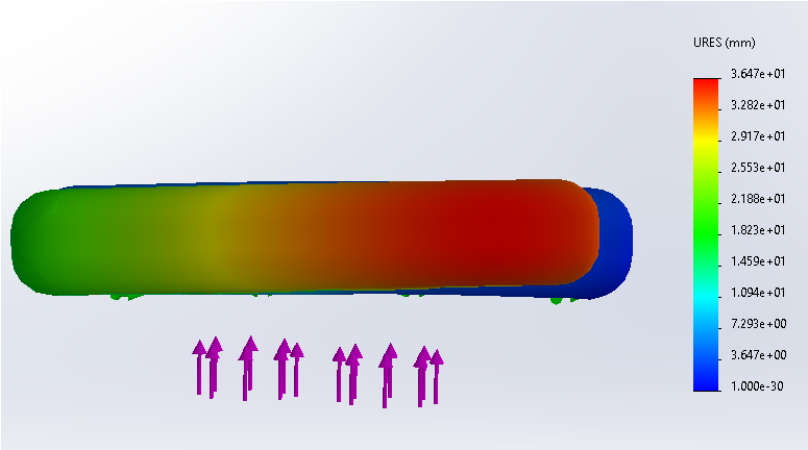
Content by: Mitchell Josvai

Present: Mitchell Josvai

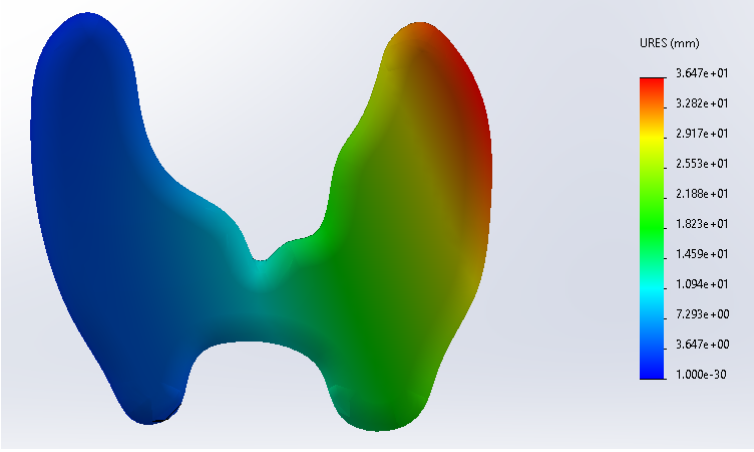
Goals: Record the results of the computational model

Content:

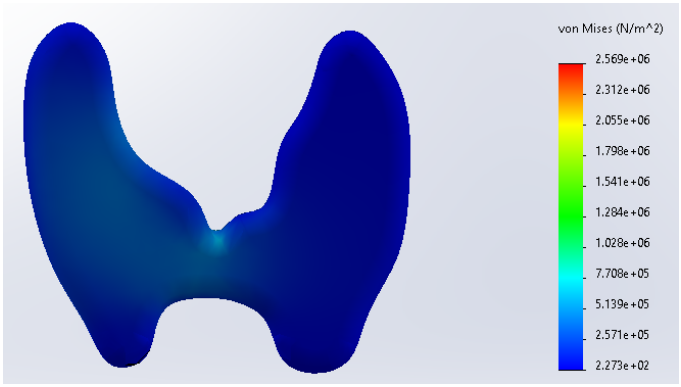
Out of plan geometry change: (1 N of force lifts the thyroid model over 3.5 mm, enough to sever the connective tissue posterior to it)



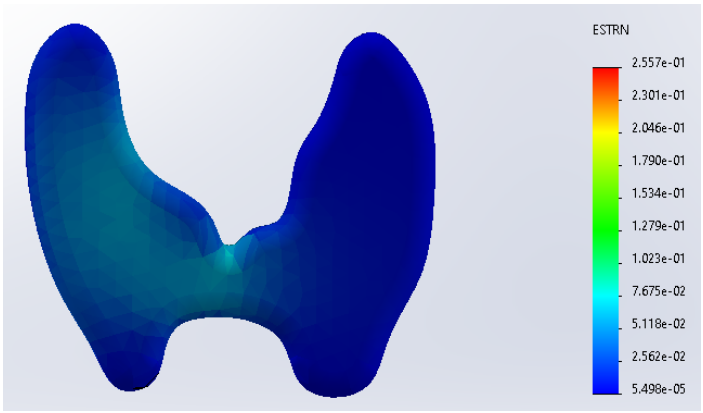
In plane geometry change:



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.

2/5/2022: Suitable Journal

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 2:27 PM CST

Title: Suitable Journal

Date: 2/5/2022

Content by: Avani

Goals: To find a peer-reviewed journal that is relevant and appropriate to the area of work for our project.

Content: **https://journaltool.asme.org/home/JournalDescriptions.cfm?JournalID=22&Journal=MED**

- The journal has papers on medical devices that improve diagnostic, interventional and therapeutic treatments
- It is focused on research and the development of new medical devices or instrumentation.
- It provides special coverage of novel devices that allow new surgical strategies, new methods of drug delivery, or possible reductions in the complexity, cost, or adverse results of health care.
- Categories:
    - Design Innovation: Features papers focusing on novel devices, including papers with limited clinical or engineering results.
    - Medical Device News: Provides coverage of advances, trends, and events.

Conclusions/action items: The Journal of Medical Devices is a suitable journal for our project. The template to follow can be found here: https://www.asme.org/publications-submissions/journals/information-for-authors for when we need to write our preliminary report following this format.

2/22/22: IDR & WARF

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 2:50 PM CST

Title: IDR & WARF

Date: 2/22/22

Content by: Avani

Goals: To gain a better understanding of the application process for an IDR through WARF.

Content:

1. Innovation Disclosure: https://www.warf.org/invent/disclose-an-invention/
    - Initiates WARF review
    - Takes ~10-15 minutes to complete
    - Determines patentability
    - Provides technical information
    - Hear back in ~1-3 business days
2. Disclosure Meeting
    - ~1 hour
    - Informal
    - Confidential
    - Details and possible applications of device
    - In person, virtually, or on the phone
3. Decision Committee Meeting
    - Committee meets once a month.
    - Decision based on patentability, market dynamics, licensing potential, public benefit, and if WARF can add value
4. Equity Review
    - Performed by Office of Vice Chancellor for Research and Graduate Education
    - Identifies contracts or funding sources that may have IP obligations.
5. Patent Application
    - Team works with IP experts to draft application
    - Moves quickly to get filed
    - Once filed, examined by patent office
        - Can take years

Conclusions/action items: The team should submit our IDR to WARF early March for review.

2/18/2022: Ergonomics Survey

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 3:39 PM CST

Title: Ergonomics Survey

Date: 2/18/2022

Content by: Avani

Goals: To provide an explanation of the ergonomics testing and why it is necessary.

Content: **https://docs.google.com/forms/d/e/1FAIpQLScRLkFCyCTyjqQx-Q1OIF4m2WA5Li8k6DQw-H7F_cRW0Kgj-A/viewform?usp=sf_link**

- 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
- Evaluate the effectiveness and the ease of use of our team's thyroid retractor.
- Have the client and other clinicians fill out, ideally 12-20 responses

Conclusions/action items: Ergonomics survey will be brought up at our client meeting, and the client will administer it to ~12 colleagues to get feedback on our device prototype. Tissue analog, further computational testing, and a biocontamination test will also be conducted and I will provide entries on why they are necessary when we complete them.

2/24/2022: Design Changes

AVANI LALL (aklall@wisc.edu) - Mar 03, 2022, 3:45 PM CST

Title: Design Changes

Date: 2/24/22

Content by: Avani

Goals: To provide an explanation of the changes being made to the device after meeting with the client.

Content:

- More textured ends, bigger coarser grooves angled up, 4-5 on each end for more grips.
    - When rapid prototyping the 3D printer isn't able to make the grooves as prominent as we would have liked or what we have in the CAD design.
    - Could possibly cut into the ends to manually create these grooves after it is printed, or super glue thin lines on the ends that would protrude out of the surface.
- Curved angles of ends.
    - The device does have a curve, but the client said if it was more drastic inward that would help when retracting the thyroid.
- Device legs or handles don't need to be longer.
    - After going to the anatomy lab with Dr. Bersu and the team and observing how our prototype looked next to the cadaver thyroid gland we discussed that having longer tips may be beneficial.
    - When brought up to the client, she expressed the change wasn't necessary as our device is about the same size as the forceps she currently uses and is comfortable with.

Conclusions/action items: Make the changes in SolidWorks and 3D print more prototypes for the client to begin administering the ergonomics survey.

4/18/2022: Testing

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 9:05 PM CDT

Title: Testing

Date: 4/18/2022

Content by: Avani

Goals: To explain both the quantitative and qualitative testing done this semester to evaluate functionality of our device.

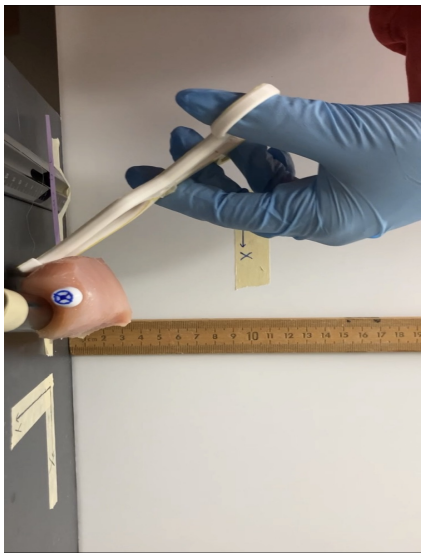
Content:

Qualitative:

- Cadaveric Testing: Performed a simulated medical retraction of the thyroid on a cadaver.
  - Results indicated legs of retractor should be longer in length.
  - 
- Ergonomics Testing: Through a google survey given to surgeons from Waukesha Surgical Specialists and UW Health with survey questions which addressed surgeon comfort, ratcheting mechanism function, finger hole comfort, distal legs length, effectiveness of treads, and ease of use.
  - Our main feedback was to create grooves on the tips of the retractor and to have the legs at an inward angle.

Quantitative:

- Tissue Analog Testing: Mimicked a thyroidectomy by using a mock thyroid, trachea, and skin. The thyroid analog was created using raw chicken breast, the mock trachea was a PVC tube, the skin analog used was 4 MPa PDMS, and the thyroid analog was attached to the tube by an adhesive mimetic of the ligaments and connective tissue that attach the thyroid to the trachea. During testing, an incision with a scalpel was made through the polymer and the mock thyroid was retracted using the printed prototype device in order to observe the ability of the prototype to lift the thyroid.
  -



Conclusions/action items: Testing gave us insight into what updates we could make to our device to really maximize its function and use.

4/22/2022: Tissue Analog Discussion

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 9:23 PM CDT

Title: Tissue Analog Discussion

Date: 4/22/2022

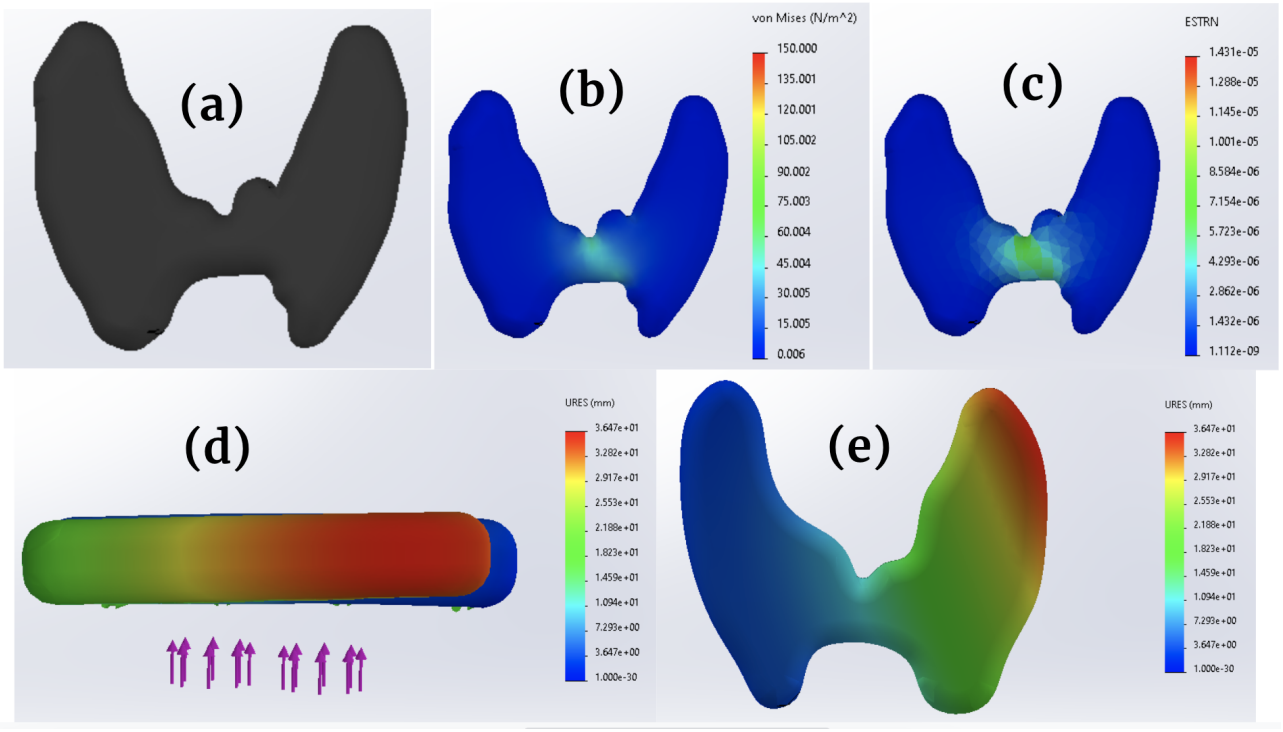
Content by: Avani

Goals: To explain the tissue analog testing and results in detail, as it was very complex.

Content:

How results were obtained:

- Optical markers were attached to the analog.
- The mock thyroid retraction tests were recorded and the video file was uploaded to the motion capture software Kinovea.
- The movement data was then exported to Matlab R2018b to calculate instantaneous acceleration and body forces applied to the tissue.
- Using the reference length in the video file and the frame rate of the recording camera, the position in space may be calculated. Using the spatial and temporal data, the instantaneous velocity and instantaneous acceleration may be calculated. With the calculated maximum accelerations, the maximum applied forces were calculated, by multiplying the acceleration and mass of the tissue analog sample.
- Force and acceleration data acquired from a simulated medial retraction of the thyroid, a computational model was constructed in Solidworks.
- A 3-dimensional model of the thyroid was constructed in the software using accurate dimensions for an *in vivo* thyroid.
- The model was optimized with the clinically reported Young's Modulus and density of a healthy thyroid of 22.3 kPa and 1.05 g/cm3, respectively.
- To apply the distributed load representative of the medial retraction by the device, each lobe of the modeled thyroid was held static at the locations of Berry's ligament, a connective tissue between the thyroid and trachea. The force was applied in the simulation as two 0.5 Newton distributed forces in the 3-dimensional geometry of the distal portion of the device, summing to 1 Newton of total force. The force was increased from the value previously reported to aid in the simulation and increase the safety factor allowed.
- Engineering strain and von Mises stress values were then calculated from the computational model to ensure an absence of soft tissue trauma due to the device.

- 

Results:

- Large deformations observed, required to dislocate thyroid from resting anatomy
- Maximum von Mises stress below failure strength for soft tissues
- Maximum engineering strain below rupture point for soft tissue

Conclusions/action items: Results indicate the device is able to retract a thyroid from multiple points of contact. The maximum von Mises stress and maximum engineering strain were below the failure strength and rupture point for soft tissues respectively.

5/5/2022: Future Work

AVANI LALL (aklall@wisc.edu) - May 05, 2022, 9:28 PM CDT

Title: Future Work

Date: 5/5/2022

Content by: Avani

Goals: To express mine and the teams view on next steps for this project.

Content:

- Most likely, no longer a BME Design project as there is not the design process left to complete, unless there is another design idea.
- Ergonomics survey sent to more clinicians.
- Device manufactured in stainless steel.
- Submit IDR to WARF.

Conclusions/action items: These are all action items :)

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:

Fall 2021 Notebook

KATE EICHSTAEDT - Jan 30, 2022, 2:46 PM CST

BME Design-Fall 2021 - Mitchell Joswi
Complete Notebook

PDF Version generated by

KATE EICHSTAEDT

on

Dec 16, 2021 @ 12:05 PM CST

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