BME Design-Fall 2024 - MARIBEL GLODOWSKI
Complete Notebook

PDF Version generated by

Jack Sperling

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Project description

MARIBEL GLODOWSKI - Sep 09, 2024, 8:59 PM CDT

Course Number: BME 200/300

Project Name: 3D Printing Airway Trainers

Short Name: Airway Trainers

Project description/problem statement:

Airway management is an important component of keeping a patient stable in various medical environments. While novel techniques and innovative devices for better airway management have decreased the difficulties medical professionals face, the development of airway management skills in difficult and unique scenarios is essential to positive and effective patient outcomes. Developing a method of using 3D printing and existing patient imaging to create realistic airway training manikins would allow medical professionals to practice airway management skills with physiologically consistent results.

About the client:

The client for this project is Dr. Kristopher Schroeder. Dr. Schroeder is an anesthesiologist who practices at various UWHealth locations in Madison. In addition, Dr. Schroeder is a professor in the Department of Anesthesiology at UWSMPH.

2024/09/12 -- Client Meeting #1

Jack Sperling - Sep 13, 2024, 8:52 AM CDT

Title: Client Meeting 1

Date: 9/12/2024

Content by: Jack

Present: Jack, Maribel, Ilia, Maiwand, Nathan

Goals: Summarize important notes and concepts from the introductory client meeting

Content:

- What's your vision for this project?
    - Swappable anatomy of an airway trainer to give residents as much practice as possible
    - Want to allow them to experience the widest range of anatomy possible
    - Stretch goal is creating patient specific ones to practice before surgery
- Budget/Funding
    - $750 max
- Requirement/Deliverables for research committee or funding
    - Uncertain
- Any past successes with the devices emailed
    - Just found online
- Specific list of what should change (vocal cords?)
    - How much anatomy should we include?
        - What features of the mouth?
        - Lungs?
        - Nose??
    - Ideally enough anatomy to ventilate with a bvm if needed
        - Can even be larynx only if focusing just on intubation
    - Stretch goal:
        - Have a splitting bronchus to place double lumen ET tubes
- Do we need to segment CT/MRI images to make the 3D models
    - Have access to images but unable to provide segmentation ability
    - Will need to learn 3D slicer to help replicate anatomy
    - We should also look up public access DICOM files to see if they are useable for proof of concept at least
- Would you like a full model, like the Laerdal models or just vocal cords and tracheal rings
    - Answered above
- Do you have any other connections to resources that might be helpful to reach out to?
    - For more design information?

    - Potential to use/ask simulation lab staff???
    - Statistics?
        - Department statistician??
    - Etc.
        - Jim de canto- vomiting manikin
- Are there any specific difficulties that you would like us to address first or focus on specifically? (vet medicine was brought up?)
    - Obesity
    - Not married to the idea of a vet trainer – focus on human anatomy first
- Any feature in current trainers that you find frustrating or wish were different?
    - Sometimes current trainers are too difficult (stiffness → muscle tone and flexibility) but this is minor
    - Ideally can keep current trainers and modify potentially?
- Anything specific you don’t like about current ones
    - Inability to replicate specific anatomy
    - Lubrication?
    - Resistant to silicone spray
    - Top suggestions:
        - 1 to start might be sublingual tonsils
    - Subglotic stenosis
    - Sublingual tonsils
- SACRIFICAL model we can use???????
    - Potentially □
    - Reach out later in the semester
- What order of importance for airway interventions?
    - 1. Is intubation
    - Then biad, bvm, and last is cryc

The novelty would be the ability to have interchangeable pathology in one manakin

Focus on making the important anatomy into a drop in block or wedge that can be swapped out for each training

Utilize imaging (DICOM files) from specific pts to replicate difficult to intubate airways

Conclusions/action items:

Team next steps:

DICOM files online

Material to replicate airway anatomy (fleshly bits)

Client next steps:

Sacrificial training manakin

DICOM files of anatomy to replicate

Funding acquisition

2024/10/04 -- Client Meeting #2

Jack Sperling - Oct 11, 2024, 10:10 AM CDT

Title: Client Meeting #2

Date: 10-4

Content by: Jack

Present: Whole team

Goals: Continue to ask the client important questions to continue the project

Content:

- Design presentation and current status of the project, next steps
    - Updated the client on the project's next steps, showed the design matricies and client agreed abut the direction of the project
- Paying for materials at maker space
    - Have $50 budget from BME Dept and can setup an extra account if we need more funds
- Trainer situation
    - Was obtained privately by another physician and not owned by the department
    - "No one knows that the trainer is missing"
    - Client ok with modifications --- confirm in email before though!
- Review schedule
    - Shared the dates for the final presentation and show and tell with the client.
    - Unlikely he will be able to attend but reminded him
        - Meet after to show him what we have
- Next steps of imaging:
    - Asking for a radiology consult to acquire scans with difficult pathology
        - Deidentification? -- https://radiology.wisc.edu/research/services/medical-imaging-research-support/image-analysis/
        - 1756999 - diffuse tracheal wall thickening (probably ulcerative colitis)
          3527545 - perforated trachea (and esophagus) after instrumentation
          1470766 - relapsing polychondritis
          50045801 - sarcoidosis with tracheal involvement
          3751237 - focal tracheal stenosis
          1560388 - extrinsic tracheal compression from metastatic squamous cell carcinoma of the trachea
          2516833 - granulomatosis with polyangiitis (9/1/2020 CT)
          3396425 - variant tracheal bronchus
          1778603 - tracheal stenosis
          3746160 - squamous cell carcinoma of the trachea
          1664190 - esophageal carcinoma invading the trachea
          3655550 - blunt tracheal injury
          3584945 - tracheal stenosis after resection of adenoid cystic carcioma
          3015076 - penetrating tracheal injury
          2749705 - progressive tracheal stenosis
          2496509 - tracheal stenosis from aortic and subclavian artery aneurysm
          3048069 - left isomerism with complete tracheal rings.

        - Also reach out to ENT to see if they can help segment or teach the client ourselves
        - Start with NIH data and go from there
            - Can potentially make a negative and print this
        - **Ask client to pick one or two of these airways to focus on!**
            - **Focus on the epiglottis and below and recreate a somewhat normal mouth potentially and add a jaw**
            - **From client: Focus on pathology from the epiglottis and below and then slowly work upwards towards the mouth**
    - Potential problems and solutions:
        - Segmentation: Potential fee for service in radiology or teach client
        - No air in mouth ---- during CT and MRI scans there is no air in pt's mouths so we cannot identify the airway passage if it is closed during the scan

Next steps:

- Work with client to identify which scans to acquire from radiology
- Play with NIH model to see if we can print a negative of the airway to test the 80A and 50A resins
    - Compare material properties to small piece of red trachea in the airway bag
- Download and begin becoming familiar with 3D Slicer
    - If possible, find a public access DICOM to show client and teach how to use 3D Slicer

2024/11/01 -- Show and Tell Feedback

Ilia Mikhailenko - Nov 07, 2024, 10:28 PM CST

Title: Show and Tell Feedback

Date: 11/1/2024

Content by: Ilia

Present: Ilia, Nathan, Jack, Maribel, Maiwand, Elle

Goals: Get feedback on where we're currently at in our design

Content:

- slits on either side of the elevated portion, running through the body and securing it in place. Some sort of divot?

- tracheal rings over the top, smaller strips of velcro, magnets?

- Dowel to secure airway on either side of raised portion with nuts on both sides

- silicone mold or beam around solid airway print.

- snapping mechanism directly on the airway and base (no slit)

Conclusions/action items:

Moving forward many of these are great options to consider. Our group will give each contemplation to decide which is best for our future design. We especially liked the snaps idea because it allows for a lot of force to be applied to the airway without the snap bond breaking, but as I previously stated this will need to be considered further. Our current idea is to use a traction velcro strip with reclosable fasteners due to its ease of implementation and design, and we will need to evaluate each of our new ideas to determine which is most promising.

2024/11/01 - Show and Tell Feedback 2

ELLE HEIMER - Nov 01, 2024, 1:35 PM CDT

Title: Show and Tell Feedback

Date: 11/1/2024

Content by: Elle

Present: Team

Goals: Gather input on how to solve current issues with our project

Content:

Nikon NIS Elements Viewer app- may be able to do slicing of DICOM

- cut holes on side of base to secure trainer

- magnets for attaching airway

-more open base?

-snaps

Further questions:

resolution of scans?

Conclusions/action items:

Look into types of snaps, explore Nikon app for slicing, and keep brainstorming new types of bases for the airway.

2024/09/13 - Advisor Meeting #1

MARIBEL GLODOWSKI - Dec 08, 2024, 8:12 PM CST

Title: Advisor Meeting #1

Date: 09/13/2024

Content by: Maribel

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, Srihari, & Dr. Puccinelli

Goals: To show our advisor the progress we have made so far, and receive any necessary feedback.

Content:

-Discussed the topic of intubations and what was brought up at our first client meeting

-Looked at some preliminary research that helped define and understand what difficult airway management is

-discussed goals for next week and expectations for upcoming notebook checks

Conclusions/action items:

At this meeting, we discussed the first steps that we have taken as a team to prepare for a successful semester with this project. The topics that were covered were the client meeting, expectations for this semester, and research topics to look into. The next steps are to continue researching different aspects of airway management and look into if there are any similar projects that have been done to print patient-specific airways.

2024/09/20 - Advisor Meeting #2

MARIBEL GLODOWSKI - Dec 11, 2024, 11:40 AM CST

Title: Advisor Meeting #2

Date: 09/20/2024

Content by: Maribel

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, & Dr. Puccinelli

Goals: To show our advisor our progress so far, and receive any necessary feedback.

Content:

-discussed research performed this week

- took a deeper look at methods

- Dr. P advised looking for more material properties of the airways for next week

- Discussed access to trainers and the ability to modify an existing trainer

- Discussed very preliminary design ideas such as considering incorporating modularity into design ideas

Conclusions/action items:

At this meeting, we took a deeper look at each team member's research. Some focused primarily on the pathology we want to reproduce while others looked at the methods that we might employ to create a patient-specific airway. The next step will be to refine the Product Design Specifications and continue looking into possible materials and methods.

2024/09/27 - Advisor Meeting #3

MARIBEL GLODOWSKI - Dec 11, 2024, 12:07 PM CST

Title: Advisor Meeting #3

Date: 09/27/2024

Content by: Maribel

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, & Dr. Puccinelli

Goals: To show our advisor the progress we have made so far, and receive any necessary feedback.

Content:

- Discussed further research into materials

- Suggested varying thicknesses of materials to get an airway that is representative of the actual mechanical properties of the airway

- Suggested that the scope of the project needed to be considered; this will be something the team will meet about and discuss

- Discussed how we are going to make our design different than the competing designs and trainers that are already on the market

Conclusions/action items:

This meeting brought good insight into the next steps of this project. Srihari and Dr. Pucinelli suggested narrowing the scope of the project. Material choice was another big consideration that was discussed. The next steps will be to look more into materials and choose what we want to use for the printed airways. Another next step is discussing what the overall goal we want to meet with our final design is to further illustrate the scope of the project.

2024/10/11 - Advisor Meeting #4

MARIBEL GLODOWSKI - Dec 11, 2024, 11:55 AM CST

Title: Advisor Meeting #4

Date: 10/11/2024

Content by:

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, & Dr. Puccinelli

Goals: To show our advisor the progress we have made so far, and receive any necessary feedback.

Content:

- Discussed the next step that will need to be taken in the fabrication

- Discussed the possibility of getting an airway scan or looking into online databases

- Discussed the possibility of testing some of the materials early or printing sample materials

Conclusions/action items:

This meeting's focus was the steps that need to be taken to start fabrication and move forward in deciding on designs. The advisors suggested that we start by printing some samples of the materials we want to use. We could potentially do some preliminary testing on these materials. The main next steps are printing samples and beginning airway base design and fabrication.

2024/10/18 - Advisor Meeting #5

Jack Sperling - Dec 11, 2024, 5:11 PM CST

Title: Advisor Meeting #5

Date: 10/18/2024

Content by:

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, & Dr. Puccinelli

Goals: To show our advisor the progress we have made so far, and receive any necessary feedback.

Content:

- **Discussed how it is difficult to find chest and head CT scans online**
- Discussed how team is reaching out to multiple companies that produce segmentation software and seeing if it is viable
  - Mentioned Democratize3D may be a potential option
- Discussed how more research needs to be done about biomechanics of the mouth and jaw, specifically how we will take that into account when connecting the airway to the jaw.

Conclusions/action items: Asked for feedback on other imaging options or pathways as well as support/knowledge about segmentation. Dr. P reiterated Mimics is what we should look for by client unable to assist. Democratize3D may be an option and we will look into it for next week. Additional research on head needed

2024/10/25 - Advisor Meeting #6

MARIBEL GLODOWSKI - Dec 11, 2024, 12:04 PM CST

Title: Advisor Meeting #6

Date: 10/11/2024

Content by: Maribel

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, & Dr. Puccinelli

Goals: To show our advisor our progress so far, and receive any necessary feedback.

Content:

-showed test 3D printed models

-suggested looking into alternatives for a 3D slicer

-look into materialize

- discussed the ongoing struggle to obtain a DICOM file that is appropriate for this project

- discussed the fabrication plans for the airway trainer base

Conclusions/action items:

At this meeting, we discussed some of the struggles we were having with the software we were using mainly 3D Slicer. Another main focus was the plans for the fabrication of the airway trainer base. The next steps to consider are continuing to reach out to the client about obtaining scans, reaching out to other auto segmentation companies, and creating models in SOLIDWORKS for the airway trainer base.

2024/11/08 - Advisor Meeting #7

MARIBEL GLODOWSKI - Dec 11, 2024, 12:17 PM CST

Title: Advisor Meeting #6

Date: 10/11/2024

Content by: Maribel

Present: Maribel, Jack, Maiwand, Nathan, Elle, Ilia, & Dr. Puccinelli

Goals: To show our advisor the progress we have made so far, and receive any necessary feedback.

Content:

-showed the printed airway base and neck hinge

-goal to have the airway trainer base completed within a week

- Further discussed struggles with airway fabrication and feedback from companies

-discuss the need for a scan and the difficulties obtaining one

- discussed possible alternatives to airway fabrication

Conclusions/action items:

At this meeting, we primarily focused on trying to create a plan for moving forward with the airway fabrication despite the challenge of not having a scan. It was suggested to refine the techniques and create a model using the available model in 3DSlicer. Another focus was the progress made on the airway trainer base. The difficulties of printing surrounding anatomy were discussed and Dr. P suggested looking into 3D scanning the existing trainer. The next steps are to create and refine a protocol for fabricating the airway and look deeper into the possibilities of 3D scanning the existing AirSim trainer to help aid in airway trainer base fabrication.

2024/11/12 - CAD Consultation with Jesse

MARIBEL GLODOWSKI - Dec 08, 2024, 8:03 PM CST

Title: CAD Consultation with Jesse

Date: 11/12/2024

Content by: Jack, Nathan

Present: Jack, Nathan, and Maribel

Goals: To better understand what the capabilities and limitations there are on the CAD software we are using to fabricate and design our project.

Content:

- Imaging Notes:
- **SLDWRKS not good**
    - **can import as graphics file to compare to**
- **Try onshape for stl manipulation**
- Smoothing STL tools
    - Maybe online or free
    - Reducing numbers of triangles --- less bumpy

- Import into onshape
    - Too many triangles
- Put into bambu slicer to cut down to 10% triangles to try and be able to offset surface after that
    - Find software to simplify the surface, the more likely it is to offset
- Once offsetting and making the model, can scale it down slightly to make it correct size
- <u>**Try scaling down or up the model and subtracting them to see if that is able to help get the inside**</u>

- How to advise client of workflow
- Ask client about if someone could segment for us
    - Fixes so many errors
    - Need to invest in the project

- If needed can try to manually model slices of the trachea and connect them
    - Not super accurate and is very time and skill intensive through
- Can also try putting lofted lines around edges and connecting them
    - Still also not super accurate and time intensive unfortunately
- OR Take that above and boolean subtract them from each other to get just the outline
-

- Hinge Notes:
    - Go must haves first then up
        - If we didnt have this we would have nothing
    - Shoot for calipers and use skills in 3d modeling
        - can use planes and orient yourself
    - Then try and simplify
    - Ex:
        - Disassemble and try to make simplified mandable as possible
        - Take trachea out and focus on joint distances and methods of mounting
    - Tough aspect

        - the teeth
    - Get top and bottom jaw and then we can figure out teeth later
    - Flexible connections also tough
        - But figuring this and above up will get us a long way
    - Add planes in to orient ourselves and sides on face
    - Try to find nice surface model of face
    - To start with to not get stuck
        - make sumple lofted surface that doesn;t look like face then start modeling joint
        - More testing we can do the better
    - Onshape and solidworks can do multibody modeling
        - model them in context with eachother
        - Especially the hinge joints
        - More natural on onshape
        - Take advantage of symetry!
        - Use mirror at the end to save work
        -
        - Method of attachment for the airway
            - Flange that came off and another rigid part that sandwiches it into some threaded holes
            - Screw it in and hold it with friction
            - Make sure rigid part doesn't get too close
            - Don't screw right through flexible material
                - Sanwich it
        - Potentially make lap joint
            - Straw inside of straw --- upper inside lower airway and flange to hold the two together
        -

Conclusions/action items:

This meeting was extremely beneficial in giving the team the insight we needed to determine what realistic goals to achieve using the software and tools we have. This consultation provided paths forward for both the airway and trainer base sub-teams. The next steps are to apply the methods discussed during this meeting to our design and fabrication process.

2024/11/22 - Advisor Meeting #8

MARIBEL GLODOWSKI - Dec 11, 2024, 12:07 PM CST

Title: Advisor Meeting #8

Date: 11/22/2024

Content by: Elle

Present: Maribel, Jack, Maiwand, Nathan, Elle, & Dr. Puccinelli

Goals: To show our advisor the progress we have made so far, and receive any necessary feedback.

Content:

- discussed failed 3D printed airway models

- the curve of the airway is likely a large reason for failed prints, the printers are meant to print sideways

- have scan from Ilia's sister at GE

- current model walls are way too thick

- 4 mm model has more realistic wall thickness

- look at different printing labs nearby, instead of makerspace

- there is a team in the past that may have a face model

- "Rising Against Cancer" senior team who used mimics

- add non-slip pads to frame

Conclusions/action items:

We need to develop testing protocols and test. Hope that our final print try does not fail. We need to finalize a way to include some sort of airway in the frame. Finally, we need to prepare our poster and final deliverables.

2024/09/29 - Design Matrix: Methods

MARIBEL GLODOWSKI - Oct 10, 2024, 10:23 PM CDT

Title: Design Matrix

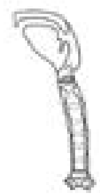
Date: 09/29/2024

Content by: Maribel, Jack, Elle, Ilia, Nathan and Maiwand

Present: Maribel, Jack, Elle, Ilia, Nathan and Maiwand

Goals: To design which design method is the strongest based on the most important criteria.

Content:

Design Criteria	Commercial Difficult Airway Trainers  TruCorp AirSim Difficult Airway		Modifications to Existing Trainers 		3D Printed Modular Airway with Patient-Specific Anatomy 	
Physiological Accuracy (25)	4/5	20	3/5	15	5/5	25
Complexity (20)	4/5	16	2/5	8	3/5	12
Cost (20)	2/5	8	1/5	4	5/5	20
Ease of Use (15)	4/5	12	2/5	6	3/5	9
Versatility (10)	2/5	4	3/5	6	4/5	8
Durability (10)	4/5	8	2/5	4	3/5	6
Total (100)	**70/100**		**41/100**		**80/100**	

Reasonings for Scores

Physiological Accuracy

Physiological accuracy is defined as the ability of the trainer to accurately replicate the anatomy of a difficult airway management case. This is weighted the highest because it is a direct representation of how well the trainer prepares professionals for realistic difficult airway situations that could be encountered in their practice.

Complexity

The complexity of the design measures the likelihood that a medical professional would be able to practice and perform medical procedures on the trainer produced by a certain method. Complexity also takes into consideration the number of changes that would need to be made to the airway anatomy to achieve a trainer on which intubation can be practiced. This is weighted highly as it demonstrates the ability of the trainer to act as an effective educational tool.

Cost

Cost is another important factor to consider. This is weighted highly as keeping the cost of each airway low allows for training on a wide range of difficult airway scenarios to be more affordable and accessible. This could greatly improve the ability of professionals to manage airways in many difficult airway scenarios.

Ease of Use

Ease of use is defined as the ability of the trainer to aid the user through training during different procedures. This is weighted somewhat highly as it includes features important to the development of the airway management skills a medical professional might need when a patient presents with a difficult airway.

Versatility

Versatility defines the ability of the trainer to provide a wide range of patient pathologies. This is important to consider as medical professionals will encounter many different pathologies in their practice and they must know how to appropriately manage each one.

Durability

Durability shows the ability of the trainer to withstand repeated training without losing qualities necessary for an accurately represented difficult airway. This is weighted the lowest because while it is important to consider it is more dependent on material choice than choice of methods.

Overall Winning Design

The proposed final design is the 3D printed modular airway with patient-specific anatomy. The decision to create patient specific anatomy for the airway trainer was based on the first design matrix proposed, where it scored highest. Particularly, the design's physiological accuracy, low cost, and versatility were the primary reasons why it was picked. The physiological accuracy of the model is a distinct feature in that it enables the molding of patient specific anatomy, which can better reflect anatomical nuances. Similarly, the versatility of this design comes from the fact that it can provide a variety of patient pathologies, widening the applications of its use to complex intubations from simple intubations because of the ability to control the entire airway anatomy rather than only a portion or none at all compared to the other two designs. Because the design will be within the provided budget of $750, it's cost efficient which is an additional strength. A drawback to using this model is the complexity of its design. This design will reflect patient specific anatomy, and more anatomical analyses will be done, requiring careful design. However, after taking into consideration all the aspects in the decision matrix, this was the winning project scope, and this is the direction the team will continue in.

Conclusions/action items:

This design matrix led us to move forward with 3D printing modular airways using patient-specific imaging. The main strengths of this design are physiological accuracy, versatility, and cost. Next steps include finding pathological imaging to segment and visiting the Makerspace where we can print a material sample with the necessary mechanical properties.

2024/10/02 - Design Matrix: Materials

MARIBEL GLODOWSKI - Oct 10, 2024, 10:35 PM CDT

Title: Design Matrix: Materials

Date: 10/02/2024

Content by: Nathan, Jack, Maribel, Maiwand, Elle, Ilia

Present: Nathan, Jack, Maribel, Maiwand, Elle, Ilia

Goals: To determine which material is best suited to the needs of this project.

Content:

Design Criteria	Material #1: Silicone 3D Printed Resin		Material #2: Formlabs 80A Resin		Material #3: Liquid Silicone	
Biomechanical Properties (25)	3/5	15	4/5	20	2/5	10
Durability (20)	3/5	12	3/5	12	2/5	8
Ease of Fabrication (20)	4/5	16	4/5	16	2/5	8
Reliability (15)	4/5	12	5/5	15	3/5	9
Cost (10)	4/5	8	2/5	4	3/5	6
Compatibility with Training Materials (10)	2/5	4	4/5	8	2/5	4
Total (100)	**67/100**		**75/100**		**45/100**	

Reasoning for Scores

Biomechanical Properties

The biomechanical properties indicate how well the material mimics the properties of the human airway, being that the material falls as close to the range 16.92 ± 8.76 MPa for its Young's Modulus, the range used for the cartilage in a human airway and within 50-80A for Shore Hardness [10, 11]. A higher score represents a closer value in either of these properties to the given range. This is weighted the highest as in order for an airway trainer to be effective it must accurately simulate a human airway.

Durability

Durability indicates the strength of the material or how well it would hold up against intubation attempts. A higher score indicates a more durable material. This is ranked highly as in order for an airway trainer to be effective it must be able to tolerate several intubation attempts.

Ease of Fabrication

Ease of fabrication is measured by the simplicity with which it takes to make an airway trainer. A higher score indicates a material that is more easily and more quickly converted into the desired product. This is weighted highly as a material with a greater ease of fabrication that would allow for the quick creation of different anatomy of the airway.

Reliability

Reliability indicates how prone the material is to flaws. A higher score indicates a material less prone to flaws. This criteria is weighted relatively important as a material that can form a design with very few flaws is ideal.

Cost

Cost refers to the price per volume of the material. A higher score indicates the material is less expensive. This is rated lower as most materials considered are relatively inexpensive.

Compatibility with training materials

Compatibility with training materials refers to the materials compatibility with lubricants used in intubation. A higher score indicates a more compatible material. This is ranked low as lubricants exist that are compatible with all the materials considered.

Overall winning material:

The trainer will consist of a 3D printed segment of the airway made out of Formlabs 80A resin. Formlabs 80A has a Young's Modulus of ~4 MPa and a Shore Hardness of 80A. This material will be resilient to most lubricants to be utilized for airway practice using typical airway equipment. Although this Young's Modulus is out of range of the ideal that was stated above, the ideal range includes the hardness and mechanical properties of the tracheal cartilaginous rings, which are not the focus of this chosen material. Future materials may be added to add specific properties where required. Additional materials are available in the Makerspace with slight variations in properties that may be utilized in testing.

Conclusions/action items:

This design matrix allowed us to come together as a team with all the research we have done and select a material that will meet the needs of this project. Overall, the Formlabs 80A resin was chosen for its advantages and likeness to biomechanical properties. The next steps should be visiting the makerspace to print a small sample of this material to determine further whether it will fit the needs of our project. If this test print produces favorable results we will continue forward with it. If not, the Makerspace has a few other material options to be consider such as FormLabs 50A.

2024/10/25 - Design Matrix: Attachment Methods

Ilia Mikhailenko - Oct 25, 2024, 12:43 PM CDT

itle: Design Matrix: Attachment

Date: 10/02/2024

Content by: Ilia, Nathan, Maribel

Present: Ilia, Nathan, Maribel

Goals: To determine which attachment is best suited to the needs of this project.

Content:

Linked below

Criteria

Effect on functionality

Does the design change the mechanics of the airway trainer?

Ease of implementation

How easy to set up and incorporate into design

Effectiveness

How well it secures airway

Ease of Exchange

How easy is it to swap in different airways

Life span

How long the design will last for

Cost

Expenses of materials

Overall winning material:

Conclusions/action items:

This design matrix allowed us to come together as a team with all the research we have done and select a material that will meet the needs of this project. Overall, the Formlabs 80A resin was chosen for its advantages and likeness to biomechanical properties. The next steps should be visiting the makerspace to print a small sample of this material to determine further whether it will fit the needs of our project. If this test print produces favorable results we will continue forward with it. If not, the Makerspace has a few other material options to be consider such as FormLabs 50A

Ilia Mikhailenko - Oct 25, 2024, 12:30 PM CDT

Design Criteria	Screw-in		Magnet		Spring loaded latch	
Effect on Functionality ([illegible])	4/5	[illegible]	5/5	[illegible]	[illegible]	[illegible]
Ease of Implementation ([illegible])	5/5	[illegible]	4/5	[illegible]	3/5	[illegible]
Effectiveness ([illegible])	5/5	[illegible]	3/5	[illegible]	4/5	[illegible]
Ease of Exchange ([illegible])	3/5	[illegible]	5/5	[illegible]	5/5	[illegible]
Life Span ([illegible])	4/5	[illegible]	5/5	[illegible]	3/5	[illegible]
Cost ([illegible])	4/5	[illegible]	3/5	[illegible]	5/5	[illegible]
Total (100)	[illegible]		[illegible]		[illegible]	

Download

Design_Matrix_Attachment_Methods.pdf (17.7 kB)

2024/10/02- FormLabs 80A Resin Data Sheet

MARIBEL GLODOWSKI - Oct 11, 2024, 11:03 AM CDT

Title: FormLabs 80A Resin Data Sheet

Date: 10/02/2024

Content by: Maribel

Present: N/A

Goals: To provide sources to identify mechanical properties of FormLabs 80A Resin

Content:

Formlabs website: https://formlabs.com/store/materials/flexible-80a-resin/

Conclusions/action items:

This entry contains the data sheet and link to the FormLabs website. It compiles the resources needed to order the resin and to look at mechanical properties of our material selection.

MARIBEL GLODOWSKI - Oct 11, 2024, 11:04 AM CDT

Download

Formlabs_80A_Resin_Data_Sheet.pdf (505 kB)

2024/11/19 - Bambu PLA Data Sheet

MARIBEL GLODOWSKI - Dec 08, 2024, 7:55 PM CST

Title: Bambu PLA Data Sheet

Date: 11/19/2024

Content by: Maribel

Present: N/A

Goals: To provide sources to identify mechanical properties of Bambu PLA

Content:

See data sheet attached.

Conclusions/action items:

This datasheet provides valuable information about the material and mechanical properties of the Bambu Labs PLA that was used to fabricate the pieces of the airway trainer base. The next step is to use the mechanical properties fo this material to create a Finite Element Analysis using SOLIDWORKS software.

MARIBEL GLODOWSKI - Dec 03, 2024, 10:22 AM CST


Bambu Filament

PLA Basic

- Basic Info
- Specifications
- Recommended Printing Settings

Download

Bambu_PLA_Basic_Technical_Data_Sheet.pdf (374 kB)

2024/10/15 - FormLabs 50A Resin Data Sheet

Jack Sperling - Dec 11, 2024, 7:56 PM CST

Title: 50A Resin Data Sheet

Date: 10-15-24

Content by: Jack

Present: Jack

Goals: Locate the data sheet for the 50A resin to allow for a reference

Content:

Attached is the data sheet found at this web address for the 50A resin: https://formlabs-media.formlabs.com/datasheets/2001420-TDS-ENUS-0.pdf, https://formlabs-media.formlabs.com/datasheets/2401869-TDS-ENUS.pdf

Conclusions/action items: Utilize this document to refer back to material properties as necessary

Jack Sperling - Dec 11, 2024, 7:57 PM CST


Elastic 50A

Download

50A-v1.pdf (70.1 kB)

Jack Sperling - Dec 11, 2024, 7:57 PM CST


Elastic 50A Resin V2

Download

50A-v2.pdf (149 kB)

2024/10/17 - Plan Moving Forward

Ilia Mikhailenko - Oct 18, 2024, 12:25 PM CDT

Title: Plan for Trainer Group

Date: 10/17/2024

Content by: Ilia

Present: N/A

Goals: Put in writing what the action steps are for our new trainer sub-group

Content:

- Disassemble Commercial Trainer
    - Take apart a commercial trainer to analyze its internal and external structure and identify components that could be incorporated into our own design.
- List Essential Features and Anatomy
    - Create a detailed list of must-have features and anatomical elements for your trainer to ensure it meets functional and educational requirements.
    - A bag valve-mask is able to be practiced by the trainee using the airway trainer. Head-tilt chin-lift should also be simulated
- 3D Scanning for External Anatomy
    - Investigate the feasibility of 3D scanning existing trainers to capture their external anatomy, which will inform the design process.
- Materials Selection (Face/Skin/Other parts)
    - Research and choose materials for the trainer's exterior (face, skin) and internal components, considering durability, realism, and cost.
- Model in SolidWorks
    - Develop a 3D model of the trainer in SolidWorks, incorporating the identified features and maintaining relative anatomical accuracy
- Test Printing and Order Materials
    - Print test parts to assess fit and functionality. Order any additional materials required for assembly or modifications based on the test results.

Conclusions/action items: Our 6-person team decided to split into 2 3-person groups, with one group responsible for creating the pathology and our group in charge of making the trainer which the pathology will attach to. This is the specific process our group will follow, which will be organized around a detailed analysis of commercial trainers, identifying key features, and incorporating advanced techniques like 3D scanning for anatomical accuracy. By modeling in SolidWorks and carefully selecting materials, we aim to create a functional and realistic trainer. Test printing and material evaluation will ensure that the final product meets our design standards.

2024/10/18 - To Do List Update

Jack Sperling - Oct 18, 2024, 12:14 PM CDT

Title: 10/18 Update to Team To Do List

Date: 10-18

Content:

Attached is the updated team task tracker showing each sub-team's goals

Jack Sperling - Oct 18, 2024, 12:11 PM CDT

Download

Material_and_Trainer_team_goals_-_Sheet1.pdf (40.7 kB)

2024/10/25 -To Do List Update

Jack Sperling - Oct 25, 2024, 10:29 AM CDT

Title: ToDo Progress Document Update

Date: 10-25

Content: Attached below is the updated task tracker for the group for the week of October 25th

Jack Sperling - Oct 25, 2024, 10:29 AM CDT

Download

Material_and_Trainer_team_goals_-_Sheet1_1_.pdf (286 kB)

2024/10/27 - Reach Out Note to Companies

Jack Sperling - Dec 11, 2024, 7:46 PM CST

Title: Email Note to Companies

Date: 10/27/24

Content by: Jack, Elle

Present: Jack, Elle

Goals: Create a template email that can be used to send to companies explaining the project and asking for software availability

Content:

Hello, we are a team of Biomedical Engineering students at the University of Wisconsin-Madison and are currently working on a design project with an anesthesiologist at UW-Health to create realistic, patient specific, intubation trainers. This requires us to convert DICOM files to 3D printable STL files that replicate the airway anatomy. We are interested in seeing if your software is able to assist us with auto-segmentation of the airway anatomy and would be interested in testing it out with some CT scans. This project is intended to be completed before the end of December, so determining if your software can be used is a top priority. Thank you very much for your consideration.

Conclusions/action items: Use this email template to ensure that we provide the same information to all the companies we contact. Ideally this will give us the best result in speed to determine if the company's software will work

2024/10/31 - Limbus.ai Message

ELLE HEIMER - Nov 07, 2024, 10:54 AM CST

Title: Limbus.ai Communication

Date: 10/31/2024

Content by: Elle

Present: Jack

Goals: Find a company to help us with our slicing problem

Content:

From Limbus:

Hello Elle,

I'm intrigued by the brief description of your project.

Can you tell me more about the workflow you imagine?
What are the structures you'd want to be contoured in DICOM RTSS?
For your purposes, how many scans do you expect to want to run?

We'd need to see a sample of the scan and output you hope for in order to consider this request.

Kevin Riddell
Product Research Coordinator

Our response:

Hello Mr. Riddell,

First, we are working on getting a real, de-identified patient CT scan of their airway. We would then need to segment out their airway in order to print it in a flexible material for anesthesiologists to practice with. This requires whatever software being used to be able to take a CT scan and create the mouth, tongue, and upper airway (epiglottis down to the bronchus) with as little human intervention as possible to streamline the process.

The structures we would need to be contoured our from the mouth, tongue, and upper airway (epiglottis, down the trachea, ending at the split of the bronchi).

We hope to only run one scan for the scope of this project.

Thank you for your interest,

Elle Heimer and the BME team

2024/12/03 - Final Airway Trainer Base Prototype

MARIBEL GLODOWSKI - Dec 11, 2024, 11:21 AM CST

Title: Final Airway Trainer Base Prototype

Date: 12/01/2024

Content by: Maribel

Present: NA

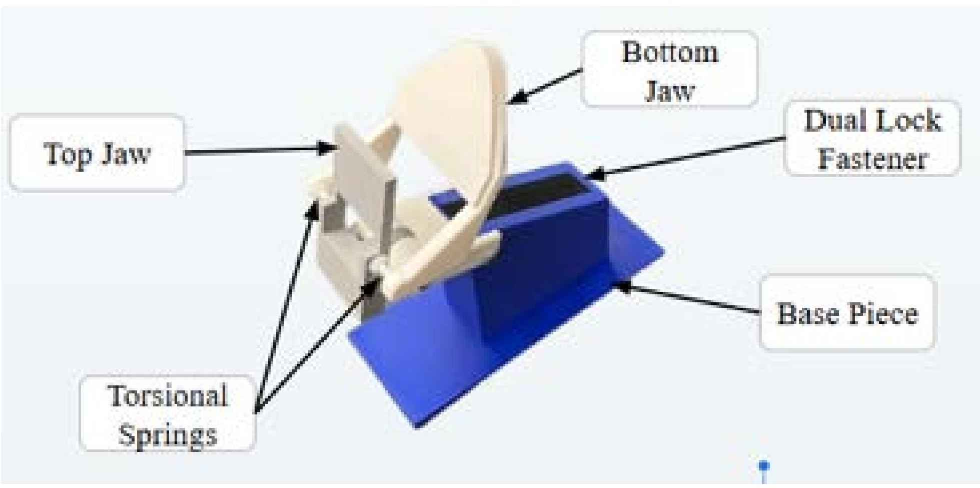
Goals: To demonstrate the final design and prototype of the airway trainer base

Content:

Main objectives:

-create a trainer base that can reflect anatomy similarly to how the AirSim trainer does

-incorporate features that allow for the printed anatomy to be swapped in and out



Main Features:

-torsional springs to represent the motion of the jaw

-dual lock fastener to allow for anatomy to be swapped in and out

-sloped surface to mimic anatomical airway placement during the procedure

Conclusions/action items:

The prototype is a great step toward a trainer base capable of swapping in and out different patient-specific anatomies. It still requires much future work and refinement to incorporate surrounding anatomy and fine-tune the range of motion and airway placement. Another step is testing whether the pieces can withstand the forces of intubation.

2024/12/01 - Finite Element Analysis Protocol

MARIBEL GLODOWSKI - Dec 08, 2024, 11:46 PM CST

Title: Finite Element Analysis Protocol

Date: 12/01/2024

Content by: Maribel

Present: NA

Goals: To lay out the process of running finite element analysis using SOLIDWORKS software to test whether the airway trainer base pieces would be able to withstand the maximum forces exhibited during intubation.

Content:

1. Open the base, neck hinge, bottom jaw, and top jaw parts in SOLIDWORKS.
2. Make sure that each of the pieces is made of the correct material (PLA). If PLA is not in the SOLIDWORKS Material Library, create a custom plastic using the mechanical properties and values listed in the Bambu Labs PLA filament datasheet.
3. Press Evaluate > SimulationXpress Analysis Wizard.
4. This should start the appropriate software required for the finite element analysis.
5. Follow the prompts to select fixtures. Select any faces that will be secured during the use of the airway trainer base.
6. Hit next, and follow the prompts to add forces to faces. Start by applying a force of 63 N to the top of the piece.
7. Run the simulation. Ensure that the displacement animation is consistent with the expected deformation. Record the outputted factor of safety.
8. Repeat this process changing only the placement of the forces to the right plane and a combination of both right and top planes. Record the factor of safety for all simulations.
9. Repeat Steps 3-8 for each of the PLA parts of the airway trainer base.

Conclusions/action items:

This lays out the process of testing the pieces of the airway trainer base. This should allow us to see whether these pieces are strong enough when printed out of PLA. The next steps are to follow this protocol to test these pieces and then analyze the result to better understand how to move forward.

2024/12/02 - MTS Testing

Jack Sperling - Dec 11, 2024, 11:17 AM CST

Title: MTS Testing

Date: 12/2/24

Content by: Jack

Present: Jack, Nathan

Goals: Test the 4 dogbone samples Makerspace printed

Content:

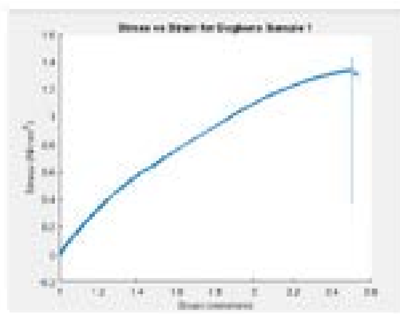
- Removed the supports from the 4 dogbone samples and utilized the MTS machine in the shared teaching lab to run an ultimate tensile stress test
- Followed the testing procedure in the final report -- located in the team activities section of the notebook
- Some of the raw data is presented below in the two attached files as well as the pictures attached
- Raw data attached as a ZIP file

Other pictures are included as attachments below

Conclusions/action items: MTS Testing went well, however there is some variability in the elastic modulus between the samples. This is likely due to the removal of supports harming the model or the slipping occuring in the grips of the MTS machine. We will continue to test with better printed dogbones with supports placed to limit this problem

---

Jack Sperling - Dec 11, 2024, 11:10 AM CST



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Graphs.pdf (286 kB)

Jack Sperling - Dec 11, 2024, 11:10 AM CST

[Download](#)

MTS_Documentation.pdf (35.3 kB)

Jack Sperling - Dec 11, 2024, 11:12 AM CST

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Data-20241211T171115Z-001.zip (1.62 MB)

Jack Sperling - Dec 11, 2024, 11:19 AM CST

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IMG_4489.HEIC (3 MB)

Jack Sperling - Dec 11, 2024, 11:19 AM CST

[Download](#)

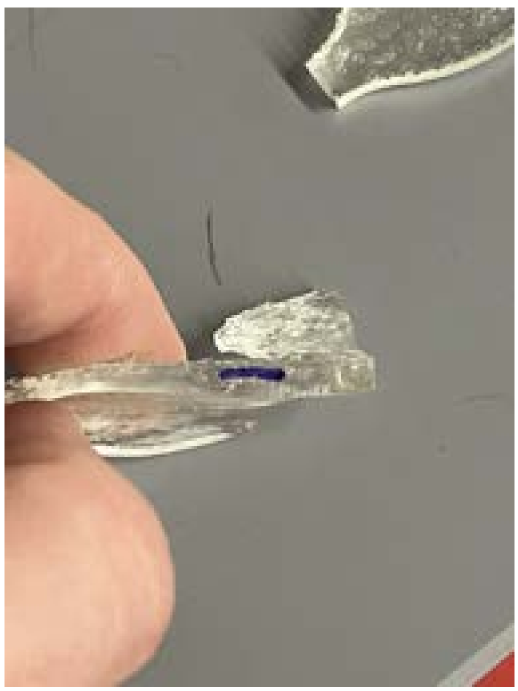
IMG_4491.HEIC (2.69 MB)

Jack Sperling - Dec 11, 2024, 11:19 AM CST

Download

4DeformedHead.jpg (1.52 MB)

Jack Sperling - Dec 11, 2024, 11:19 AM CST



Download

1Failure.jpg (1.56 MB)

Jack Sperling - Dec 11, 2024, 11:19 AM CST

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IMG_4502.jpg (2.69 MB)

Jack Sperling - Dec 11, 2024, 11:19 AM CST

Download

IMG_4501.jpg (1.68 MB)

Jack Sperling - Dec 11, 2024, 7:43 PM CST

MTS Testing Protocol:

1. Load the tensile testing jaws into the grey MTS machine in the BME shared teaching lab in ECB
2. Log into the computer and open the BME 315 rat tendon tensile test file. This is preprogrammed to achieve a variable strain rate ultimate tensile test which limits the amount of extra work needed to be done

3. Turn on the MTS machine and ensure the load cell is connected and data can be read from the computer
4. Remove supports from the dogbone samples that were printed at the Makerspace
5. Place the dogbone sample into the jaws of the MTS machine, ensuring that the part is securely gripped on both ends
6. Ensure that the entire thinner portion of the sample is not clamped as this will be the gauge length
7. Measure the cross-sectional area of the thinner section. This can change as support material may remain or some of the model’s material may have been removed during the support removal process
8. Change the strain rate to 10mm/min and begin the test. The testing setup should look like this picture

9. Export each run as a seperate data set and ensure that force, displacement, and time are all exported
10. Repeat the test as many times as desired
11. Safely shut down the MTS machine, and return the tensile testing aparatus to the case, and log off of the computer
12. Process the MTS data using the Matlab code found in section 11.5B

2024/12/03 - ROM Testing

Jack Sperling - Dec 11, 2024, 4:04 PM CST

Title: ROM Testing

Date: 11/3/24

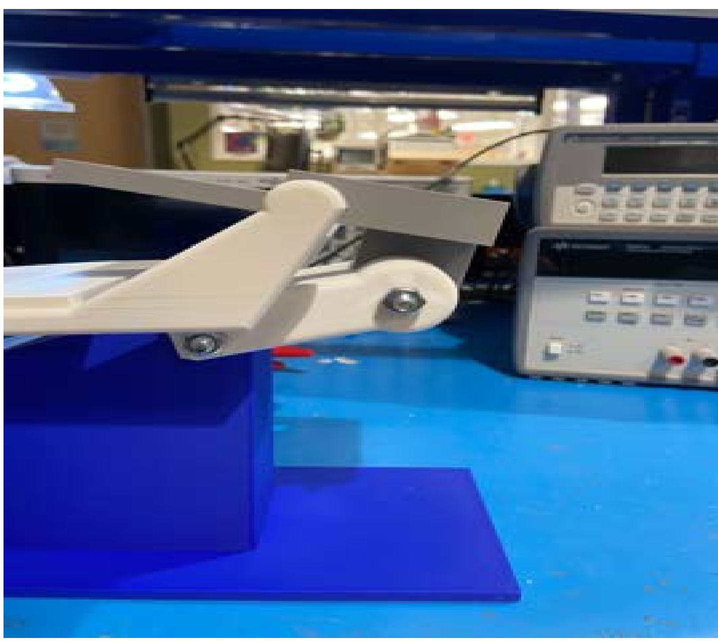
Content by: Jack

Present: Jack

Goals: Complete the Range of Motion testing on the completed base

Content:

- The range of motion testing done here was done by following the steps in the final report
- The testing was conducted with the connector piece attached to the neck portion of the trainer to simulate an airway being present
- Results showed that the flexion is sufficient and more than the AirSim trainer, however in extension there still needs to be work done to provide an increased ROM
- As noted in the final report, it appeared that the AirSim trainer had a piece broken which allowed it to hyperextend its neck, which may have given it too large of a ROM compared to an actual human neck
- Next steps include determining what the expected ROM is for the AirSim as well as a human head



Conclusions/action items: The ROM test was conducted using the outline provided below and the AirSim may have been broken before the test. Therefore next steps include determining what the expected ROM is for the AirSim as well as a human head

Jack Sperling - Dec 11, 2024, 7:43 PM CST

ROM Testing Protocol

1. Acquire the final prototype and ensure the entire neck hinge mechanism is fully assembled
2. Ensure the bolts that hold the model together are firmly screwed together to limit play within the connections

3. Rotate the white and grey (bottom and top jaw pieces, respectively) pieces until they are approximately horizontal
4. Attach the modular connector to the dual lock on the blue sloped surface of the trainer
5. Take a phone or any other device that is able to internally measure angles
6. Place the device along the thick back portion of the top jaw mechanism and ensure it reads approximately 0. This is our reference plane, replicating a neutral neck position
7. Rotate the head fully forward (flexion) and backward (extension) as shown in Figures 11 and 12 above
8. Record the maximum angles that can be reached from these maneuvers and this is the range of motion of the model

Jack Sperling - Dec 11, 2024, 4:04 PM CST

Download

IMG_4580.jpg (3.29 MB)

2024/12/02- FEA Data and Results

MARIBEL GLODOWSKI - Dec 09, 2024, 12:04 AM CST

Title: FEA Data and Results

Date: 12/02/2024

Content by: Maribel

Present: NA

Goals: To evaluate whether the PLA airway trainer base pieces can withstand the forces exhibited during intubation.

Content:

Refer to the FEA protocol by going to Testing and Results folder > Protocols > FEA Protocol

Below are the raw data results of the test. Each number represents a factor of safety

Where Force was Applied	Base Piece	Neck Hinge	Top Jaw	Bottom Jaw
Top	131.427	139.702	3.17467	4.02414
Right	111.911	50.0847	16.9	16.8553
Both	116.451	49.8	2.9559	3.30452

We considered a FOS > 5 as a success

The top and bottom jaw failed when forces where applied to the top and combination of faces.

Conclusions/action items:

This test showed that the base piece and neck hinge were able to withstand intubation forces but the top and bottom jaw did not pass the test. Therefore moving forward these pieces should be printed using a stronger material. One material that could be used is ABS. The next steps are to reprint the necessary parts and assemble the airway trainer base.

2024/12/04 - Analyzing MTS Testing Data

Jack Sperling - Dec 11, 2024, 3:43 PM CST

Title: Analyze MTS Testing Data

Date: 12/4/24

Content by: Jack

Present: Jack

Goals: Analyze the MTS Testing Data to Determine the Young's Modulus of the material samples

Content:

- Attached are the final results of the MTS testing along with the code that was run to create them
- Also, there is the raw data attached as well
- This utilized code that is very similar to BME 315 code that was used in rat tendon tensile testing, so the code was modified to fit this application
- Overall, I took the force and displacement data from the MTS machine and turned it into Stress vs Strain that could be graphed

Conclusions/action items: The data was fairly good from these tensile tests. There was one test that had a slight bit more error on it but other than that, the test was successful

Jack Sperling - Dec 11, 2024, 3:45 PM CST

Download

Pictures-20241211T214415Z-001.zip (45.6 MB)

Jack Sperling - Dec 11, 2024, 3:45 PM CST

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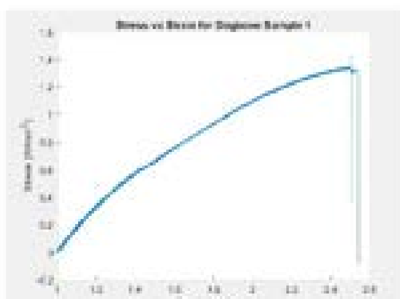
BME300StressVsStrainGrapher.m (1.31 kB)

Jack Sperling - Dec 11, 2024, 3:45 PM CST

Download

MTS_Documentation.docx (7.25 kB)

Jack Sperling - Dec 11, 2024, 3:45 PM CST



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Graphs.docx (343 kB)

Jack Sperling - Dec 11, 2024, 3:45 PM CST

Download

Data-20241211T214412Z-001.zip (1.62 MB)

2024/09/20 - Product Design Specifications

MARIBEL GLODOWSKI - Dec 11, 2024, 11:07 AM CST

Download

Airway_Trainers_PDS-Version_1_1_.pdf (249 kB)

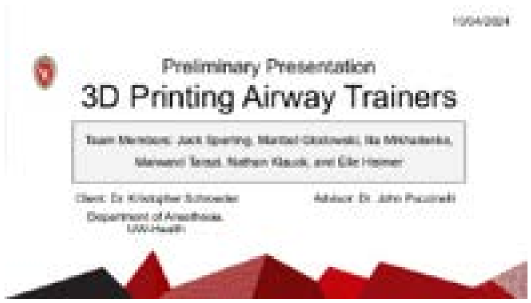
MARIBEL GLODOWSKI - Dec 11, 2024, 11:08 AM CST

Download

V2_Airway_Trainers_PDS.pdf (271 kB) Updated Version

2024/10/04 - Preliminary Presentation

MARIBEL GLODOWSKI - Dec 09, 2024, 12:15 AM CST



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Airway_Trainer_Preliminary_Presentation_.pdf (1.23 MB)

2024/10/09 - Preliminary Report

MARIBEL GLODOWSKI - Dec 09, 2024, 12:18 AM CST

3D Printing Airway Trainers

Download

Airway_Trainers_Preliminary_Report.pdf (3.64 MB)

2024/12/06 - Final Poster

MARIBEL GLODOWSKI - Dec 09, 2024, 12:20 AM CST

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Final_Poster_2_.pdf (1.61 MB)

2024/12/11 - Final Report

Jack Sperling - Dec 11, 2024, 10:22 PM CST

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AirwayTrainersFinalReport.pdf (13.1 MB)

2024/09/13 - "The Emerging Role of 3D Printing in Airway Training: A Narrative Review"

MARIBEL GLODOWSKI - Sep 13, 2024, 11:48 AM CDT

Title: "The Emerging Role of 3D Printing in Airway Training: A Narrative Review"

Date: 09/13/2024

Content by: Maribel

Present: N/A

Goals: To gain a better understanding of the role of 3D printing in airway management and airway management training.

Search Term: "3D printing airways"

Link: https://www.ijohs.com/article/doi/10.54531/FWBG1538

Citation:

[] G. Picton, "The emerging role of 3D Printing in airway training: A narrative review," International Journal of Healthcare Simulation, https://www.ijohs.com/article/doi/10.54531/FWBG1538 (accessed Sep. 13, 2024).

Content:

- -current 3d airway training models were created using "de novo design"
  - -uses pre-existing electronic 3D renders
  - -or cross-sectional imaging -> using computer processing to extract a 3D render (optimized before printing)
    - -images come from patient-specific datasets
    - -open source image libraries
  - -*one paper looked at recreating patient-specific pathology for preop simulation and discussions with patients

Conclusions/action items:

This article gave a good overview of what has already been started in 3D printing airway management trainers. The next steps would be to find the paper that looked at creating patient-specific pathology, understand their methods, and brainstorm whether these methods could be applied and improved upon in our project.

MARIBEL GLODOWSKI - Sep 13, 2024, 11:46 AM CDT

Download

10.54531_FWBG1538_ijohs_2_Supplement_1.pdf (107 kB)

2014/09/26 - "Multi-material three dimensional printed models for simulation of bronchoscopy"

MARIBEL GLODOWSKI - Sep 26, 2024, 7:45 PM CDT

Title: "Multi-material three dimensional printed models for simulation of bronchoscopy"

Date: 9/26/2024

Content by: Maribel

Present: N/A

Goals: To understand what methods others have used to select materials that are representative of airway tissues.

Search Term: "Materials used to simulate human airway tissue for models"

Link: https://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-019-1677-9

Citation:

B. H. K. Ho et al., "Multi-material three dimensional printed models for simulation of bronchoscopy - BMC Medical Education," BioMed Central, https://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-019-1677-9 (accessed Sep. 26, 2024).

Content:

Main aim of the study is to develop a multi-material 3D 3D-printed airway model

- Methods of development
  - Ct scans of the thorax were obtained from patients
    - Segmenting was done using OsiriX Lite
    - Processing in Autodesk Meshmixer
    - Printer used Objet500 Connex
      - Features multi-material jet capable of fusing plastic and rubber
    - Mechanical measures used to ensure property was shore hardness
    - Two materials used to achieve haptic representation
      - A custom mix of plastic and rubber approximately ratio of 1g plastic for 2 grams of rubber
        - Plastic: FullCure RGD851, VeroMagenta
        - FullCure 930 TangoPlus
        - Shores hardness from the D40-D60 range
        - Fully rubber material was used for the tumor
          - FullCure FLX930, Tango Plus
        - Support resin
          - FullCure 705
- Results
  - Found reasonably good results
  - The cost of design was $135
  - Ability to modify shore hardness by altering proportions of rubber and plastic

Conclusions/action items:

This study achieved a goal very close to our own projects goal to recreate difficult airway pathology for training purposes using patient data and accurate pathological airways. The information I found most applicable for our projects was the methods and materials which they used. I find the method of using shores hardness to determine the ratio of materials to be and interesting method of determining materials. My next steps are to look more into what shore hardnes is and what shore hardness is consistent with tissue of the trachea.

MARIBEL GLODOWSKI - Sep 26, 2024, 6:59 PM CDT


BMC Medical Education

RESEARCH ARTICLE Open Access

Multi-material three dimensional printed models for simulation of bronchoscopy

BMC

Download

s12909-019-1677-9.pdf (2.81 MB)

2014/09/26 - "Fabrication and assessment of a bio-inspired synthetic tracheal tissue model for tracheal tub cuff leakage testing"

NATHAN KLAUCK - Sep 27, 2024, 1:59 PM CDT

Title: "Fabrication and assessment of a bio-inspired synthetic tracheal tissue model for tracheal tub cuff leakage testing"

Date: 09/26/2024

Content by: Maribel

Present: N/A

Goals: To better understand the biomechanical properties of tracheal tissue and find methods to incorporate these properties into the design.

Search Term: "shore hardness of the trachea"

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11223077/

Citation:

[1] T. Agbiki *et al.*, "Fabrication and assessment of a bio-inspired synthetic tracheal tissue model for tracheal tube cuff leakage testing," *BJA Open*, vol. 10, p. 100290, Jun. 2024. doi:10.1016/j.bjao.2024.100290

Content:

Their goal was to create a more realistic model to test tracheal tube leakage because it leads to pneumonia

- Focused on creating a model that focuses on replicating the biomechanical properties of different anatomical structures in the airway
- Segmented tracheal mucosa, tracheal cartilages, thyroid cartilage, tracheal rings, thyroid gland, and cricoid cartilage as individual components
- **Polydimethylsiloxane gels Platsil© gel 00–30 and Transil© 20 with additives** to alter mechanical properties
    - Mucosa membrane and thyroid gland -> platsil
    - Cartilages used transil with the addition of polydimethylsiloxane hardener and kaolinite powder to increase shore hardness
- Table provides young modulus values from previous literature converted to shore hardness

Table 1

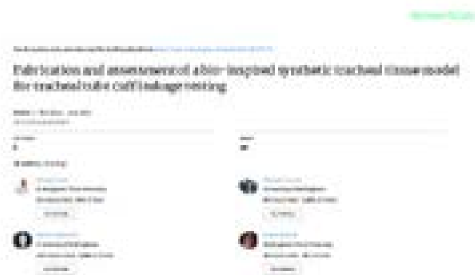
Published *ex vivo* biomechanical data.

Component	Young's modulus	Shore hardness	Source
Cartilage	3.2–23 MPa	59.6–91 ShA	Rains, 1992[17]; Sicard, 2018[18]
Tracheal mucosa membrane (TMM) and glandular surrogate material	4–18 kPa	35–40 Sh00	Wang, 2000[19]

Conclusions/action items:

This source provided very valuable information about the mechanical properties that a model should recreate if it is trying to replicate a physiologically created model. While the purpose of their model is slightly different than our own, the thorough research and testing of their models shows their commitment to physiological accuracy. The next steps are to explore the access we have to 3D printing and find materials available to us with these mechanical properties.

MARIBEL GLODOWSKI - Sep 26, 2024, 8:28 PM CDT



Fabrication and assessment of a bio-inspired synthetic tracheal tissue model for tracheal tube cuff leakage testing

Download

Tracheapaper.pdf (1.5 MB)

2024/09/11 - "Decent Simulators: Airway Management Task Trainer"

MARIBEL GLODOWSKI - Sep 12, 2024, 12:27 PM CDT

Title: Decent Simulators: Airway Management Task Trainer

Date: 09/11/2024

Content by: Maribel

Present: N/A

Goals: To understand what is currently available on the market for airway management training.

Search Term: "Airway Management Trainer"

Link: https://www.decentsimulators.com/airway-management

Citation:

"Airway management," Decent Simulators, https://www.decentsimulators.com/airway-management (accessed Sep. 12, 2024).

Content:

Figure above shows Decent Simulators Airway management Task Trainer

-3D printed and silicone cast

-strengthened with "power mesh" in airway and mouth; anatomically correct

-can be used to teach

-Intubation algorithms

- laryngeal anatomy

- mask ventilation

- the use of diff. laryngoscopes and supraglottic devices

- nasal intubation

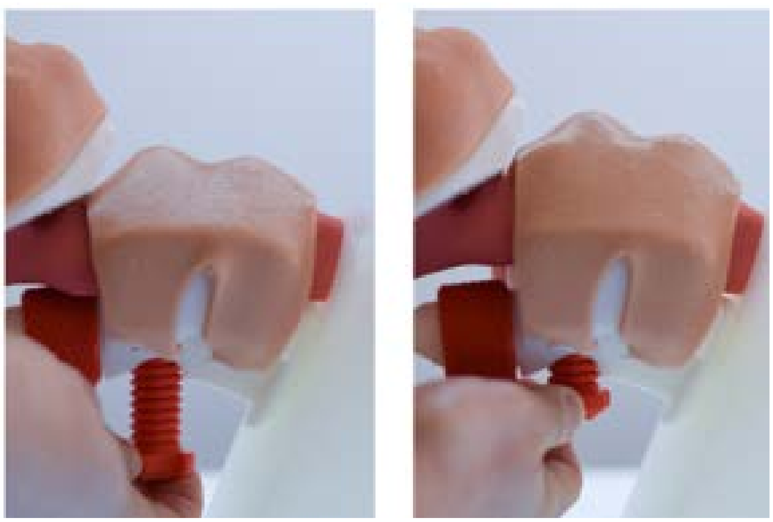
Main Features:

- made using real data

  - used MRI Data and photogrammetry files

- adjustable difficulty (shown in figure below)

  - can be adjusted from grades 1 to 3 in Cormack-Lehane Scale



- Stiff Neck (see image below)
  - can adjust the mobility of the neck

- 

- Realistic landmarks:
  - true and false vocal cords
  - posterior cartilages
  - epiglottis
  - inter arytenoid notch
  -  

Conclusions/action items:

This is a great competing design to look at because it shows us what features we should consider when looking at our designs. The next step is to meet with the client and set clear expectations on what should be improved upon.

MARIBEL GLODOWSKI - Sep 12, 2024, 12:28 PM CDT

Download

Airway_management___Decent_Simulators.pdf (6.58 MB)

2024/09/19 - Laerdal Airway Trainer

MARIBEL GLODOWSKI - Sep 19, 2024, 7:33 PM CDT

Title: Laerdel Airway Trainer

Date: 9/19/2024

Content by: Maribel

Present: N/A

Goals: To better understand how the Laerdal trainer is composed in case it is necessary to take one apart.

Search Term: "laerdal airway trainer"

Link: **https://laerdal.com/us/doc/2163/Laerdal-Airway-Management-Trainer#/Downloads**

Citation:

[1] “Airway management trainer,” Laerdal Medical, https://laerdal.com/us/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

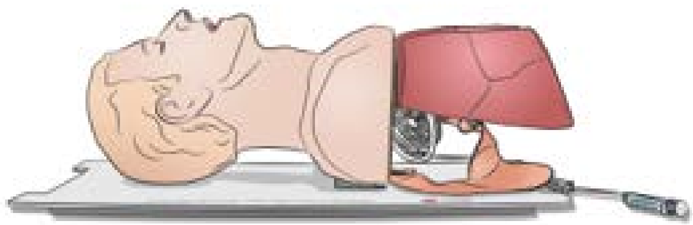
Content:

-current cost of entire unit: $2799

-note: many of the trainer's parts are sold separately

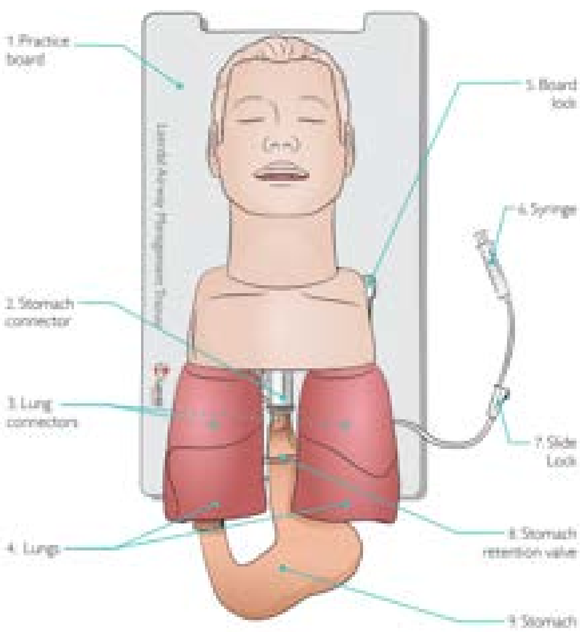
-one document below is the spec sheet for the airway management trainer

-while this document does not provide many descriptions it contains many useful diagrams of the trainer



1. Main Simulator

2. Airway Demonstration Model



-also demonstrates cleaning methods which may be helpful in disassembling the device

-advertised features:

- -realistic human anatomy
- -directly transferable
- -practice training in cleaning obstructed airway
- -minimal maintenance

Conclusions/action items:

This product will likely be incorporated into our design in some way. We must understand how this model function and what we can do to improve it and make it modular and patient-specific. The company website offer much valuable information on how there product is constructed and what features are important to it. They also sell individual parts for the trainer which may be helpful later in the semester. The next step is to start brainstorming design ideas and create a design matrix.

MARIBEL GLODOWSKI - Sep 19, 2024, 7:16 PM CDT


Laerdal

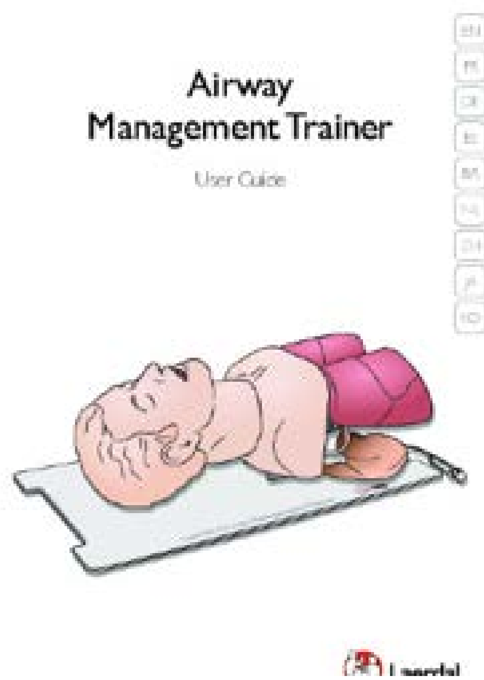
Laerdal Airway Management Trainer

Realistic practice for developing proficiency in airway management skills

[Download](#)

LaerdalAirwayManagementTrainerSellSheet.pdf (1.45 MB)

MARIBEL GLODOWSKI - Sep 19, 2024, 7:16 PM CDT


Airway Management Trainer

User Guide

[Download](#)

spec__pn_6511-dfu__amt_ie_version.pdf (4.16 MB)

2024/9/18 - "Patient Specific 3D Models for Education, Research, and Surgical Simulation"

MARIBEL GLODOWSKI - Sep 19, 2024, 7:06 PM CDT

Title: "Patient-Specific 3D Printed Models for Education, Research and Surgical Simulation"

Date: 9/18/24

Content by: Maribel

Present: N/A

Goals: To better understand what methods have been used to create patient specific educational models.

Search Term: "3D Printing in Medicine"

Link: https://www.researchgate.net/publication/328201273_Patient-Specific_3D_Printed_Models_for_Education_Research_and_Surgical_Simulation

Citation:

[1] D. I. Nikitichev *et al.*, “Patient-specific 3D printed models for education, research and surgical simulation,” *3D Printing*, Oct. 2018. doi:10.5772/intechopen.79667

Content:

-there is a trend towards the development of "personalized medicine"

-uses of 3D printing in medicine:

- -patient education
- -education for healthcare professionals
- -procedure planning
- -prosthesis and implant production
- -promising in the areas of regenerative medicine and tissue engineering

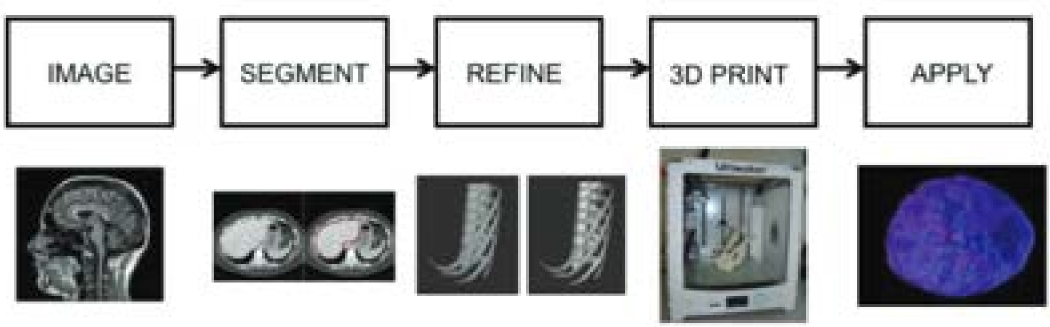


Figure 2. Outline of the workflow from medical images acquisition to application of 3D printed models.

-

-this is the process that 3D printing applications typically follow

-Section 2: Workflow

-Model production includes:

-knowledge of how to segment the region of interest from emdicalimage data

-manipulate the resulting 3D model

-prepare stereolithographic (.stl) files for printing

-2.1 imaging

-DICOM is a universal image format

-2.2 Segmentation: the extraction of a specific 3D volume from a set of image dataslices; used to locate objects and boundaries in each slice that corresponds to the tissue of interest

Modality	"Type"	Intensity from:	Resolution
CT	Structural	Photoelectric coefficient ≈ Density	0.5 - 1.5 mm
MRI	Structural/ Functional	Proton Relaxation Time	0.3 - 1.0 mm
SPECT/PET	Structural/ Functional	Particle emission from radioisotope	3.0 - 8.0 mm
Ultrasound	Structural	Reflections from changes in acoustic impedance	0.3 - 0.5 mm
Photoacoustic	Structural	Absorption of laser light by chromophores	~ 0.1 mm (depth dependent)

Table 1. Main imaging modalities. CT-computed tomography. MRI-magnetic resonance imaging. SPECT/PET-single photon emission computed tomography/positron emission tomography

-this table shows different imaging types and their resolutions

-basic techniques

-Manual Segmentation: user identifies boundaries and manually draws around the shapes using a paintbrush tool

- thresholding

-pixels are partitioned depending on grayscale value

converts grey-scale image to a binary image with one intensity representing tissue to be included in the model and what should be excluded

-most effective when the target tissue is a different intensity to the background

-cropping

-restricting the segmentation to a certain volume of space

-advanced techniques

-edge based methods - region growing

-seeds are positioned by the user and grow to fill regions defined by boundaries in the image. Works well when regions are well defined

-if data is noisy or edges are not clear the segmentation may 'leak'

-parametric models-snakes

-algorithm attempts to model the edges by minimising an energy term

-minimized when contour is on the object boundary and when the contour is as regular and as smooth as possible

useful for interpreting incomplete images

robust to noise, but slow

-expectation maximization (EM)

-algorithm find the maximum likelihood of label distribution in a probablistic manner

-framework is highly complex but can be a powerful tool for modelling the data accurately

-refinement techniques (tools: FreeCAD, MeshLab, Blender)

-repairing

-errors and discontinuities can sometimes arise in the segmentation and exporting process which need to be repaired before printing

-smoothing

staircasing errors resulting from the resolution of the original medical image can be mitigated by smoothing the surface of the mesh model

-appending

-segmentation will often only be one component of a final model

-combine with other structure to,or subtracting volumes from the mesh

-2.4: 3D printing

-3 main groups

-extrusion printing:

-material is molten; deposited on the layer underneath

-thermoplastics using filament deposition modelling

-photopolymerisation

-slectively solidifies photopolymer; liquid materials that harden by exposure to light

-can only print plastics

-powder binding techniques

-binds granules of the material by gluing or melting them

-widest range of materials

Conclusions/action items:

This was an extremely helpful source that laid out the basics of 3D printing biological models using imaging. It even had a step by step example of how imaging could be used to print a lung. Despite this useful information some challenges and considerations are still present such as materials that reflect mechanical properties of the airway anatomy and whether one single strategy will be able to effectively segment images. The next step is too look further into what materials might be useful for our project.

MARIBEL GLODOWSKI - Sep 19, 2024, 6:33 PM CDT


Chapter 6

Patient-Specific 3D Printed Models for Education, Research and Surgical Simulation

Download

Patient-Specific_3D_Printed_Models_for_Education_R.pdf (5.64 MB)

2024/09/20 - "Comprehensive evaluation fo manikin-based airway training with second generation supraglottic airway devices"

MARIBEL GLODOWSKI - Sep 20, 2024, 11:49 AM CDT

Title: "Comprehensive evaluation of manikin-based airway training with second generation supraglottic airway devices"

Date: 9/20/2024

Content by: Maribel

Present: N/A

Goals: To get a better understanding of what should be considered to be an effective training manikin for a wide range of airway management techniques including supraglottic airway devices.

Search Term:

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6400128/pdf/tcrm-15-367.pdf

Citation:

[1] A. Schmutz, E. Bohn, J. Spaeth, and S. Heinrich, “Comprehensive evaluation of manikin-based airway training with second generation supraglottic airway devices,” *Therapeutics and Clinical Risk Management*, vol. Volume 15, pp. 367–376, Mar. 2019. doi:10.2147/tcrm.s194728

Content:

-supraglottic airway devices (SADs):

-becoming a more essential part of airway management especially in difficult cases

-frequent airway trainings are essential with this technique

-Manikin considered

-TruCorp AirSim

-anatomically correct airway created from DICOM data

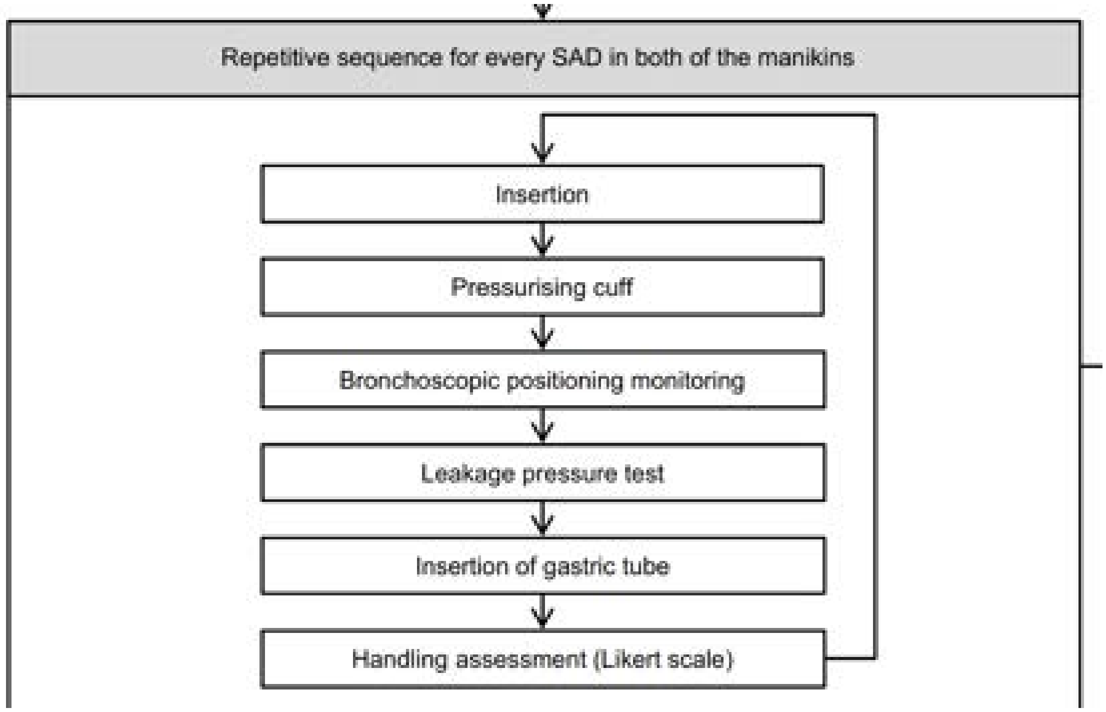
-Laerdal Resusci Annne Airway Trainer

-complete anatomy with elastic skin and tissue properties

-methods

-each participant (80 anesthesia residents):

-



-time was also recorded

-OLP (oropharyngeal leakage pressure) was one main measurement taken

-breathing system occluded and a closed system was inflated with a gas flow of 3 L per min

-pressure in the breathing system expected to exceed threshold of 10 cm H2O if reached rated passed and clinically sufficient

-if under 10 cm leakage exceed 3 L per min

-pressure was measured using differential pressure sensor

-results: only reached this threshold in very few cases ~6%

-the most important factor in resident ratings was the flexible material used in laerdal trainer

Conclusions/action items:

This article considered the effectiveness of current airway trainer models on training with supraglottic airway devices. This article presented some interesting methods of measuring the compatibility of the models and SAD methods including OLP and accuracy of positioning (Brimacombe score). This could be useful in testing a prototype on its compatibility with SAD training. It also showed that the easiest trainer to manipulate for the residence was the Laerdal model that is made of a material that has similar elastic properties to skin and other tissues. This indicates that the elasticity of the material we choose is important. Next step is to look further into materials that would be suitable for this application and start brainstorming designs.

MARIBEL GLODOWSKI - Sep 20, 2024, 10:57 AM CDT


Comprehensive evaluation of manikin-based airway training with second generation supraglottic airway devices

Introduction

Download

tcrm-15-367.pdf (2.38 MB)

2024/09/26 - "A Guide to Shore Hardness"

MARIBEL GLODOWSKI - Sep 26, 2024, 8:40 PM CDT

Title: "A Guide to Shore Hardness"

Date: 9/29/2024

Content by: Maribel

Present: N/A

Goals: To better understand the measurement of shore hardness and how it can be applied to our project.

Search Term: "shore hardness"

Link: https://hapcoincorporated.com/resources/guide-to-shore-hardness/

Citation:

[1] “Guide to shore hardness,” Hapco, Inc., https://hapcoincorporated.com/resources/guide-to-shore-hardness/.

Content:

-What is shore hardness?

-measures the level of resistance a material demonstrates against indentation pressure

-device used to perform this test is known as a durometer

-the higher the number the greater resistance to indentation a material displays

-Importance of shore hardness

-in almost every application important to assess

-helps determine what materials are ideal for a specific use

-Shore hardness scales

-grouped into categories based on similarity

-several durometer scales used to measure hardness

-three most common scales include Shore A, Shore D, and Shore 00

-used to measure non-metallic materials

Conclusions/action items:

Selecting a material based on shore hardness seems like a realistic and appropriate method to selecting a material with physiological mechanical properties. This would also provide us with simple yet effective ways to test the mechanical properties of our materials. The next step is to look into appropriate shore hardness materials.

2024/10/30 - "Importing STL files into SolidWorks"

MARIBEL GLODOWSKI - Nov 15, 2024, 8:40 PM CST

Title: Importing STL files into SolidWorks

Date: 10/30/2024

Content by: Maribel

Present: N/A

Goals: To get a better understanding of how to import stl. files to SolidWorks and figure out how these file can be applied for our needs.

Search Term: "stl. to solidworks"

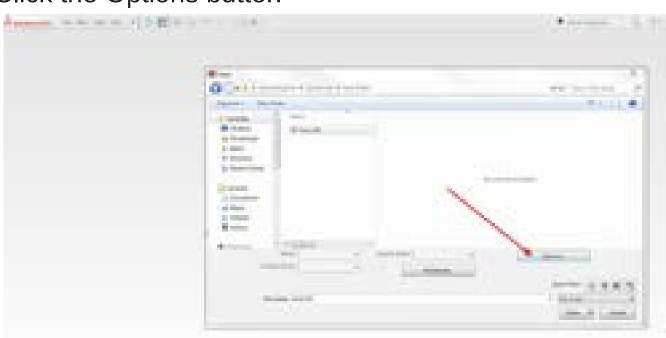
Link: https://www.javelin-tech.com/blog/2015/12/importing-stl-files-into-solidworks-solid-surface-model/

Citation:

[1] “https://www.javelin-tech.com/blog/2015/12/importing-stl-files-into-solidworks-solid-surface-model/,” The Javelin Blog, https://www.javelin-tech.com/blog/2015/12/importing-stl-files-into-solidworks-solid-surface-model/

Content:

The following are the steps detailed in this article:

- Start SolidWorks; click Open
- Change the file type to .stl file
- Click the Options button
- 
- Change the import body option to "Solid Body" or "Surface Body" and click OK.
- Open .stl file in SolidWorks
- Press Instant 3D button
- Use FeatureWorks > Recognize Features to convert the imported body into SOLIDWORKS features.
    - can find on the left hand side of page

Conclusions/action items:

This article was helpful in a few ways. The first was converting the airway mold into SolidWorks so that is could be manipulated. The second way was so that the team could convert .stl files from online libraries so that these .stl files could be modified to meet the framework team's needs. The next step is to use this technique to test the ability to alter stl. files using this method. If it works the next step is to print a face structure for the trainer.

MARIBEL GLODOWSKI - Nov 15, 2024, 8:30 PM CST

Download

Importing_STL_files_into_SOLIDWORKS_as_a_Solid_or_Surface.pdf (408 kB)

2024/11/01 - Head stl. obtained from online source

MARIBEL GLODOWSKI - Nov 15, 2024, 9:02 PM CST

Title: Head stl.

Date: 11/01/2024

Content by: Maribel

Present: N/A

Goals: To find an online source that would provide for a human face for the trainer framework.

Search Term:

Link: https://www.thingiverse.com/thing:979818/files

Citation:

[1] Thingiverse.com, "Head ," Thingiverse, https://www.thingiverse.com/thing:979818/files

Content:

- Consulted with Makerspace about the feasibility of 3D scanning commercial trainer for more complex parts
- 3D scanning was determine to be too difficult for the size and scope of our project
- suggestions were
  - model what is possible in CAD using digital calipers to measure
  - find existing files on the internets and modify them to fit our needs
- Below is a screenshot of stl. file of a human head that could be useful for the face of the trainer
- 

Conclusions/action items:

This could be useful in the fabrication of the airway trainer framework. A method of modifying this file would have to be applied though which could potentially be a difficulty. The next steps will be to fabricate the base and essential parts of the framework. Then the team should explore different methods of constructing the face. One of these methods considered should be editing an stl. file like this one.

2024/10/17 - Framework Design Ideas

MARIBEL GLODOWSKI - Oct 18, 2024, 11:25 AM CDT

Title: Framework Design Ideas

Date: 10/17/2024

Content by: Maribel

Present: N/A

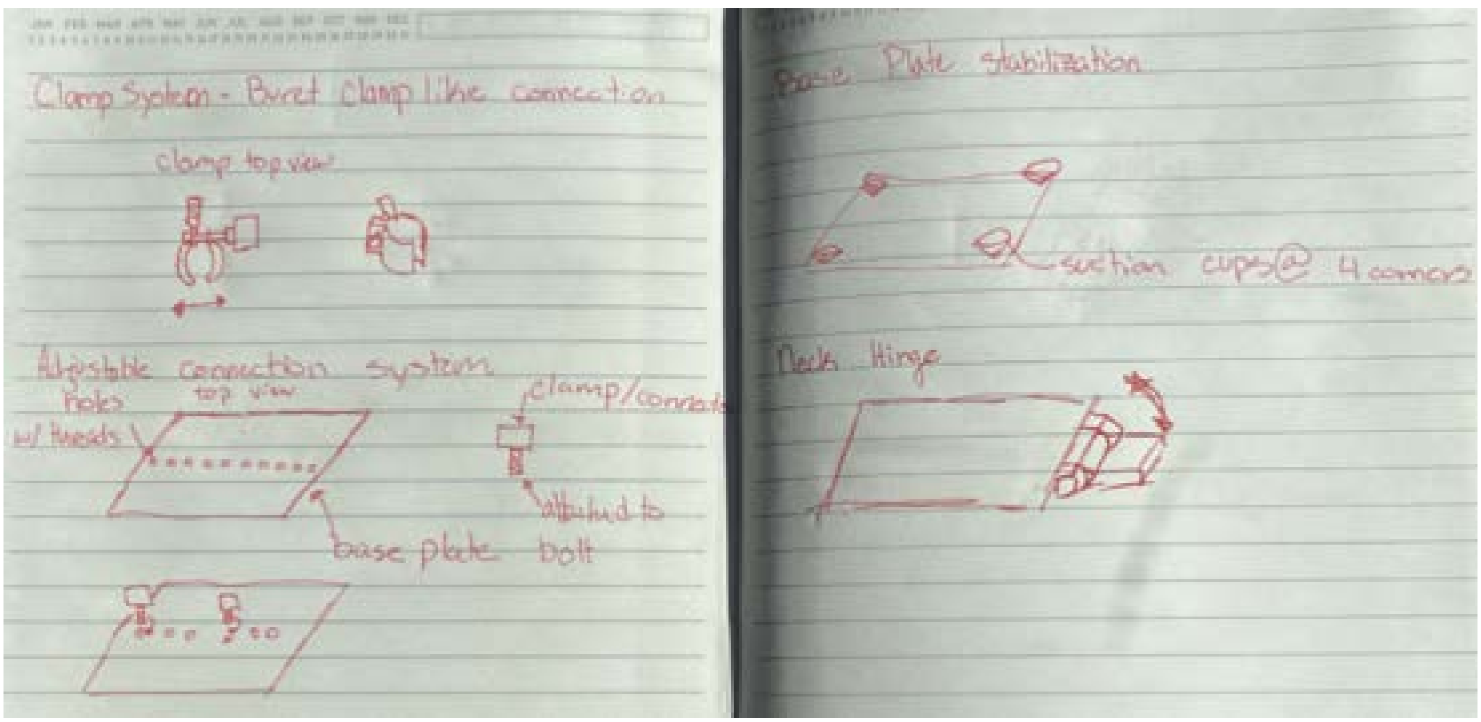
Goals: To brainstorm and document potential designs for the framework of the trainer.

Content:

See drawings attached below.

Features:

- clamp system
  - this design uses a bolt to adjust the collar of the clamp
  - this would all for the user to adjust the size of the clamp to fit any trachea by simply twisting a knob
- adjustable connection system
  - base plate has a row of many threaded holes
  - the clamp will be connected to a bolt and can be connected to the base plate using any of the holes
- base plate stabiliazation
  - base plate will have suction cups on the bottom to stabilize it on flat surfaces
  - ideally these would easily be removed if desired
- neck hinge
  - this hinge would rotate upward 90 degrees only
  - ideally will be connected to facial anatomy



Conclusions/action items:

This provides an overview of the ideas for the framework that I brainstormed. The next step is to meet with the rest of my team and see what designs they have come up with. After that we will narrow down materials and fabrication steps.

2024/10/20 - Paracord Fastener Design

MARIBEL GLODOWSKI - Nov 15, 2024, 7:25 PM CST

Title: Paracord Fastener Design

Date: 10/20/2024

Content by: Maribel

Present: N/A

Goals: To determine a method to fasten the printed airway to the training base.

Content:

Features:

- paracord running through a bold and 3 washers
    - paracord is knotted at the ends and sealed with a lighter
- between the 2nd and 3rd washer is a strip of velcro
- the airway would have the complementary strip of velcro

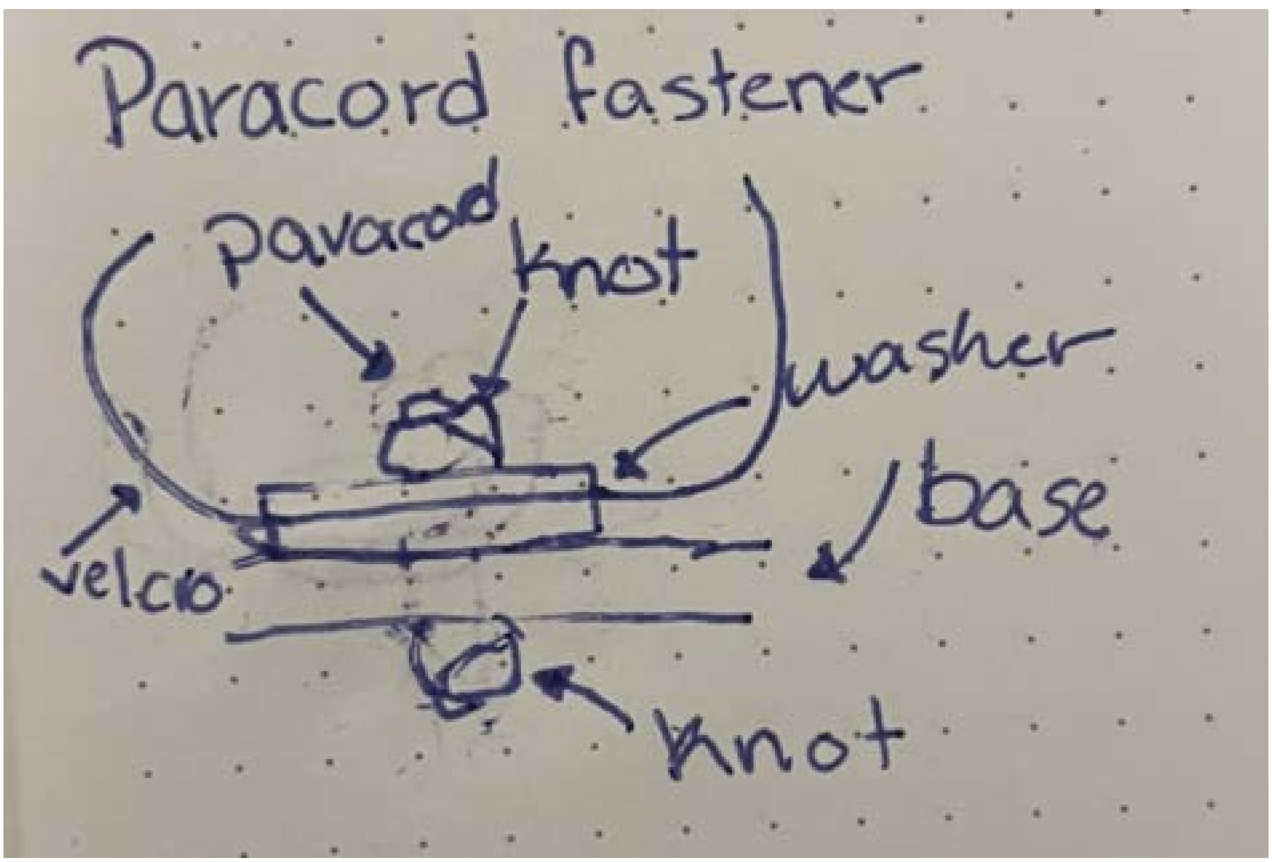
Pros:

- Easy to fabricate
- cost effective
- paracord is strong and easy to costumize size and seal

Cons:

- airway does not lay flat which could cause instability and issues with preforming procedures
- fasteners are able to slide laterally which could create issues with stability

Below is an drawing of the design:



Conclusions/action items:

This fastener idea is quick and simple way to attach the airway to the the current version of the base. While this design has some faults, the ease of prototyping and low cost should allow us to create and test this design idea. The next step is to purchase the necessary materials and create the prototype. In addition, the team need to keep brainstorming and fabricating for each component of the airway framework.

2024/10/25 - Updated Fastener Design: Dual Lock Velcro Fastener

MARIBEL GLODOWSKI - Nov 15, 2024, 8:21 PM CST

Title: Dual Lock Velcro Fastener

Date: 11/25/2024

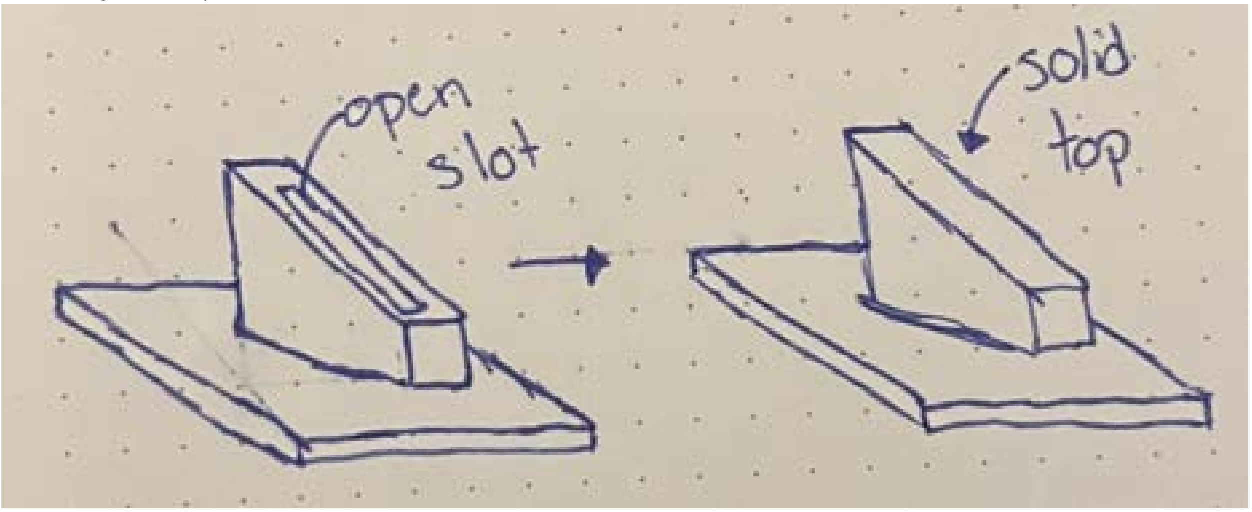
Content by: Maribel

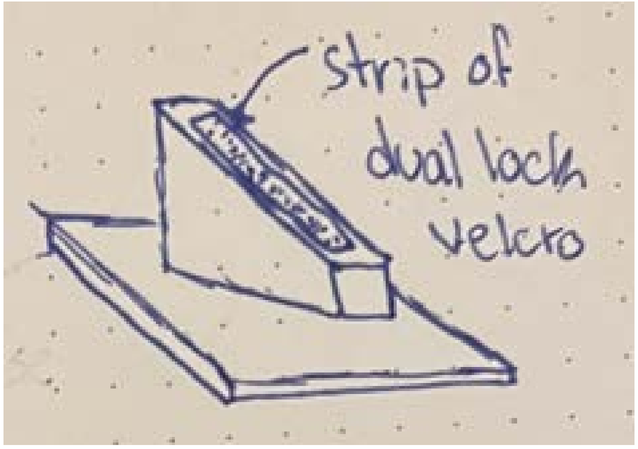
Present: N/A

Goals: To portray the finalized fastener design for attachment of the airway to the airway base.

Content:

Features:

- Solid surface for trainer to rest on
- Strip of dual lock Velcro attached to the solid surface of the airway trainer
  - attached via adhesive
- Dual lock adhesive will be attached to 3D printed airways
- See drawings below:
  - Slotted design to solid top
  - 

  - Velcro attachment:
  - 

Pros

- user friendly
- cost effective
- easy fabrication
- high stability
  - dual lock velcro has a double mushroom cap design so each strip of the velcro interlocks with the other
  - creates a strong attachment

Cons

- might be difficult to adhere velcro to the airway material

Conclusions/action items:

While this design is extremely simple, it provides an effective method of attachment for the airway. The only difficulty the team foresees might be finding an adhesive that is compatible with the airway material. The next steps are to fabricate the airway framework base and to order the necessary materials.

2024/11/04- First Section of Neck Hinge Design

MARIBEL GLODOWSKI - Nov 15, 2024, 9:51 PM CST

Title: First Section of Neck Hinge Design

Date: 11/04/2024

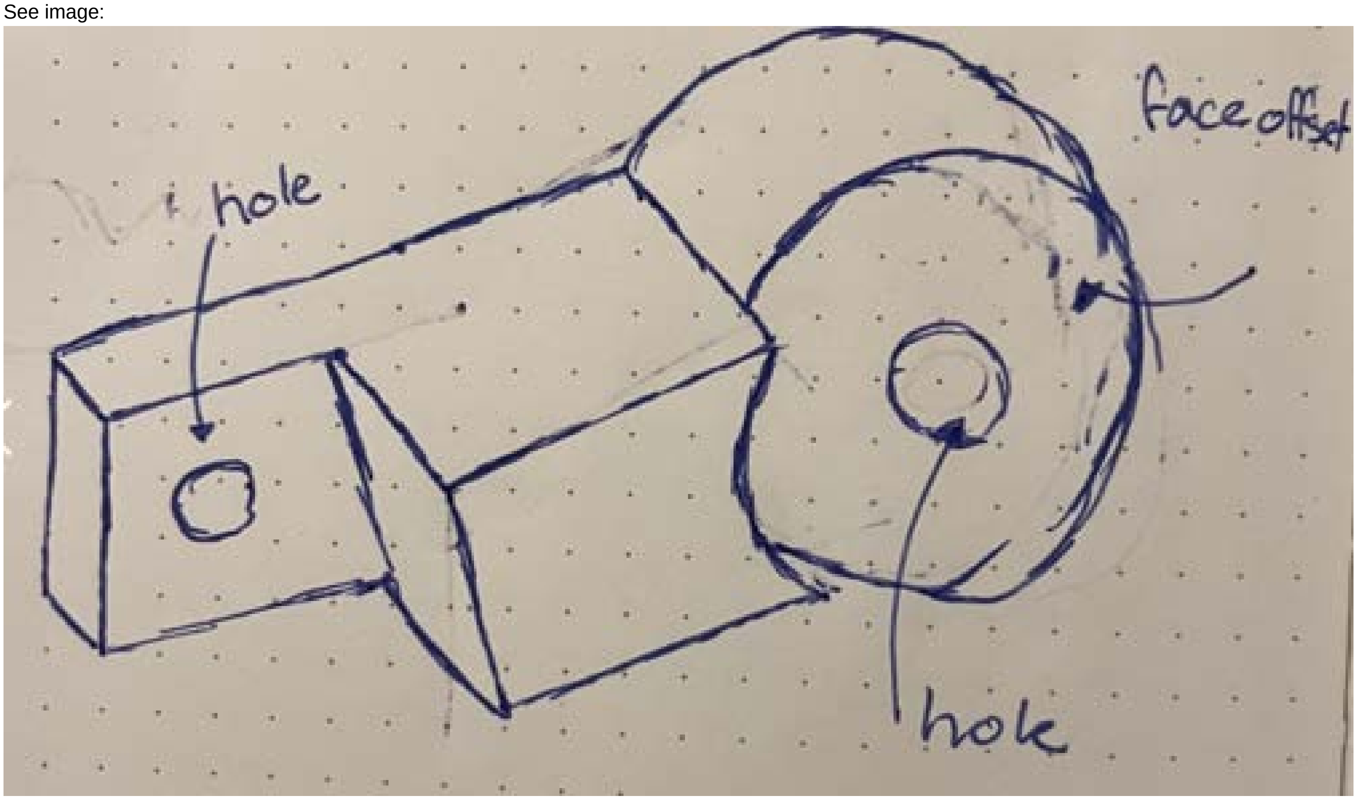
Content by: Maribel

Present: N/A

Goals: To sketch and show the first section of the neck hinge design.

Content:

Features

- Holes at each end
    - one secure allow to be secured to the base at an angle
    - the other is round and allows for the complementary section of the hinge to have a limited angle of rotation
- See image:
- 

Pros

- can use similar dimensions to the commercial airway trainer as it is very similar to their design
- small and easy to print; inexpensive

Cons

- failure of this part is observed in the commercial trainer

Conclusions/action items:

This is the hinge design we are moving forward with. The next step will be to model it in SolidWorks. We are brainstorming ways to make this part more stable and stronger since this part failed in the commercial air trainer that we were provided. Another next step is designing the complementary part to this hinge and finding a bolt that can connect these pieces. A challenge with the complementary hinge is finding how to create the appropriate angle for where the hinge needs to stop. This could be done by calculating the arc length that is necessary for the appropriate angle. Exploring this further and modeling and printing this piece are the next priorities.

2024/11/15 - Flange airway attachment design

MARIBEL GLODOWSKI - Nov 15, 2024, 10:25 PM CST

Title: Flange Airway Attachment Design

Date: 11/15/2024

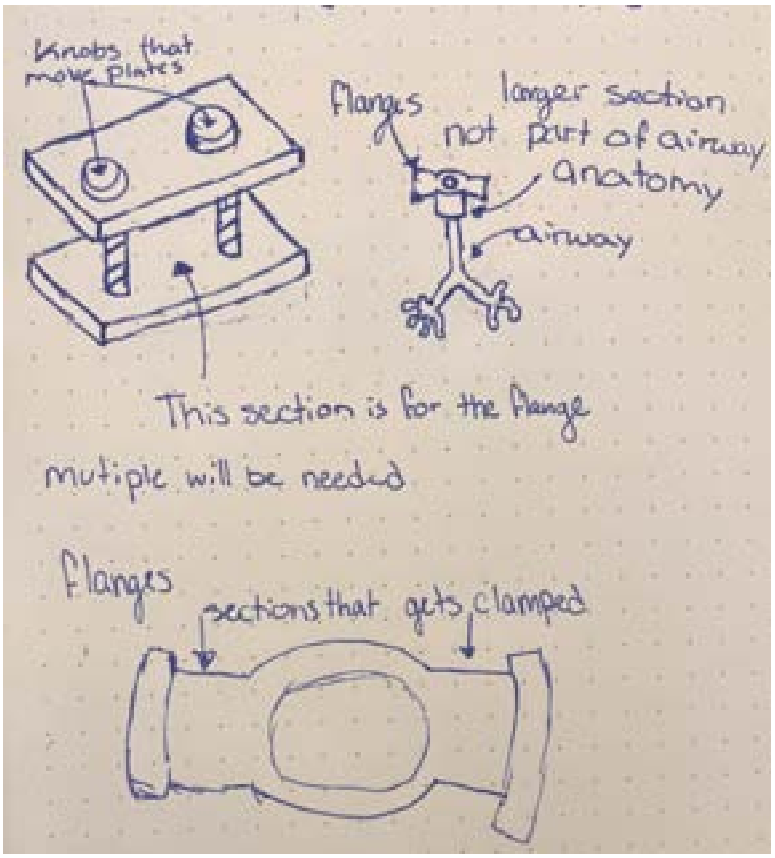
Content by: Maribel

Present: N/A

Goals: To outline a possible attachment technique of the top of the airway to the trainer framework if the upper airway cannot be replicated using DICOM files.

Content:

The image below describes the attachment strategy:



- Pros
    - No alteration to anatomy
    - No gaps between sections of the trainer
- Cons
    - May be difficult to add flanges to airway .stl fil
    - may put stress on flexible material
    - may be bulky

Conclusions/action items:

This is a feasible design idea of how the airway could attach to the trainer framework if the mouth is not included in the airway print. This is necessary to consider because it is not clear what availability and resolution we will have in the upper airway. The next steps would be to get a clearer picture of what the airway attachment site will look like by developing a method to 3d print the airway. After that, it can be determined how likely this design is to be needed and to work.

2024/11/27 - Connector Prototype

MARIBEL GLODOWSKI - Dec 08, 2024, 11:55 PM CST

Title: Connector Prototype

Date: 11/27/2024

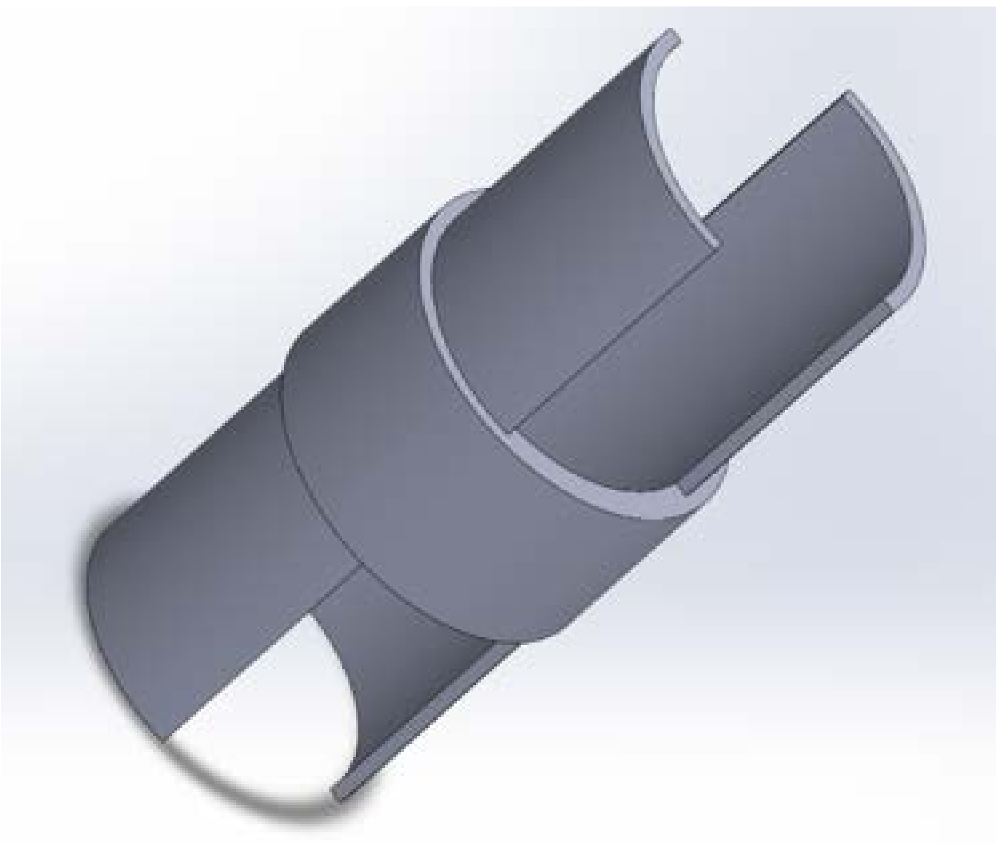
Content by: Maribel

Present: N/A

Goals: To create a prototype system that would be capable of attaching a variety of different printed airways to the rest of the trainer.

Content:

See image below:



Features:

- A hollowed cylindrical center that would allow for the lower patient-specific section of the airway to connect with the upper generic airway.

-2 flaps extending off of the hollowed cylinder; these will be lined with dual lock velcro to create a secure but easily interchangeable attachment

-easily fabricated using 3D printing

-Main material: TPU; the flexibility of TPU will allow for it to be bent to fit the needs of different airway models

Conclusions/action items:

This provides a good start as far as prototyping swappable connections goes. Designing a connector was a unique challenge because without a scan and the ability of the airway printing group to understand what the 3D printed airway would look like it was difficult to know what the connector between the airway and the trainer base should look like. For example, if the printed airway included the tongue and feature of the mouth then a simple dual lock velcro system could be utilized, but if the connection needs to be lower in the airway this connector piece could provide the ability to bridge the two pieces together without gaps. The next steps would be to print this prototype and evaluate its compatibility with the base and printed airways.

2024/10/23 - Paracord Fastener Fabrication

MARIBEL GLODOWSKI - Nov 15, 2024, 7:51 PM CST

Title: Paracord Fastener Fabrication

Date: 10/23/2024

Content by: Maribel

Present: N/A

Goals: To prototype the Paracord Fastener Design of attachment.

Content:

Below is a photo of the prototype:

Materials:

- 1 6 in of velcro
- 1 3 in of paracord
- 3 Large washers (unknown size; must fit snuggly around the paracord; larger surface area supports the velcro better)
- 1 nut (unknown size; must fit snuggly around the paracord)
- Scissors
- Ruler
- Lighter
- Airway Trainer Base

Steps:

1. Gather supplies. Cut the velcro into two three inch pieces
    1. a. Save one velcro piece for the printed airway.
2. Tie a knot at one end of the paracord
3. Cut a small hole in the velcro; large enough to thread the paracord through
4. Thread the paracord through the components in the following order:
    1. nut
    2. washer
    3. airway trainer base
    4. washer

    5. velcro
    6. washer
5. Before tying the final know, check that the section of the fastener that is on top of the trainer contains two washers and the strip of velcro. Then tie a knot as tightly to trainers surface as possible.
6. Trim any excess velcro off the end of the paracord.
7. Carefully use the lighter to seal of each end of the paracord.

Conclusions/action items:

This fabrication is relatively fast and easy. In total the materials cost less than a dollar. Yet, the downsides of this prototype unfortunately outweigh the positive features. The lack of stability and amount of interference the knot of the paracord would have on the airways attachment make it an inefficient fastening system. Two future approaches can be taken in regards to fastening the airway to the airway trainer base. The first possible option is to look at the faults in this design and refine it to create a more effective fastener. The other option and the one that the team has agreed on is to alter the airway trainer base and simplify the design. Future work includes incorporating and fabricating an improved fastener system.

2024/11/07 - Updated Base in SolidWorks

MARIBEL GLODOWSKI - Nov 15, 2024, 9:27 PM CST

Title: Updated Base in Solidworks

Date: 11/07/2024

Content by: Maribel

Present: N/A

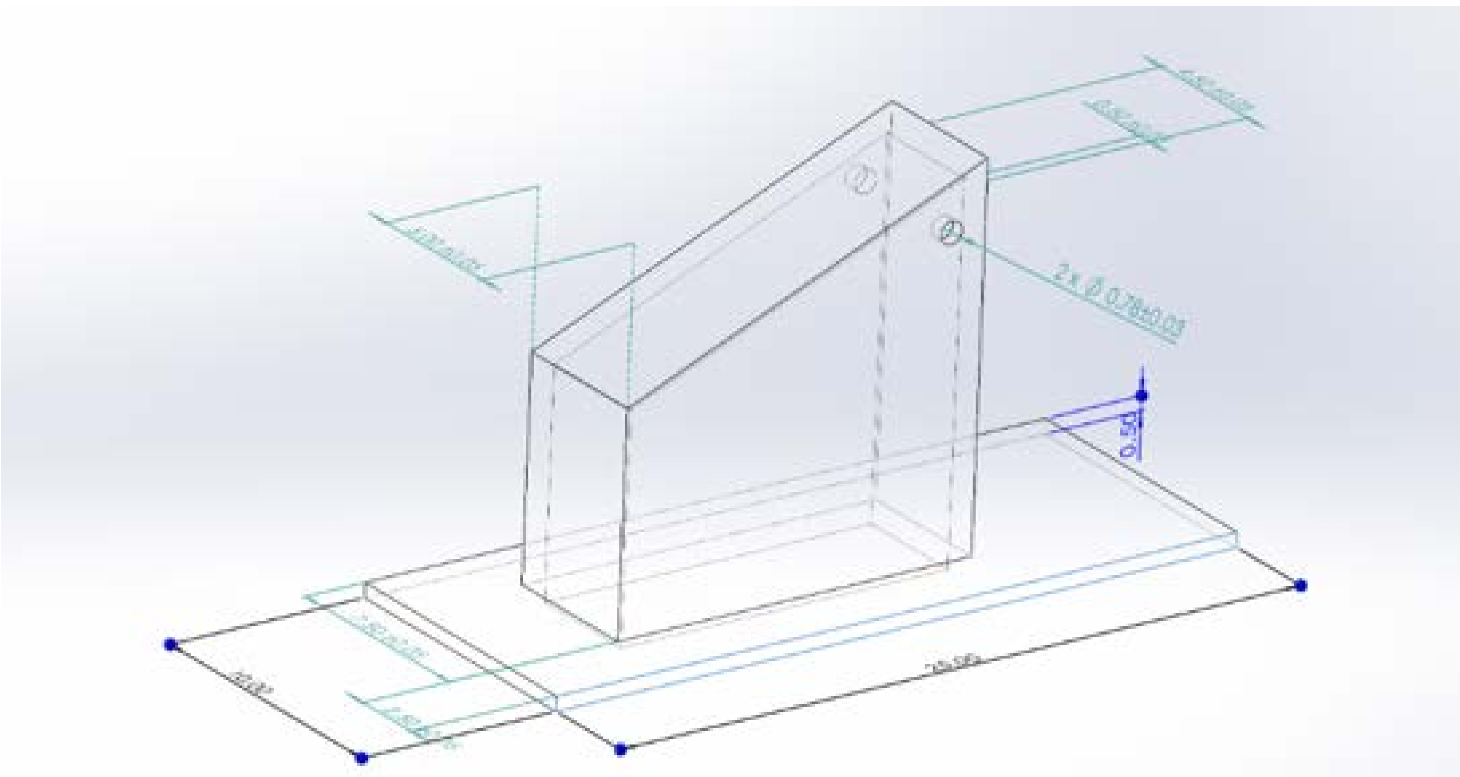
Goals: To update the CAD file of the base so that it is ready to print.

Content:

Reference previous notebook entry: Ilia>Design Ideas>2nd Model of Base

Updates

- Shorten the base to 25 cm so print time is shorter
- shell the raised portion so that less material is used
- add holes for attaching neck joint



Conclusions/action items:

The base is ready to be printed. The next step would be to determine what material to print the base out of. PLA is the likely option, but it will be necessary to consult with the Makerspace staff. Another next step is to determine what will keep the base in place during practice procedures. Also, the fabrication of the neck hinge will be another priority.

2024/11/11 - Neck Joint Model

MARIBEL GLODOWSKI - Nov 15, 2024, 10:03 PM CST

Title: Neck Joint Model

Date: 11/11/2024

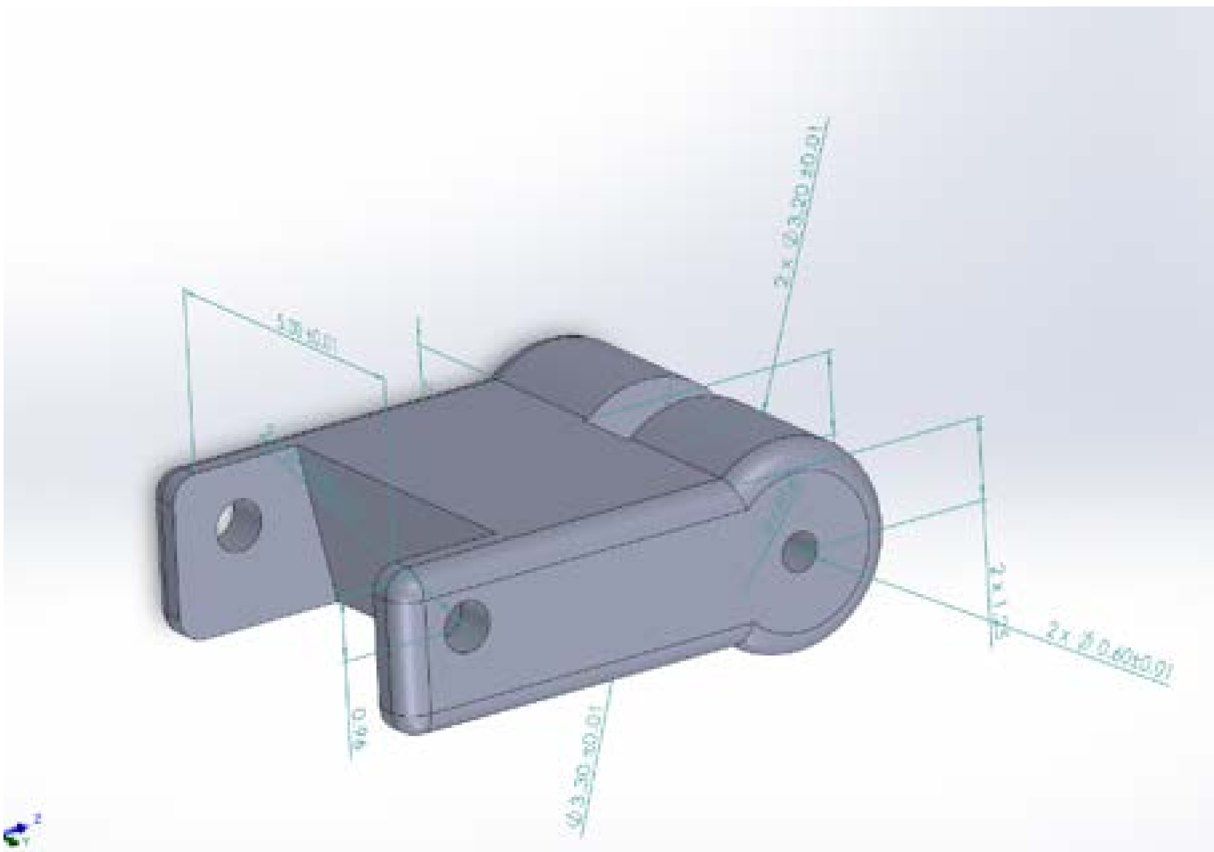
Content by: Maribel

Present: N/A

Goals: To show the printable SolidWorks file of the Neck Joint and explain a few updates to the design.

Content:

The following image shows the finalized SolidWorks model of the first section of the neck hinge:



Updates to the previous design:

- This design originally consisted of two separate pieces, but it was determined that it would be more effective to combine those pieces into one
- This will be attached to the base by a bolt

Conclusions/action items:

This is the finalized neck hinge model in SolidWorks. The next step is to start 3D printing this piece. Another important next step is to finalize the design and model of the complementary hinge part. This section is more difficult to construct due to the necessary dimensioning that controls the range of motion of the hinge. This complementary section as well as the jaw section should also be modelled and printed within the next week. An additional piece that would be helpful would be a flexible material to create torsion as a form of resistance in the jaw, but the necessary sections of the framework design are the priority.

2024/11/26 - Fabrication Protocol for Airway Trainer Base

MARIBEL GLODOWSKI - Dec 08, 2024, 9:37 PM CST

Title: Fabrication Protocol for Airway Trainer Base

Date: 11/26/2024

Content by: Maribel

Present: N/A

Goals: To lay out the steps necessary to fabricate the airway trainer base.

Content:

Fabrication protocol:

1. Obtain a caliper and take measurements on the base, bottom jaw, top jaw, and neck hinge of the AirSim airway trainer.
2. Using the measurements taken on the AirSim trainer, design the simplified base within SOLIDWORKS using the measured dimensions.
3. To ensure the pieces fit correctly, a tolerance should be added. This tolerance was in the range of 2-5 mm in each of the dimensions measured.
4. Once the base is created, the neck hinge will be the next piece fabricated. The measurements from the AirSim trainer are used again.
5. After replicating the neck hinge piece using the AirSim dimensions, the design will diverge from that seen in the AirSim. This design modification is done by using the mirror function to create a singular neck hinge piece whereas the AirSim's neck hinge used two symmetrical pieces.
6. Model the top and bottom jaws using the AirSim dimensions and the SOLIDWORKS features: Extrude, Extrude Cut, Mirror, Loft, etc.
7. With the base, top jaw, bottom jaw, and neck hinge modeled start an assembly and add these four parts into the assembly. Use the Mate feature to ensure that each piece fits together correctly.
8. Convert each SOLIDWORKS part file to an stl file that can be 3D printed.
9. The material used was Bambu Lab's PLA filament. Use Bambu Slicer software to select the material and a compatible printing orientation.
10. Print the pieces using Bambu Lab's 3D printer.
11. After printing follow any necessary post-processing instructions and remove the supports.
12. Next use SOLIDWORKS to model the torsional springs needed to connect the jaw pieces. Use the dimensions:
    1. Diameter of ends: 5 mm
    2. Diameter of center: 3 mm
    3. Length of piece: 7.5 mm
13. Convert these files to a stl file. Print using the same process as listed in steps 9-11. The material used for these pieces is TPU.
14. Obtain all materials required for the assembly of the airway trainer base:
    1. Printed pieces (base, bottom jaw, top jaw, neck hinge, and TPU torsional springs)
    2. Two bolts and four nuts (ensure that they can fit in the holes on the base and neck hinge)

    3. Super glue
    4. Dual lock fastener tape

15. Use the bolts and nuts to connect the base piece with the neck hinge so that the inside face of the hinge is flush with the base. Then connect the neck hinge with the top jaw in the same manner.
16. Use the super glue to adhere the torsional springs to the top and bottom jaw. Be careful to align the jaw pieces properly.
17. Carefully place an 8 cm piece of Dual Lock fastener tape on the sloped surface of the base.

Conclusions/action items:

This entry list out each step that was taken to create the airway trainer base. This protocol could be followed to replicate the airway trainer base. The next steps are to continue working on any improvements that can be made to the base, create a connector system, and update this protocol as more features are added to the design.

2024/11/18 - Finalized Bottom Jaw Piece

MARIBEL GLODOWSKI - Dec 11, 2024, 12:23 PM CST

Title: Finalized Bottom Jaw Piece

Date: 2024/11/18

Content by: Maribel

Present: NA

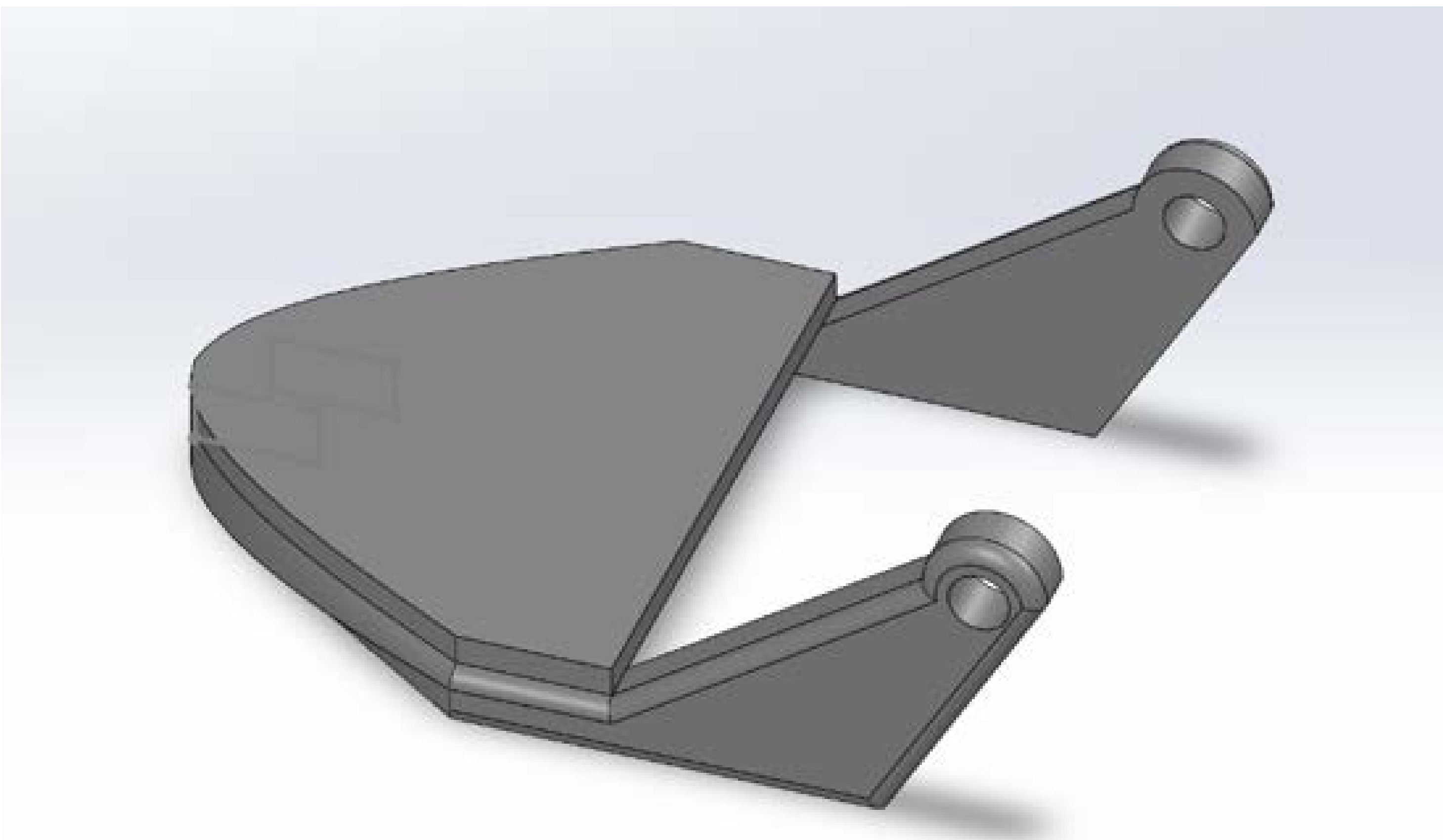
Goals: To show the finalized version of the Bottom Jaw part

Content:

- dimensions of the AirSim airway trainer were used as a guide

- the loft features and mirror feature in SOLIDWORKS were used to create a rounded jaw that is representative of a human jaw

- the rounded jaw would be compatible with the future placement of teeth and other surrounding anatomy



Conclusions/action items:

This is the finalized Bottom Jaw Piece. The next step regarding this piece will be to print it using PLA at the Makerspace. An FEA analysis will also be performed to ensure that the part can withstand the forces exhibited during intubation. If the test is successful this piece does not need to be altered but if not the FEA will highlight areas that the piece should be changed.

2023/10/25 - Biosafety Training

MARIBEL GLODOWSKI - Nov 10, 2023, 2:14 AM CST


VCRGE Training Information Lookup Tool University of Wisconsin-Madison

WISCONSIN

Course	Assignment	Completion	Expiration
Biosafety Required Training	[illegible]	[illegible]	[illegible]
Chemical Safety: The OSHA Lab Standard	Final Quiz	[illegible]	
Performing a Risk Assessment	Survey	[illegible]	

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2023/10/18 - Chemical Safety

MARIBEL GLODOWSKI - Nov 10, 2023, 2:16 AM CST

VCRGE Training Information Lookup Tool University of Wisconsin-Madison

WISCONSIN

Course	Assignment	Completion	Expiration
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	

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2023/10/16 - Risk Assessment Training

MARIBEL GLODOWSKI - Nov 10, 2023, 2:18 AM CST

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2024/01/23 - Machining

MARIBEL GLODOWSKI - Jan 23, 2024, 8:46 PM CST

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2024/01/23 - Shop Tools

MARIBEL GLODOWSKI - Jan 25, 2024, 8:40 PM CST

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2024/09/11 - Lecture #1

MARIBEL GLODOWSKI - Sep 11, 2024, 1:57 PM CDT

Job search tips

- keep track of what you do - ECS tracking sheet
- Quality of source matters - Handshake, LinkedIn, Indeed...
- Connect before you are a candidate - use your people
- Applying is step 1 - follow up is required (2-3 weeks)
- Think beyond the title - focus on skills, industry exposure
- It takes time
- Don't let perfection be the enemy of good

Resume Tips

- Tailor your resume to the position - quick changes
- Create balance - show a full picture of your experience
- "Flawless" product - ATS proofed resume is do-able
    - MS word
    - No columns, charts, colors
    - Design projects without years or semesters - what did you do?
    - Technical skills and coursework
    - Jobs- Organization and Location, Position tile and Dates

Career Fair Advice for BME

- identify your purpose - more than just an internship
- looking beyond the obvious overlap with other disciplines
- Research the employer - feedback from our partners
- Develop your "valued added" statement - why you?

2024/09/11 - Lecture #2

MARIBEL GLODOWSKI - Sep 18, 2024, 2:02 PM CDT

Do you see yourself as a leader?

- Anatomy of a good leader
  - Self-awareness
    - understand your strengths and weaknesses
  - Vision
    - provide direction and purpose, set goals
  - Transparent
- Leadership Styles
  - power model of leadership
    - thought process: someone has to take control here, and it should be me
  - Defining qualities
    - being in control is the most important thing
    - "Great Man Theory"
  - Servant Leadership
    - thought process
      - its not about me and my needs, the needs of my followers is most important
  - Authetic Leadership
    - Thought process
      - by being my genuine self, I will gain and build trust
    - Defining qualities
  - People-Oriented Leader
    - glue that holds the team together; you get to know everyone as individuals
      - skilled at building trust and an inclusive environment
  - Process-Oriented

Team goal:

-To function better I think that we need to prioritize open communication and a culture that promotes asking each other question. To promote this I can encourage my teammates to reach out when they need help.

Self goal:

-I want to become more intuitive when it come to anticipating my teammates needs.

2024/09/25 - Lecture #3

MARIBEL GLODOWSKI - Sep 25, 2024, 2:09 PM CDT

Post Grad Preparation

- What does your ideal position look like? Is this something that you would like to do?
- Start diving in now! --- Begin looking at schools and requirements now!
- Writing your story
    - Here's what not to do
    - I did this, then that, then the other thing -- chronological regurgitation of what you did
    - I will do anything there
    - Here is what to do
    - Start with what you want to do -- thesis statement
    - Narrow experiences and how that applied to broad interest
    - Specific to each position and place to which you will apply
    - Show a reasonable idea of what you will achieve. do afterwards, and name faculty there who are in your field of intereste (mostly phd)
    - Defend your plan with LIFE EXPERIENCES -- Most recent first!
    - CV to some extent in paragraph form --- but be specific! -- doesn't have to be choroological order through
- MS stepping stone and expand credentials for future medical schools
    - Industry focused
    - Generally 1 year
    - Lots of MS go to get MD
    - Can get lots of other experiences that you have to be student for -- like places in hospital
- PHd
    - Work in acaedmia, research grants, work as PI
    - Lead projects in industry and startups
- MS as a stepping stone!
    - Rewrite story
    - MD -- need time to prep for MCAT or apply for Med Schools
    - Fill gaps in resume
    - higher level of skills
    - More lab time with less class time
    - More experiences -- teaching, menotoring, research thesis
    - Older, more maturity
    - Really powerful if you add industry experience
- MS for industry
    - Higher starting salary
    - Can coop during MS as well
    - Time to find the dream job
    - MS will make you more desireable
- Dr. Suarez heads MS program in BME
- 3 MS programs
    - Research -- MD/PhD program 1.5-2 yrs
        - Required thesis
    - Accelerated program -- independent study/research allowed
        - Coursework only -- can take advanced courses but 24 credits of courses
        - Can still do a project
    - Biomedical Innovation, Design, and Entrepreneurship (accelerated 1yr)
        - Project based -- project required (BME design community project)
            - Can continue BME capstone project
            - Can be something else too with a random company or lab or faculty or research based project kinda too
        - Partnership with buisness school
        - Finding by TA
        - Instead of electives -- focused on courses in the buisness school
            - Buisness management
            - Entrepreneurship
        - Specifically designed to take projects and show you how to market
    - Making MS affordable by paying TAs full tuition and stipend
    - ALL 24 credits
    - BME is highest paid department in the entire university

  - Application requirements:
    - Applying next fall
    - Statement of purpose
    - No recs but put jana (someone in BME) down 3 times!
    - If research MS -- 1 letter from PI and agree to take into lab
    - Can switch between them
    - 12/15 is deadline but still flexibility
      - If don't find a job, we can still find a spot for the MS program
      - Essentially take all students -- all if over 3.0 -- automatic in if you click apply button
- MS programs elsewhere
  - MEng -- terminal degree
  - MS in Global health
  - MS in other Engr Dept -- usually longer
  - MBA -- industry pays for credits or evening options
    - Most often not right after graduation
- Other PhD programs
  - find faculty/labs performing research in your passion area
  - Less competitive than PhD programs often are not funded
  - MN MS doesn't let you work on projects
  - Duke has a projects based program --- like our Entrepreneurship program
- PhD advice
  - Network!
  - Conferences!!!!!!
  - Utilize your lab PI here at madison --- Collaborators
  - Build your resume/CV
  - Research is a must -- Honors in Research
  - External finding from NSF-GRFP ---- scholarship for PhD (4 free years)
  - Due October 15th
  - Apply Fall senior year (1st time) then once more in 1st year grad school
  - 3.5+ GPA and 75% percentile for quantitative GRE
  - Faculty individually review applications that align with their research
  - Tour the department, meet faculty!
  - Visit weekends!
- Med school advice!
  - Special req
    - Chem 109
    - Chemistry 344 and 345
    - 2 sem physics
    - 2 sem english (Lit or Communications) --- look at specific med school requirements
    - I/A & S/H & CommB -- use liberal studies -- Minnesota and Madison have backed off the req but still potential problem
    - Physcholohu 202 and soc
    - Biochem 501
    - All can be satisfied with BME 128 credits!!!!!!!
  - Check premed advising!!!
- Clinical engineer -- short term position -- biosense webster!
  - Position might be sales associate but its actually implant of device with DR in OR
- Beyond the classroom
  - Research is required
  - Volunteer -- clinical setting desired
  - Shadow physicians
  - Patent contact time
  - Build relationships --- letter writers!!
  - Use your design experiences! Physician clients
  - Requirements vary by degree -- check pre health specific website!

2024/10/2 - Lecture #4

MARIBEL GLODOWSKI - Oct 02, 2024, 2:09 PM CDT

Why are you mentoring BME 200 students?

- additional instructional and emotional support for students
- peer mentors are more approachable, mentees are more willing to ask quesions
- share experiences (courses, co-ops, internships, research, etc)
- Increases belonging
- mutual skills

Transferrable skills

- leadership
- communication
- active listening
- study practices
- interpersonal skills

General benefits of mentoring

- increased self-esteem/confidence
- increased patience
- build positive habits
- foster personal growth
- help identify gaps in your own knowledge
- sense of accomplishment

What does it mean to be a "good mentor"?

- Build Trust
- Psychological Safety
- Reliability
- Support and Enthusiasm
- Being Available
- Transparent (open and honest)
- Humanizing there challenges

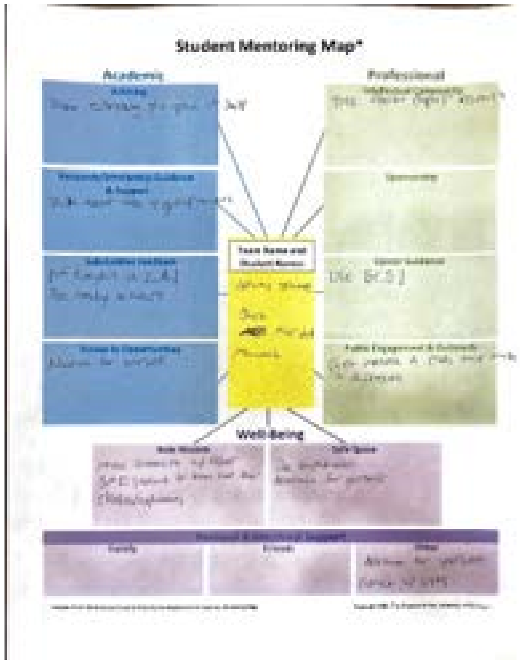
Listening effectively

- get rid of distractions
- stop talking
- act like you're interested
- look at the other person
- get the main idea
- ask questions
- react to ideas, not the person
- avoid hasty judgments

What do you wish you knew in BME 200?

- List in Jack's note

MARIBEL GLODOWSKI - Oct 02, 2024, 2:10 PM CDT



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BME_300_Lecture.pdf (377 kB)

2024/10/09 - Lecture #5

MARIBEL GLODOWSKI - Oct 09, 2024, 1:58 PM CDT

Sustainable energy

- Life cycle assessment
  - resources
  - processing
  - manufacturing
  - distribution
  - use
  - end of life
- Example life cycle assessment
  - blood pressure cuffs (disposable or reusable)
- The versatility of the airway trainers could address a lack of sustainability in the existing commercial products

2024/10/16 - Lecture #6

MARIBEL GLODOWSKI - Oct 16, 2024, 1:57 PM CDT

WARF

- Technology transfer
  - moving research results from campus out into the market
    - warf works at this interface to facilitate securing IP rights and commercial licenses
  - Ex
    - intellectual property licenses
    - industry-sponsored research
    - consulting arrangements
    - fee for service
- Intellectual property overview
  - the four common types of IP
    - Patents
    - copyrights
    - trademarks
    - trade secrets
  - Other, WARF IP:
    - biomaterials
    - technique and know-how (akin in some ways to Trade Secrets)
    - Data
  - overview of non-patent IP
    - copyrights
      - protection for creative works that are expressed in a tangible medium
      - a wide range of subject matter, including software code
    - trademarks
      - protection for names, marks, logos, dress, etc.
      - requires use in commerce
      - source-identifying function
    - trade secrets
      - can be used to protect anything of value
      - protection is good so long as the concept is not generally known
  - Patents
    - a patent is a property right, granted by a governmental agency
      - e.g. USPatent and Trademark Office
      - no global patents
    - patent holder has right to exclude others from making, using, selling, or importing the claimed invention
    - There are three different types of U.S. patents:
      - design
        - 15 year term, limited to ornamental features
      - plant
        - new variety
        - 20 year term
      - utility
        - provisional effectively 1 year placeholder
        - non provisional 20 year term

- issued for the invention of a new and useful process, machine, manufacture, or composition of matter
  - also includes new and useful improvements therof
- a quid pro quo with the USPTO and the public
  - applicant gets a time limited monopoly on your invention (20 years from filing)
- Often take 20years to issue after filing (patent examination

- Requirments for patenting
  - statutory requirements
    - eligible
      - cannot be a product of nature, abstract idea, or natural phenomenon
    - novel
      - must be new
    - non-obvious
      - it acnnot be simple modification or combination of existing concepts
    - enable and described
      - must provide enough detail to teach other how to make or use the invention
  - Patent examiners are scientists hired and trained by the USPTO to review patent applications for these requirements

- disclosing an innovation to Warf
  - receives 400 innovation disclosures each year
  - disclosing
    - describe the innovation
    - identify its advantages & potential applications
    - name contributors
    - provide funding and public disclosure details
  - Meeting with WARF
    - discuss the innovation in more detail

        - ask questions about warf and patenting processes
        - discuss next steps
- assessing university inventions
    - warf bases its decision on accepting innovation into our portfolio on
        - IP considerations
            - types of IP protection
            - potential breadth and strength of IP protection
            - public disclosure (past and planned)
            - stage of development
        - Licensing considerations
            - application
            - likelihood of identifying a commercial partner
            - likely return from licensing

2024/10/23 - Lecture #7

MARIBEL GLODOWSKI - Oct 23, 2024, 2:05 PM CDT

IRB

- unethical research -> ethical principles -> human research regulations
  - infamous studies
    - WWII Nazi prisoners experiments -> 1947 Nuremberg Code
    - Hepatitis studies at Willowbrook State School for Children
    - Milgram shock experiments at Yale
    - Tuskegee Syphilis Study -> 1974 National Research Act
  - Belmont principles: Respect for Persons | Beneficence | Justice
  - Regulations for protection of human "subjects"
    - dept of health and human services (DHHS), aka "Common Rule"
    - FDA
- UW-Madison IRBs
  - Minimal Risk Research IRB
    - biomedical, education, and social/behavioral sciences research
    - Secondary anaylsis of data, survey research, behavioral health interventions, evaluations of educational practice
- Does it involve human subjects?
  - human subject means a living individual about whom an investigator conducting research
    - obtains info or biospecimens through intervention or interaction, and uses, studies, or analyzes the information or biospecimens; or
    - obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
- Is it human research under FDA device regs?
  - device = intended for use in diagnosis, treatment, or prevention of disease, or that affects structure or function of the body
  - research/clinical investigation = involves on or more subjects to determine device safety or effectiveness
  - subject - individual on whom or on whose specimen an investigation device is used or as a control in an investigation
- Researcher responsibilities
    - complete required training for researchers through CITI
      - human subject protection Training
      - conflict of interest training
      - good clinical practice training
      - HIPAA Privacy and Research training
    - Complete annual Outside Activities Reports

2024/10/30 - Lecture #8

MARIBEL GLODOWSKI - Oct 30, 2024, 2:20 PM CDT

FDA Approval

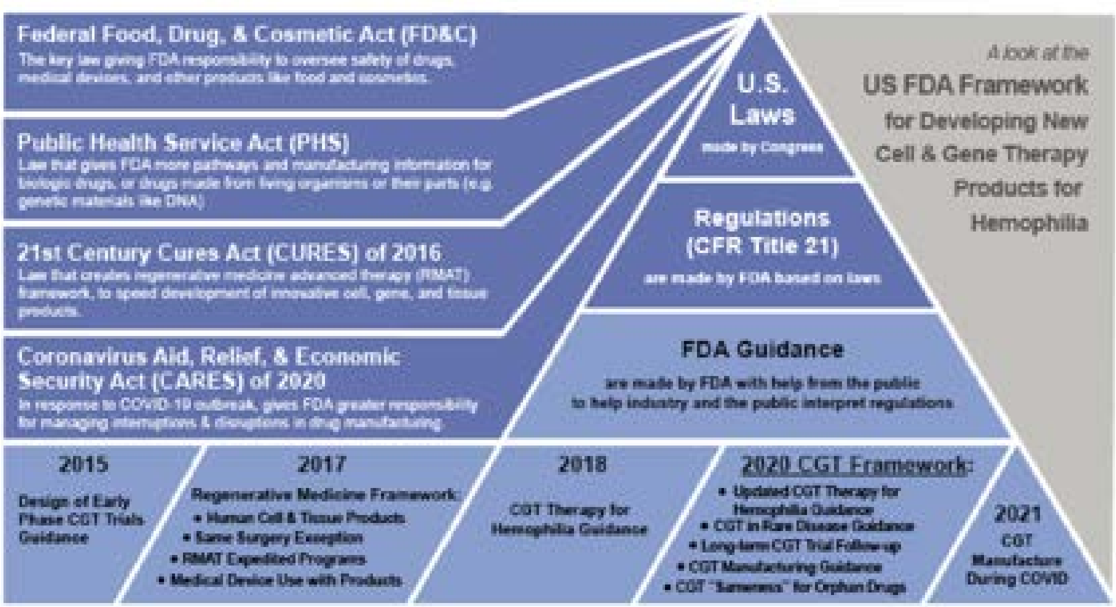
- What is a medical device
  - intended to improve health
  - But not through chemical or biological action
  - extremely broad
- Traditional medical devices
  - MRI machines
  - IV Pumps
  - Cardiac monitors
  - Elastic bandages
  - Table you sit on for examination
- Non traditional medical devices
  - Oral hygeine rinse -- mouthwash
  - Lab developed medical tests -- like Cologuard
  - Smart watches and medical mobile apps
  - Software -- CT/MRI reading
- Software as a Medical Device (SaMD)
  - Software in a medical device is stuff inside CT machine -- falls under CT
  - SaMD has its own regulation and status
- FDA Regulations
  - Once you identify something as a medical device --- need lots of regulation
  - Some apply from the day you say I am going to make this device until you stop
  - Others start only when manufacturing or actively producing.
- Device Classification Overview
  - US uses 3 classes
- General controls
  - general labeling
  - Good manufacturing practice
  - registration and listing
  - Event reporting requirements
  - Found all over code of regulations
- Special controls
  - Performance standards
  - special labeling requirements
  - Post market surveillance
  - potential data requirements
- Pre-market approval
  - data to show safety and effectiveness
- Class 1 Devices:
  - Low risk level
  - Self registration and listing with the FDA
  - Examples include bandages and manual toothbrushes
- Class 2 Devices:
  - Higher risk than Class 1
  - Submission of 501K may be needed to show substantial equivalance

    - Integrated glucose monitoring systems, non invasive BP monitor, catheter are examples
- Class 3 Devices:
    - Sustain or support life or implanted
    - 10% of all devices in market
    - Must have comprehensive FDA review of safety and effectiveness data before marketing
    - Hip joints, heart valves, and implantable pacemakers are examples
- Market Submission Types
    - 510K exempt
        - Doesn't require 510k
        - Still need to list your device though
        - $8000 per year
    - 510k premarket notification
        - Outlines device, here is similar device, here is why they are similar, here is what's different
        - not approval
        - Devices generally get more complicated and slowly drift farther and farther from original submission
    - Premarket approval
        - FDA comes and inspect you
        - Determines if device is safe and effective
        - Then can legally market it
    - DeNovo Classification
        - if it doesn't look like or function as any other device
        - FDA tells you which class it is

2024/11/06 - Lecture #9

MARIBEL GLODOWSKI - Nov 06, 2024, 2:02 PM CST

<u>Bringing Biologics to the Market</u>

- Objectives
    - Understand the overall structure of the FDA, including the framework of laws, regulations, and guidances for advanced therapeutics
    - Understand how these regulations guide product development
    - Learn what a "Quality" mindset is and how that helps to navigate the regulatory framework during product development
    - learn about science/engineering career opportunities within a regulated industry
- FDA Structure and Advanced Therapeutics
    - Device
        - PMA
        - 510(k)
        - IDE
    - Biologic
        - BLA
        - IND
    - Drug
        - NDA
        - IND
        -
- FDA Framework
    - developing CGT Products for Hemophilia
    -
    - 

- Dramatic Implications: 351 vs. 361
    - Human cells, tissues and cellular and tissue-based products
    - Markedly different in terms of the time, effort, and xpense required to bring a product
        - 351 products are regulated as drugs and/or biologics
        - 361 products are largely unregulated
- Risks and safety concerns
- Product Development Life Cycle

- Product Development Life Cycle
    - Extremely important to be able to distinguish between studies that are "on the critical path" vs. "good research projects"
- A Target Product Profile (TPP) is your Product Vision
    - When to use it?
    - Why to use it?
    - How to use it?
    - Patient identification: Indication
    - Patient benefits: Efficacy profile
    - Patient risks: Safety profile
    - Is it medically and commercially compelling?
- Considerations when Developing a 351-Regulated CGT
    - GLP: Good Laboratory Practice
    - CMC: Chemical Manufacturing Controls
    - Regulatory meetings
        - interact meeting TPP
        - Pre-IND
            - IND submission
        - Pre-BLA
            - BLA submission

2024/11/13 - Lecture #10

MARIBEL GLODOWSKI - Nov 13, 2024, 1:57 PM CST

Administrative perspectives on new technology adoption

- Medical device process at a glace
  - innovation idea and development
  - Human Testing Data Acquisition with IRB Oversight
  - FDA Regulatory Process
  - Reimbursement or Financial Incentive
  - Sales
- New Medical Technology Ecosystem
- General Steps from Approval to Adoption
  - Clinical Studies
    - fda apporval
    - CPT codes
- Workflow: Patient Care Pathway as a Starting Point
  - Diagnosis, intervention, orders
    - clinician
    - MD, surgeon
    - PharmD
  - Procedure, Recovery
    - patient
  - Support, track, intervene
    - RN, OT, PT, Rx, PharmD Lab
  - Billing
    - CPT
    - ICD 10
    - insurance
- Stakeholders
  - admin
  - national clinical oversight
  - patient point of care
  - national regional groups
  - standards organization
  - nation and regional payment/reimbursement
- Value Based HealthCare
  - define value more broadly
  - improving patinet outome while making it more affordable to deliver those outcomes
  - wider range of possibilities for product developers
- Trickle-Down Influence for New Technology
  - National Policy, standard of practice and clinical practice guidelines
    - health system and provider
      - payor
- Key terms to uncover payment
  - CMS for medicar and medicaid services
  - DRG diagnostic related groups
  - CPT current Procedural codes
  - ICD 10 international categorization of Diseases

- GPO group purchasing organization
- IDN Integrated delivery networks
- payer mix (% private, capitated, medicare)

2024/11/20 - Lecture #11

MARIBEL GLODOWSKI - Nov 20, 2024, 1:49 PM CST

How New Product Development Works in the Medical Device Industry

- NPD in the medical device industry is:
  - highly regulated
    - FDA and other regulatory bodies have a significant impact
  - expensive
    - requirement for verification and validation is a cost multiplier
  - resource intense
    - involves sizeable teams to execute projects
  - competitive
    - competition is fierce; speed to market is vital
- Selecting and prioritizing projects
- Types of NPD Projects
  - line extensions
    - addition of additional sizes and config
  - product improvements
    - existing product change due to market feedback and or new customer needs
  - new to ocmpnay
    - product line that is not new to market but is new for the compnay
  - new to world
  - innovative products that create completely new markets
- stage gate process
  - stage 0:
    - choose area of opportunity
    - review market trends and or competitive threats
    - conduct primary and secondary market research
  - Stage 1 : exploration
    - define problem to be solved and customer requirements
    - review refine and screen list of ideas from stage 0
    -

2024/11/15 -Tong Lecture Notes and Reflection

MARIBEL GLODOWSKI - Nov 15, 2024, 12:57 PM CST

Title: Tong Lecture

Date: 11/15/2024

Content by: Maribel

Present: N/A

Goals: To learn about Tasso and the journey of its founders.

Content:

- The future of healthcare is in the home
  - here is where the ideas came in
  - blood sampling in the home
- Finding Resources
  - law and entrepreneurship clinic
  - get scrappy with funding opportunities
- Evolution of the technology
  - make a better product
  - kill your product when needed
- Finding a key customer
- Scaling up
  - lessons in quality, culture, and HR
- FDA
  - place for creativity
    - class II IVD super hard clearance
    - Class I medical device super easy clearance
  - Read the labels
    - easy to overanalyze what regulators say they "want" to do

Conclusions/action items:

This lecture was very engaging. Hearing the story of building a company from the bottom up was very interesting.

MARIBEL GLODOWSKI - Nov 15, 2024, 1:30 PM CST

Continuing the conclusion:

They did a very good job at laying out each step in their journey, and it was quite impressive to see how far they have come. I think the dedication to their idea is something that propelled them to where they are today. I definitely will be following this company to see how they grow.

9-20 -- Methods to Make Artifical Skin

Jack Sperling - Sep 20, 2024, 10:14 AM CDT

Title: Materials used to simulate physical properties of human skin

Date: 9-20

Content by: Jack

Present: Jack

Goals: Identify what materials we should be researching to make our airway out of

Search Term: "silicone or latex to simulate human flesh"

Link: https://onlinelibrary.wiley.com/doi/full/10.1111/srt.12235

Citation:

A. K. Dąbrowska *et al.*, “Materials used to simulate physical properties of human skin,” *Skin Research and Technology*, vol. 22, no. 1, pp. 3–14, 2016, doi: 10.1111/srt.12235.

Content:

This paper discusses the variety of past and present techniques to replicate human skin. Unfortunately, this is not exactly what we need but it is still extremely close to what we are looking for. The paper lists some great options that we should still look into though

Gelatine -- closely replicates the density and viscosity of human tissue and is often what ballistic jelly is made out of

PVA Gels -- this is used as a skin and soft tissue phantom for MRIs and can replicate the mechanical properties of soft tissues

Silicones -- this is often chosen due to its durability and is easily manipulated and non toxic during and after manufacturing. It's refractory index can easily be tuned to be within tolerances of human flesh and its interaction with light is realistic, ensuring that users cannot look through the mannequin when light is shined on it

Polyurethane -- replicates more of the skin feel and texture and is often used for subcutaneous injection training

Metals, Textiles, and nano - and micro-fillers --- Some of these materials have not been fully tested yet or are not at full maturity. These materials are also better at representing the physical properties of skin rather than internal tissue, such as porosity, heat transferability, and chemical resistance

Conclusions/action items: This paper describes multiple different materials that are able to replicate human tissue, and points us in the right direction towards silicones and PVA gels.

Jack Sperling - Sep 20, 2024, 10:00 AM CDT


Invited Review

Materials used to simulate physical properties of human skin

Download

Skin_Research_and_Technology_-_2015_-_Dąbrowska_-_Materials_used_to_simulate_physical_properties_of_human_skin.pdf (306 kB)

9-25 -- Mechanical Properties of a Human Airway

Jack Sperling - Sep 25, 2024, 5:13 PM CDT

Title: Mechanical Properties of the airway tree

Date: 9-25

Content by: Jack

Present: Jack

Goals: Understand critical numerical values that we must replicate in order to have our anatomy be as realistic as possible

Search Term: "mechanical properties of human airway"

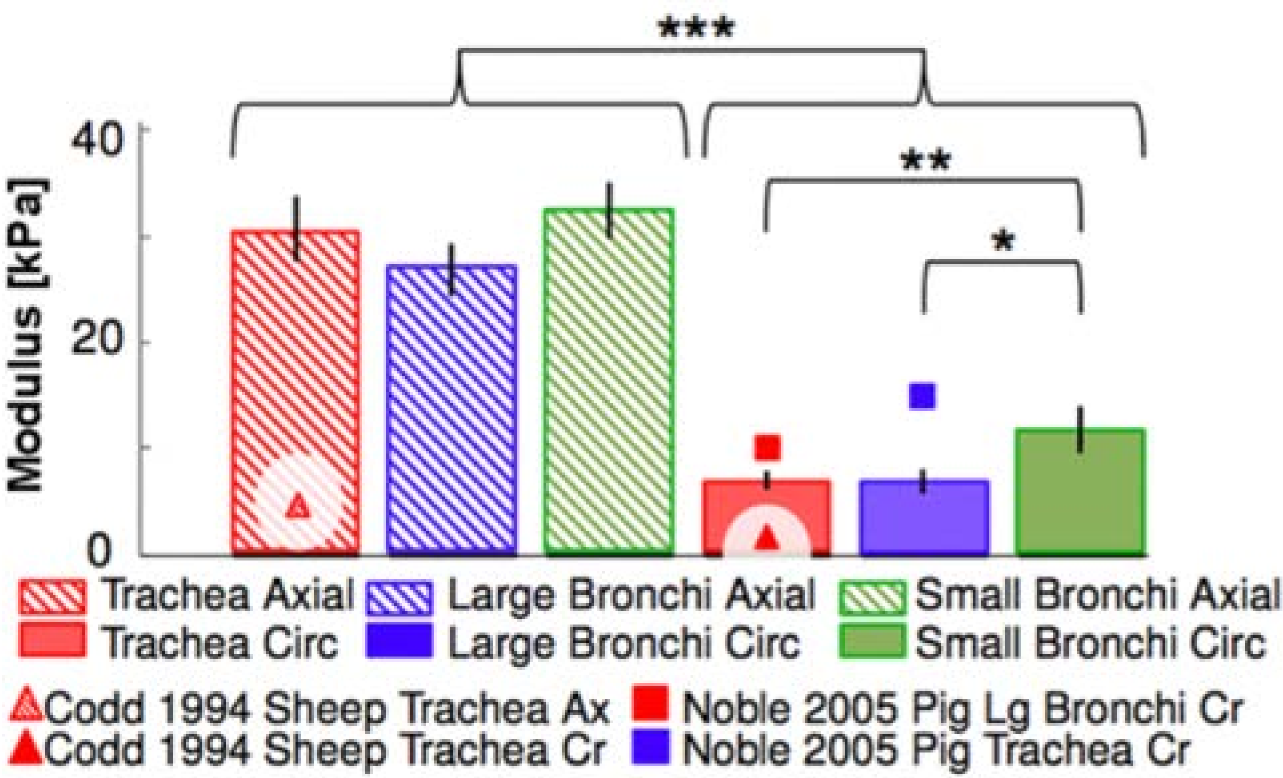
Link: https://journals.physiology.org/doi/full/10.1152/japplphysiol.00090.2018

Citation:

M. Eskandari, A. L. Arvayo, and M. E. Levenston, "Mechanical properties of the airway tree: heterogeneous and anisotropic pseudoelastic and viscoelastic tissue responses," *Journal of Applied Physiology*, vol. 125, no. 3, pp. 878–888, Sep. 2018, doi: 10.1152/japplphysiol.00090.2018.

Content:

Pictured below are critical measurements for the various parts of the airway



Unfortunately, this article focused mostly on the vertical stretching of the airway anatomy and has many tables showing that, however only the two images posted above showcase what will be helpful for this project. We now have a Young's Modulus we can shoot for as well as understanding that basing our project and research off animal models is not appropriate as the graph above shows how the pig and sheep tracheas are either significantly too strong or weak compared to the human trachea, large bronchi, and small bronchi.

Conclusions/action items:

Now that we have specific measurements conducted on actual human cadavers for identifying the size and mechanical properties of the trachea, we can continue to search for latex or silicone materials that would be able to fit these criteria. We can also adapt some of the scans received to ensure they adhere or do not adhere to the average sizes for the anatomy listed above -- this will depend on what the client wants and how difficult the intubation should be for a given model.

Jack Sperling - Sep 25, 2024, 5:06 PM CDT

RESEARCH ARTICLE

Mechanical properties of the airway tree: heterogeneous and anisotropic pseudoelastic and viscoelastic tissue responses

Download

eskandari-et-al-2018-mechanical-properties-of-the-airway-tree-heterogeneous-and-anisotropic-pseudoelastic-and.pdf (1.81 MB)

9-11 -- 3D Printable Airway Trainers

Jack Sperling - Sep 13, 2024, 9:04 AM CDT

REBECCA POOR - Jan 24, 2023, 7:53 PM CST

Title: Summary of open-source 3D printable airway trainers

Date: 9-11-24

Content by: Jack Sperling

Goals: Identify if any of the openly accessible STL models found online would be helpful in creating the anatomy we are looking for

Search Term: Provided by client

Links: **https://www.printables.com/model/381364-simple-intubation-task-trainer**

https://www.airwaymanagement.dk/ressources/larynx-model-for-3d-print-duggan

https://www.yeggi.com/q/airway+trainer/

Content:

The printables model is actually from Decent Simulators, a company that our client also provided links to. This model also appears to be a **MOLD in which you pour silicone** or rubber into to harden and provide the correct anatomical stiffness

Yeggi appears to be an aggregator site for many other free 3D modeling sites. The models available appear to be crycothyrotomy trainers compared to intubation trainers

The larynx model from airway management appears to be high quality and could definitely be helpful in our search for finding correct anatomy to be the foundation of our model.

Conclusions/action items:

Continue researching models but know that there will be a fork in the road soon; to POUR or NOT TO POUR, that is the question!

9-19 -- Seven Sigma Simulation Systems

Jack Sperling - Sep 20, 2024, 9:00 AM CDT

Title: Seven Sigma Simulation Systems

Date: 9/19

Content by: Jack

Goals: Identify why 7S3 simulators are so effective and what we can learn from them

Search Term: "7 sigma simulation systems" also provided by client originally

Link: https://7-s3.com/shop/

Citation:

"African American Burn Victim Skills Torso Airway Trainer," 7S3. Accessed: Sep. 20, 2024. [Online]. Available: https://7-s3.com/product/african-american-burn-victim-skills-torso-airway-trainer/

Content:

The website has a significant offering of various airway trainers, varying in race and injury. Interestingly enough, even though there are not any prices listed, they offer I wide variety of various parts from each of their trainers as individual purchases. For example, pictured below is the standard caucasian airway trainer, the complete airway assembly, and then just the base airway.

Caucasian Complete Airway Assembly
Call for Price

Caucasian Base Airway
Call for Price

Therefore, it appears that this modular approach to airway trainers is definitely a potential option, but it does show that there need to be specific material choices (like latex molds for the actual airway and hard plastic to support it) for specific parts of the project.

I think that attempting to replicate something like this but with patient specific anatomy could significantly aid our client in his ability to train himself as well as other residents and physicians

Conclusions/action items:

The 7S3 training mannequins are a great foundation for how we could base our project. The ability to intermix latex and hard plastic to create the rigidity around the jaw and nasal region compared with the softer latex to replicate the epiglottis is fantastic.

9-19 -- Decent Simulators

Jack Sperling - Sep 20, 2024, 9:17 AM CDT

Title: Decent Simulators Airway Management Products

Date: 9-18

Content by: Jack

Present: Jack

Goals: Understand how and why Decent Simulators are used and if there are any shortcuts they used to create a model that still looks professional but does not cost thousands of dollars

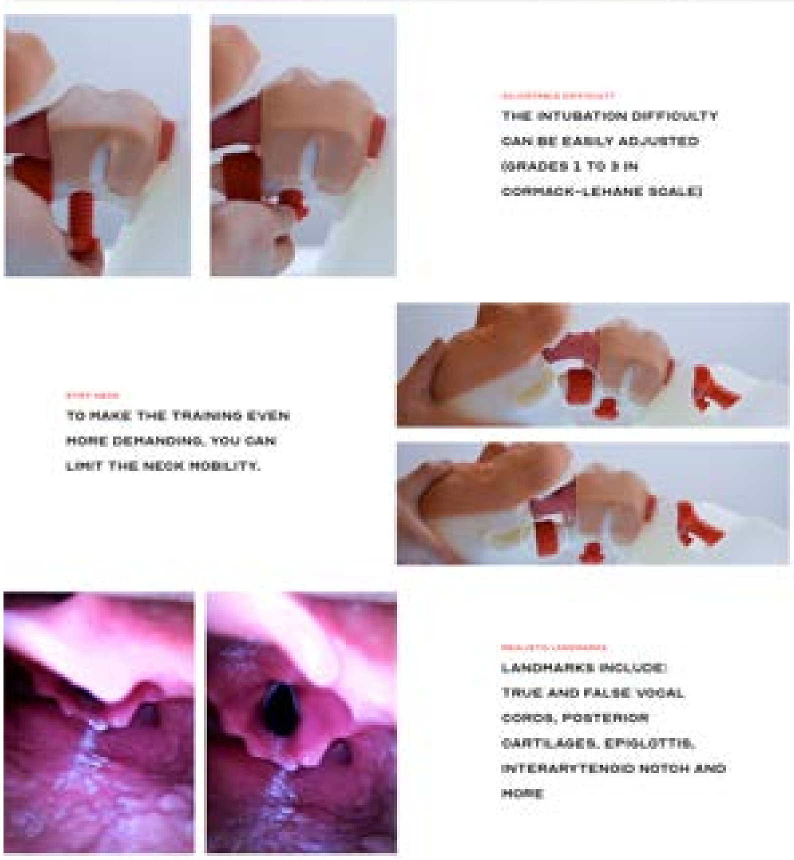
Search Term: "Decent simulators" also provided by client

Link: https://www.decentsimulators.com/

Citation:

> “Decent Simulators | medical task trainers,” Decent Simulators. Accessed: Sep. 20, 2024. [Online]. Available: https://www.decentsimulators.com

Content: According to their website and online store, Decent Simulators has a variety of products from stop the bleed training to foley catheter placement trainers. They appear to only have 1 intubation airway trainer with an accessory cric trainer, but our client does not require that skill to be practiced, so we will focus on the intubation trainer. Pictured below is the trainer.



Some various selling points include the ability to change the difficulty of intubation based on neck flexion, cord visibility according to the cormack-lehane scale, and the basis of this anatomy on direct patient scans. It does not appear that this trainer has a removeable airway, just options to adjust it through a couple various settings. Also, from the looks of it, it appears that most of this model is 3D printed as well.

This is a stretch goal, but fabricating our own airway but utilizing parts from commercial companies, like the latex face molds available from decent simulators (pictured below) to supplement our model will allow us to focus on the airway portion of the project and allow it to have a clean and professional final finish.

ANAPHYLAXIS FACE

SKU: P0053

Swollen face for a complete version of the airway management task trainer.

ELDERLY FACE

SKU: P0047

The elderly version of the face for the airway management task trainer.

Conclusions/action items:

Decent simulators has a great showcase of what can be done with imaging of an airway, 3D printing, and some silicone molds. We hope to look to this model as an inspiration for our design and even use some of the modular parts that can be purchased individually to supplement our final design.

9-20 -- Laerdal Airway Management Trainer

Jack Sperling - Sep 20, 2024, 9:40 AM CDT

Title: Laerdal Airway Management Trainer

Date: 9-20

Content by: Jack

Present: Jack

Goals: Identify how the Laerdal airway trainer is built and why it is so successful

Search Term: "Laerdal airway trainer" also client provided

Link: https://laerdal.com/us/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

Citation:

> "Airway Management Trainer," Laerdal Medical. Accessed: Sep. 20, 2024. [Online]. Available: https://laerdal.com/us/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

Content: The Laerdal airway management trainer has been the gold standard for training in medical facilities for a while. It is also what we train on at Belleville EMS and how our paramedics in Dane County practice intubations. These models are extremely accurate and often are the best in their field for representing the biomechanics of the head, neck, and upper airway to replicate a realistic intubation. They also seem much more professional than other simulators, like the Decent Simulators offering.

Unfortunately, it does not appear that you can remove the airway from the trainer and swap it for a new one or study it, however there is a picture of a small demonstration model that comes with each trainer meant to show the full scale internal anatomy to help the medical professionals understand what they need to navigate when performing an intubation.

Other big selling points for this trainer include the ability to simulate vomit, a larngypspasm, and the teeth click to let the provider know they would've chipped a tooth on an actual patient. A lot of these selling points are not specific client requirements/requests, so this simulators appears to be slightly overkill but the concepts we can take from this trainer are valuable.

If we would be able to get our hands on one of the airway demonstration models that might allow us to easily identify some of the materials used and even take readings with a durometer, for example. I have been discussing with the client about picking up one of these trainers, and the tentative date is this coming Monday, September 23rd.

Conclusions/action items:

While the Laerdal airway trainer is a fantastic product, I am not sure how much we are able to learn from it due to a lot of its selling features not mattering to our client and the inability to remove the airway to examine it. However, the possibility still remains that we could learn what materials the model is made out of if we were able to examine an Airway Demonstration Model. I am discussing with our client now to pick up this trainer early next week.

9-25 -- Trucorp Difficult Airway Trainer

Jack Sperling - Sep 25, 2024, 5:01 PM CDT

Title: TruCorp AirSim Difficult Airway

Date: 9/25

Content by: Jack

Present: Jack

Goals: Understand some of the key features that our client likes about this specific airway trainer that we should attempt to replictate

Search Term: Pictures provided by client stating he liked this model

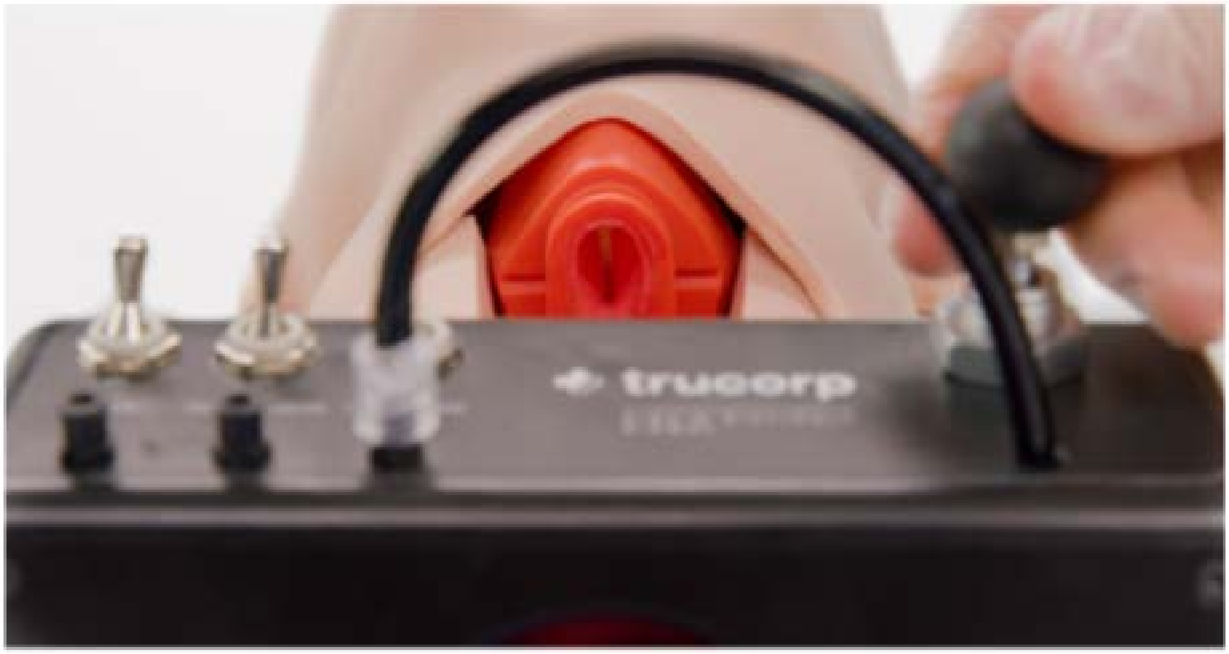
Link: https://trucorp.com/en/procedure/difficult-airway-trainers/

Citation:

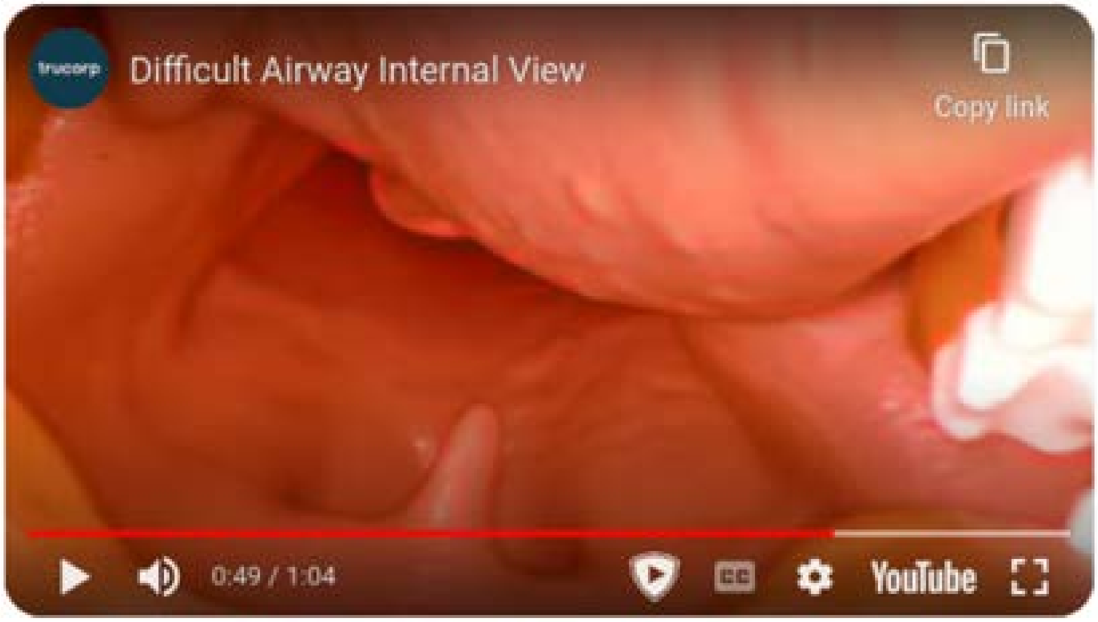
> "Difficult Airway Trainers," Trucorp. Accessed: Sep. 25, 2024. [Online]. Available: https://trucorp.com/en/procedure/difficult-airway-trainers/

Content:

Pictured below is an example of one of the features that this difficult airway simulator can do, along with tounge edema, as pictured below


trucorp


trucorp



AirSim Difficult Airway Internal view

It appears that many, if not all, functions in this manakin that can change and make the airway more difficult come from pressure bags that can be inflated to enlarge certain portions of the anatomy. This includes shrinking the tracheal opening and causing edema of the tongue and upper airway.

Some specific measurements that they include on their spec sheet are: **7-7.5mm ID for nasal intubation and 8-9mm for oral intubation** as well as **sizes 3-5 for LMA or BIAD laryngeal masks** (standard adult male size is a 4), size 35F-37F endo-bronchial tubes

Also from the spec sheet is that silicone lubricant will damage the model, meaning that **this is probably made out of silicone** and the website specifically states ***"the skin is made of silicone and the airway is made out of latex"***

Conclusions/action items:

Although this was a short research entry, this helped us get quantitative numbers on the sizes our trainer should accommodate, examples of difficult airway considerations and methods on how to create that sitation, and probable material choice for the vast majority of trainers throughout the market.

9-17 -- ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives

Jack Sperling - Sep 20, 2024, 9:56 AM CDT

Title: ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives

Date: 9-17

Content by: Jack

Present: Jack

Goals: Identify how this ISO standard could be applied to this project if we use animal tissues

Search Term: "animal tissue for medical training standard"

Link: https://www.iso.org/standard/39351.html

Citation:

ISO, "ISO 22442-3:2007," ISO. Accessed: Sep. 18, 2024. [Online]. Available: https://www.iso.org/standard/39351.html

Content:

There still remains a slight chance that throughout this semester we may identify a better material to simulate the internals of a human airway, and if that material happens to be or be derivatived from an animal tissue, our project would need to follow this ISO standard.

The standard specificlly outlines what must be done in order to elimate or inactivate any of the potnetial viruses or pathogens found in animal tissues before it comes in contact with humans. Luckily, if we were to go down this route, I believe whoever is providing the animal tissue for this medical device also has to follow this ISO standard and we should not have to do any additional work. However, we still must be aware of the possability that this falls onto our shoulders. For now, my plan if this happens to follow this ISO standard is to reach out to the client and ask if his wife (Anesthesia at the UW Vet Hospital) for assistance in this sanitation and if she has any contacts who could assist us with this sitatuon. Ideally this does not happen, but it is good to have a plan just in case.

Conclusions/action items:

This ISO standard will ideally not apply to our project, but if we end up using animal tissues and they are not already sterilized, we can reach out to the client's wife who works as an anesthesiologist at the UW Vet Hospital for assistance in finding someone who can help us.

10-8 -- First pass at Design 3: 3D Printed Custom Airway Trainer

Jack Sperling - Oct 11, 2024, 11:39 AM CDT

Title: First pass at Design 3: 3D Printed Custom Airway Trainer

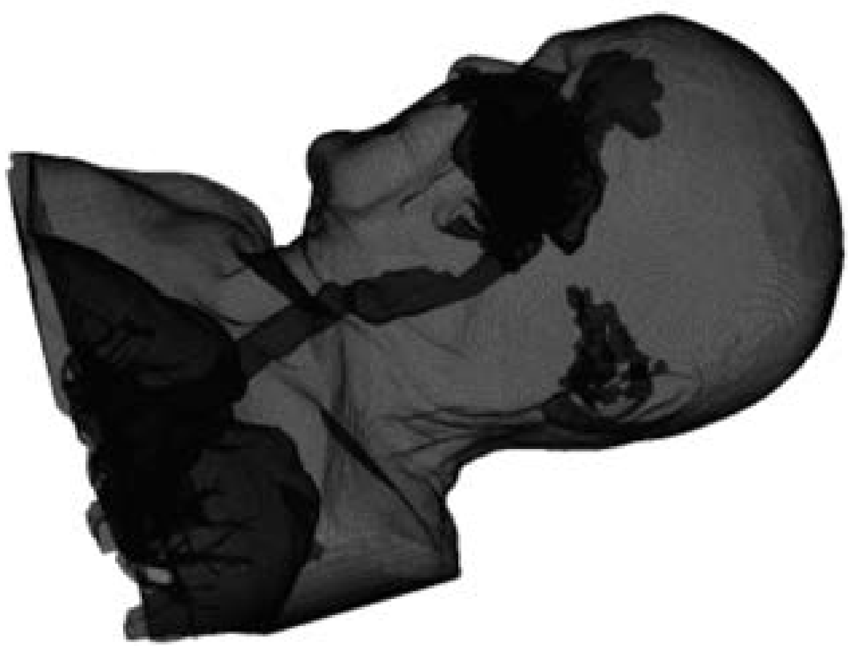
Date: 10-8

Content by: Jack

Goals: Identify a process where we can print out a first custom airway part

Content:

- Client provided us with an open access scan from NIH
    - Contains a head and upper chest with accurate nose, nasopharynx, and tracheal space
    - Was converted using https://www.embodi3d.com/democratiz3d/ --> LOOK MORE INTO THIS!
    - Create a negative inside SOLIDWORKS and try printing this to help gauge material properties and ensure we are matching anatomy
- Make 2 test prints, one in 80A and other in 50A (both are present in Makerspace



Conclusions/action items:

Jack Sperling - Oct 11, 2024, 10:24 AM CDT

Download

Download-files-for-3DPX-004646.zip (55.6 MB)

10-11 Alternative to Segmenting

Jack Sperling - Oct 11, 2024, 11:55 AM CDT

Title: embodi3D and democratize3D

Date: 10-11

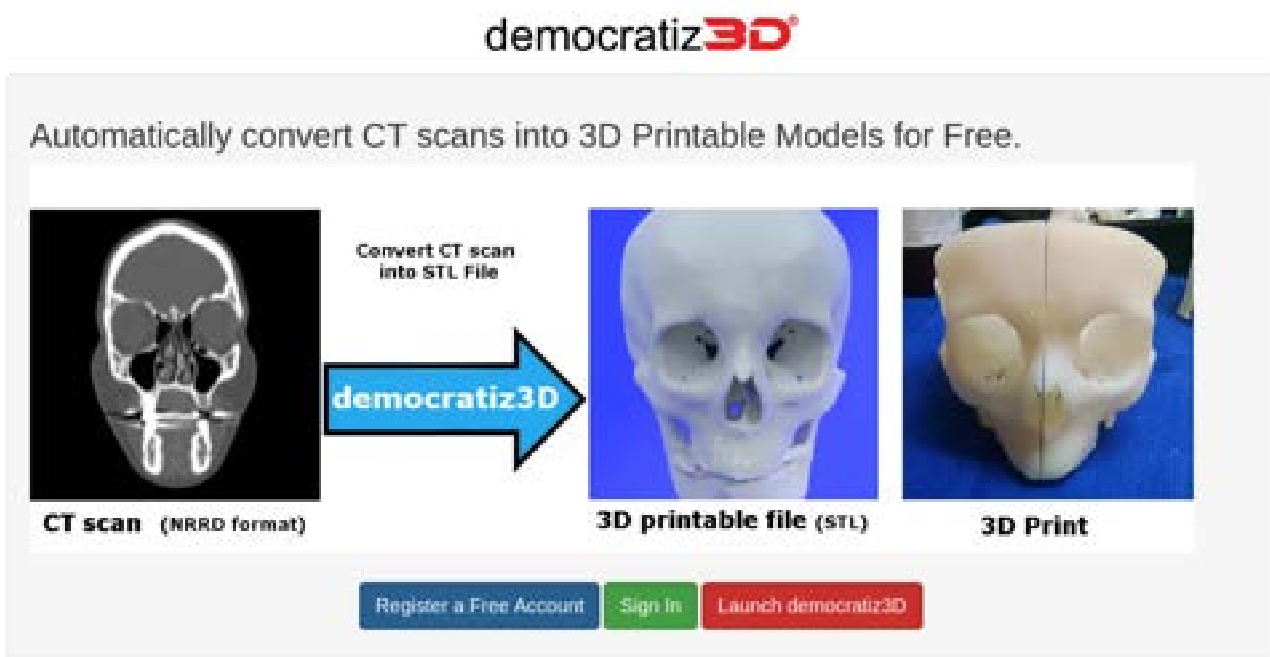
Content by: Jack

Goals: Identify if these pieces of software/web utilities are worth using in our project

Link: https://www.embodi3d.com/

Content:

The main page of the website shows a promising piece of software that could get our DICOM files into an STL that we can then edit in SOLIDWORKS before printing!



Further down the page shows promising pictures of actual models and the way it works:

Why Choose democratiz3D?

- **It's Easy.** democratiz3D is designed to be used by anyone. You don't need to be an expert in medical imaging or segmentation software to use it, unlike alternatives.
- **It's Fast.** Upload your scan and your model is usually ready in under 20 minutes. Even experts can take much longer than that to manually create a model.
- **It's Efficient.** While democratiz3D is working on your model you can do other things. You can even batch process and upload multiple scans simultaneously.
- **It's High Quality.** Output models are error free and ready for 3D printing. Extraneous objects in the scan (EKG leads, wires, head rests, etc.) are automatically removed. Models have high detail, up to 2.5 million polygons.
- **It's Free.** All basic services are free and private. Subscribers get unlimited access to premium services. Regular members can also get free access to premium services if they share their models with the community. Learn more.

An easy and free way to make 3D printable bones from CT scans.

Create 3D printable medical models with democratiz3D.

Bone Models

Muscle Models

Skin Models

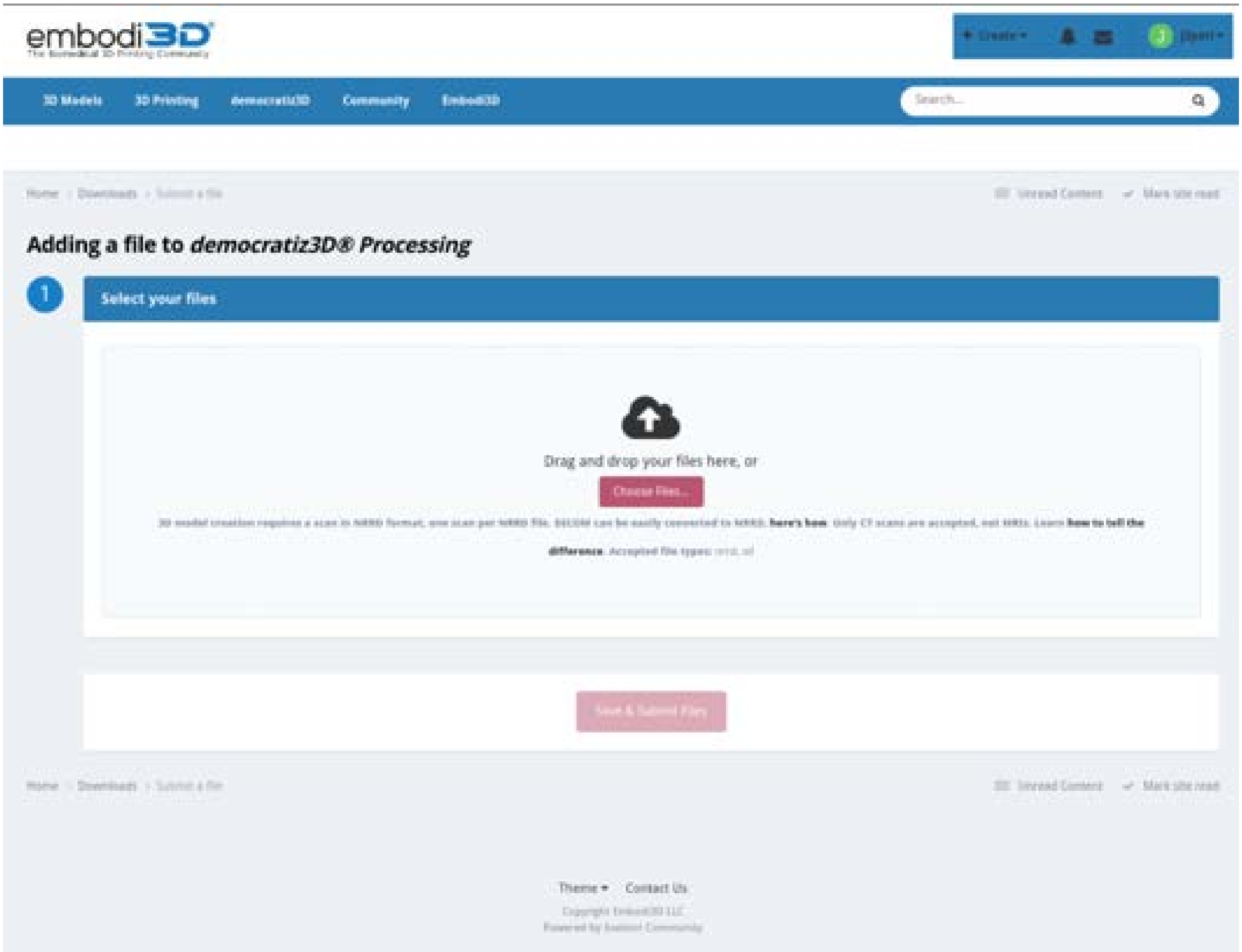
Dental Models

Vascular Models

Detailed Bone Models

The user manual can be found here: https://www.embodi3d.com/democratiz3d-user-manual/#Operation

A screenshot below is what is shown after making an account. It appears we can upload a NRRD file (can easily be converted to this from DICOM) and then upload. We will need to find a suitable DICOM to test this, but this is looking promising!!!



It does appear the website is built on a discussion forum style webserver so it is a little difficult to navigate, but we'll have to test and see how well this works!

Conclusions/action items: From what the website shows, this appears to be a great option to look into! There is either a $10 payment per model or creation of a premium account to not publicly share files. There are however some broken links on the website which is a slight cause for concern, however additional research must be done to determine if this will be able to do what we want (create a model that is just the air gaps rather than bone, flesh, or muscles)

Jack Sperling - Oct 11, 2024, 11:49 AM CDT

democratiz3D

User Manual: Easy Medical 3D Printing

Create Medical Models Automatically

User Manual Navigation

Download

Democratiz3D_User_Manual_-_embodi3D.com.pdf (8.09 MB)

10-25 -- Democratize 3D Update

Jack Sperling - Oct 25, 2024, 10:18 AM CDT

Title: Democratize 3D Update

Date: 10-25

Content by: Jack

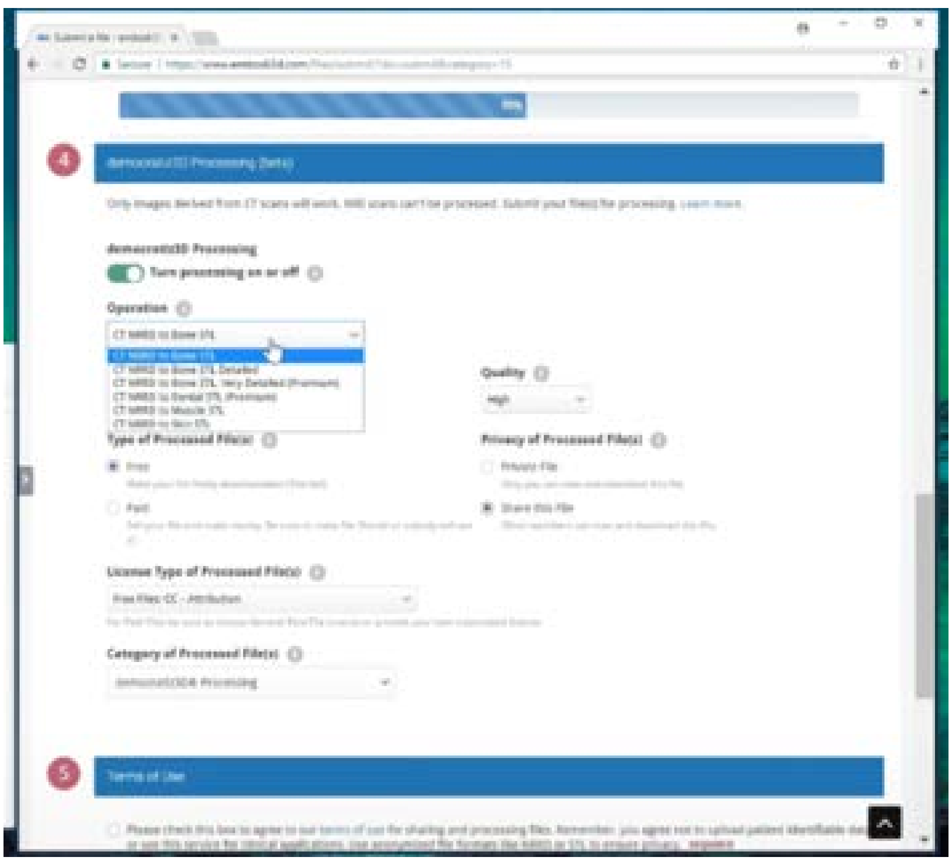
Present: Jack

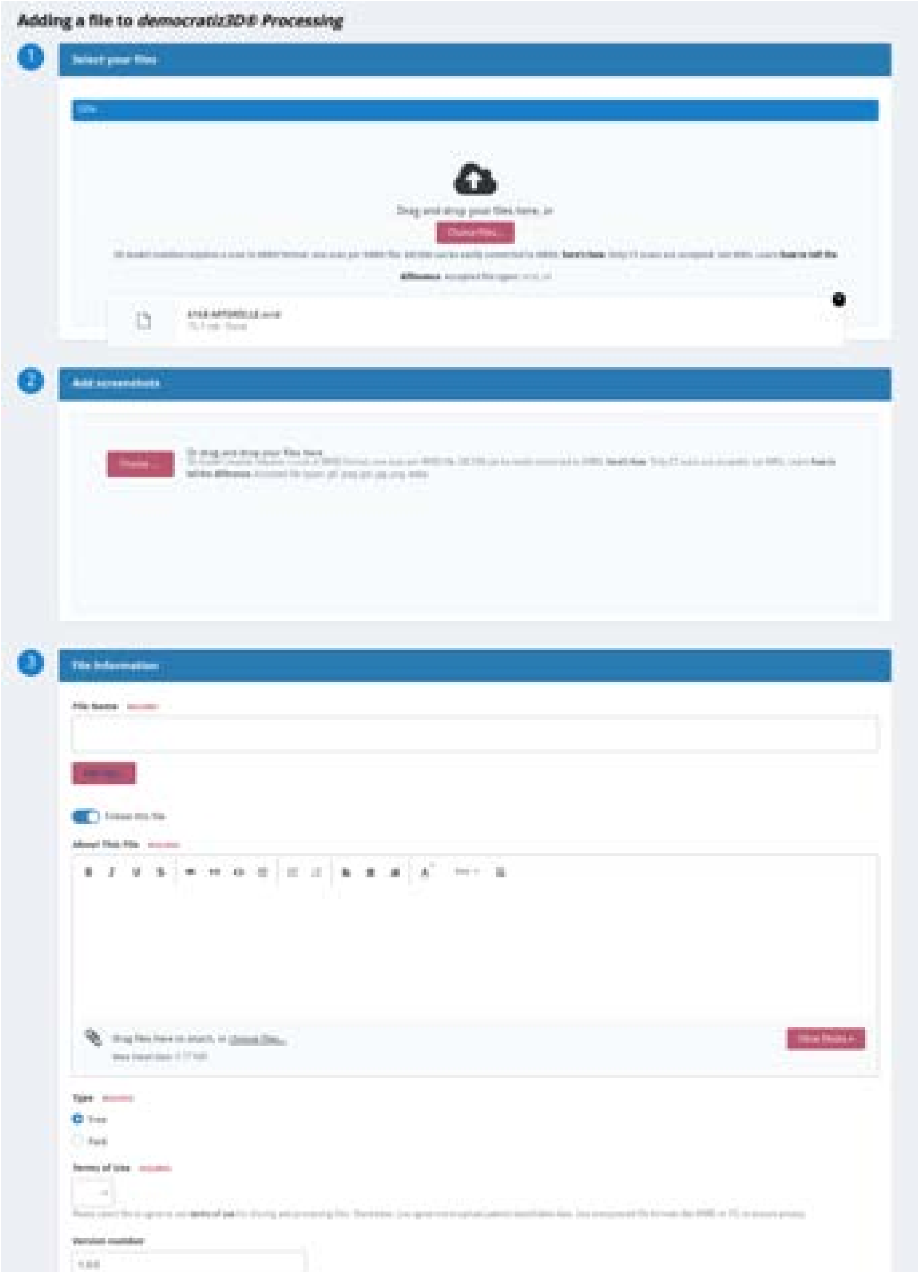
Goals: Identify if democrtatiz3D is possible to use for this project

Content:

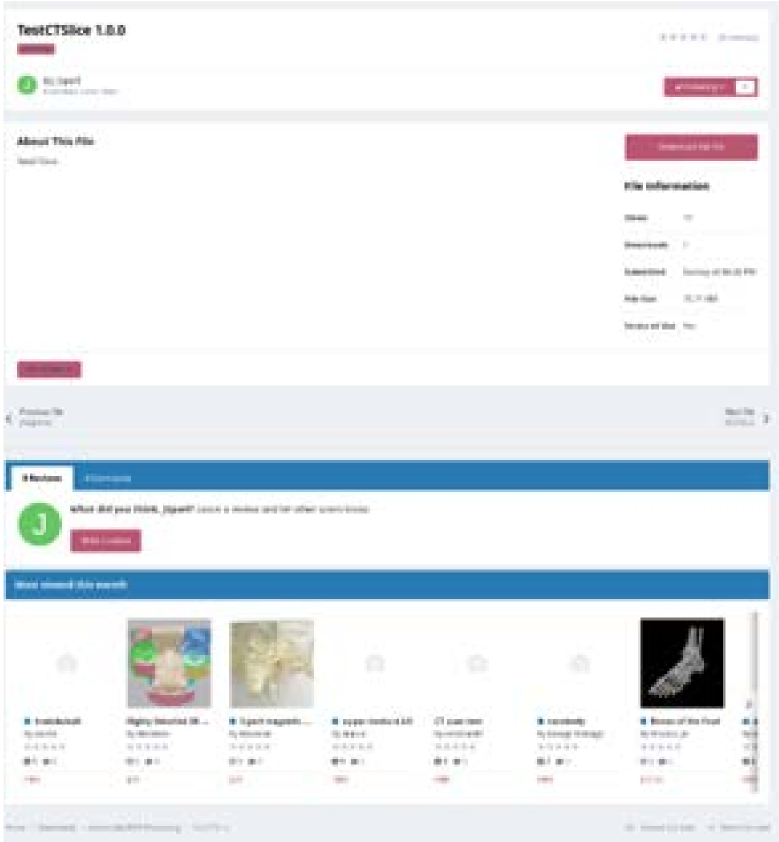
After going through multiple submissions, it appears like the CT to 3D converter does not work.

When uploading the files, the screen that is supposed to be shown does not appear. The menu that should appear is below and my view is below that





I have uploaded a public access chest CT to determine if it is able to be sliced, and this is what the page shows

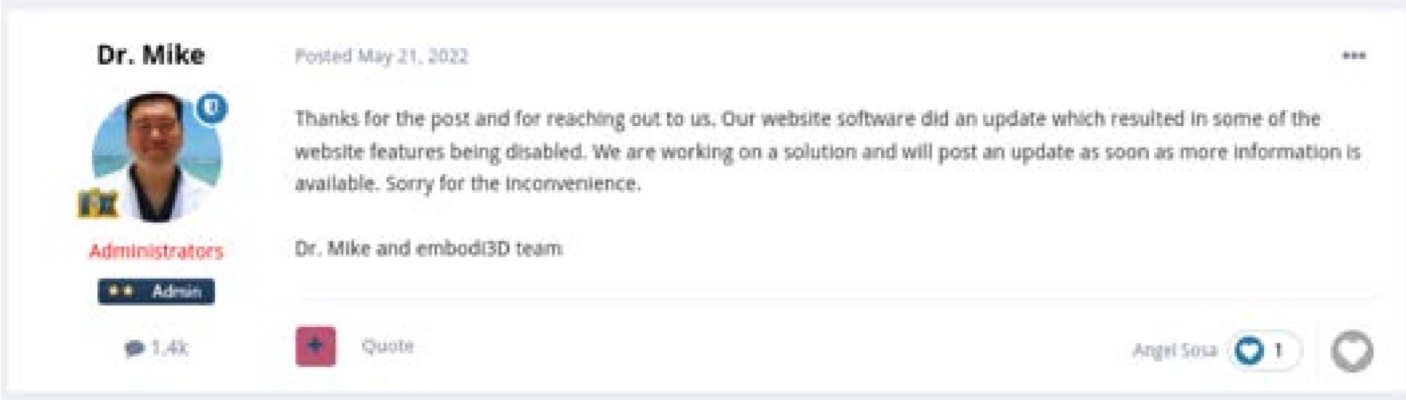


When downloading, it just reuploads the .nrrd anonymized, packaged CT scan.

Other users are seeming to have the same difficulty, shown below

export file stl By dat.dentpro, 8 hours ago	1 reply 5 views	dat.dentpro 8 hours ago
Unable to find processing options 1 2 By Chris Cam, May 15, 2022	30 replies 2.5k views	gbittner1 October 2
Missing elements in democratized form By ahazen2013, June 19	1 reply 270 views	bijibijmak July 12
adding a file to create an .STL By EMM, September 5, 2023	6 replies 1k views	Stater7 March 15
NRRD will not convert By zleb, November 26, 2023	5 replies 806 views	221ali February 5
I just purchased a premium membership and realized the site was broken... By joshdanielsjr, March 28, 2023	4 replies 866 views	Dr. Mike September 28, 2023
Is the converter working? By SuperArmySoldiers, June 14, 2023	2 replies 794 views	joshdanielsjr August 4, 2023
how do I continue? By Islandvert23, March 7, 2023	0 replies 518 views	Islandvert23 March 7, 2023
Dicom folder with .enc files By Dizzwold, January 1, 2023	6 replies 779 views	Nirvenesh January 22, 2023
CT scan data uploaded as NRRD - Nothing happens By ajt, September 15, 2022	5 replies 647 views	Sam D January 14, 2023
Is the website still working? By Parlos, October 25, 2022	1 reply 627 views	ATD November 2, 2022
Is the service running? By Steven_A, October 22, 2022	0 replies 631 views	Steven_A October 22, 2022
File isn't in STL By Anya18, August 21, 2022	0 replies 223 views	Anya18 August 21, 2022
Account removal By Jakub123, August 7, 2022	0 replies 368 views	Jakub123 August 7, 2022
Unable to process my nrrd file to STL By John Tjelta, June 23, 2022	1 reply 701 views	rgriffin4 July 1, 2022

The owner has replied to various blog posts but has not given a firm ETA of when the website will be back up and running. I think it would be best to move on...



Dr. Mike

Administrators

Admin

1.4k

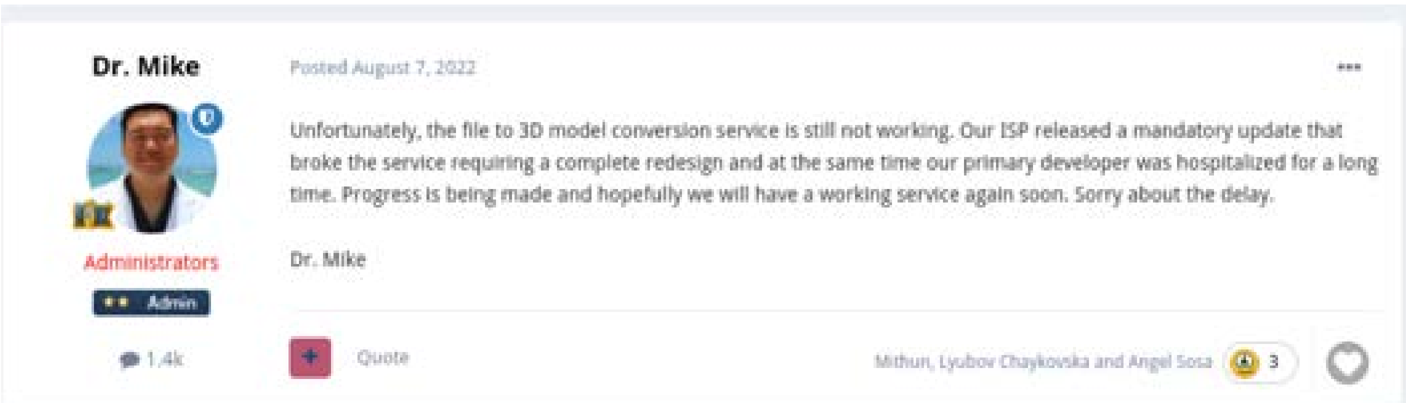
Posted May 21, 2022

Thanks for the post and for reaching out to us. Our website software did an update which resulted in some of the website features being disabled. We are working on a solution and will post an update as soon as more information is available. Sorry for the inconvenience.

Dr. Mike and embodi3D team

Quote

Angel Sosa 1



Dr. Mike

Administrators

Admin

1.4k

Posted August 7, 2022

Unfortunately, the file to 3D model conversion service is still not working. Our ISP released a mandatory update that broke the service requiring a complete redesign and at the same time our primary developer was hospitalized for a long time. Progress is being made and hopefully we will have a working service again soon. Sorry about the delay.

Dr. Mike

Quote

Mithun, Lyubov Chaykovska and Angel Sosa 3

Conclusions/action items: Unfortunately, this piece of software will not work for this project. I will begin to look into other alternatives that may work.

10-25 -- Potential alternatives to auto segmentation

Jack Sperling - Oct 25, 2024, 10:55 AM CDT

Title: Alternatives options for auto segmentation of the patient CT scan

Date: 10-25

Content by: Jack

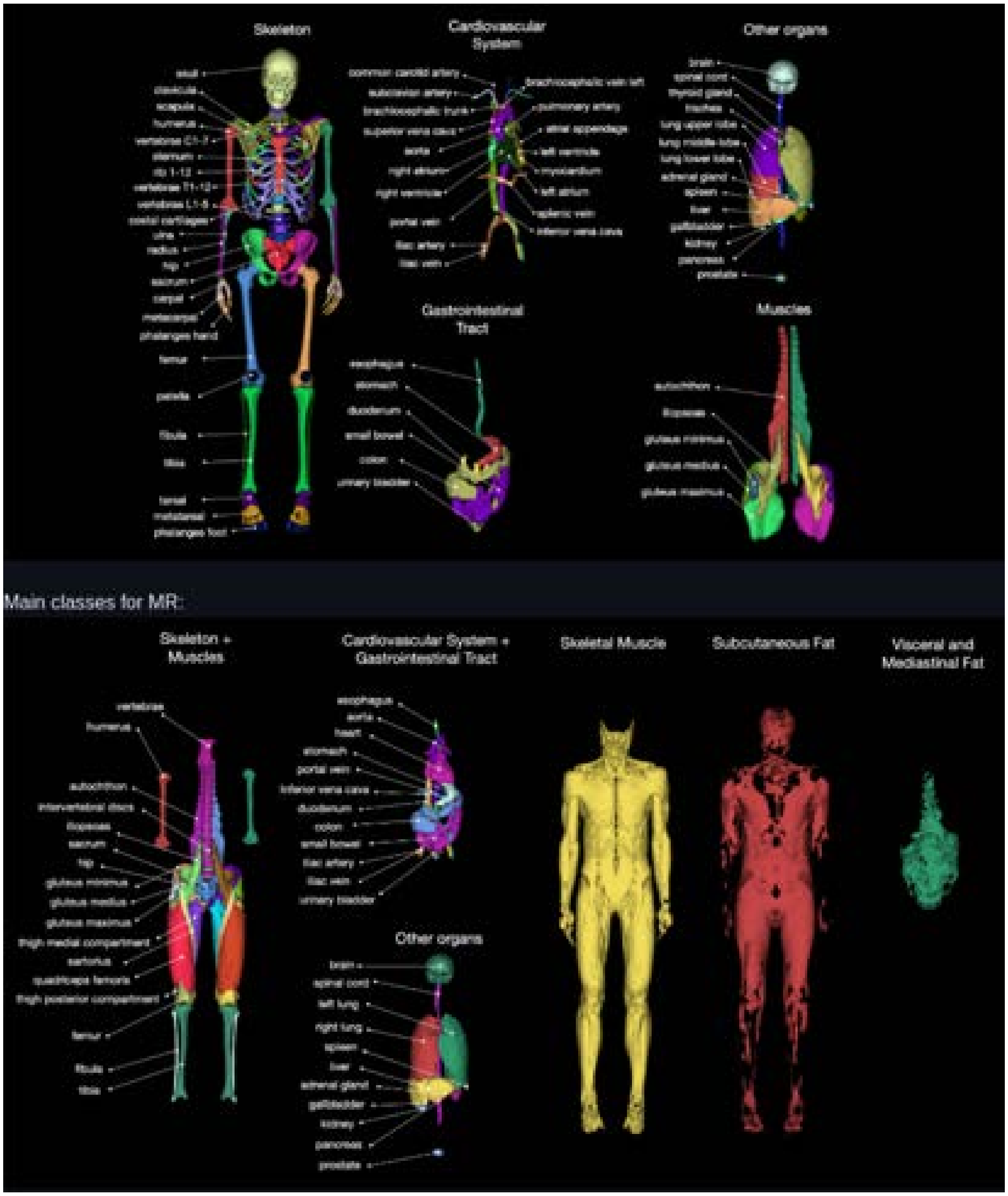
Present: Jack

Goals: Identify if there are any autosegmentation alternatives that we can utilize for this project to help minimize the work our client needs to do in order to get a 3D model from a CT scan

Content:

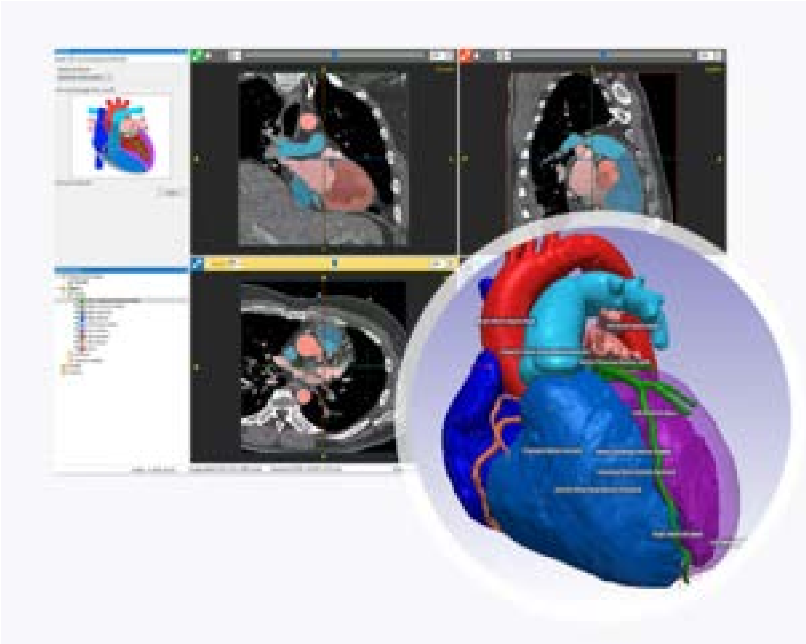
TotalSegmentor: https://github.com/wasserth/TotalSegmentator?tab=readme-ov-file

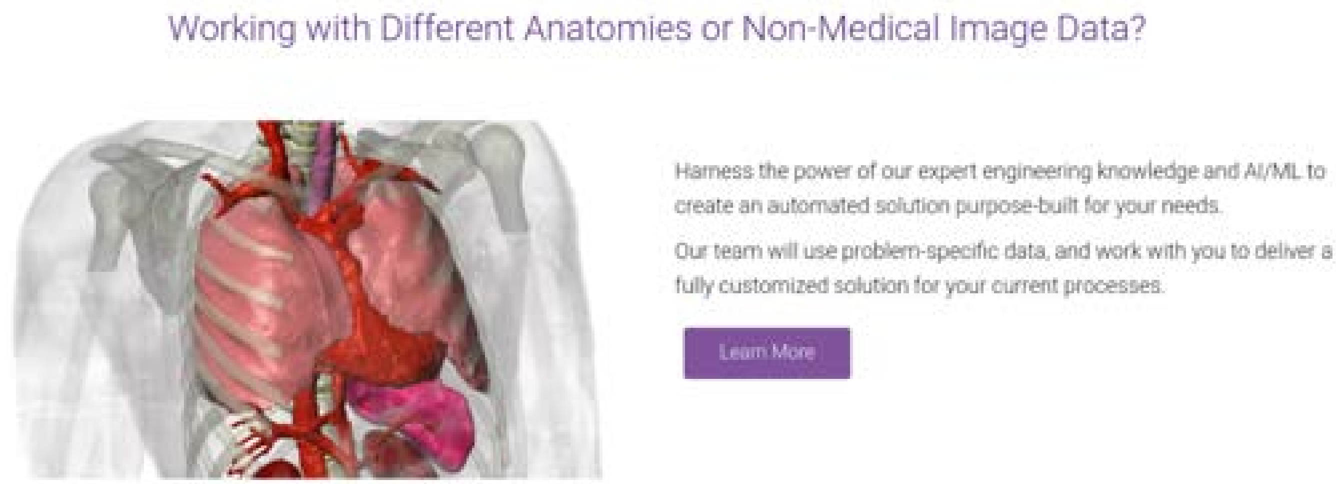
- Run locally within 3dSlicer
- Free and open source
    - Does come with a learning curve
- Has specific training for tracheas and lungs, but potentially lacks training for upper airway
- deep learning model run locally, so utilized PyTorch
- Run via command line
- Limited patient privacy concerns due to local running, however time to segment is dependent on GPU and CPU inside computer



Synopsys Auto Segmentation Tools: https://www.synopsys.com/simpleware/software/auto-segmentation.html

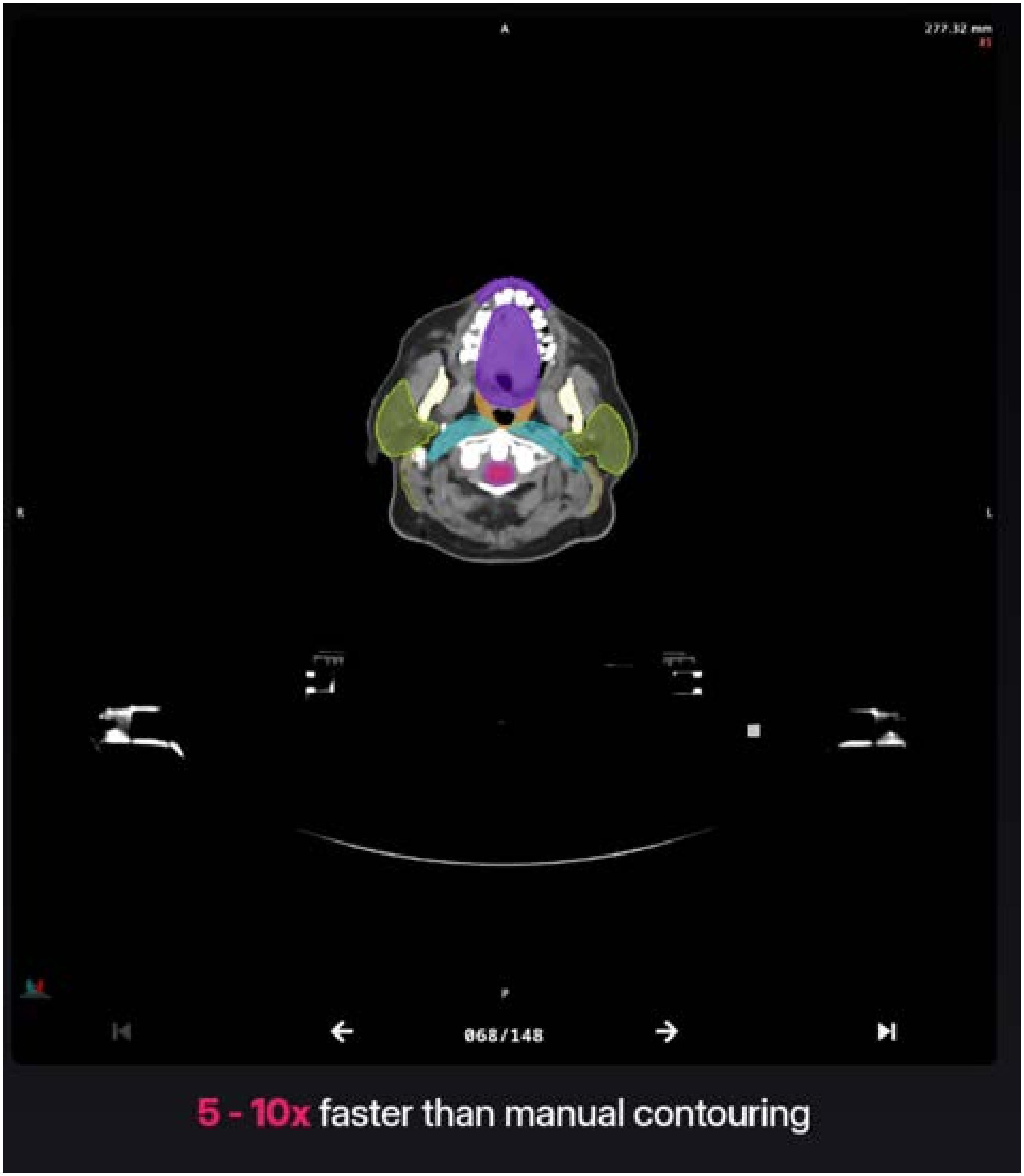
- Dedicated piece of software
- Specifies ankle, CMF, heart, hip, knee, shoulder, and spine data in its training data
- machine learning based algorithm
- Locally run, with results in 1-3 minutes on engineering spec laptop -- sufficient GPU and CPU
- 1 click use
- If the software does not work for airways, the company will create a custom ML algorithm just for you
    - Probably highly costly
- Free trial available, unsure about cost after that

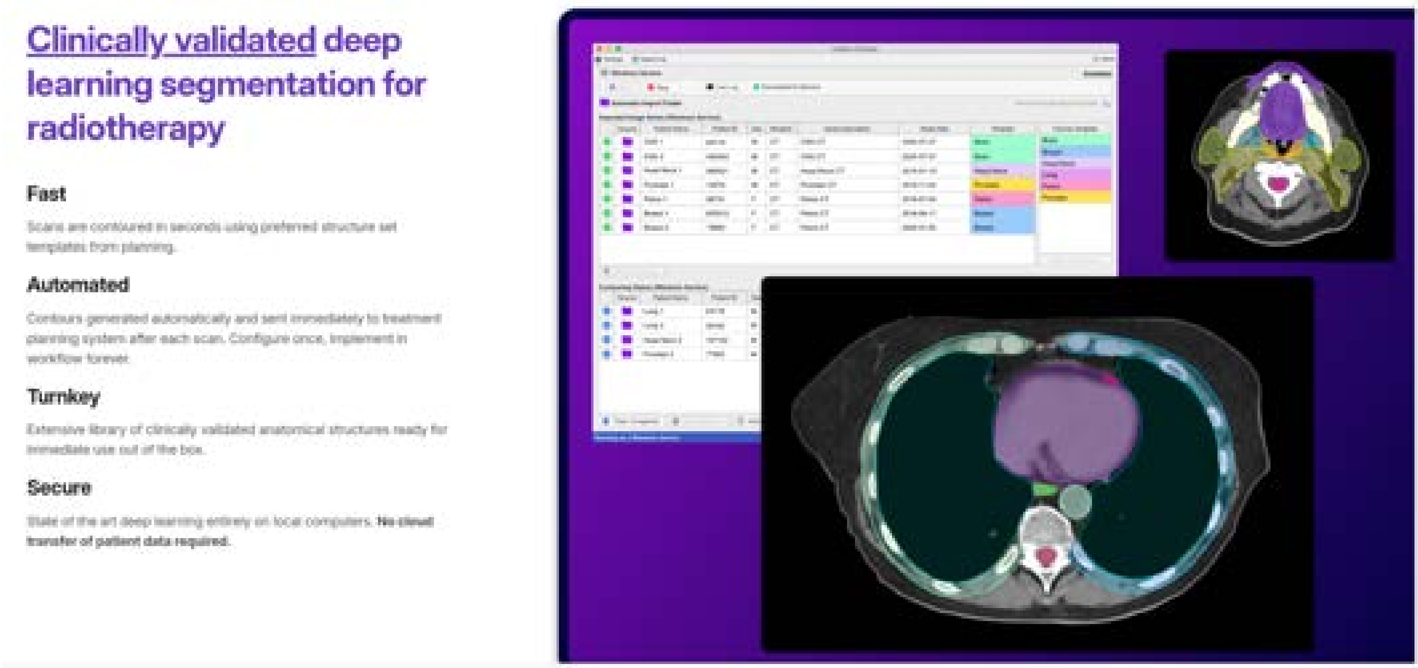




Limbus.ai: https://limbus.ai/

- Clinically validated deep learning segmentation model
- originally developed for radiotherapy
    - Ideally this means it is more tissue focused rather than bone based
- Run locally so no patient privacy concerns
- Dedicated software called Limbus Contour
- Works efficiently without GPU
    - under 3 minutes only CPU
    - 1 minute with GPU
- From examples online, looks like it is able to detect mouth/tongue and lower airway easily
    - Has specific lung scan too
- No pricing information
- Must request a demo


068/148
5 - 10x faster than manual contouring



Conclusions/action items: The team should begin reaching out to these companies to determine if these products would be cost effective and feasible. Additionally, we should move forward with the TotgalSegmentor as it is free and run locally within 3DSlicer

11-12 Jesse TEAMLab Meeting

Jack Sperling - Nov 22, 2024, 9:44 AM CST

Title: Meeting Recap with Jesse

Date: 11/12

Content by: Jack

Present: Jack, Maribel, and Nathan

Goals: Understand what roadblocks we are facing during the design process and how they can be alleviated

Content:

- Began with discussing the hinge mechanism and Maribel and Nathan's side of the project
- Discussed how 3D scanning will be difficult and probably not worthwhile in the long run due to difficulties
    - Future paths:
        - Find a low-ish resolution STL online that we don't have to edit and can easily slice with a plane and print to fit our model
        - Make a face and jaw assembly in SOLIDWORKS that replicates the functional anatomy enough to make it a functioning prototype
    - His suggestion: Start at the hinge where it connects to the base and work up starting with the jaw mechanism. This will allow the most crucial parts to be worked on first and thus give us the best chance of making a working prototype by the end of the semester.
        - This is what we ended up doing and should have the model soon.
- Next, we discussed the imaging possibilities of creating the trachea
    - The overarching problem is that we have a STL file and there are no CAD programs that work incredibly well with these files
        - Our trachea model is solid because it represents the air inside the airway rather than the soft tissue lining.
        - Unfortunately, this means that there are a tremendous amount of small triangles which make offsetting or making a surface of the model essentially impossible
        - There are two options we could potentially do:
            - Start from the top and move down to create our own "slices" of the outline and loft them together where more slices means more detail in the final model
            - The second option is to put a lofted cylinder around the model and subtract the inside so that way we have the outer surface of the airway imprinted on the inside of this now hollow-ish cylinder
                - We ended up trying this idea and are in the process of printing it with the Makerspace

Conclusions/action items: STL files are incredibly difficult to work with, which causes problems for both aspects of the project. For the head, we are going to model it from the hinge moving upwards to make the most crucial parts first. For the airway, we are going to have to re-evaluate if it can be segmented automatically or if we will need to reach out to a commercial software company. For now, we are printing a negative that will suffice.

11-13 OnShape Mesh and Surfaces Methods

Jack Sperling - Nov 22, 2024, 10:28 AM CST

Title: OnShape Mesh and Surfaces Methods and Modeling Potential

Date: 11/13

Content by: Jack

Present: Jack and Nathan

Goals: Determine if offsetting surfaces is possible inside OnShape compared to SOLIDWORKS

Content:

- During our meeting with Jesse, we learned that OnShape tends to do a better job at handling meshes and surfaces of STL files compared to SOLIDWORKS
- Nathan and I discussed how this might be of great use to the team and how if we could get a mesh this would allow us to offset the surfaces, effectively creating a thin trachea
- Nathan was able to make significant progress on this and created an offset surface that allowed us to take the difference between them to get a thin model, representing the soft tissue lining the trachea.
- You can find more about this in his folder of the notebook
- Attached is the document I assisted Nathan with creating, but the majority of it is his work

Conclusions/action items: There is a slight chance this method will be possible for future scans, but due to each scan being different, the offsetting instructions would have to be changed. It is still up to determination

Jack Sperling - Nov 22, 2024, 10:25 AM CST

Download

TracheaHollow_Procedure.pdf (1.61 MB)

11-14 -- Imaging Updates

Jack Sperling - Nov 22, 2024, 11:40 AM CST

Title: Imaging Updates

Date: 11-22

Content by: Jack

Present: Jack

Goals: Provide a written update and progress report on imaging timeline throughout this term

Content:

- At the start of the term, Dr. Schroeder said he would provide a list of patients whose airways would be beneficial to print
    - 1756999 - diffuse tracheal wall thickening (probably ulcerative colitis)
      3527545 - perforated trachea (and esophagus) after instrumentation
      1470766 - relapsing polychondritis
      50045801 - sarcoidosis with tracheal involvement
      3751237 - focal tracheal stenosis
      1560388 - extrinsic tracheal compression from metastatic squamous cell carcinoma of the trachea
      2516833 - granulomatosis with polyangiitis (9/1/2020 CT)
      3396425 - variant tracheal bronchus
      1778603 - tracheal stenosis
      3746160 - squamous cell carcinoma of the trachea
      1664190 - esophageal carcinoma invading the trachea
      3655550 - blunt tracheal injury
      3584945 - tracheal stenosis after resection of adenoid cystic carcioma
      3015076 - penetrating tracheal injury
      2749705 - progressive tracheal stenosis
      2496509 - tracheal stenosis from aortic and subclavian artery aneurysm
      3048069 - left isomerism with complete tracheal rings.
- From there, we needed additional information, like exam date and billing information, before submitting the attached form to the Radius lab.
    - We reached out and did not get a response when we mentioned this in the progress report emails for around 4 weeks until out client copied someone else who gave us some dates
    - During October, our client reached out to RADIUS with no reply
- Once we had a few dates, we forwarded the sheet to Judy Helt, who filled in the finance parts and submitted the document
- Around a week later we received an email from RADIUS saying that they required the HIPAA and consent forms in order to process the images on 11/13.
- After this occured, our client began reaching out to his industry contacts at GE Healthcare and MedInstitute
    - Elle and I were copied on the emails that went out on 11/14
    - Freddy, the contact at GE Healthcare asked us to fill out a form (attached) that specified our image request. I originally thought that our client was going to do this, however after a couple days he replied asking what we thought. I emailed Freddy back a thank you note and information but did not get a response until I copied my words into the template and sent him that email
    - I requested the images be returned to us by today, 11/22 but have not heard back from GE Healthcare on this email thread

  - Luke, at MedInstitute, said that he was unable to find any scans and when hearing our problem suggest we try ITK-SNAP, a program that has been released in the past few years to auto segment our images. We will be looking into this
  - Maribel and I discussed, and I offered to get a CT of my head and chest with my mouth open to use for the project but our client, understandably, said that it would be best to not irradiate me.
- On 11/17, Ilia mentioned that his sister works at GE Healthcare and on Monday 11/19, we received an email from a coworker who stated that they found a trauma CT scan with the mouth open and could send it to us. The scan was recieved and uploaded to Google Drive this morning 11/22.

Conclusion: We just recieved our first non-example set of images this morning and are still struggling with printing and processing them. We have tried to get images unsuccessfully for over two months and will do what we can with the scan that Ilia's sister was able to provide

11-16 --- Making of the Jaw, Hinge, and Torsional Components

Jack Sperling - Nov 22, 2024, 10:14 AM CST

Title: Progress update for Modeling after Jesse Discussion

Date: 11-16

Content by: Jack

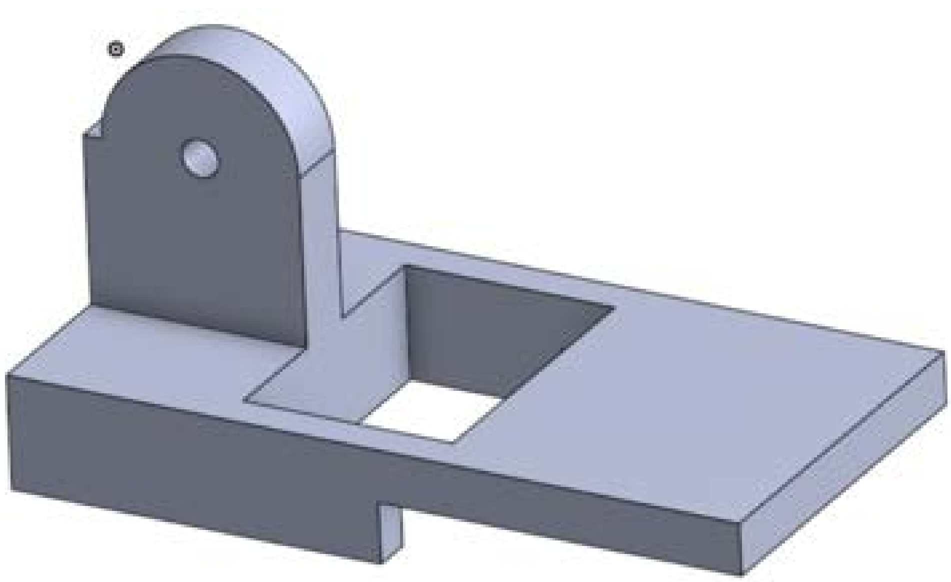
Present: Jack, Nathan, Ilia, Maiwand

Goals: Create as much as possible of the components outlined by Jesse and document their progress

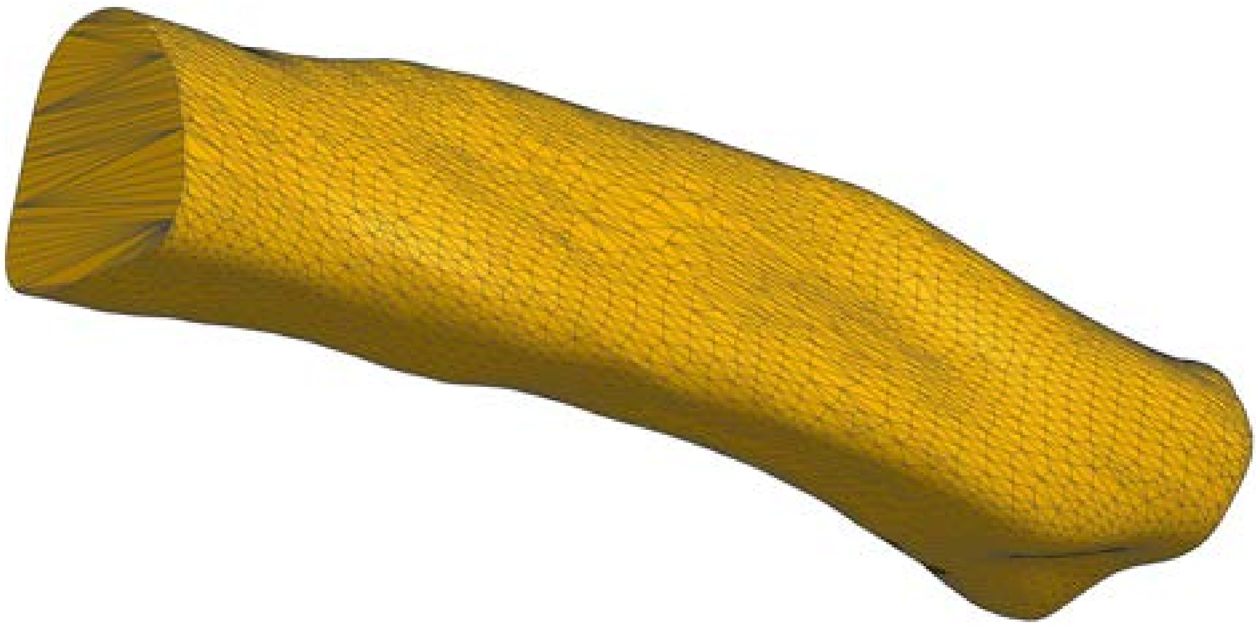
Content:

- Below are pictures of each of the 3D files attached to this notebook entry

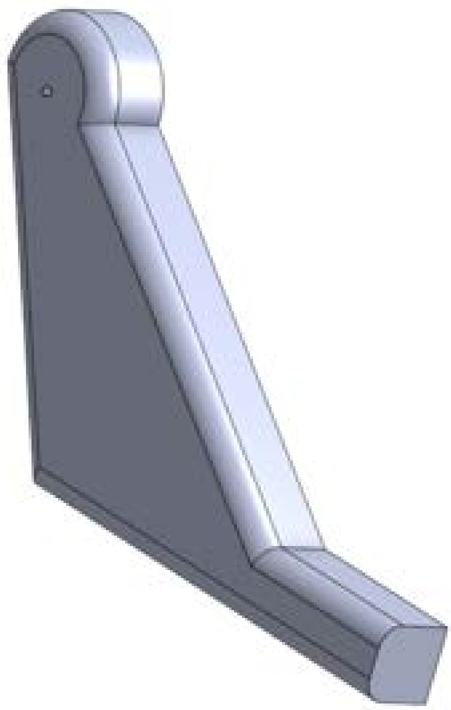
This is the image of the "TopJaw" component which serves as the secondary hinge at the very base of the neck to allow for rotation of the head backwards in order to allow the mouth to open



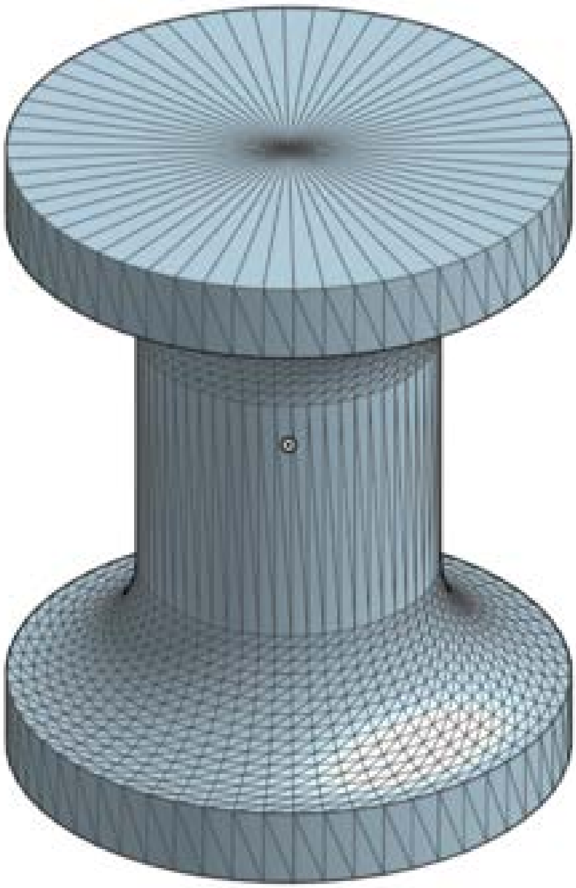
This is the image of a ***HOLLOW*** surface which is the trachea. Unfortunately, there are ends on this model, so it is not completely printing ready, but this will eventually become printed and hopefully not fail!



This is the incomplete bottom jaw mechanism that still needs to be lofted and mirrored. Once this is created, there will be 2 of the torsional TPU components (pictured below) which will allow rotation without nuts and bolts



This is a picture of what we are calling the "TorsionalTPU" component. It is acting like a torsional spring where it resists movement and rotates back if rotated from rest. This will act like the muscles in the jaw that allow for the opening of the mouth with some resistance as you go. These were printed in TPU in order to make sure they are flexible and will rotate



Conclusions/action items: The team is making great progress with the models, however there is still more work to be done! We still do not have any images, unfortunately...

Jack Sperling - Nov 22, 2024, 10:08 AM CST

Download

Jaw_Spring_1_.stl (209 kB)

Jack Sperling - Nov 22, 2024, 10:08 AM CST

Download

16_mm_TracheaHollow.stl (825 kB)

Jack Sperling - Nov 22, 2024, 10:08 AM CST

Download

BottomJaw.SLDPRT (100 kB)

Jack Sperling - Nov 22, 2024, 10:08 AM CST

Download

Top_Jaw.SLDPRT (140 kB)

11-18 - Creating Torsional TPU Pieces with Nathan

Jack Sperling - Nov 22, 2024, 10:34 AM CST

Title: Creating Torsional TPU Pieces to Replace Rubber

Date: 11-18

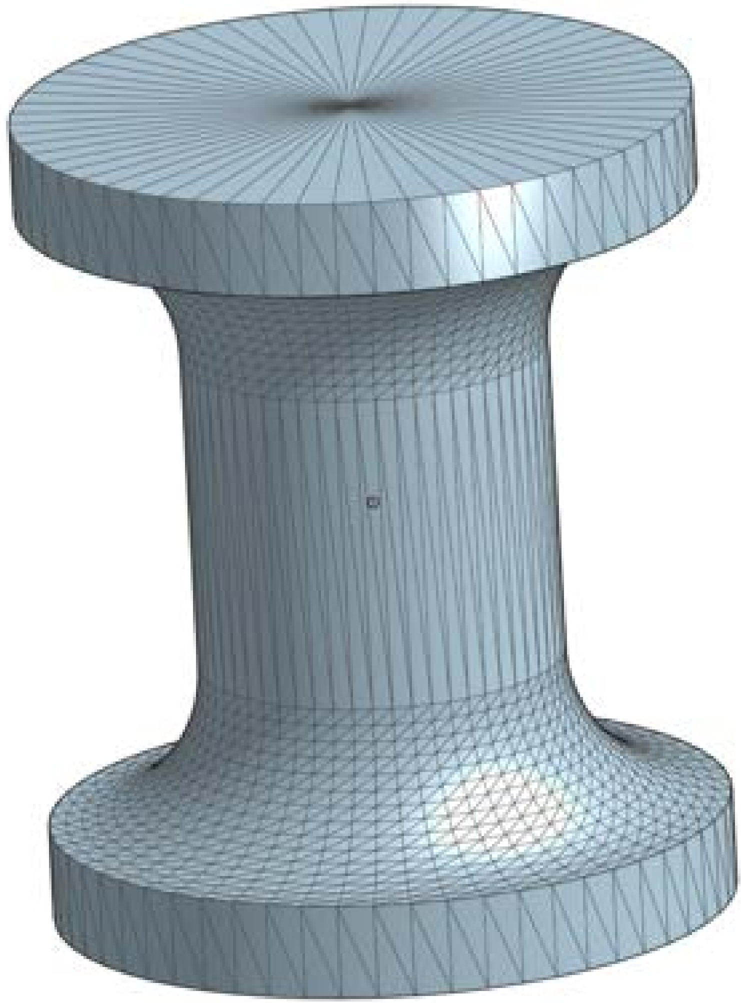
Content by: Jack

Present: Jack and Nathan

Goals: Create a piece that can be printed to replace rubber found in the AirSim model

Content:

- When opening someone's mouth, there is a resistance due to the muscles that close the jaw. In the AirSim trainer, this is accomplished by gluing a small rubber piece to the jaw piece as well as the base part of the neck.
  - This allows the jaw to rotate with some resistance and will return to its neutral position when force is removed
  - The one problem is that we do not have access to create a piece like this, so we created something similar and printed it in TPU
- Unfortunately, the first design ended up too difficult to rotate, so I suggested to Nathan to shrink the diameter if the middle of the part to make it easier to rotate
- We currently have 3 different sizes printed in the same BambuLabs TPU that the Makerspace stocks.
- Attached below are the 3 files and a picture of one of these pieces



Conclusions/action items: In order to allow the jaw to rotate with resistance, we created a small piece that can be 3D printed in TPU to allow for rotation with added effort and return to resting position after force is removed.

Jack Sperling - Nov 22, 2024, 10:35 AM CST

Download

Jaw_Spring_smaller.stl (209 kB)

Jack Sperling - Nov 22, 2024, 10:35 AM CST

Download

Jaw_Spring_Small.stl (209 kB)

Jack Sperling - Nov 22, 2024, 10:35 AM CST

Download

Jaw_Spring_1_.stl (209 kB)

11/20/24 - Makerspace Printer Status Update

Jack Sperling - Dec 11, 2024, 3:50 PM CST

Title: Makerspace Printer Status Update

Date: 11/20/24

Content by: Jack

Present: Jack

Goals: Provide an update from Makerspace on Flexible material printing

Content:

- The past few weeks have been difficult working with the Makerspace
- There is only 1 printer with flexible resin in it and the prints continue to fail (pictures attached)
- It was decided that due to mechanical errors with the pump inside the printer and potential resin difficulties that they are putting further elastic prints on hold until a service technician can come out and repair the printer
- Unfortunately this means that all future prototyping must be placed on hold
- I reached out to Sector67 and spoke with the founder and he said that unfortunately they cannot assist and other contract 3D printing companies will be too expensive
- Currently, we are forced to wait and hope that the printer works soon

Conclusions/action items: Unfortunately, the Makerspace placed all elastic and flexible prints on hold due to mechanical difficulties. Currently, we cannot keep prototyping without the printer working and there are very few other options. We must sit tight for the time being.

Jack Sperling - Dec 11, 2024, 3:51 PM CST

Download

IMG_4586.jpg (2.46 MB)

Jack Sperling - Dec 11, 2024, 3:51 PM CST

Download

IMG_4585.jpg (4.26 MB)

11-21-24 Makerspace Printing Consultation/Lessons Learned & Summary of Failed Prints

Jack Sperling - Nov 22, 2024, 10:27 AM CST

Title: Makerspace Printing Lessons Learned

Date: 11/21

Content by: Jack

Present: Jack

Goals: Summarize what I have learned from discussing with the Makerspace staff about printing our models

Content:

- Below are pictures of two models that we have created
  - The first model is a cylinder that has the negative of the airway removed in order to get the inside of the cylinder anatomically accurate
  - The second model is a very thin model which presents the soft tissue lining the airway that was made by offsetting the airway model on itself by 0.4mm
    - This was the maximum possible offset without object collisions in OnShape
- The two slicer pictures represent what the models look like in PreForm
  - This is the second iteration of these models that were trying to be printed
    - Those models are on the FormLabs printer now, as of 11/22 AM
- The last picture below shows the first round of the models being printed and how they failed
  - After extensive talking with one of the graduate student Fab Fellows, we came to the conclusion that it may be due to a combination of orientation, thickness, and material properties
  - They have been having difficulties with the FormLabs 50A resin printing correctly, and combined with the inability to change the layer height to less than 0.1mm, the only thing we could do was rotate the model in PreForm
    - **Therefore, I worked with the Fab Fellow for an hour, hand painting the supports with her guidance to give these models the best chance of being printed correctly. She supervised and told me this is the best shot we have. These models are the ones currently printing**
      - **If the updated models (printing now, and the PreForm slicer images below) *do not work* then she said there is a high possibility that the models are not printable using this type of resin**

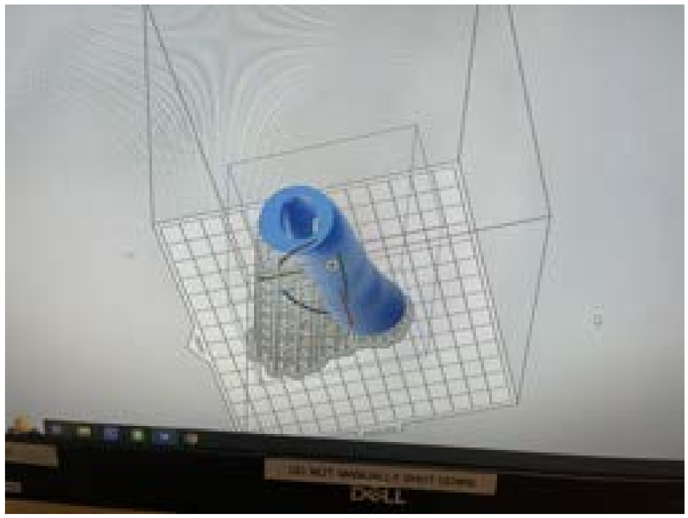
Multiple Makerspace staff said what we created was very good, but due to the material properties and printers, there is a chance that the model is too thin in certain parts to be printed correctly due to the increased supports needed for flexible resin like the 50A we are using

- Side note:
  - I ran into Becca Poor, who Maribel and I worked on BME 200 with, and she told me that her project involved segmenting and printing a flexible heart!
    - Some of her observations and lessons learned:
      - ***<u>There is no substitute for manual segmentation!</u>***
      - If we could print these models in multiple pieces, that may increase the chance of success because we can orient each piece to limit it's failure

rate
- Hunter and Becca are happy to help however they can with slicing :)

Conclusions/action items: The material that we are printing our models with is notoriously difficult, and even after hand painting supports with Makerspace staff, it is unlikely that we will be able to print the entire model without failure. Becca offered some of her experience, which was greatly appreciated

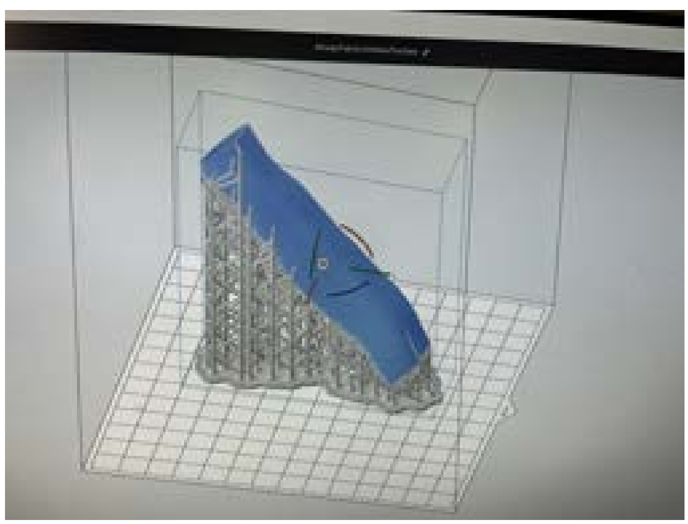
Jack Sperling - Nov 22, 2024, 9:46 AM CST



Download

IMG_4330.jpg (7.1 MB)

Jack Sperling - Nov 22, 2024, 9:46 AM CST



Download

IMG_4329.jpg (6.78 MB)

Jack Sperling - Nov 22, 2024, 9:46 AM CST

Download

IMG_4352.jpg (2.69 MB)

Summary of 11-7 to 11-21

Jack Sperling - Nov 22, 2024, 11:53 AM CST

Title: Updates from the past two weeks and discussion points for Advisor Meeting

Date: 11/22

Content by: Jack

Present: Team

Goals: Provide discussion points for the advisor meeting today

Content:

- **Recap what has occurred in the past two weeks since the last advisor meeting**
- Group updates:
  - Met with Jesse from TEAMLab and received lots of good information
    - LA entry about this
- Stand/Mechanical group
  - Moving along well creating prototype with base, top jaw, and torsional TPU pieces printed
    - Finishing the bottom jaw soon
  - Continuing to iterate and test to create a mechanism that replicate the ROM which the AirSim had
- Imaging group:
  - Unsuccessfully contacted RADIUS
  - Unsuccessful in getting images from client's industry connections
  - Ilia's sister was able to get us scan through GE Healthcare which was uploaded this morning
  - Printing difficulties
    - LA entry on this too
    - Multiple failed prints due to combination of wall thickness, orientation required, and material choice
    - Have one more attempt printing now after working with makerspace staff to hand paint supports on
  - Modeling difficulties:
    - Jesse discussed how difficult it is to edit STL files
    - Both companies that we reached out to either left us on read or emailed with Elle 20+ times and then said no
    - Worked with Nathan and was able to create 2 different types of models which may work (same ones that failed in printing)
      - Have LA entry on this too
    - Ran into Becca at Makerspace
      - They have similar project but key difference is they hand segmented it to exactly what they printed
        - When I talked this out with her, I realized the key decision that we made:
        - **Our client wanted this to be reproducible in a time frame of 1 week, and because he did not know anyone who could segment images, we took that on along with physically building the model. Auto segmentation is**

incredibly difficult, and due to a combination of lack of access to commercial software, sample CT scans, and lack of experience with the anatomy, modeling the anatomy to print became extremely complex

- Potentially making the decision to hand segment and either teaching the client or having the client find someone who could would've led us down a completely different design path, but these are the decisions and rationale that caused us to get here today.

Conclusions/action items: In summary, we are running into difficulties, but after meeting with Jesse, working together as a team, and narrowing our focus, we have come together to ensure we are able to make the most out of the project as a team. We will focus on creating as much of the hinge/neck/base as possible with a rotatable lower jaw, and get as far as possible printing the sample CT scans while looking into segmenting the full CT that was just provided today.

12/2/24 - Final Assembly of Trainer Base

Jack Sperling - Dec 11, 2024, 4:09 PM CST

Title: Final Assembly of Trainer Base

Date: 12/3/24

Content by: Jack

Present: Jack

Goals: Complete the assembly of the trainer base

Content:

- A new part was created out of two 3D printed models made out of TPU
- Incorporated the dual lock mushroom caps to allow the airway mimic (tube on the left) to fit into a connector piece (right) and facilitate quick swapping between the airways
- Final hinges were placed on the model as well as dual lock placed on the sloping neck portion
- ROM testing was conducted after the final model was created
- Overall, the model was a success for what we had planned to create
- Unfortunately, the setback at the Makerspace with 3D scanning ability and STL manipulating caused the base to not have nearly as much anatomy as we had originally hoped, but it represents the ROM fairly well and has a mechanism for easy swapping in and out of an airway

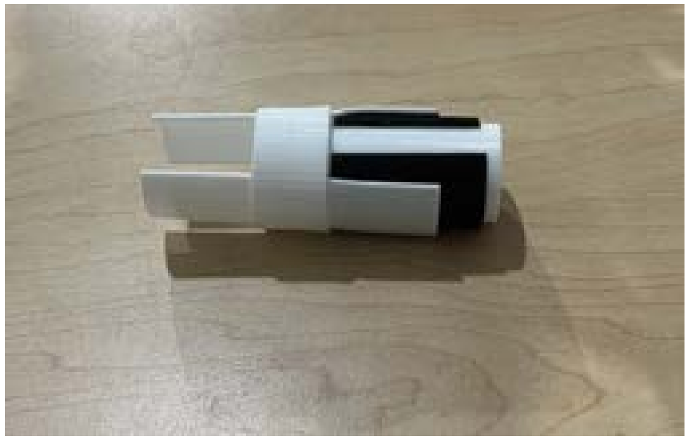
Conclusions/action items: Now that the base is completed, ROM testing can be completed and methods of adding additional anatomy can be brainstormed for potential future work

Jack Sperling - Dec 11, 2024, 4:06 PM CST

Download

IMG_4584.jpg (2.41 MB)

Jack Sperling - Dec 11, 2024, 4:06 PM CST



Download

IMG_4583.jpg (2.84 MB)

Jack Sperling - Dec 11, 2024, 4:06 PM CST

Download

Hollowed_cylinder_1_.STL (18.1 kB)

Jack Sperling - Dec 11, 2024, 4:06 PM CST

Download

connector_piece_1_.STL (29.7 kB)

Jack Sperling - Dec 11, 2024, 4:06 PM CST

Download

IMG_4580.jpg (3.29 MB)

12/5/24 - Makerspace Material Update

Jack Sperling - Dec 11, 2024, 3:55 PM CST

Title: Makerspace Material/Printing Update

Date: 12/5/24

Content by: Jack

Present: Jack

Goals: Provide an update on the Makerspace printer status

Content:

- After returning from Thanksgiving break, the Makerspace said they were able to print an initial round of Dogbone samples for tensile testing
- They were able to fine tune some properties on the printer to allow it to print high enough to complete dogbones printed flat as previous prints began failing at the 2-3 inch mark, vertically
- They also updated us that they switched from V1 to V2 of the 50A flexible resin which now prints correctly without errors
- This morning we recently picked up a completed model that Nathan created and we can use for the poster presentation
- Fortunately, this means that we are able to get some of our models we attempted to print back in the middle of November but unfortunately we did not have enough time to prototype to create a functioning airway for the trainer

Conclusions/action items: The makerspace printer is back up and running! We were able to receive a model for the poster presentation but unfortunately we do not have enough time to continue prototyping as this set us 3-4 weeks behind schedule. We were able to show at the poster presentation that the offset method of creating the model works and provides a somewhat accurate representation of the trachea (picture attached below)

Jack Sperling - Dec 11, 2024, 3:56 PM CST

Download

IMG_4587.jpg (2.42 MB)

Jack Sperling - Dec 11, 2024, 3:58 PM CST

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IMG_4484.jpg (2.29 MB)

12/10/24 - Final Summary of 3D Prints from the Makerspace and anticipated next steps

Jack Sperling - Dec 11, 2024, 4:22 PM CST

Title: Final Summary of 3D prints from Makerspace and next steps

Date: 12/10/24

Content by: Jack

Present: Jack

Goals: Summarize the progress we have made with printing models and identify areas of improvement for the future

Content:

- After deciding to move forward with 80A and 50A resin for testing, we began printing these models at the Makerspace
- Once these were printed, the team decided that the 50A was the path forward due to its more pliable nature which represented tissue better than cartilage
- From here, the team worked on segmenting the sample CT available online for the next few weeks to find methods of working with the solid air and making an intubatable model
- Here, we began printing models in flexible 50A to ensure that the biomechanical properties aligned with what we were feeling when handling the models
- The models began failing and some failed up to 3 times at Makerspace only printing a few milimeters before failing and having to be restarted
- Some, however, did print but failed halfway through and are pictured below
- During this time, the rest of the airway trainer base was being printed out of PLA and TPU (other notebook entries on this)
- After the Formlabs printer that printed 50A and 80A was shut down, we continued to attempt to prototype using TPU however some of these failed too or printed too small due to Makerspace staff changing the size after we sliced the model
- Once the printer was back up and running, we were able to print a few dogbone samples to use in the MTS machine as well as a singular offset model which was used at the poster presentation to demonstrate how this could've provided appropriate airway biomechanics for intubation.

Conclusions/action items: Though there were ups and downs with the Makerspace throughout the semester, the team persevered and continued prototyping however we could. After learning how dependent we were on one printer, the next steps of working with the facial anatomy to provide a cohesive airway may be to reach out to contract companies who can print parts on demand and post-process them before shipping them to the client. This would ensure high quality prints that do not suffer from print failures

Jack Sperling - Dec 11, 2024, 4:24 PM CST

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IMG_4590.jpg (1.89 MB)

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Jack Sperling - Dec 11, 2024, 4:24 PM CST

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IMG_4580.jpg (3.29 MB)

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IMG_4579.jpg (3.36 MB)

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Jack Sperling - Dec 11, 2024, 4:24 PM CST

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IMG_4586.jpg (2.46 MB)

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IMG_4585.jpg (4.26 MB)

Jack Sperling - Dec 11, 2024, 4:25 PM CST

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75495773975__B1A65ED6-B893-42D0-9202-7E2EA471C013.jpg (2.29 MB)

11-5 -- SOLIDWORKS Processing Start

Jack Sperling - Nov 06, 2024, 9:15 AM CST

Title: SOLIDWORKS Post Processing of Trachea Model

Date: 11-6

Content by: Jack

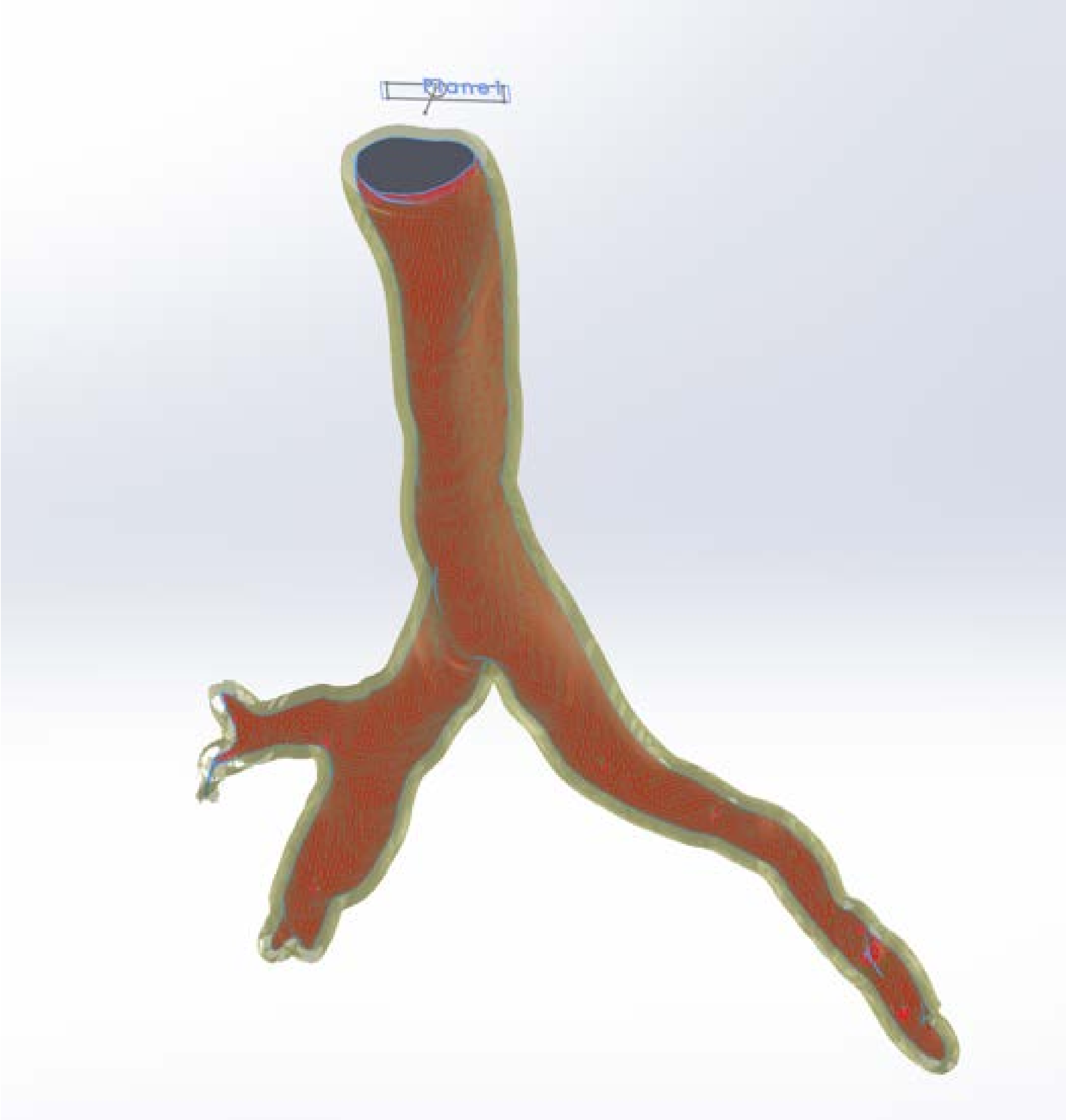
Goals: Begin working through the process of post processing the solid trachea model that was exported from 3DSlicer

Content:

I have begun the process of working with the STL file we were able to export from 3DSlicer. The main hurdle to jump over is turning this solid cast that represents air into a thin membrane which represents the tissue that makes up the trachea and airway. I had a couple of ideas, and I think we're slowly making progress but are not completed yet.

1. First, I needed to make a clean cut off the top of the trachea to flatten it out to see if this will be the best method for "shelling" out the model
   1. The way my model imported, I made a reference plane in the XZ plane near the top of the model and was able to extrude cut through the model to cut off the top few mm
   2. This is fairly tedious as you need to arbitrarily make a plane in the 3D space as nothing snaps to the model because it is an STL and SOLIDWORKS does not understand what it is trying to represent
      1. I am working on a way to turn this stl into a mesh that can be converted into a SLDPRT
2. From here, I tried to create a shell of the object but it did not work because I was misunderstanding the tool
   1. After more research it needs 2 meshes and takes the space in between them, so I was able to make a mesh which was raised a couple mm's above the current model to test (yellow over the red model)
      1. **Yes, I understand this distorts the size of the anatomy! In the future, I am hoping we can shrink the STL, but remember that this current trachea actually represents the air and not the tissue**
      2. **We will have to do more discussing to determine if this is a feasible method**
   2. Unfortunately, I ran into multiple mesh errors with the underlying STL file (pictured below, in red)
   3. I am now tryng to work through whatever method allows me to turn the STL into a mesh, turn the mesh into a smoothed SLDPRT and potentially turn that SLDPRT back into a mesh that does not have any errors
      1. **Just a thought but the smoothing option in 3DSlicer may be to blame for this...**

The file attached below is the same one in the picture -- the sliced solid trachea with a reference plane created but failing the mesh "expansion" step



Conclusions/action items: We have started taking the first stab at post processing the STL file in SOLIDWORKS and have made some improvements. Currently, the biggest roadblock is ***still not having any patient scans*** and working through turning the STL file from 3DSlicer into an object SOLIDWORKS knows how to create a raised mesh over. We will continue to do more research but currently I think this is the best route to continue down because ***we still have not heard back from any company which creates automated slicing software***.

Loading [MathJax]/extensions/Safe.js

Jack Sperling - Nov 15, 2024, 4:55 PM CST

Addition to the above template: I was the only one present when working through this problem in SOLIDWORKS

Jack Sperling - Nov 05, 2024, 10:40 PM CST

Download

CutSolidTrachea.SLDPRT (2.14 MB)

Jack Sperling - Dec 11, 2024, 10:28 PM CST

Update: Attached final document for OnShape

Jack Sperling - Dec 11, 2024, 10:28 PM CST

Download

Airway_Fabrication_Procedure.pdf (2.17 MB)

11/5 -- Segmenting and Exporting Training Documentation

Jack Sperling - Nov 05, 2024, 9:48 PM CST

Title: Segmenting and Exporting Training Documentation

Date: 11-5

Content by: Jack

Goals: Create the first draft of a training document that can be used by the client in order to streamline the process of segmenting CT scans

Content:

Attached below is a first draft of a training document walking the user through the steps to create a tracheal segmentation from a CT scan in 3DSlicer. Currently, this is the best option as other companies have not been responding to us. This caused us to lean more on 3DSlicer than originally expected.

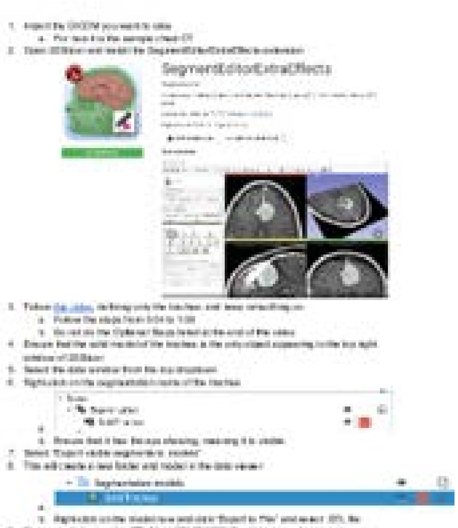
There is also the Youtube video attached below in case it gets removed, the client can still have a copy to reference.

Currently, I am in the process of working through the preparation of the model in SOLIDWORKS (mainly working on hollowing it out so we can turn our air-based segmentation into something that represents the soft tissue that lines the trachea). There will be another page added once that is completed.

There are also preliminary STL models attached below this document that were produced using the steps in the documentation.

Conclusions/action items: We have completed the first draft of a training document outlining the segmentation and exporting process for the airway in 3DSlicer. They are attached below. Additional post processing will occur in SOLIDWORKS, and that documentation is in progress.

Jack Sperling - Nov 05, 2024, 9:52 PM CST



Download

Rev1_SegmentationDocumentation.pdf (1.34 MB)

Jack Sperling - Nov 05, 2024, 9:48 PM CST

Download

Airway_segmentation_from_CT_in_1_minute_using_3D_Slicer_tJMGe3FMTk0_.mp4 (13.6 MB)

Jack Sperling - Nov 05, 2024, 9:49 PM CST

Download

UncompressedSolidTrachea.stl (7.45 MB)

Jack Sperling - Nov 05, 2024, 9:49 PM CST

Download

trachea.stl (1.16 MB)

9-11-24 - BME Career Prep

Jack Sperling - Sep 11, 2024, 1:54 PM CDT

Title: BME Career Prep Lecture

Date: 9/11

Content by: Jack

Content:

- Connect before you are a canditate
  - Once you become candidate, they normally can't give extra information
  - Applying is just a step in the process
- Quality of source matters -- Handshake or Linkedin
  - Handshake -- all info is directly from the company
- Keep track of what you do!
  - Keep track of your applications -- use ECS tracking sheet
  - ecs.wisc.edu/resources
- Coops are very previlent in BME
- Resume tips
  - Tailor resume to the position ---- quick changes
  - Create balance -- show a picture of your experience
  - ATS resume is doable
    - no columns, charts, colors
    - Desing projects without years or semesters ---- what did you do??
    - jobs --- organization + location, position title + Dates
  - ATSes do not SCAN HEADERS AND FOOTERS
- Career fairs do not need cover letters
  - Expand on resume
- Advice for BMEs
  - Identify your purpose -- more than just an internship
  - Looking beyond the obvious -- overlap with other disciplines
  - Research the employer -- feedback from our partners
  - Develop your valued added statement -- WHY YOU??
  - We all have great experiences -- showcase them to others
    - Example --- design projects compared to ME
- Handshake posting logic
  - Only get 1 type of engineering jobs
  - Many employers just click all engineering so don't be frustrated
  - Healthcare tech and CS, IS, and technology --- all skills we have
  - DONT JUST LOOK AT EMPLOYERS WHO SELECTED BME
- Industries in Handshake
  - Look at lots of industries across handshake -- companies only pick 1
  - Lots of people want us! Get experience to get better experience next year!
- Career fair
  - Each day is different employers
  - Every employer is only here 1 day!!!
- 3 columns
  - EE, ME, and BME --- look at all these columns

•

Jack Sperling - Nov 20, 2024, 10:19 PM CST

Download

BME_300_-_Lecture_-_Career_Prep_ECS.pdf (1.96 MB)

9-18 -- Leadership Styles

Jack Sperling - Sep 18, 2024, 2:02 PM CDT

Title: Leadership Styles

Date: 9/18

Content:

Leadership: How do you define a leader?

- Important leadership qualities:
    - Admitting failure
    - Organized
    - Inclusive
    - Communicative
    - Patient
    - Reliable
    - Enthusiastic
    - Understanding
- Anatomy of a good leader:
    - Self-awareness
    - Vision
    - Transparent
    - Communication
    - Decision-making
    - Empathy

Styles:

- Power
    - Someone has to take control and it's me
    - Great man and trait theory
    - Being in control is the most important thing
    - Hierarchy, authority, command
    - Can happen in industry but design projects don't really have these drastic levels of experience
- Servant/Service
    - Leader now at the bottom of the pyramid
    - Needs of the people who I am leading are the most important
    - Shared decision making
    - Listening and understanding
    - This can happen in BME design and is a really good type of leader here
- Authentic
    - By being my genuine self I can gain and build trust
    - Transparency, genuineness, honesty
    - More about the person rather than the process

- People oriented leader
    - Skilled at building trust
    - Relationship building skills
- Process oriented

- Willing to work alongside everyone
- Create systems to make work get done efficiently

- Thought oriented
  - See the big picture and open to new ideas
  - Looking ahead
- Impact oriented
  - Set the bar high and inspire people to follow your cause and mission

Connect

- Develop leadership skills regardless of your position
- Leading others starts with leading yourself
- Explore and define how you want to lead
  - Self-assess -- values and beliefs
  - Observation and self reflection -- what types of environments work well, what gives you a sense of accomplishment
  - Seek out feedback -- others may be able to identify strengths and areas for growth you're not actively aware of

Goal Setting

- How can I put this into practice
- Start small and slow down
- Focus on one element to practice
- Look for mentors
- Ask questions, partner with others
- Consider tracking your progress

Team goal:

My goal for our design team this semester is to have every member feel comfortable speaking their opinion through open communication and using their decision-making ability to contribute to the project without any pushback from other members. I can play a part in this by allowing every member of the team to be heard and not discount any ideas or contributions due to a team member's position or year.

Personal goal:

Personal leadership goal, how will that look, what will you define success as

My personal goal for the semester is to ensure that I don't discount any team member's ideas or let any personal prejudices about any of the design ideas stop us from executing the best plan and project that is possible.

Conclusions/action items:

In order to focus on leadership, we need to look into ourselves first. I think I find myself leading the best when we are feeling comfortable in our team environment and feel comfortable speaking to anyone and make their decisions and ideas heard towards everyone regardless of year or position.

Jack Sperling - Nov 20, 2024, 10:18 PM CST

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BME_300_-_Lecture_-_Leadership_-_Angela_Kita.pdf (1.55 MB)

9-25 -- Post Grad Planning

Jack Sperling - Sep 25, 2024, 2:11 PM CDT

Title: Post Grad Planning

Date: 9-18

Content by: Jack

Content:

- Use undergrad experience to build a story
- Tie them together!!!! Big picture
- Research -- important for alll post degrees
- Do your homework
  - Think about letter writers EARLY -- **3 STRONG ones**
  - Prepare for MCAT --- summer before senior year
- What does your ideal position look like? Is this something that you would like to do?
- Start diving in now! --- Begin looking at schools and requirements now!
- Writing your story
  - Here's what **not to do**
  - Leog -- engineer -- aunt dies of cancer -- phd in BME
  - I did this, then that, then the other thing -- chronological regurgitation of what you did
  - I will do anything there
  - Here is **what to do**
  - Start with what you want to do -- thesis statement
  - Narrow experiences and how that applied to broad interest
  - Specific to each position and place to which you will apply
  - Show a reasonable idea of what you will achieve. do afterwards, and name faculty there who are in your field of intereste (mostly phd)
  - Defend your plan with LIFE EXPERIENCES -- Most recent first!
  - CV to some extent in paragraph form --- but be specific! -- doesn't have to be choroological order through
- MS stepping stone and expand credentials for future medical schools
  - Industry focused
  - Generally 1 year
  - Lots of MS go to get MD
  - Can get lots of other experiences that you have to be student for -- like places in hospital
- PHd
  - Work in acaedmia, research grants, work as PI
  - Lead projects in industry and startups
- MS as a stepping stone!
  - Rewrite story
  - MD -- need time to prep for MCAT or apply for Med Schools
  - Fill gaps in resume
  - higher level of skills
  - More lab time with less class time
  - More experiences -- teaching, menotoring, research thesis
  - Older, more maturity
  - Really powerful if you add industry experience
- MS for industry
  - Higher starting salary
  - Can coop during MS as well
  - Time to find the dream job
  - MS will make you more desireable
- Dr. Suarez heads MS program in BME
- 3 MS programs
  - Research -- MD/PhD program 1.5-2 yrs
    - Required thesis
  - Accelerated program -- independent study/research allowed
    - Coursework only -- can take advanced courses but 24 credits of courses
    - Can still do a project
  - Biomedical Innovation, Design, and Entrepreneurship (accelerated 1yr)

        - Project based -- project required (BME design community project)
            - Can continue BME capstone project
            - Can be something else too with a random company or lab or faculty or research based project kinda too
        - Partnership with buisness school
        - Finding by TA
        - Instead of electives -- focused on courses in the buisness school
            - Buisness management
            - Entrepreneurship
        - Specifically designed to take projects and show you how to market
    - Making MS affordable by paying TAs full tuition and stipend
    - ALL 24 credits
    - BME is highest paid department in the entire university
    - Application requirements:
        - Applying next fall
        - Statement of purpose
        - No recs but put jana (someone in BME) down 3 times!
        - If research MS -- 1 letter from PI and agree to take into lab
        - Can switch between them
        - 12/15 is deadline but still flexibility
            - If don't find a job, we can still find a spot for the MS program
            - Essentially take all students -- all if over 3.0 -- automatic in if you click apply button
- MS programs elsewhere
    - MEng -- terminal degree
    - MS in Global health
    - MS in other Engr Dept -- usually longer
    - MBA -- industry pays for credits or evening options
        - Most often not right after graduation
- Other PhD programs
    - find faculty/labs performing research in your passion area
    - Less competitive than PhD programs often are not funded
    - **MN MS doesn't let you work on projects**
    - **Duke has a projects based program --- like our Entrepreneurship program**
- PhD advice
    - Network!
    - Conferences!!!!!!!
    - Utilize your lab PI here at madison --- Collaborators
    - Build your resume/CV
    - Research is a must -- Honors in Research
    - External finding from NSF-GRFP ---- scholarship for PhD (4 free years)
    - Due October 15th
    - Apply Fall senior year (1st time) then once more in 1st year grad school
    - 3.5+ GPA and 75% percentile for quantitative GRE
    - Faculty individually review applications that align with their research
    - Tour the department, meet faculty!
    - Visit weekends!
- Med school advice!
    - Special req
        - Chem 109
        - Chemistry 344 and 345
        - 2 sem physics
        - **2 sem english (Lit or Communications) --- look at specific med school requirements**
        - I/A & S/H & CommB -- use liberal studies -- **Minnesota and Madison have backed off the req but still potential problem**
        - Physcholohu 202 and soc
        - Biochem 501
        - All can be satisfied with BME 128 credits!!!!!!!!
    - Check premed advising!!!
- Clinical engineer -- short term position -**- biosense webster!**
    - Position might be sales associate but its actually implant of device with DR in OR
- Beyond the classroom
    - Research is required
    - Volunteer -- clinical setting desired

    - Shadow physicians
    - Patent contact time
    - Build relationships --- letter writers!!
    - Use your design experiences! Physician clients
    - Requirements vary by degree -- check pre health specific website!
- Research -- demonstrate skills outside the classroom
    - Utilize BME Design projects
    - BUild skill sets to get into labs
    - Previous research expiereince
    - Publications!!!!
    - After these, leadership and extracurriculars

BIDE program to MBA

- Not an MBA but intro --- push a little BME design and design process and market potential
- Insurance and reimburaseability
- Helps becoming a design engineer
- Doesnt stop from getting MBA in future but doesn't replace it

Conclusions/action items: Plan early for Med School reqs and classes to take!!!!!! Can take the MS program if not get into med school

---

Jack Sperling - Nov 20, 2024, 10:17 PM CST

Download

BME_Advising_Days.pdf (4.46 MB)

10-2--Near Peer Mentoring

Jack Sperling - Oct 02, 2024, 2:06 PM CDT

Title: Near Peer Mentoring

Date: 10-2

Content by: Jack

Content:

Why are we mentoring 200s?

- Get them comfortable with working with clients and showing them the ropes of the design process
- We're close to them in age group and let them feel more comfortable
- Instructional and emotional support
- Share experiences
- Increases belonging

Transferrable Skill

- Leadership
- Communication
- Active listening
- Study practices
- Self awareness
- Interpersonal skills

General benefits of mentoring

- Increased patience
- increased self-esteem/confidence
- Build positive habits
- Foster personal growth
- Help identify gaps in your own knowledge
- Sense of accomplishment

What does it mean to be a good mentor

- Building trust
- Psychological safety
- Reliability
- Support and enthusiasm
- Being available -- open and honest
- Humanizing their challenges: Be the coach
- Good listening

Listening effectively

- Get rid of distractions
- Stop talking
- Act like you're interested

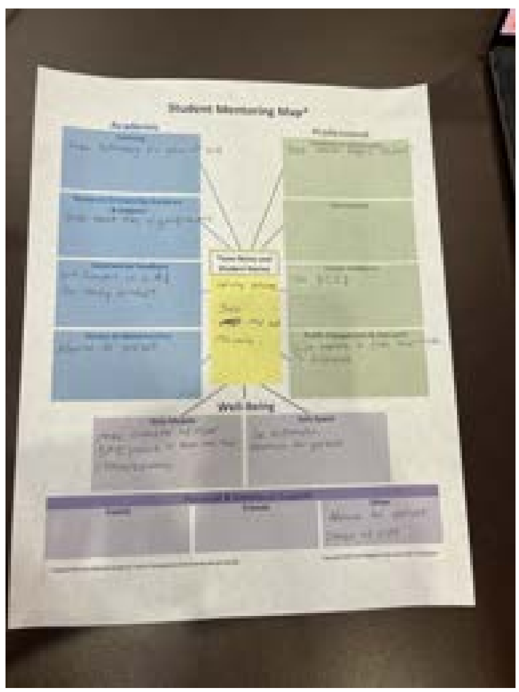
- Get the main idea
- Ask questions
- Check for understanding
- React to ideas --- not the person
- Avoid hasty judgements

What do you wish you knew in BME 200?

- Take everything with a grain of salt
- You're going to fail, and that's ok --- use that experience as a learning opportunity
- This class is just effort and two presentations
    - It's not did you get a product or do it correctly
    - Do your best but getting actual product is a longshot
- Be ready to adapt -- things will be changing
- Advocate for yourself --- in classes, in BME, and in every aspect of your life
- People aren't going to like you and that's ok
    - Don't assume someone doesn't like you
- Put everything in lab archives :)

Picture attached below of the mentoring map for the group

Jack Sperling - Oct 02, 2024, 2:05 PM CDT



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IMG_3911.jpg (3.38 MB)

Jack Sperling - Nov 20, 2024, 10:16 PM CST

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BME_300_-_Lecture_-_Near_Peer_Mentoring_-_PuccinelliTJ.pdf (666 kB)

10-9

Jack Sperling - Oct 09, 2024, 2:02 PM CDT

Title: Sustainable Engineering

Date: 10-9

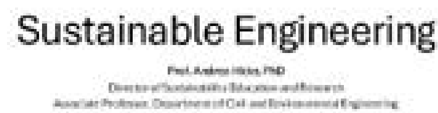
Content:

- United Nations sustainability definition
  - Meets the needs of today with allowing the future to meet their own needs
- Healthcare sector is 5% of global emissions and 8.5% of domestic emissions
- 388,000 disability adjusted life year -- loss of life and self care ability
- Circular economy -- keeping things out of landfills
  - Recycling is keeping in the economy
  - Don't throw things in the landfill and want to recover these things
- Lifecycle assessment
  - Hitting one whackamole down and another pops up
  - Eutrification -- too much nutrients in water way
  - Switch from fossil fuel to bio based --- CO_2 goes down, eutrification goes up
- If you never think ahead, playing this constant game
- Life Cycle Assesment
  - Get carbon footprint and further things
  - Impacts throughout the life cycle --- raw resources to landfill
- Using a LCA we can help determine overall impact before picking a solution
- Example -- environmental impacts of different blood pressure cuffs
  - Scope diagram --- go from raw materials to use settings, cleaning scenarios, and disposal.
  - Find material composition of the resuable and disposable products
    - Weights and materials
  - Cleaning also -- disinfection rate
  - Kg of CO_2 per use ---- help identify the emissions based on each category and stack to find total of emissions
- How does sustainability in your project
  - If reusable devices are cleaned, are they not as good as brand new
  - Example as N95 masks in the pandemic -- how do we balance waste with resilience
  - If you have supply line storage, how does making it be reusable help alleviate supply chain problems
- In our project
  - We can determine if a degradable resin is possible to use during the creation process for our device to allow it to be recycled or degraded at the end
    - Also look into if there is a similar resin that we can create the model out of that can remain just as
  - We can also use incredibly durable material so they can be used as a trainer many times over the years
  - Incorporating some modularity would make it be easier to reuse some components of the device
  - If we were to revert and go back down the route of pouring a mold, determine if using natural rubber or latex is something to consider
  - If we want to end up taking some anatomy from another trainer, it would be more sustainable to remove it from a used trainer and one that is planned to be scrapped rather than purchasing a brand new device just to throw parts of it away.

Conclusions/action items:

In order to thoroughly understand which design has the greatest or least environmental impacts, we must think about the long term life cycle of the design. For us, we need to determine which material will last the longest to limit the amount of times the airway trainer needs to be printed

Jack Sperling - Nov 20, 2024, 10:15 PM CST



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BME_300_-_Lecture_-_Sustainable_Engineering_-_Andrea_Hicks.pdf (1.26 MB)

10-16 -- IP and Patents

Jack Sperling - Oct 16, 2024, 2:06 PM CDT

Title: Introduction to WARF

Date: 10-16

Content by: Jack

Content:

WARF and disclosure process

WARF supports the university's mission to solve the world's problems

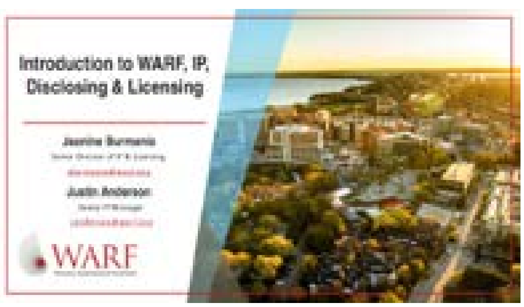
- WARF is a nonprofit
- serves at pattening and liscencing office
- Support research in many other contects -- have venture office too
- Theraputics program
- Technology transfer
  - invention
  - invention disclosure
  - assessment
  - protection
  - marketing
  - licensing
  - financial return
- Protect inventions made on this campus and licence out to companies
- Also helps with industry sponsored research and fee for service and consulting
- Intellectual property overview
  - 4 common types
    - Patents
      - 20 years
      - Only given by government agency -- each country as its own patenting office
      - Monopolistic right
      - Have to disclose enough for someone to practice it
      - Tells everyone what it is but get right to use it
      - 3 different types
        - Design -- 15 year term, limited to features
        - Plant -- 20 year term -- actually a plant
        - Utility -- provisional -- effective 1 yr placeholder
          - new and useful process
          - also includes improvements
          - 30k in cost and takes 2-5 years
          - Must teach others how to do it explicitly
          - 90% of patents issued are these
        - nonprovisional -- 20 year term
        - Requirements for patenting
          - must be new

            - cannot be a product of nature
            - non-obvious ---- used to not issue patents often
            - must be able to provude enough detail to teach others how to make or use the invention
         - Patent examiners -- scientists hired and trained by USPTO to review patent applications
    - copyrights
        - protection for creative works
        - Very long terms
        - 75 years after life of the author and then some after
    - trademarks
        - requires use in commerce
        - power to allow customer to discern products
    - trade secrets
        - protect anything of value
        - protection as long as concept is not generally known
        - Coke recipe
  - Other WARF IP:
    - biomaterials
    - Technicuqes and know how -- kind of like trade secretes -- WARF does deal with this
    - Data
- WARF
  - 400 new invention disclosures each year across campus
  - 50 - 50 -- life science vs engineering
  - Disclosing
    - Name
    - Identify its advantages and potential applications
    - Name contributors
    - Provide finding and public disclosure details
        - Public disclosure -- enough detail to replicate what you made to someone not bound to confidentiality
  - Meeting with WARF
    - discuss the innovation in more detail
    - What problem were you trying to solve
    - How is it different from other technologies
    - ask questions about WARF and patenting processes
    - discuss next steps
  - IP considerations
    - type of IP protection
    - breadth and strength of IP protection
    - public disclosure -- past and present
    - Stage of development
  - Liscencing considerations
    - Applications
    - Likelihood of identifying a commercial partner
    - likely return from licencing
    - Essentially a big sales process
  - Marketing and Liscencing
    - market analysis
        - size and type
        - market status

            - potential liscensees
        - License negotiation
            - exclusivity
        - Ongoing
            - Patent reimbursement
            - Royalities
    - Why liscence?
        - Bring in new technology that fits into a company's product lines
        - Sometimes companies want to acquire startups
- AI and IP
- Patents
    - Can AI invent -- no -- inventor must be person
    - Can ai assist?
        - Yes but under pannu factors
- Copyright:
    - original works of HUMAN authorship
    - Prompts are not sufficient
    - Traditional elements of authorship generated by AI? -- no
- Power is in the data!

Conclusions/action items:

Jack Sperling - Nov 20, 2024, 10:15 PM CST



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BME_300_-_Lecture_-_WARF.pdf (3.4 MB)

10-23 -- IRB

Jack Sperling - Oct 23, 2024, 2:10 PM CDT

Title: Do I need an IRB

Date: 10-23

Content by: Jack

Content:

- IRB -- institutional review board
- Unethical principles are the foundation of IRBs and the reasons we have them
    - Hepatitis studies
    - Tuskegee Syphilis study
        - 1932-1972 -- run by public health service
        - Black men who were given syphilis
        - Told them they would be cured of their "bad blood"
        - No treatment during start but were not given access to drug and continued infecting others
    - Shock experiments at Yale
        - Deception and uninformed concent
    - Nazi prisoner experiments
- Belmont principles
    - Led to respect for persons, beneficence, and justice
- Regulation for human subjects
    - Led to the creation DHHS and Common Rile
        - FDA as well
- Need to make sure that all people can benefit from the research!
- Contents of the IRB
    - 1 scientist
    - 1 non scientist
    - 1 community member who does not have ties to the institution
- At UW, 2 IRBs
    - Minimal risk research
        - Educational research, biomedical, analysis of data
        - Generally less risky and record reviews
    - Health Sciences IRB
        - Biomedical, international, any risk level
        - All FDA regulated and VA regulated research
    - Oversee UW Health, VA, UW-Madison
        - Sometimes ask other instituions to review, like with multisite study
        - Industry sponsored research -- commerical IRBS
- DOES MY PROJECT NEED AN IRB REVIEW
    - Research is a systematic investigation that is designed to develop or contribute to generalize-able knowledge
        - Need to have a plan for data collection and how you are going to collect it
        - Intent -- must be for generalizeable knowledge -- goes beyond particular group or institution that is looking into it
    - Does it involve human subjects?
        - A human subject is a living indivudal that:

      - A human subject is a living indivudal that:
        - Information or interaction from them
        - Or that generated identifiable private information and identifiable biospecimines
  - Is human research under FDA regulation?
    - Device = intended for use in diagnosis, tearment or prevention of disease
    - Research and clinical investigation = involves one or more subjects determine device safety or effectiveness
    - Subject = indivudal whose specimen is an investigational device
- Example project:
  - Making biodegradable adhesive bandage, now you are refining a protype
  - Want to find out how well the bandage performs on human skin
  - If this is a course assignment --- this isn't for research or marketing and it'll just end at class, does not need IRB because not for general knowledge
  - If this isn't a course assignment, Follow a flow chart!
    - Need to have generalizability, specific plan, and methods of getting information from participants
- Preparing for an IRB review
  - Researcher responsibilities
    - Need lots of training
    - Complete outside activities reports
- PBA components
  - Informed consent forms
  - Recruitment tools, screening scripts
  - Written assessments
  - submit via ARROW
- Because we are using UW Health Patients,
  - need to go through UW Health SMPH health operations comittee
- UROC review if needed
- SRC/PRMC review if needed
- Pre-review by IRB staff
  - Make sure the application is consistent enough
- Review at IRB meeting
  - criteria for approval
  - minimizing risks, reasonable for the outcome
  - Participant selection equitable
  - Safety monitoring
  - Confidentialiy adequate
- Either approved, modifications requested, deferred
- Post approval
  - Cannot alter the procedure
  - Submit annual continuing review
  - Report unanticipated problems
- Review:
  - IRB for beginners workshop -- sign up if needed or reach out to staffing offices
  - Recording on the IRB educational outreach
  - Reach out if needed

Conclusions/action items: Because we are using patient information to create this model, there is a slight chance we would need to go through SMPH health operations comittee, but because it is not for conveying public information and furthering knowledge. For now, we will start moving forward with deidentified patient information scans to start printing those trainers

---

Jack Sperling - Nov 20, 2024, 10:14 PM CST

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BME_300_-_Lecture_-_IRB.pdf (141 kB)

10-30 --- Navigating FDA Device Requirements

Jack Sperling - Oct 30, 2024, 2:14 PM CDT

Title: FDA Device Requirements Lecture

Date: 10/30

Content by: Jack

Content:

- What is a medical device
  - anything that is intended to improve health
  - But not through chemical or biological action
  - Intended to be extremely broad
- Certain software functions are slightly differently
- Traditional medical devices
  - MRI machines
  - IV Pumps
  - Cardiac monitors
  - Elastic bandages
  - Table you sit on for examination
- Non traditional medical devices
  - Oral hygeine rinse -- mouthwash
  - Lab developed medical tests -- like Cologuard
  - Smart watches and medical mobile apps
  - Software -- CT/MRI reading
- Software as a Medical Device (SaMD)
  - Software in a medical device is stuff inside CT machine -- falls under CT
  - SaMD has its own regulation and status
- Traditional or non traditional --- wheelchair tank
  - Is a medical device
  - There are medical versions and non medical versions
  - If it is medical device -- can get medicare and medicaid to pay for it
- FDA Regulations
  - Once you identify something as a medical device --- need lots of regulation
  - Some apply from the day you say I am going to make this device until you stop
  - Others start only when manufacturing or actively producing.
- Device Classification Overview
  - US uses 3 classes
    - Broken down by risk
    - What is required for marketing submission and regulatory controls
  - If you want to expand in the future, different countries may have different classifications
- General controls
  - general labeling
  - Good manufacturing practice
  - registration and listing
  - Event reporting requirements
  - Found all over code of regulations!
- Special controls
  - Performance standards
  - special labeling requirements
  - Post market surveillance
  - potential data requirements
- Pre-market approval
  - data to show safety and effectiveness
- Class 1 Devices:
  - Low risk level
  - Self registration and listing with the FDA
  - Examples include bandages and manual toothbrushes
- Class 2 Devices:
  - Higher risk than Class 1

- Submission of 501K may be needed to show substantial equivalance
- Integrated glucose monitoring systems, non invasive BP monitor, catheter are examples
- Class 3 Devices:
  - Sustain or support life or implanted
  - 10% of all devices in market
  - Must have comprehensive FDA review of safety and effectiveness data before marketing
  - Hip joints, heart valves, and implantable pacemakers are examples
- Market Submission Types
  - 510K exempt
    - Doesn't require 510k
    - Still need to list your device though
    - $8000 per year
  - 510k premarket notification
    - Outlines device, here is similar device, here is why they are similar, here is what's different, here's why the differences don't matter, please let me market :)
    - This is NOT APPROVAL!
    - Devices generally get more complicated and slowly drift farther and farther from original submission
  - Premarket approval
    - FDA comes and inspect you
    - Determines if device is safe and effective
    - Then can legally market it
  - DeNovo Classification
    - if it doesn't look like or function as any other device
    - FDA tells you which class it is
- Want to get your device in the lowest class possible!!!!
  - 53% in class 2
  - 10% in class 3
  - Rest in class 1
- How to classify a medical device?
  - Can search database to find like items
  - Go to FDA's website and search product classification
  - Do a lot of searches
  - Product Code
    - Gives definition and classification
    - Submission type
    - GMP requirements
    - Recognized consensus and standards
  - Then you can search for a regulation number to see all similar products with the same regulation number
  - Key points for classification
    - Depends on intended use and indications for use
      - General purpose of the device
      - Specify which conditions and populations or situations where device is intended to be used
  - Once you've identified your medical device, you can look up the 510k database and see what the documents were and what the applicants were
  - Use the resources the FDA makes available
  - ALSO PMA devices
    - can search for applicant or device name
    - Different documents about their approval and study
- SaMD
  - Starting to trickle down to general database
  - AI database and VR medical devices
  - Very new so just look around :)
- Quality Management Systems
  - Document control requirements
  - Audit trails
  - No one did anything incorrectly or anything went sideways
  - Labeling and records requirements
  - Document why you made these decisions, what factors, and who signed on it
  - Design controls --- these are most important
    - Planning of device
    - Risk assessments
    - Design control processes
- Risk assessments important for clinical trials you want to conduct

    - What do you expect vs what you don't expect
    - How critical are they
    - Risk matrix with all risks
        - How do you mitigate and why you don't mitigate it
- Clinical Investigations
    - Parts 50/56
    - Part 812
- Safety and Effectiveness
    - Not defined in FDA Guidance
    - Very broad
- Applying Device Regulations
- IDE Exemptions
    - Non invasive
- Significant risk vs Non significant risk

Conclusions/action items: Because our device does not need to have direct contact with patients and is just used as a training aid, we probably do not need to register this with the FDA and should mostly not have any problems with our product in terms of FDA regulation

Jack Sperling - Nov 20, 2024, 10:14 PM CST

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BME_300_-_Lecture_-_FDA.pdf (3 MB)

11-6 -- Therapeutic Product Development

Jack Sperling - Nov 06, 2024, 1:22 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

Jack Sperling - Nov 20, 2024, 10:12 PM CST

I was having difficulty editing this template so I had to make a new entry below this file. I do not want to change the name now to mess up the time stamps, but I wanted to let you know why the names are messed up

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Jack Sperling - Nov 20, 2024, 10:13 PM CST

Download

BME_300_-_Lecture_-_FDA_Regulation_for_Cell_and_Gene_Therapy_1_.pdf (2.21 MB)

USE THIS 2014/11/03-Template - Copy

Jack Sperling - Nov 06, 2024, 2:07 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Theraputic Device regulatory management

- Understand regulations, quality, and jobs that revolve around this
- Regulatory Toolkit
- FDA Structure and Advanced Therapeutics
    - Examples are genome editing, gene delivery, and cell therapy
    - Sub components of the FDA: Devices, Drugs, and Biologic products
    - IDE is what you apply for if you want to do clinical studies with a clinical device
    - Once you're through investigation device studies, ask FDA to approve device for marketing
        - Asking to say safe and effective
        - PMA or 510(k) approval
    - Drug -- Center for Drug Evaluation
        - Investigation New Drug --- can start clinical trials with this
        - New Drug Application -- if the investigation goes well now FDA can approve drug
    - Biological Evaluation and Reserch
        - Invenstigational New Drug --- once complete, submit bla
        - Biological Licence Agreement
    - Drugs are synthetic
    - Biologics -- living thing or produced by a living thing
    - Regulated differently because processes to produce are very different
- FDA begins with US laws
    - Define how the molecules are regulated
        - Like FD&C -- gives FDA oversight and responsibility
        - CURES act --- speeds up development for innovative drugs or biologics to treat people faster
        - CARES -- gave FDA responsibility to manage covid responses
    - Those laws influence regulations
        - Made by FDA
        - Guidance is made to help understand the regulations
        - Helps reduce the money spent on studies that the FDA won't accept
- Designations for human cell and tissue products (HCT)
    - 351 vs 361 product
    - 361 are minimal manipulated products -- take blood transfusion from one pt and transfuse to another patient
        - Or take liposuction fat and inject it somewhere as bulking agent
        - Don;t have to go through safe and effective trials ----- already considered safe and using for essentially same use
    - 351 --- bone marrow sample from you, isolate cell type, deliver gene to cell type, then put super cell back into body
        - This is NOT minimal maniupulation
        - Will have safety and efficacy concerns
        - Regulated like traditional biologic
        - Must demonstrate safe and effective use
        - Novel design and high barrier to entry
        - Randomized control trial
        - Marketing exclusivity -- 12 years
        - Every decision to call it 351 vs 361 is a risk
- Product Development Life Cycle
    - each stage is risky
    - Extremely important to distinguish studies between critical path vs good research projects
- Developing Target Product Profile
    - This is your product vision
    - When to use product, how and why
    - Pt identification/indication, efficacy profile, safety profile
    - Is this medically and commercially compelling
    - Contract research or manufacturing organizations want the TPP to get what you want out of it
    - Investors also!
    - Will payers reimburse for it?
- Considerations when Developing a 351-regulated CGT
    - essentially every step costs lots of money!!!!!!
    - start with pilot toxicology studies
        - the lab that is running this study doesn't need to be perfect right now
    - CMC development --- chemistry and manufacturing controls --- this also starts at the beginning
    - Need to demonstrate manufacturing consistency before phase 1
    - During all this, have early meeting with FDA to figure out best way to evaluate this product
        - The interact meeting is less value than pre-ind and ind submission

        - Ready to do clinical trials
    - Need to anticipate FDA moves and plan
- Quality --- what does quality mean for industry
    - Quality management system
    - Ensuring the controlled environment
        - Clean rooms and gowns
        - Different than university environment
    - Quality exercise

    - Lots of potential for problems or hazards
    - Then start figuring out the "do next for next time"
- Career Options
    - Process in industry and R&D
    - Opens lots of jobs if you're good at it
    - Also there is quality, compliance and regulatory!

Conclusions/action items: Overall, our product is not classified as a biologic or drug, so we do not need to follow these regulations. These are still great to learn about

---

Jack Sperling - Nov 06, 2024, 1:42 PM CST

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BME_300_-_Lecture_-_FDA_Regulation_for_Cell_and_Gene_Therapy.pdf (2.21 MB)

Jack Sperling - Dec 11, 2024, 4:31 PM CST

Lab archives was giving me troubles day of so I had to copy the notes to this file but forgot to change the title. I don't want to mess up the time stamp so I am leaving it be, but I wanted to explain why

11/13 -- Medical Device Innovation

Jack Sperling - Nov 13, 2024, 2:10 PM CST

Title: Medical Device Innovation

Date: 11/13

Content by: Jack

Content:

- Medical Device Innovation From Prototype to Commercial Clinical use
- Important steps
    - Testing
        - Need an IRB protocol to test
        - University based IRB is for here
        - Private IRB companies also exist
    - Now Regulatory Process
        - Device Classifications
        - Try to do 510k is easiest to prove that another legally marketed device has the same purpose
        - 510k de novo process --- FDA can create a new category for you
        - May also try to get the Humanitarian device exemption
            - Easy to get through because requires least proof to help few people quickly with specific problem
        - This takes a lot of time!!!!
            - Double your estimate of time
            - FDA has rules about how fast they respond, but every time they ask a question, the clock restarts
        - Breakthrough Device Program
            - Expedited access program
                - expedite development and prioritized review of device to treat irreversibly or debilitating disease
            - Doesn't mean it is fully done, still needs lots of research
    - Reimbursement or Financial Incentives OR even Sales and generating profit

This is the main goal of the lecture

- New medical technology --- who buys it?
    - Medical device needs to please champion physician
    - Also follow rules for the supply department for the hospital
    - Does it interact with the EHR and follow rules
    - Patient safety or impacts for other departments
    - Wholistic review -- decisions aren't made alone
- General steps from approval to adoption
    - Once FDA clears it, now we need a sales idea!
    - WHAT CODES DO THESE FALL UNDER
        - CPT is common
            - Irrigate wound, take BP, etc
        - Eventially a coder will use these to submit for reimbursement
    - Just because there are codes describing your technology doesn't mean you'll get money from it
    - Medicare!
        - They cover lots of people
        - Private insurance follows what Medicare chooses
    - Understand standard practice of utilizing vs not utilizing this device
        - Refer to clinical practice guidlines
    - If our idea isn't standard practice, try and make that happen
    - Look at regional buying groups and what contracts there are
    - Physicians don't often know, ordering through hospital's purchasing organization
- Some hopsitals look at all equiptment or some just expensive new technology
    - Whole hospital decision making step
- Product evaluation
    - More the clinician can use it, the more internal data to help sell it

  - Even small implants may have expiration date
- We've developed this idea, FDA cleared, etc THIS ISN'T THE FINISH LINE!
- Think about what physician is doing
  - How is this activity done without you device?
    - What codes? Do patients have choice? Whose experiece are you improving?
  - Who should we focus on?
    - Improvement of patient care can look very different
      - Davinci robot helps surgeons
    - Find where that value is and for whom
- Can our device still fit withinside the new standardized care to reduce cost?
  - COLOGUARD was able to go to the guidlines people and got the dna stool sample and said that this is not experimental, this should be happen all the time
- Moving from fee for service to value based healthcare
- Capitance healthcare plan
  - Medicare ---- given hopsital lump sum to care for a year
    - If spend less, earn money
  - Different incentives for health insurance

- Hospital New Product Adoption Process
  - Find physician to take it through the process
  - Review Process
  - Technology Assessment
  - C-Suite strategy
    - CEO, CTO, CIO -- ultimately have final decision
  - Final Decision
  - Trial, Evaluation, and Metrics
    - Some may ask for this before making final decision
- Value drivers
  - Economic
  - Clinical
  - Mission Impact
    - Might also just want to be first to a space
- DATA is very strong at convincing people!
  - Think about metrics of success and how to prove them to the company
- Existance of medical codes do not equal financially favorable!
  - If there is a predicate, how is it reimburased
  - CMS makes public for what they reimburse for different procedures
  - If medical device goes into DRG (the big lump sum), may get pushback
    - But if increase cost but decrease stay length, thats great
  - Getting at the money isn't always easily, but need to figure out how it fits to save money overall
  - Payer mix:
    - medicare is poorest
    - Capitated payment -- value based
    - Ortho -- lucrative because still 50-60 that are covered under insurance
    - Peds -- covered under parent's private insurance
  - Understand potential reimbursement path
    - Is it group of services or point of care type activity
    - Am I direct replacement or an add on?
    - Is my drug covered under a good discount?
    - Bring in regulatory consultant!!!!
  - Start with the patient and see their pathway
    - Then clinician
    - See pain points or where to improve care
    - what payment codes?
    - Tell me process about how new products get brought into the hopsital
  - Once you figure this out, now make a company and now successs and sales being :)
- Look at some of these resources
  - D2P
    - Mentoring
    - startups
    - Funding opportunities
      - For WARF technologies

    - innovate.wisc.edu
    - Gener8tor
- Innovation journey
    - Get out of string mess and on top successful pathway
- Next steps:
    - Speak with a mentor!
    - Apply to a program!

Conclusions/action items:

Jack Sperling - Nov 20, 2024, 10:12 PM CST

Download

BME_300_-_Lecture_-_D2P.pdf (1.87 MB)

Tong Lecture

Jack Sperling - Nov 15, 2024, 12:56 PM CST

Title: Starting from scratch: how we built Tasso

Date:

Content by:

Present:

Goals:

Content:

- How to start a buisness:
- Tasso:
  - Painless at home blood collection technology
  - Easy to collect blood and send in blood to lab for analysis
- Both founders don't have conventional background
  - Walk anywhere on campus and anyone will help you
- Simple idea:
  - People don't like their blood drawn!
  - 10B blood tests per year, 1B blood draws
- Future of Healthcare is at the home!
  - Just like amazon, netflix, doordash
  - Nobody wants to do anything outside their house!
  - Same thing, now drive and get stabbed with neddle!
    - Need it to be consumer friendly and transport it
- Start prototyping
  - Tight on expenses but build prototypes
  - Scraped together whatever we could to prototype
  - Asked around, who can help?
    - Law and Entrepeneaur clinic!
      - Set up core documents
      - Wrote first patent
- Now some funding
  - DARPA, DOD, and NIH
  - Write grants all the time
  - Flush out tech without venture money
  - Fit technology with the need present
    - IE some people didn't have cars in rural areas
- Evolution of the technology
  - Make a product better
  - Kill product when needed
    - Be careful though, consumers won't be happy
    - Understand the right reasons
  - Main idea is to make open fluidic chambers
  - PHD research was applied to product
  - But not need more research about capilary mapping and vacuums

  - With the vacuum, allows to triple amount of blood removed
- Finding key customer
  - You can trick someone to do a lancet once, but not twice!
    - Bring this person in and make them your chief marketing officer
  - need a champion --- someone pulling the company forward!
  - Leadership in pharma pulled much of the success
  - Followed this person to conference and talk with everyone they did
- Once converted the pharma industry
  - Move to other industries
  - USADA wanted antidoping blood but everyone hates needles
  - UFC and MLB and UFC all use tasso for anti doping
- DROWNING IN A SEA OF POSSIBILITY
  - Identify one problem for your champion
  - If you solve this problem can it scale?
  - If you make it work, that champion will be your best person spreading info
  - Another one was antidoping --- we need this one thing, figure this out!
    - Then go from there
- Scaling up!
  - lessons in quality, culture, and HR
  - Derisking technology and filling out grants
  - Continual iteration!
  - 2018 Venture financing
  - 2020 was hard becuase middle of financing
    - Everyone cancelled everything
  - Covid antibodies needed to be tested
    - Within 2 months, so many people now needing this for at home testing!
  - Figure out the core steps that lead to good quality
    - QUALITY IS KEY
    - One customer will kill you!
  - Other piece is culture side
    - Small feel and everyone collaborative
    - Now, how do we make 300k a month?
    - Now you need to figure out culture and have everyone understand mission
  - How can you get small scale to larger where 100 people make decsions
- FDA
  - Class 2 -- IVD (2 million dollar clinical trial)
  - Class 1
  - Turns out, lancet collects blood and we ARE NOT DOING analysis, so try to find predicate
  - Sold two things seperate --- tube is fine, now lancet is class 1 so super easy
  - Read the labels --- easy to over analyze what regulators say they want to do
    - Try to find good predicates that work well and make it easier to get it through FDA
  - Find agressive person who knows what to do haha
- Summarize:
  - If you have idea, go for it
  - Figure it out along the way, so many people here to help
  - Just go for it and try it
  - Definately going to hit roadblocks
    - Focus on core tennants, some one rpboelm
    - Find people to help you through
  - Tasso is italian for badger
- We need to make sure to respect the people who support you

- Signficant others and other important people

Conclusions/action items:

11-20 -- New Product Development

Jack Sperling - Nov 20, 2024, 2:09 PM CST

Title: How New Product Development Works in the Medical Device Industry

Date: 11/20

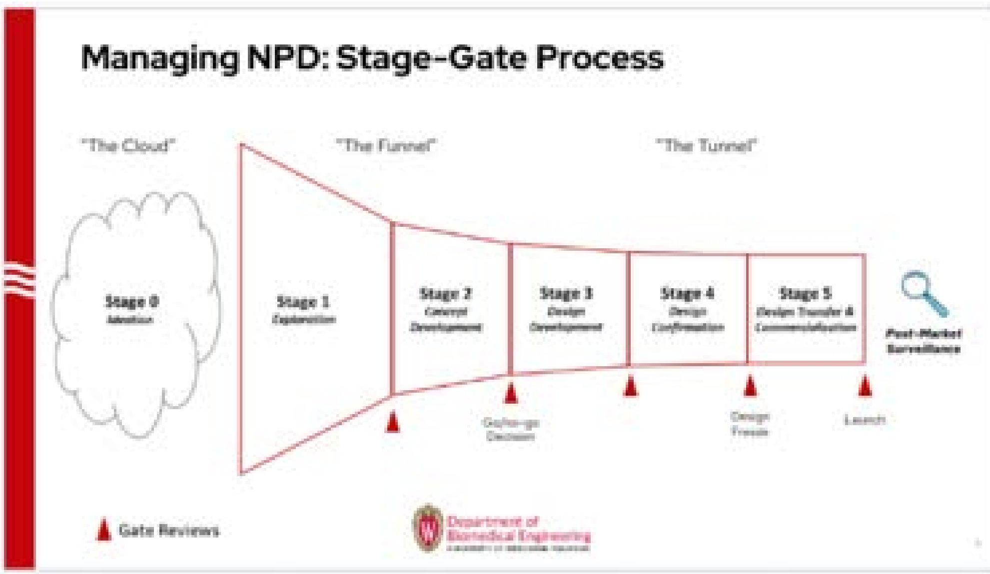
Content by: Jack

Present: Jack

Goals:

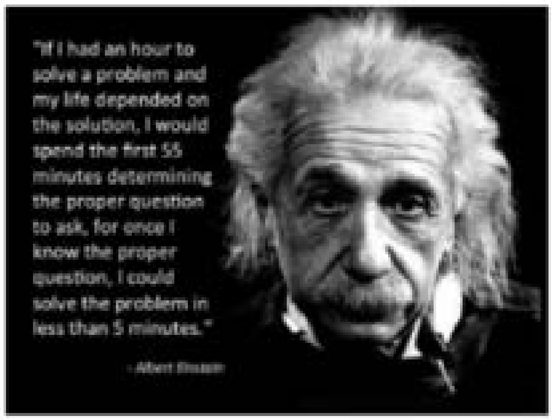
Content:

- Director of Office of Corporate Relations
- Spent 25 years in industries
- Understand how new products are selected in companies
  - How are they selected and priotizized
  - managed and resourced
  - and how to get through the hurdles and barriers
- NPD in med device industry
  - Very expensive
  - Regulated by the FDA
  - Document and prove you meet your specs
  - Speed to market is vital
- Selecting and prioritizing products
  - How will the buisness sustain itself
  - Then how do we prioritize projects to support the next few years
  - Then allocate budget
  - Stretegy, product portfolio review, project review, resource allocation
- Types of NPD
  - Line extensions -- additional sizes
  - Produce imrpovement
  - New to company -- not new to the market but new to company
  - New to world -- first ever device
  - Top to bottom is increasing risk, cost, and time to market
- Team members
  - Highly interdisciplinary team
    - Legal
    - Finance
    - Sales rep
    - Manufacturing engineer
    - QA
    - Project management
    - Product Dev Engr
    - marketing
    - Packaging engineer
- Stage-gate process: How companies manage their process
  - Stage 0: Ideation
    - Think of hundreds of ideas that you have of problems

        - Stickinotes and whiteboard ideas
    - Stage 1: Exploration
        - Tone down to 8-10 that fit company and can make money
        - Not indepth
    - Stage 2: Concept development
        - Foam models and renderings
        - Find 1 product to continue
    - Stage 3: Design Development
        - Engineer makes it work
        - Regulatory documentation
    - Stage 4: Design Confirmation
        - Verification and validation
        - Regulatory documentation
        - FDA submission
    - Stage 5: Design Transfer & Commercialization
    - The Cloud, The Funnel, The Tunnel
        - 

    - Limits financial risk
- Case Study! Fluid management solutions for high volume cases (>8L)
    - Cardinal: Used cascading canisters to hold all of this fluid
    - Stryker: Found this problem, made their own vacuum instead of hospital vacuum
        - During procedure, collect up to 20L of fluid
        - Cap off manifold and throw it out
        - Then dock in docking station and empties fluid out then sprays inside with cleaner
    - Solution!
        - ORwell Fluid Mangagement system
        - Cleaner -- reduce contamination
        - Simpler -- allows just a couple buttons
- Stage 0:
    - Choosing area of opportunity
    - Went to customers and wanted to hear what is going on
    - GO OUT AND TALK AND OBSERVE!
    - Heard about competitive product
        - Hear what the problems are for the competitive product
    - Now make hundreds of ideas
- Stage 1: Exploration
    - General Concepts

- 

- SPEND THE TIME TO ASK QUESTIONS FROM CUSTOMERS AND WHY!
- 

- Stage 2: Design Conception:
  - Turn these ideas into 1 leading concept
  - Keep working with customers to narrow down what they want
  - Forecasting products, bring sales team in
  - IP side and examination
    - Patent ability and freedom to operate
  - go/no go decision
  - Need to differentiate from the competition and is a good fit with the company manufacturing and other ideas
- Stage 3: Design Development
  - Now actually make it work :)
  - This case, electromechanical device
  - How to get fluid out of plastic bag
  - Confirm regulatory pathway
  - Start making technical drawings to match visual design
- Design Control
  - DOCUMENATION!
  - Mandatory for class 2 and 3
  - For europe, need for every class of device
  - Helps you document everything
    - Like original customer needs
    - Then into design specs
    - Then those are inputs
      - Specific requirements about pressure and volume

    - Tightly alligned with Risk Management
- Stage 4: Design Confirmation
    - 80-90% done with design
    - Verification -- did you design the product correctly
        - Did it hold certain pressure
        - Noise threshold
    - Validation -- did you design the correct product
        - Clinical interactions
        - Does it solve their problems
    - Drawings, models, manufacturing engineers
        - Manufactiring engineers crutial here
        - How are we going to make it???
    - Freeze design at the end of this stage
    - With all test info, file with FDA now
- Case study:
    - Mimic procedure
    - Disposal station was hardest to figure out
    - Plunger pierced through foil and applied vacuum
- Stage 5: Design Transfer and Commercialization
    - Complete remaining testing
    - Build molts, assembly, and test equiptment
    - Put in place service plan!
        - Need instalation
    - Finalize go to market strategy and start limited release
- Post Market Surveillance
    - 4-6 months project teams report out to stakeholders
    - How is customer experience
    - How is sales cycle
    - How do we track complaints
    - 8 months after they launched, stryker launched second design
    - Stryker had smaller consumable
    - Stryker decreased the price of their consumable right before launching
    - Unfortunately removed product from market at 8 months
- Summary:
    - Very hard to manufacture products
    - Expesnive and complex!
    - Collaborative effort
    - Just because you have great product doesn't mean great product success
    - Good product design and development is necessary for commercial success but not sufficient!

Conclusions/action items: Just making a great product does not mean your company will make money and it will be commercial success! Ensuring you are focused on pleasing your customers and fixing their problem while remaining commercially viable by working closely with sales and marketing. Combining this with marketing analysis ensures the commercial success of the product. Unless of course, Strkyer comes in and takes your product out of market because they made something better :(

Jack Sperling - Nov 20, 2024, 2:07 PM CST

Download

BME_300_-_Lecture_-_Russ_Johnson.pdf (1.95 MB)

12/10/24 - Next Steps: Additional Software to Research for Imaging Group

Jack Sperling - Dec 11, 2024, 5:06 PM CST

Title: Additional Software to Research for Future Work on this Project

Date: 12/10/24

Content by: Jack

Present: Jack

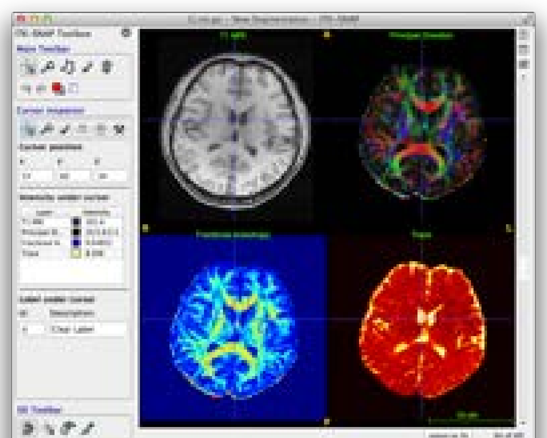
Goals: Identify next steps for the Imaging side of the project if the team or project continues to another semester

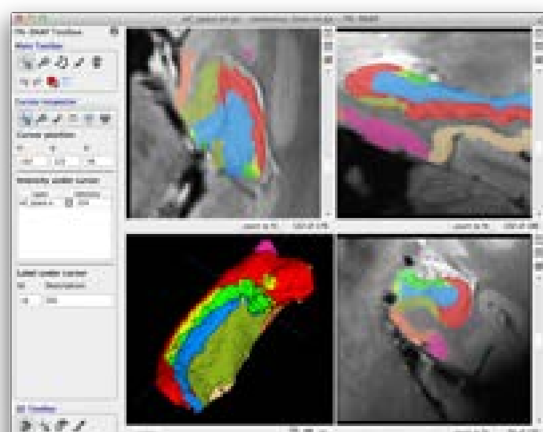
Content:

- Throughout communication with the client and any other professionals that were looped into his emails throughout the semester combined with personal experiences and information from a fellow BME Design Team, I put this list of software together that should allow for an easier time at segmenting, preparing, and arranging the airway and facial feature models to assist in complete model creation.

1. ITK-snap: http://www.itksnap.org/pmwiki/pmwiki.php

- ITK-snap provides "semi-automatic segmentation using active contour methods"
- Can also have manual input added to better focus the model's definition
- Appears to be a better, free version of 3DSlicer
- Luke from MedInstitute suggested that this software may work as he said he used it personally
- Documentation suggests that this works well for neurology or hematology/oncology but unsure about respiratory or circulatory application

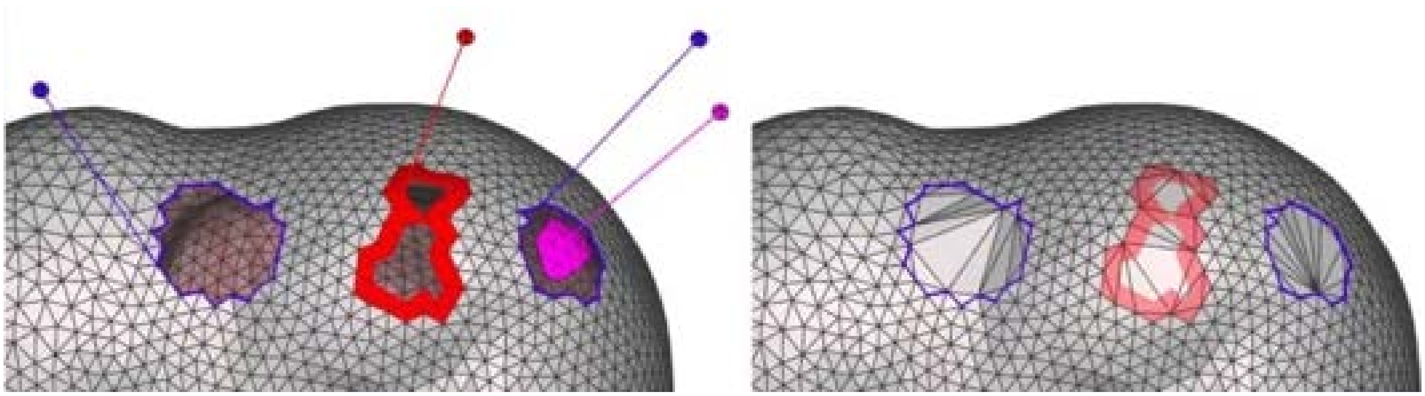


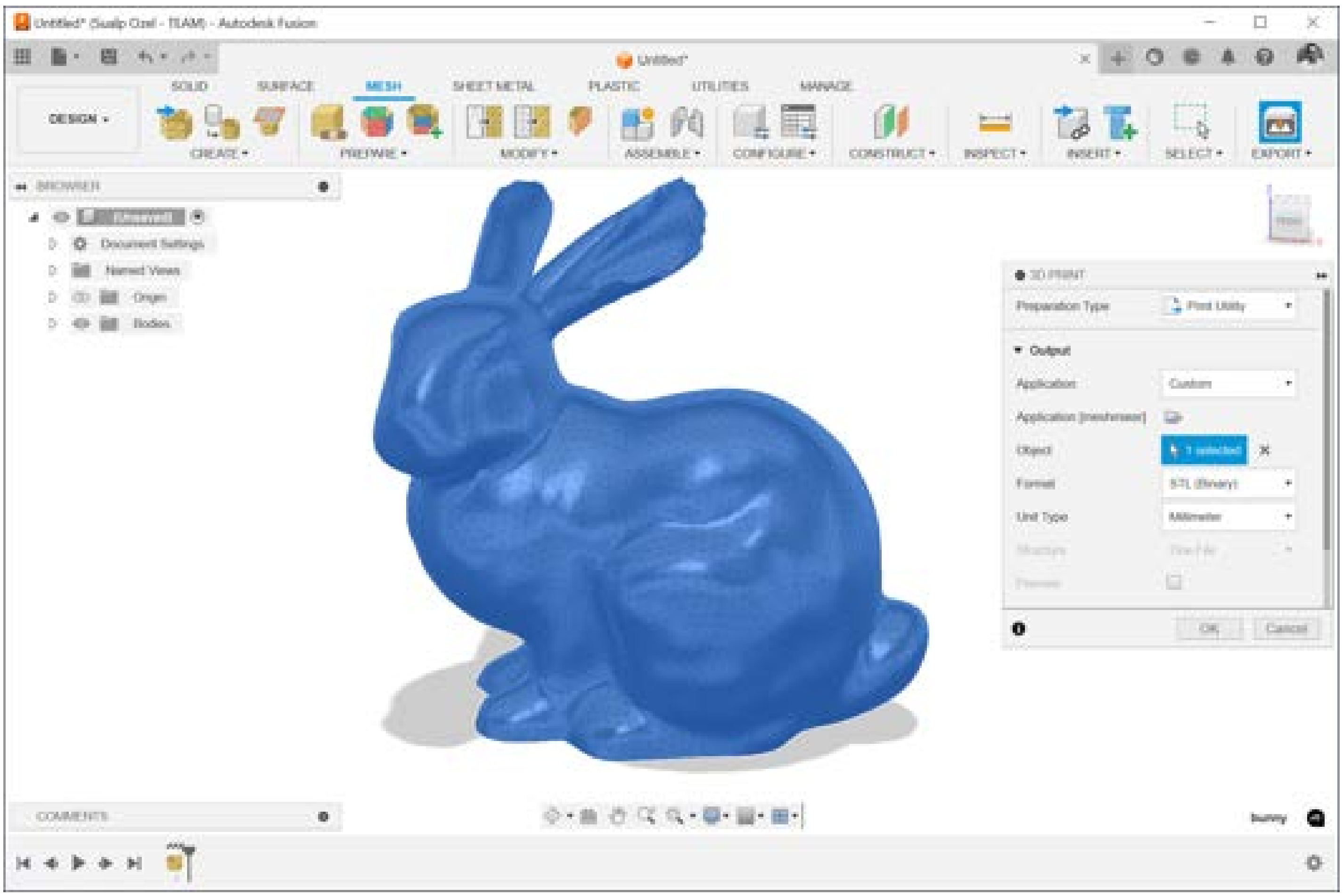


2. Meshmixer by Autodesk: https://apps.autodesk.com/FUSION/en/Detail/Index?id=4108920185261935100&appLang=en&os=Win64

- Focused on editing STL mesh which conventional CAD software (SOLIDWORKS, OnShape, Fusion) tend to struggle with

- Follows Autodesk general format so users familiar with Fusion will have easier time picking up subtle details
- Lots of tools for remeshing and mesh simplificiation
  - This caused many problems in OnShape and we originally used BambuSlicer to try and simplify meshes but this might've been a better option
- Massive user base and custom made introductions widely available
- Free for education users
- Used and recommended by the Rising Against Cancer BME Design Group linked above

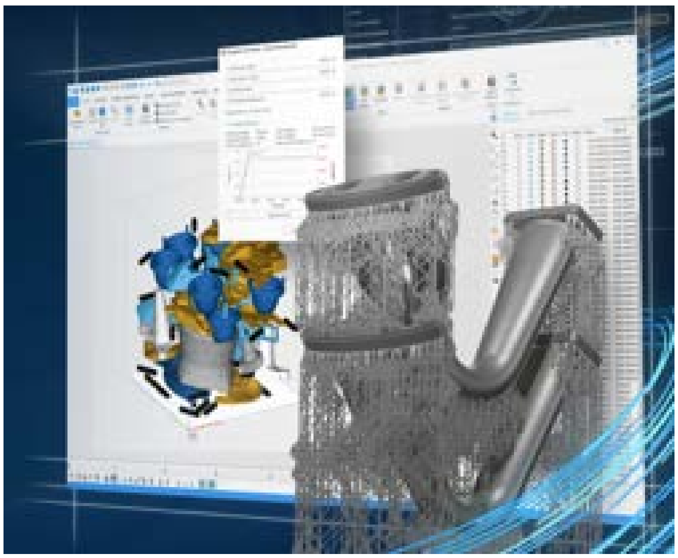
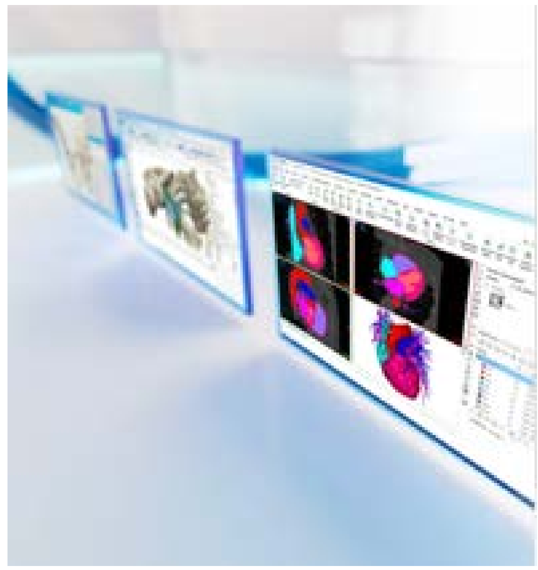




3. Mimics and Magics from Materialise:

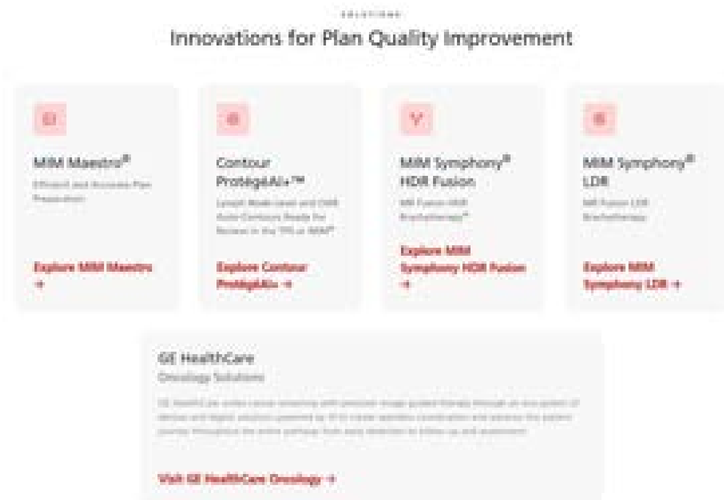
- Ai-enabled auto-segmentation tools trained on medical images that were used to plan for procedures
- Used by many large hospitals and educational institutions & industry standard medical slicing software
- Expensive and UW does not own licence
  - Client unable to find out if UW-Health has access to this software

- Mimics --> focused on segmentation of CT and MRI images
- Magics --> 3D printing and preparation software
  - Appears to be like Meshmixer but proprietary and tightly integrated with Mimics
  - Has easy to use tools that reduce repetitive setup and printing tasks -- this would be incredibly helpful for our client
  - Sort of like program and repeat for 3D printing processing and preparing
- Used in many journal articles and highly regarded in this article from Dr. P: https://link.springer.com/article/10.1186/s41205-017-0011-6
- **Now having a retrospective look on the semester, having access to this software would have been instrumental in the speeding up, automation, and innovation of new ways to print the airways depicted in the scans**
- **This should be a HIGH PRIORITY for the near future!**

4. Mim Maestro (a GE Healthcare Company): https://www.mimsoftware.com/solutions/radiation-oncology

- Focused on Radiation Oncology as well as Radiology & Nuclear Medicine
  - Ideally this means that the software is focused on soft tissue recognition compared to bones
- Utilizes AI to create "Auto-Contours" which are very similar to segmentations
- The base of this software is cancer screening and image guided therapy
  - Recommended by Rising Against Cancer group
- Very little information provided on website, but reaching out and discussing the software available would be highly beneficial



Conclusions/action items: The team has made extraordinary progress this semester despite many imaging setbacks. Utilizing 3DSlicer's auto-segmentation tools to begin processing CT scans and creating two potential methods for printing the segmented airways is phenominal. If the client is able to provide the team actual patient airways if the project continues, this document outlines the future work and software that will be required to segment the imaging to properly create the models required for the trainer. The first priority should the Materialise suite as this is highly regarded by both BME Design teams and clinicians writing reserach articles. Unfortunately, the client did not know anyone in Radiology, and the team did not push hard enough to find out this information. This should be top priority if this project is to continue.

9-8-24 Complications of Intubation

NATHAN KLAUCK - Sep 20, 2024, 12:38 PM CDT

Title: Complications of Intubation in the critically ill

Date: 9-8-24

Content by: Nathan Klauck

Present: N/A

Goals: Learn more about common complications associated with intubation

Search Term: Complications with intubation

Link: file:///Users/nathanklauck/Downloads/s00134-008-1205-6.pdf

Content:

In this study 10% of the intubations required 10 or more minutes

Difficult intubation occurred in 7% of the tests

Chance of complication was 39%, including severe hypoxemia (19.1%), severe hypotension (9.6%), esophageal intubation (7.4%) and frank aspiration (5.9%)

ICU and hospital mortality were 15.4 and 29.4%

additional attempts at intubation increase risk of complication

Some complications include esophageal intubation, aspiration, hypoxemia, severe hypotension

Non-experts require significantly more attempts at intubation

Conclusions/action items:

Multiple attempts at intubation increase risks, and since non-experts typically take more attempts at intubation on average we should attempt to design an accurate airway trainer. Our trainers should attempt to incorporate some of the greater risks listed in this study including possibly esophageal intubation and aspiration.

9-10-24 Tracheal Intubation

NATHAN KLAUCK - Sep 20, 2024, 12:39 PM CDT

Title: Tracheal Intubation

Date: 9-10-24

Content by: Nathan Klauck

Present: N/A

Goals: Learn more about the process of intubation

Search Term: How Intubation works

Link: https://www.sciencedirect.com/science/article/abs/pii/S1472029922001825

Content:

Intubation is conducted both to enable o2 delivery to the lungs as well as to remove co2 from the lungs

Most reliable method of maintaining airway under anaesthesia and for protecting against aspiration

Placed by visualization of the glottis or through indirect laryngoscopy (videolaryngoscope)

Monitored after placement via capnography

cricothyrotomy is an alternative method of intubation

the ET tube has a cuff that inflates beneath the vocal cords to seal airway

indicated for an obstructed upper airway

It is recommended to to examine the pt history before attempts at intubation

The Miller and Macintosh laryngoscopes have been the main design for use in intubations since the 1940s

pt should be positioned supine, but be able to be moved to a Trendelenburg position should the pt vomit

Conclusions/action items:

Intubation involves various methodologies and procedures. It would be nice to design the model so that the model appears visually accurate throughout so that videolaryngoscope can be used on the trainer. Additionally designing the model to incorporate a method of practice for cricothyrotomy might be nice. Design must also be made to allow for the cuff to inflate and do its job.

9-16-24 Education and Training in Airway Management

NATHAN KLAUCK - Sep 20, 2024, 12:39 PM CDT

Title: Education and Training in airway management

Date: 9-16-24

Content by: Nathan Klauck

Present: N/A

Goals: Learn more about how airway management and intubation is taught

Search Term: Use of Airway Trainer

Link: https://www.sciencedirect.com/science/article/abs/pii/S1521689605000509?casa_token=4LQRsg18PowAAAAA:PmsDh7DcVw1VJXxMOwE_OZPCR13qP3egyIRNMuz0PpzwEnb-L1haRpWaDZ-thu5B1391elD9HA

Content:

Less time is being spent in the operating room by trainees

The operating room is where trainees are able to practice difficult airways

Training outside the operating room is becoming more crucial

Airway management skills used to only be development in situations where a training opportunity arose

training residents in the OR is becoming less practical

Conclusions/action items:

Trainees would benefit from access to training methods outside the OR. This seems like exactly what are design is targeting. Perhaps by looking further into what training opportunities arose in the OR we could find good conditions to base our design off of.

09/26/24 3D Bioprinted Artificial Trachea

NATHAN KLAUCK - Sep 29, 2024, 2:49 PM CDT

Title: Experimental Tracheal Replacement Using 3-dimensional Bioprinted Artificial Trachea with Autologous Epithelial Cells and Chondrocytes

Date: 09/26/24

Content by: Nathan Klauck

Present: N/A

Goals:

Determine materials with properties similar to that of a human trachea, or possible more about the properties of the human trachea

Search Term:

material similar to that of human trachea

Link:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375946/

Citation:

J.-H. Park et al., "Experimental Tracheal Replacement Using 3-dimensional Bioprinted Artificial Trachea with Autologous Epithelial Cells and Chondrocytes," Sci Rep, vol. 9, p. 2103, Feb. 2019, doi: 10.1038/s41598-019-38565-z.

Content:

-Method used **Polycaprolactone (PCL) and hydrogel** were used with nasal epithelial and auricular cartilage cells to replicate trachea

-> seems to be used as more of a frame work then an actual replacement (which makes sense)

-framework (of this study) still designed to have strength and flexibility of normal trachea (worth further reading)

-one method of replicating a trachea involved cylindrical implants but failed due to bio-compatibility (not an issue for our applications)

->https://pubmed.ncbi.nlm.nih.gov/13770279/

->https://pubmed.ncbi.nlm.nih.gov/4267428/

-->**Silastic** tracheal bifurcation

-PCL is biodegradable, maybe not a great choice, but has similar strengths to tracheal cartilage, along with **polyglycolic acid (PGA), polylactic acid (PLA), and poly(lactic-co-glycolic) acid (PLGA)** (also biodegradable

->suggest further research into the properties of these materials due to their similarity to tracheal cartilage

Loading [MathJax]/extensions/Safe.js

-**Living cells added to hydrogel**, hydrogel therefore was not likely used for its properties (understandable)

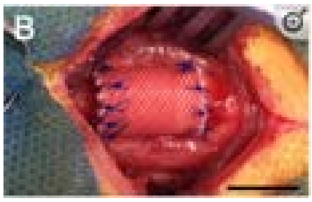
-tests conducted on rabbits, still have applications for humans

-**cartilage and epithelium** play a large role in the function of the trachea

-**human tracheal cartilage = 16.92 ± 8.76 MPa (Young's Modulus)**

->https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5456771/

-Made use of a 3D bio-printer, not very applicable to our design but worth mentioning



artificial trachea developed by this group placed in bunny/rabbit/whatever

Conclusions/action items:

Look into the biodegradable materials used in the construction of this framework (**PCL, PGA, PLA, PLGA**) as they have properties similar to that of a human trachea. Additional look further into the meaning of **16.92 ± 8.76 MPa**, as it seems to be a valuable descriptor of the human trachea. Lastly, look more into the material referenced in the papers cited which mention **Silastic** tracheal bifurcation

NATHAN KLAUCK - Sep 27, 2024, 2:00 PM CDT

-In advisor meeting mention PDMS

-Formlabs Flexible 80A

09/26/24 Mechanical Characterization of Human Trachea

NATHAN KLAUCK - Sep 27, 2024, 1:23 AM CDT

Title: Mechanical Characterization and Constitutive Modeling of Human Trachea: Age and Gender Dependency

Date: 09/26/24

Content by: Nathan Klauck

Present: N/A

Goals: Determine mechanical properties of trachea

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5456771/

Citation:

F. Safshekan, M. Tafazzoli-Shadpour, M. Abdouss, and M. B. Shadmehr, “Mechanical Characterization and Constitutive Modeling of Human Trachea: Age and Gender Dependency,” Materials (Basel), vol. 9, no. 6, p. 456, Jun. 2016, doi: 10.3390/ma9060456.

Content:

-Elastic modulus of human tracheal cartilage was calculated in this study to be **16.92 ± 8.76 MPa**

-trachea tended to be more stiff in older populations

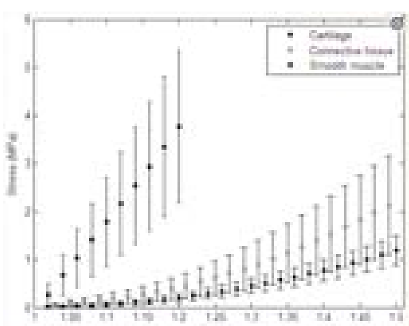
-The human trachea is made of **18 to 22 C-shaped cartilaginous rings**

->these are incomplete in the posterior region of the trachea and completed by the trachealis muscle

-other tissues of interest in the trachea include **adventitia membrane**(outermost layer) and mucosa and submucosa membranes (most likely not important to us)

-certain conditions can result in reduction in the diameter of the trachea of reduction in wall stiffness

-graph of different tracheal components under force until a stretch of 20%



->**16.92 ± 8.76 MPa**

-Different Hyper-elastic models

Model	Cartilage	Smooth Muscle	Connective Tissue
Mooney-Rivlin	0.999	0.999	0.999
Yeoh	0.999	1.000	1.000
Fung	0.999	0.988	0.995
Neo-Hookean	0.999	0.871	0.923
Humphrey	0.999	0.988	0.995
Ogden	0.999	0.927	0.968
Veronda-Westmann	0.994	0.993	0.998

->tracheal cartilage exhibited a linear stress-stretch behavior

Model	Tissue	R^2	a_1	a_2	a_3
	Cartilage	0.999	3.583	−2.534	12.020
Yeoh	Smooth Muscle	1.000	0.063	0.394	−0.171
	Connective Tissue	1.000	0.257	0.483	−0.148
	Cartilage	0.999	2.766	0.770	-
Mooney-Rivlin	Smooth Muscle	0.999	1.164	−1.223	-
	Connective Tissue	0.999	1.836	−1.775	-

-young population 13.30 ± 5.72 MPa

-old population 20.71 ± 10.17 MPa

-smooth muscle is least age-sensitive component

Conclusions/action items:

Lots of data was gathered regarding the properties of different aspects of the trachea, but little means anything to me. I plan to do further research on many of these values and determine their meanings and how they can be used to assist in the construction of our design.

09/26/24 Mechanical Properties of Human Tracheal Cartilage

NATHAN KLAUCK - Sep 27, 2024, 1:37 AM CDT

Title: Investigation of the Mechanical Properties of the Human Tracheal Cartilage

Date: 09/26/24

Content by: Nathan Klauck

Present: N/A

Goals: Determine mechanical properties of trachea

Link: https://pubmed.ncbi.nlm.nih.gov/29308075/

Citation:

F. Safshekan, M. Tafazzoli-Shadpour, M. Abdouss, M. Behgam Shadmehr, and F. Ghorbani, "Investigation of the Mechanical Properties of the Human Tracheal Cartilage," Tanaffos, vol. 16, no. 2, pp. 107–114, 2017.

Content:

-Trachea cartilage's elastic behavior has been assessed to be both linear and non-linear

-The stress-strain behavior of the cartilaginous rings of a single trachea varies accross its longitudinal axis

-this study found no difference between sex and their respective elasticity

Factor	Group	Young's modulus	F value	P value
Age	Young	12.178±1.265	0.022	0.004
	Old	20.540±1.840		
Gender	Female	16.227±1.623	0.084	0.908
	Male	16.491±1.534		
Position	Cranial	18.119±1.538	2.486	0.146
	Caudal	14.597±1.692		

-stress strain curves included in paper, not included in notes (I don't know if they have significance)

-Comparison of the relaxation percentage values for tracheal cartilage, in terms of age, gender and position in trachea (cranial vs. caudal) depicted below

Factor	Group	Relaxation percentage (%)	F value	P value
Age	Young	22.71±4.12	7.002	0.061
	Old	24.13±7.11		
Gender	Female	22.67±5.15	6.944	0.069
	Male	24.01±3.65		
Position	Cranial	23.45±6.17	0.301	0.612
	Caudal	23.06±5.34		

-The tips of the C-shaped cartilages are closer to each other in the cranial region than in the caudal region of the trachea

Conclusions/action items:

A few more considerations for the construction of our design, but nothing that wasn't already brought up in other papers.

10/8/24 - Anatomy of the Upper Airway

NATHAN KLAUCK - Oct 11, 2024, 11:36 AM CDT

Title: Anatomy, Airway

Date: 10/8/24

Content by: Nathan Klauck

Present: N/A

Goals: Determine important features of the airway

Search Term: -

Link: https://www.ncbi.nlm.nih.gov/books/NBK459258/

Citation:

M. Ball, M. Hossain, and D. Padalia, "Anatomy, Airway," in StatPearls [Internet], StatPearls Publishing, 2023. Accessed: Oct. 11, 2024. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK459258/

Content:

Upper Airway

-Nasopharynx/rhino-pharynx

-> muscular tube from nares

->includes the back of the nasal cavity

->separates from the oropharynx by the palate

-Oropharynx

-> connects nasopharynx and hypo-pharynx

->area between palate and hyoid bone

-> separated from oral cavity by the tonsillar arch

-Hypo-pharynx

->connects oropharynx to the esophagus and the larynx

->pharynx beneath the hyoid bone

Lower Airway

-trachea

->ciliated pseudostratified columnar epithelium-lined tubular structure supported by C-shaped rings of of hyaline cartilage

->C-shaped rings allow for expansion during swallowing

->bifurcates superior to the heart

Functions

-barrier of moisture in mucous prevents loss of excess moisture during ventilation

-serves as a temperature barrier from outside weather

-barrier to infection because of a rich lymphatic system lining the trachea

Conclusions/action items:

Add to preliminary report regarding anatomy of the airway

10/10/2024 - Airway management in obese patients

NATHAN KLAUCK - Oct 11, 2024, 12:27 PM CDT

Title: Airway management in obese patients

Date: 10/10/2024

Content by: Nathan Klauck

Present: N/A

Goals: Learn more about common pathologies in airways

Search Term: -

Link: https://pubmed.ncbi.nlm.nih.gov/23810609/

Citation: P. Aceto, V. Perilli, C. Modesti, P. Ciocchetti, F. Vitale, and L. Sollazzi, "Airway management in obese patients," Surg Obes Relat Dis, vol. 9, no. 5, pp. 809–815, 2013, doi: 10.1016/j.soard.2013.04.013.

Content:

-difficult to mask ventilate

-often require alternate airways

-video laryngoscopes help with intubation

-**fibrobronchoscope** with sedation and anesthesia

-decreased pharyngeal area

-> excess of tissue accumulation into pharyngeal tissues such as lateral pharyngeal walls, uvula, tonsils, tonsillar pillars, tongue, and aryepiglottic folds

-increaseed intraabdominal pressure and decreased chest wall compliance

-decreases tidal volume and expiratory reserves

->decrease more significant in higher BMI

Conclusions/action items:

Include pathology in the anatomy section of the report.

9-19-24 AirSim Pierre Robin X

NATHAN KLAUCK - Sep 20, 2024, 12:41 PM CDT

Title: AirSim Pierre Robin X

Date: 9-19-24

Content by: Nathan Klauck

Present: NA

Goals:

Obtain a greater insight on competing models on the market.

Search Term: Difficult Airway Trainers

Link: https://trucorp.com/en/product/airsim-pierre-robin-x/

Content:

Accurate pediatric, anatomically correct patient model

Simulates real skin

Designed to handle up to 20000 intubation cycles

Designed for double nasotracheal intubation, endotracheal tube insertion, bag-valve-mask (BVM) ventilation techniques, full range of supraglottic devices, and direct and video laryngoscopy

Conclusions/action items:

Model simulates the difficult airway of a pediatric pt and is designed to handle a range of different practice techniques. In the future I plan to look into other difficult airways to have unique approach to the one linked.

9-19-24 AirSim Difficult Airway

NATHAN KLAUCK - Sep 20, 2024, 12:42 PM CDT

Title: AirSim Difficult Airway

Date: 9-19-24

Content by: Nathan Klauck

Present: N/A

Goals: Learn more about competing designs

Search Term: Difficult Airway Trainer

Link: https://trucorp.com/en/product/airsim-difficult-airway/

Content:

This model is designed to be realistic and durable

The model supports a range of different intubation challenges including laryngospasm, displaced larynx, tongue edema, receding/protruding mandible, trismus, head rotation restrictions, and designed to ismulate needle and surgical cricothyroidotomy and percutaneous tracheostomy.

Designed to incorporate an instructors input to change the function of the device

Conclusions/action items:

This device simulates a lot of different intubation difficulties, something that we are attempting to accomplish with our model. This encourages me to search for ways we can make our design more practical or generally better than this option.

10/14/2024 - Laerdal Material

NATHAN KLAUCK - Oct 17, 2024, 10:34 PM CDT

Title: CPR Manikins & CPR Dummies

Date: 10/14/2024

Content by: Nathan Klauck

Present: N/A

Goals: Look for materials to make airway holder out of

Search Term: what are cpr manikins made out of

Link: **https://www.aedsuperstore.com/training-manikins.html?srsltid=AfmBOopWHm78xnyMHN1O_FtCSeTFF8A-3bSxDVw43CsRRjPV-govpdTF**

Citation:

"CPR Manikins & CPR Dummies." Accessed: Oct. 14, 2024. [Online]. Available: https://www.aedsuperstore.com/training-manikins.html?srsltid=AfmBOopWHm78xnyMHN1O_FtCSeTFF8A-3bSxDVw43CsRRjPV-govpdTF

Content:

-vinyl plastic over polyurethane foam

Conclusions/action items:

Look into this material further for use in printing of airway holder.

11/19/2024 - Cyclic Fatigue of TPU

NATHAN KLAUCK - Dec 10, 2024, 5:56 PM CST

Title: Cyclic Fatigue of TPU

Date: 11/19/2024

Content by: Nathan Klauck

Present: N/A

Goals: Learn about the cyclic fatigue of TPU

Search Term: fatigue resistance in TPU

Link: https://www.sciencedirect.com/science/article/pii/S0142941821000908

Citation: G. Scetta, N. Selles, P. Heuillet, M. Ciccotti, and C. Creton, “Cyclic fatigue failure of TPU using a crack propagation approach,” Polymer Testing, vol. 97, p. 107140, May 2021, doi: 10.1016/j.polymertesting.2021.107140.

Content:

-TPU has a high fatigue threshold and low stiffness

-TPU, unlike SBR, were not cyclicly strained at deformation larger than those used in cyclic fatigue

Conclusions/action items:

TPU has qualities which make it resilient to repeated instances of cyclic stress. This makes it ideal for use as a torsional spring in our design as it will be flexible enough to rotate, but also resilient enough to endure several cyclic rotations. This is great as it demonstrated similar properties to that of the material found in the AirSim Model.

11/19/2024 - Bambu Lab Material Properties

NATHAN KLAUCK - Dec 10, 2024, 6:04 PM CST

Title: Bambu Lab Material Properties

Date: 11/19/2024

Content by: Nathan Klauck

Present: N/A

Goals: Learn about the properties of the materials we print with

Search Term: Bambu Labs PLA properties

Link: https://bambulab.com/en/filament-guide

Citation:

"Choose the right filament - 3D Filaments Guide for Bambu Lab Printers." Accessed: Dec. 10, 2024. [Online]. Available: https://bambulab.com/en/filament-guide

Content:

PLA

Toughness Impact Strength - XY	26.6 kJ/m²
Strength Bending Strength - XY	76 MPa
Stiffness Bending Modulus - XY	2750 MPa
Layer Adhesion Impact Strength - Z	13.8 kJ/m²

TPU

Toughness Impact Strength - XY	123.2 kJ/m²
Strength Bending Strength - XY	N/A
Stiffness Bending Modulus - XY	N/A
Layer Adhesion Impact Strength - Z	86.3 kJ/m²

ABS

Toughness Impact Strength - XY	39.3 kJ/m²
Strength Bending Strength - XY	62 MPa
Stiffness Bending Modulus - XY	1880 MPa
Layer Adhesion Impact Strength - Z	7.4 kJ/m²

Conclusions/action items:

PLA appears to have better properties than ABS for use as base material and for the components in our prototype. TPU additionally looks like it is highly durable and may function well as a spring. Further discussion with Maribel and Jack is necessary in order to determine how exactly they plan to use these materials and whether this information changes anything.

N.D. - Buckle Design

NATHAN KLAUCK - Nov 15, 2024, 5:05 PM CST

Title: Buckle Desing

Content by: Nathan Klauck

Present: N/A

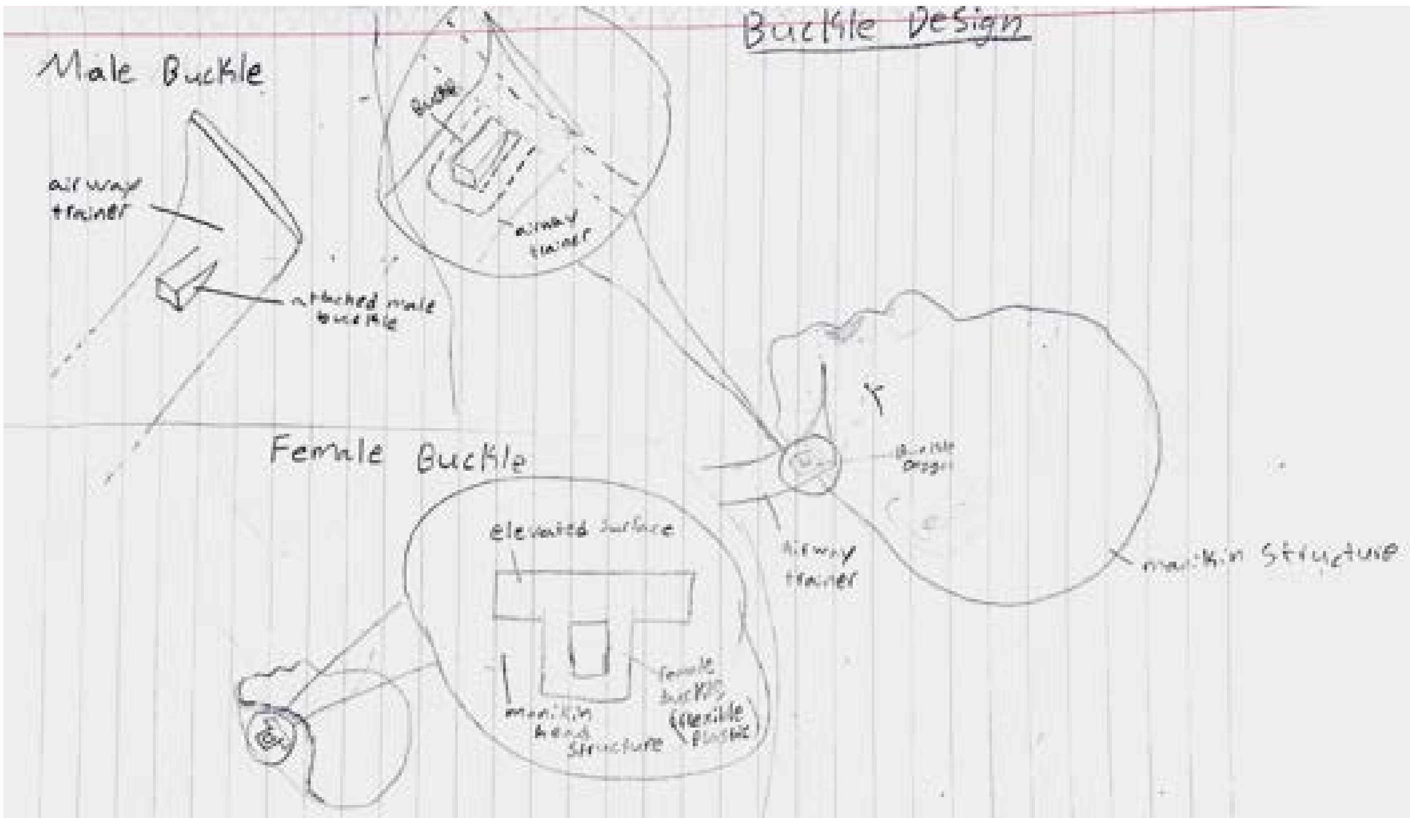
Goals: design a method for securing the trachea component

Content:

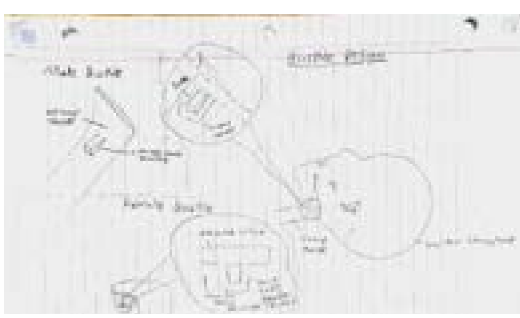
This design would consist of a buckle where the airway would be slid under the flexible portion in order to secure the trainer to the structure.

Action items

Compare to other methods and possibly design prototype



NATHAN KLAUCK - Oct 18, 2024, 12:16 PM CDT



Download

Buckle_Design.pdf (291 kB)

N.D. Latch Design

NATHAN KLAUCK - Nov 15, 2024, 8:36 AM CST

Title: Latch Design

Content by: Nathan Klauck

Present: N/A

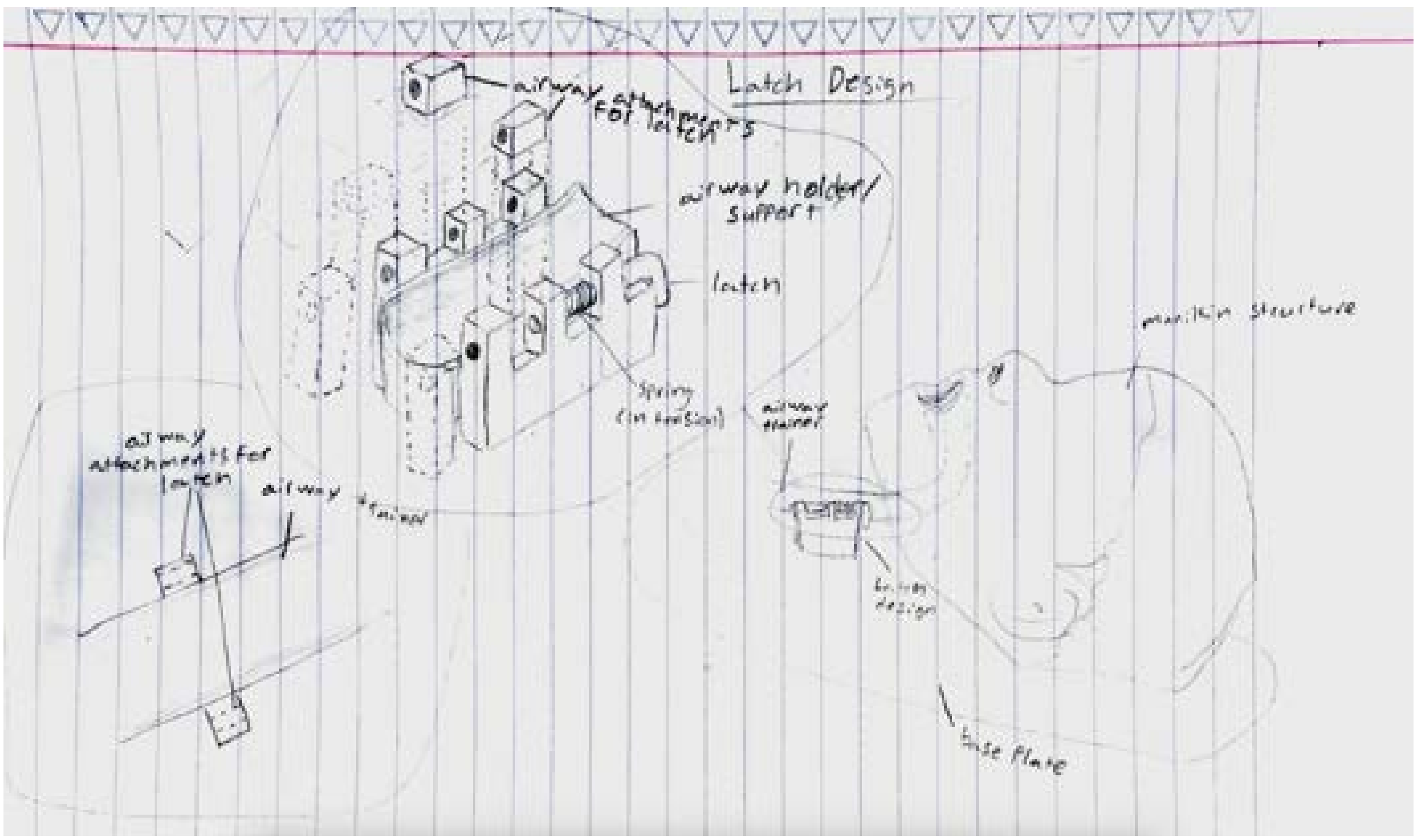
Goals: create viable design for attachment of trachea

Content:

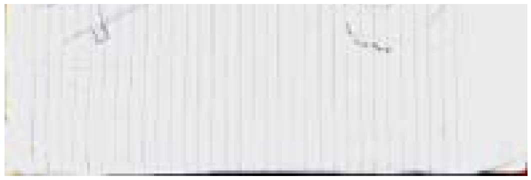
This design would consist of an airway support which would be secured to the airway trainer via a latch. The number of points of contact and the length of the points of connection may be varied to achieve necessary support for intubation practice.

Action items:

compare to other methods and possible test implementation.



NATHAN KLAUCK - Oct 18, 2024, 12:18 PM CDT



Download

Latch_Design.pdf (386 kB)

11/3/2024 - Materials Group Plan

NATHAN KLAUCK - Nov 15, 2024, 5:02 PM CST

Title: Materials Group Plan

Date: 11-3-24

Content by: Nathan Klauck

Present: All

Goals: determine what needs to be done to construct a viable model for our trachea

Content:

- scanning manikin head will take too long

-look for reasonable stl for the head of our model online

-look for a model of teeth and mouth interior as well

- work on basic base for model that incorporate the slanted solution and a hole for the hinge

- start modeling hinge pieces in solid works

Action items

work on completing base and getting that printed, start modeling hinge, and look for head stl

11/12/2024 - Consultation

NATHAN KLAUCK - Nov 15, 2024, 11:57 AM CST

Title: Consultations

Date: 11-12-24

Content by: Nathan Klauck

Present: Jack, Maribel, Nathan

Goals: determine a way forward in relation to how to edit an stl

Content:

- Hard to edit an stl

-> recommends using CAD to construct structure for head and connecting elements

->> this allows for modifications later on and for easier incorporation of other parts

-> try using OnShape for some of the modeling especially in relation to the trachea

->> some files were made including an attempt using negatives and scaling

- consider attaching trachea by adding a extrusion to it and screwing that into part of the structure

-> should secure it with minimal effect of material properties

Action items:

-model head, teeth, and connection portions in CAD

-play around with imported stl in OnShape

11/12/2024 - Consultation Post-meeting

NATHAN KLAUCK - Nov 15, 2024, 4:42 PM CST

Title: Consultation Post-Meeting Notes

Date: 11-12-24

Content by: Nathan Klauck

Present: Nathan, Jack, Maribel

Goals: Notes regarding next steps

Content:

- should look at editing stl in OnShape

-> specifically for the trachea look into taking the negative in a cylinder

- start modeling head in OnShape or try to get our stl to work

- print models to see how they relate to the base

Action items

Start modeling parts in OnShape and print whatever we can finish

11/15/2024 - Trachea stl OnShape work

NATHAN KLAUCK - Nov 15, 2024, 5:30 PM CST

Title: Trachea stl OnShape work

Date: 11/15/2024

Content by: Nathan Klauck

Present: N/A

Goals: attempt to get some semblance of a trachea to print

Content:

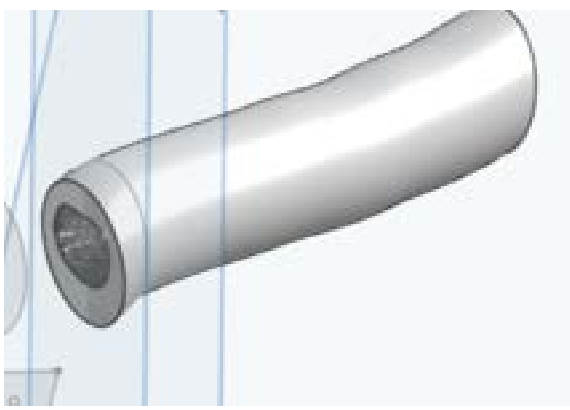
Attempted three different methods of getting a shell of the trachea

- first: take a negative of the trachea using a cylinder

-second: take negative of a scaled down version of the trachea using the unscaled trachea

-third: find the intersection the trachea and the cylinder and take the shell of it

The first and third method were successful, but the second failed as I was not able to successfully indicate the mate connector on the interior of the solid. The first and third methods have a few draw backs. The first method has the draw back of have excess material around certain parts of the trachea and thus will influence their mechanical properties. The third method currently can't form a shell thicker than 4 mm without encountering an error


Method 1


Method 2

Action items:

Work on reattempting the Third method so that we can increase the thickness further and write a procedure for it

11/17/2024 - OnShape Shell Functionality

NATHAN KLAUCK - Dec 10, 2024, 6:17 PM CST

Title: OnShape Shell Functionality

Date: 11/17/2024

Content by: Nathan Klauck

Present: N/A

Goals: Determine why shell function demonstrates issues in OnShape

Search Term:

Link: https://forum.onshape.com/discussion/3834/shelling-issues

Citation:

“Shelling issues,” Onshape. Accessed: Dec. 10, 2024. [Online]. Available: https://forum.onshape.com/discussion/3834/shelling-issues

Content:

- In general, shell may not work if there is "self-intersecting geometry"

-Adjusting local geometry around the problem may allow the function to work again

Conclusions/action items:

May have to look into a way to safely modify the structure of the imported file to affect these conflicts with the shell. Additionally, it may just be easy to find another program that is capable of shelling regardless of conflicts.

11/19/2024 - .jt file significance

NATHAN KLAUCK - Dec 10, 2024, 6:33 PM CST

Title: .jt file significance

Date: 11/19/2024

Content by: Nathan Klauck

Present: N/A

Goals: record the use of the .jt file

Search Term: -

Link: -

Citation: -

Content:

Different file formats save data in different formats, so I decided to try playing around with this feature by exporting a file in a certain format and re-uploading it to OnShape, hoping that the way the data was saved might remove the aspect of the airway model that results in conflicting geometry when using the shell functionality (or just change the data in some way that makes it more shell-friendly).

Heres what I found:

-.jt files work for this (i.e. export as a .jt file from Onshape and re-upload it)

-this allows for very specific shell thicknesses above 5 mm, including but not limited to 15 mm, 16 mm, and 11 mm.

Conclusions/action items:

This means that we have a way to triple the shell thickness of our trachea model. However, due to the variability in the values that actually work for shell thickness, this method wont necessarily work for any model or work in the same way. This means that while this gives us a way to print out what we need, a better method is still need if we want to make this process something significant. Thus getting a sliced file is still at the top of the teams priority list.

11/20/2024 - TPU Spring Modeling

NATHAN KLAUCK - Dec 10, 2024, 6:56 PM CST

Title: TPU Spring Modeling

Date: 11/20/2024

Content by: Nathan Klauck

Present: N/A

Goals: Model a torsional TPU spring

Search Term: -

Link: -

Citation: -

Content:

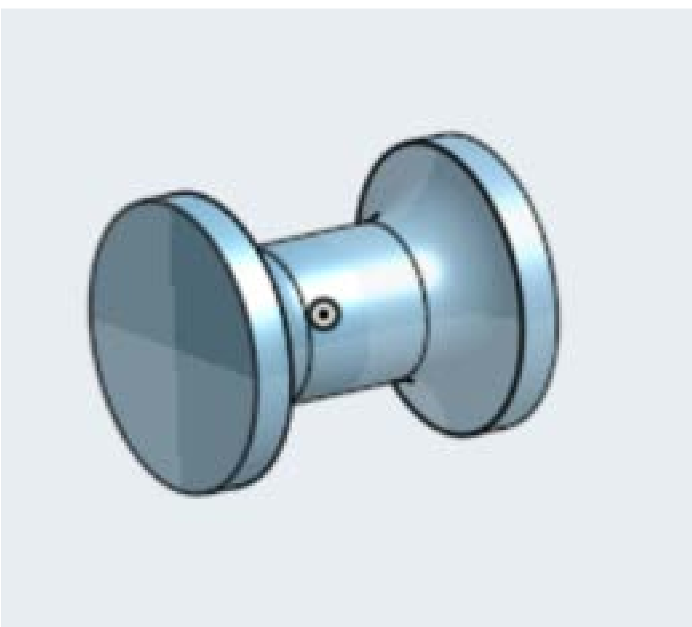
-we want a torsional spring for the neck hinge similar to that present in the AirSim trainer

-Decided to use TPU for its properties

-Measurements of spring in AirSim were taken and placed directly into an OnShape model

-Model consists of two discs to attach to jaw and neck hinge connected by a cylinder

-filets were used to add support and mimic design in AirSim



-Spring tested and seems to have significantly more torque than desired

-several more models were made reducing the central cylinders diameter to the following percentages

.85, .723,

-needed to reduce further

.51, .252

Conclusions/action items:

We'll have to test the newly printed springs and incorporate the functional versions into our model. additionally may have to look into a different material with weaker rotational resistances.

11/25/2024 - attempting to modify head stl

NATHAN KLAUCK - Dec 10, 2024, 6:46 PM CST

Title: attempting to modify head stl

Date: 11/25/2024

Content by: Nathan Klauck

Present: N/A

Goals: see if I can modify a head stl file inorder to incorporate it into our prototype

Search Term: -

Link: -

Citation: -

Content:

As the .jt file method allows for the creation of semi-thick shell walls for stl files, I looked into editing a head stl from the internet to potentially connect to our prototype to incorporate more features typically associated with an airway trainer. However, there were very few head stl files that appeared to be functional, and of the one I found, when taking a slice of the part of the head we would like to include, noticed that there was weird geometry near the mouth. This geometry, which was probably used to replicate the interior of the mouth, is probably what led to the further failure of the shell function, as the function wouldn't even run, even at very small thicknesses

Conclusions/action items:

.jt method therefore is not a functional method on any stl file, as it appears you need a shell-able model first anyways. This means that for further development of the model including features such as the face would require extensive modeling outside of my capabilities or finding a good model somewhere else on the internet.

12/02/2024 - MTS Testing

NATHAN KLAUCK - Dec 10, 2024, 10:53 PM CST

Title: MTS

Date: 12/02/2024

Content by: Nathan Klauck

Present: N/A

Goals: Testing material properties of formlabs resin 50A

Search Term: -

Link: -

Citation: -

Content:

-We tested the tensile strength of dog bone samples of formlabs 50A

-supports were fused to large portion of the model (more than should be typical)

-Noted that the removal of supports damaged dog bone structure

-Several dogbones failed suddenly

-Jack analyzed MTS data further for YM

Conclusions/action items:

Results of the test show that the removal of supports effect the material properties. This may play a role in any future models we print, not necessarily dogbone samples. Further testing may be required to see how undamaged dogbones preform, however acquiring these samples may be difficult.

12/03/2024 - Base Assembly

NATHAN KLAUCK - Dec 10, 2024, 10:35 PM CST

Title: Base Assembly

Date: 12/03/2024

Content by: Nathan Klauck

Present: N/A

Goals: Assemble Base

Search Term: -

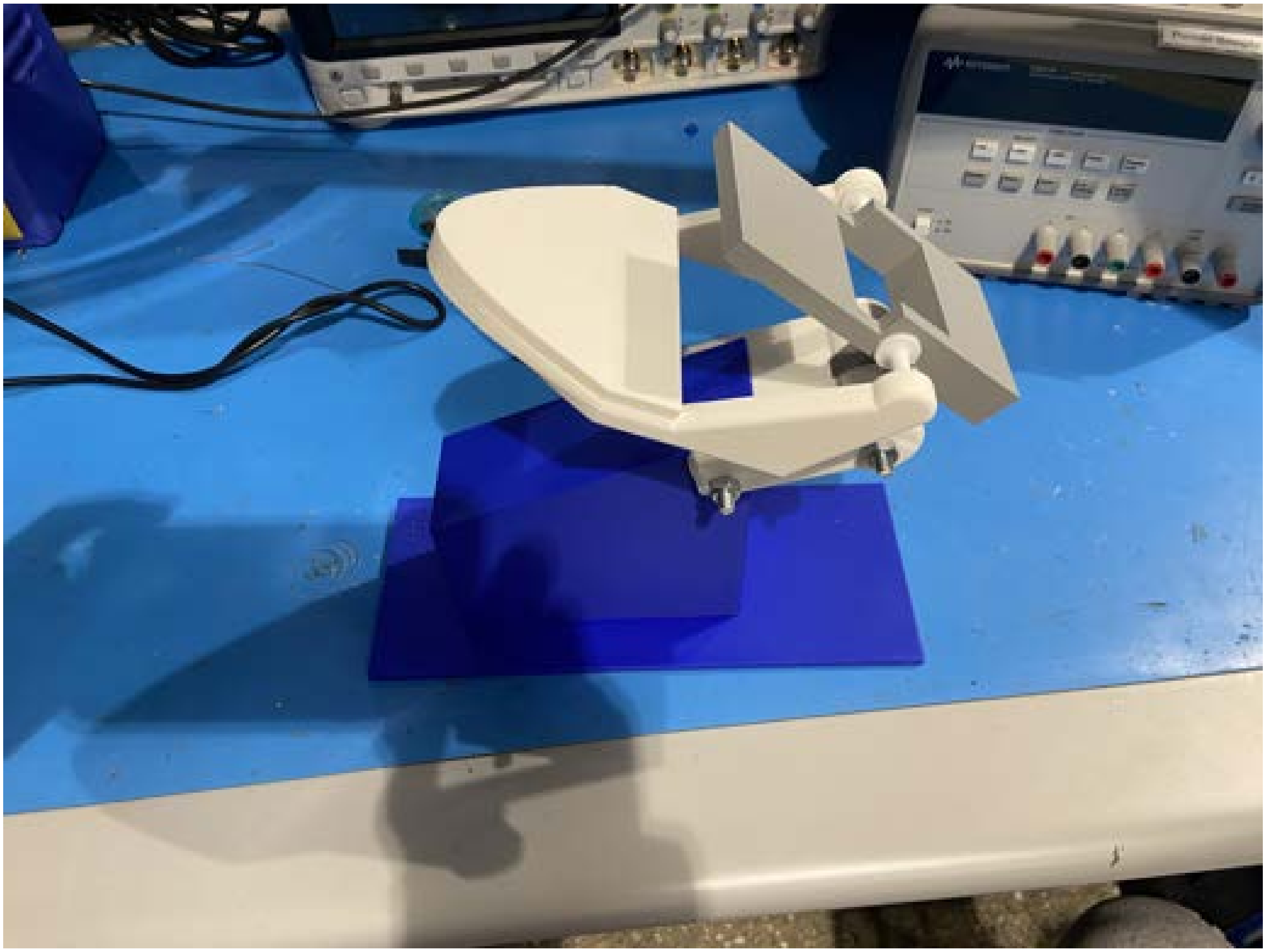
Link: -

Citation: -

Content:

Constructed base, some things to note:

-two bolts used to secure the hinge to the base, and the hinge to the top jaw. Top jaw connected to bottom jaw using superglue and the print TPU tosional springs



Conclusions/action items:

Possibly consider reprinting springs to allow for a more stable jaw hinge, and look into modeling something for the back of the head. Still have to attach dual lock on the base.

12/03/2024 - Fromlabs 50A resin v2

NATHAN KLAUCK - Dec 10, 2024, 10:48 PM CST

Title: Fromlabs 50A resin v2

Date: 12/03/2024

Content by: Nathan Klauck

Present: N/A

Goals: record change in resin at design lab

Search Term: -

Link: -

Citation: -

Content:

-Makerspace replaced Fromlabs 50A resin with Fromlabs 50A resin v2

-increased YM from 1.59 to 1.7

-Shore hardness from 50A to 55A

-prints more successful

->Dogbone samples printed without conflicting suppport material

->First print of trachea shell successful as compared to all other attempts

Conclusions/action items:

Many conflicts we encountered with our models failing may just be a result of using an outdated resin. Additionally, this means any future dogbones tests will result in better results.

Meeting Notes

NATHAN KLAUCK - Nov 15, 2024, 5:09 PM CST

Title: Meeting Notes

Content by: Nathan Klauck

Present: all

Goals: determine goals for team

Content:

Next Steps

-Research effects on anatomy of closed and open mouthed patients and how to change a scan to mimic one from the other

-Reach out to the designers of the dicom file conversion site to talk about options for confidentiality

-Research mechanics of the neck and how to imitate in design

-pick conditions to design

-Work on stability of the model for intubation attempts

-Test prototype for properties, consider thickness of airway (properties of material structure)

NATHAN KLAUCK - Oct 13, 2024, 5:53 PM CDT

-methods of constructing different mechanics

-method of attachment for trachea

-3d scan

Show and tell

NATHAN KLAUCK - Nov 15, 2024, 5:08 PM CST

Title: Show and Teall

Content by: Nathan Klauck

Present: All

Goals: Get inputs from other teams

Content:

- add slots in side for rod to secure trachea (holes with dowels)

-include clips to secure trachea

- try taking the negative of our 3d model to get some form of its outline

- use snap attachments for trachea, glue flat plate to trachea

Action Items:

Consider given methods of attaching airway to base, and look into taking the negative of the trachea

Tong Lecture

NATHAN KLAUCK - Nov 15, 2024, 12:47 PM CST

Title: Tong Lecture

Date: 11-15-24

Content by: Nathan Klauck

Present: All

Goals: Gain useful insight into how a company was built

Content:

- painless blood sampling method that uses suspended microfluidics

- both have backgrounds in BME

- considered the importance of doing things at home

- considered current method of transferring products

- wanted something that was user friendly and easy to transport

- got started on prototyping right away

- reached out on campus for more resources

- Law and entrepreneurship clinic helped them set up core documents for their program

- SBIR grants, DARPA, NIH

- make a better product, kill it when needed

- needed small 3D printed design and balloon for grant

- considered open fluidics design

- have to be careful about changing your product, but sometimes change is necessary

- find people who have problems with current design and learn from them

- developed tamper-proof security

- expanded range of application

- focus on single isolated problem and do it well

-> if it works well that can spread good reputation

- focus on core steps that lead to success

- focus on quality, bad quality can lead to bead rep

- started with small team

- regulatory strategy

-> regulated by FDA-> expensive and long test

-> simplified device to run less expensive and quicker clinical trial

-> IVD label already existed, found where it existed and implemented

-> good regulatory people are people

- if you have an idea, just go for it

-> there are people here willing to support for you

-> expect road blocks

-> find collaborators that can help you with it

12/05/2024 - Poster Presentation Practice

NATHAN KLAUCK - Dec 10, 2024, 11:00 PM CST

Title: Poster Presentation Practice

Date: 12/05/2024

Content by: Nathan Klauck

Present: N/A

Goals: record progress in poster presentation

Search Term: -

Link: -

Citation: -

Content:

-Trachea shell model printed as well as additionally dogbone models in new resin

-2 minutes overtime with first attempt

-I struggle with flow

Conclusions/action items:

Work on presentation, and try to only focus on the main points of your topic. \

2024/09/13 - 3D printed device to enhance orotracheal intubation success in rabbits

ELLE HEIMER - Sep 13, 2024, 3:43 PM CDT

Title: Development and evaluation of an anatomically designed and 3D printed device to enhance orotracheal intubation success in rabbits by inexperienced veterinarians

Date: 09/13/2024

Content by: Elle

Present: N/A

Goals: Learn about intubation techniques and the effectiveness of a 3D printed device

Search Term: Intubation Techniques

Link: https://www.sciencedirect.com/science/article/pii/S1467298723000491

Citation:

[x] Author links open overlay panelPablo Nejamkin a b et al., “Development and evaluation of an anatomically designed and 3D printed device to enhance orotracheal intubation success in rabbits by inexperienced veterinarians,” Veterinary Anaesthesia and Analgesia, https://www.sciencedirect.com/science/article/pii/S1467298723000491?via%3Dihub (accessed Sep. 13, 2024).

Content:

- Problem: intubation is challenging in rabbits due to their unique anatomy (narrow oral cavity, broad tongue, small mouth opening, acute angle between mouth and larynex, laryngospasm susceptibility)

- compared intubation techniques:

1. blind intubation (BLI)-- endotracheal tube guided by breath sounds and tube clouding

2. flexible borescope use (BOR)

3. 3D printed device (DEV)-- device is a guide for the endotracheal tube

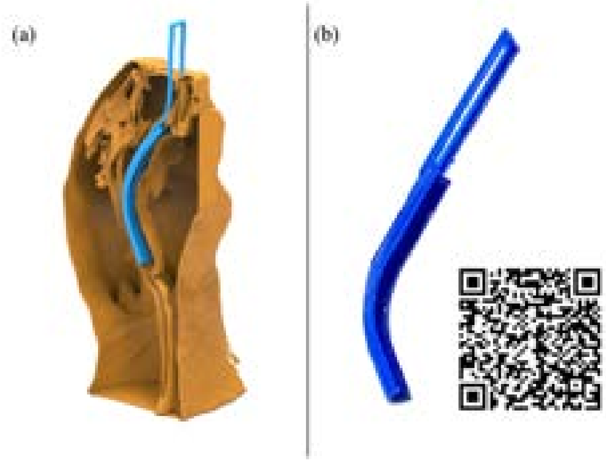


Figure 1 (a) Digital model of rabbit oropharynx and trachea generated from computed tomography images (orange) with the designed device inside (blue). (b) Three-dimensional printed device obtained from the digital model. The device presents an inverted 'U' shape and respects the angulation of the rabbit oropharynx. At the rostral end, a handle was incorporated to operate the device while avoiding the prominent incisor teeth. The QR code opens a link to the file to print the device. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

-used thermoplastic polyurethane filament (has a rubber-like elasticity)

Order of effectiveness: Tied for best= BOR and DEV

-the DEV prevented tube movement near the glottis, leading to decreased risk of laryngospasm (an "atraumatic alternative" to borescope-guided techniques)

Conclusions/action items:

A 3D printed device is a viable option for intubation. A possible material for our design is thermoplastic polyurethane filament. Additionally, a CT/MRI scan will prove to be an extremely useful tool in determining the measurements/qualities of our design. Finally, the team will need to look into the needs of a 3D printed intubation device that is flexible for a wide variety of anatomies.

2024/09/16 - Endotracheal Tube Intubation: Anatomy and Physiology

ELLE HEIMER - Sep 20, 2024, 12:43 PM CDT

Title: Endotracheal Tube Intubation Techniques + Criteria

Date: 2024/09/16

Content by: Elle

Present: N/A

Goals: Gather a better understanding of the reason and goals of intubation

Search Term: Endotracheal Intubation

Link: https://www.ncbi.nlm.nih.gov/books/NBK560730/

Citation: A. C. Alvarado and P. Panakos, "Endotracheal tube intubation techniques," ***PubMed*****, 2023. https://www.ncbi.nlm.nih.gov/books/NBK560730/**

Content:

Reasons for intubation: poor oxygenation or ventilation, or poor mental status (hypoxia and hypercarbia)

Anatomy and physiology:

-adult trachea varies in diameter from 15 to 20 mm

-made up of cartilaginous rings anterior

-upper airway consists of oral cavity and pharynx (includes nasopharynx, oropharynx, hypopharynx, and larynx)

-at fifth thoracic spine, the trachea bifurcates into right and left bronchi

-vagus nerve

-endotracheal tube sizes are different for men, women, and children

-in anticipated difficult intubations, a video laryngoscope should be used

-intubation is a risky procedure and many back up techniques should be in place

Testing:
-successful intubation means end-tidal carbon dioxide measures 0 mmHg of extratracheal carbon dioxide

-patient's arterial partial pressure of CO2 will correlate with endotracheal intubation

Conclusions/action items:

The team must consider the key anatomy and physiology aspects of endotracheal intubation when creating our designs. Variants of our device will come from things such as gender, age, weight, and special

disorders. Overall, intubation is a critical procedure that requires sufficient training before attempting.

2024/09/17 - Time Taken to Perform an RSI

ELLE HEIMER - Sep 19, 20

Title: Time taken to perform a rapid sequence intubation within a simulated prehospital environment

Date: 09/17/2024

Content by: Elle

Present: N/A

Goals: Determine the safe time for intubation for PDS

Search Term: Successful intubation time

Link:
https://www.researchgate.net/publication/337123520_Time_taken_to_perform_a_rapid_sequence_intubation_within_a_simulated_prehospital_e

Citation: C. Vincent-Lambert and R. Loftus, "Time taken to perform a rapid sequence intubation within a simulated prehospital environment," S African Journal of Critical Care, vol. 35, no. 2, p. 70, Nov. 2019, doi: https://doi.org/10.7196/sajcc.2019.v35i2.368.

Content:

- RSI = rapid sequence intubation

(unconciousness and paralysis performed in quick succession in order for intubation to then occur)

-intubation process to be completed in 45 seconds or less to prevent patient hypoxia

-mean time of 15 minutes and 5 seconds for full RSI

Conclusions/action items:

RSI is the fastset procedure in which intubation would take place. Our team can use this information/data as the criteria for whether our device well or not. If the device is faulty and training intubation is taking longer than 45 seconds, than we will have to reevaluate our design.

2024/09/20 - Difficult Airway: Subglottic Stenosis

ELLE HEIMER - Nov 13, 2024, 5:13 PM CST

Title: Subglottic Stenosis

Date: 09/20/2024

Content by: Elle

Present: N/A

Goals: Find out more about complications in airway anatomy

Search Term: Subglottic Stenosis

Link: https://my.clevelandclinic.org/health/diseases/22031-subglottic-stenosis

Citation: "Subglottic Stenosis (Idiopathic): Grading, Symptoms, Treatment & What It Is," *Cleveland Clinic*. https://my.clevelandclinic.org/health/diseases/22031-subglottic-stenosis

Content:

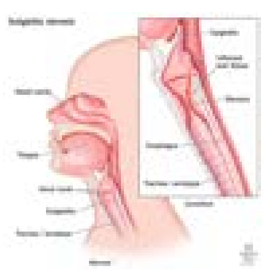
-a narrowing of the upper portion of the trachea, right below vocal cords

-cause stridor (whistling noise when exhaling), dyspnea (difficulty breathing)

-can be caused by being intubated for more than two weeks

-most common in females, age 30 to 60

-is quite rare



Conclusions/action items:

The team must consider different conditions (like this) that effect the shape of an individuals airway, in order to create a design that is as diverse and flexible as possible. We must also use this information to inform our design in a way that helps prevent subglottic stenosis.

2024/09/26 - Development of a Realistic Human Airway Model

ELLE HEIMER - Sep 27, 2024, 1:52 PM CDT

Title: Development of a realistic human airway model

Date: 09/26/2024

Content by: Elle

Present: N/A

Goals: Learn more about the process of modeling an airway

Search Term: human airway model

Link: **https://journals.sagepub.com/doi/full/10.1177/0954411911430188?casa_token=YuubzD3ajiEAAAAA%3A5H_EMS1t8fjsYXbxIzq4IfVCFGshrnwBpbFo34hjUCHR2WmgJQ9hgv02UD9wurMerGLtBRu72I8TSww**

Citation:
Lizal F, Elcner J, Hopke PK, Jedelsky J, Jicha M. Development of a realistic human airway model. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine. 2012;226(3):197-207. doi:10.1177/0954411911430188

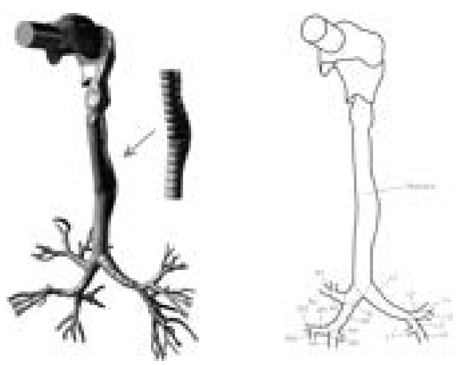
Content:

Model to study flow field and particle transport in human airways

First took real 3D CT airway scans to replicate the mid-pharynx and trachea

-"Marching cubes tracing method"

Next, added a oral cavity model based on preexisting model



polymer SR-30

sylgard 184 - individual layers added after, good for transparent and mechanical properties

(**PDMS**)

-each layer cured for 10 min at 150 degrees C

Conclusions/action items:

We may use this information to make decisions on which material is best for our project. We also now have a method of "marching cubes tracing method" for dissecting the scans. We must look further into the inclusion of an oral cavity or not.

2024/10/02 - Trucorp Airsim Difficult Airway Trainer

ELLE HEIMER - Oct 11, 2024, 12:38 PM CDT

Title: Trucorp Airsim Difficult Airway Trainer

Date: 10/2/2025

Content by: Elle

Present: N/A

Goals: Discover more features of this trainer

Search Term: Trucorp Airsim Difficult Airway Trainer

Link: https://trucorp.com/en/product/airsim-difficult-airway-with-bronchi/

Citation: "AirSim Difficult Airway with Bronchi," Trucorp. Accessed: Oct. 02, 2024. [Online]. Available: https://trucorp.com/en/produto/airsim-difficult-airway-with-bronchi/

Content:

Can simulate:

laryngospasm, displaced larynx, tongue edema, difficult airway, trismus,

features:

pump and house mechanism to inflate different pathologies - enlarged tongue, elongated epiglottis, swollen tonsils

ranges from challenging to very difficult intubation

Conclusions/action items: This entry is in addition to Jack's previous entry. We now have more of this trainer's features and why it is a high-quality design. We can base some of our final design on this existing trainer.

2024/09/25 - 3D Printing Medical Device Materials

ELLE HEIMER - Sep 27, 2024, 1:52 PM CDT

Title: 3D Printing Medical Device Materials

Date: 09/25/2024

Content by: Elle

Present: NA

Goals: Determine possible materials to print with

Link: https://rapidmade.com/3d-printing/in-the-medical-industry/

Citation: "What You Need to Know About 3D Printing in the Medical Field," *RapidMade*. https://rapidmade.com/3d-printing/in-the-medical-industry/

Content:

PC-ISO: commonly used in prototypes, surgical guides, and molds

-biocompatible (non-toxic)

-engineering thermoplastic

ABS M30: idea for functional prototypes

-biocompatible

-engineering thermoplastic

laryngoscope?

TPU: (thermoplastic polyurethane)

-very commonly used in medical and food industry

-flexible rubber material

Conclusions/action items:

We must look more into the feasibility of obtaining these materials. Things such as cost, location, and weight are important next steps of research. Overall, there are a lot of materials that would be suitable for our project.

ELLE HEIMER - Sep 27, 2024, 12:28 PM CDT

ABS-M30i

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FDM_Fused_Deposition_Modeling_ABS_M30i-1.pdf (880 kB)

ELLE HEIMER - Sep 27, 2024, 12:28 PM CDT

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FDM_Fused_Deposition_Modeling_PC_ISO.pdf (400 kB)

2024/11/27 - Intubation Forces for FEA Analysis

ELLE HEIMER - Dec 09, 2024, 12:45 PM CST

Title: FEA Intubation Forces 1

Date: 11/27/2024

Content by: Elle

Present: N/A

Goals: Determine the maximum value for FEA testing on the trainer

Search Term: Intubation Forces

Link:

https://pubmed.ncbi.nlm.nih.gov/1539823/

Citation:

M. J. Bishop, R. M. Harrington, and A. F. Tencer, "Force applied during tracheal intubation," *Anesthesia and Analgesia*, vol. 74, no. 3, pp. 411–414, Mar. 1992, doi: https://doi.org/10.1213/00000539-199203000-00016.

Content:

Novice(less experienced) intubators maximum force applied: 55.1 +/- 6.5 N
Force applied to laerdal airway trainer: 58.3 +/- 4.7 N

Conclusions/action items:

The maximum force found so far is 58.3 N. We will use this value to conduct FEA analysis on our base. Each part of the base will need to experience this force.

2014/11/28 - Intubation Forces for FEA Part 2

ELLE HEIMER - Dec 09, 2024, 12:48 PM CST

Title: Intubation Forces For FEA Analysis Part 2

Date: 11/28/2024

Content by: Elle

Present: N/A

Goals: Determine maximum force that will be applied on our airway trainer

Search Term: Intubation force maximum

Link:

https://search.library.wisc.edu/article/cdi_proquest_miscellaneous_2119929844

Citation:

"Measurement of forces applied using a Macintosh direct laryngoscope compared with a Glidescope video laryngoscope in patients with predictors of difficult laryngoscopy: A randomised controlled trial - Articles - UW-Madison Libraries," *Wisc.edu*, 2019. https://search.library.wisc.edu/article/cdi_proquest_miscellaneous_2119929844 (accessed Dec. 09, 2024).

Content:

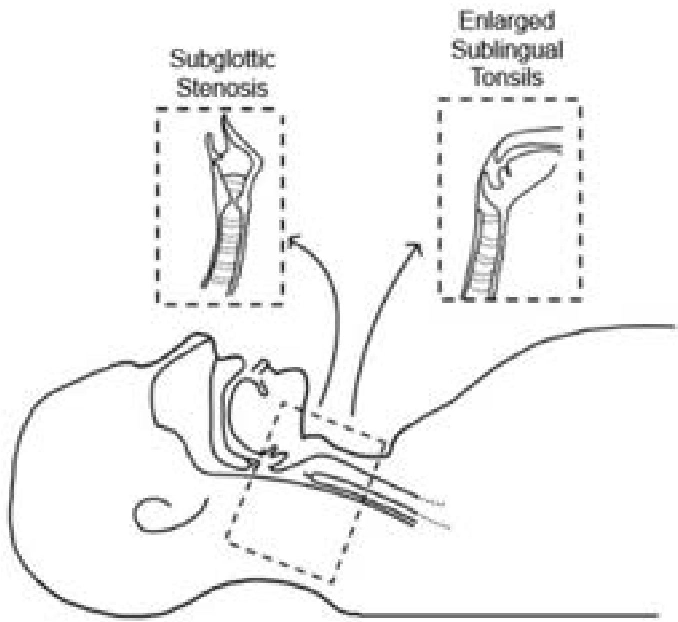
Maximum force applied to oropharyngeal tissues using a Macintosh laryngoscope: 21N

Conclusions/action items:

We may adjust the maximum force applied to just the oropharyngeal tissue to less than what we had before. This tissue is more sensitive. Individual parts of the trainer may experience different maximum forces.

2024/10/1: Design #2 Modification to Existing Trainer Drawing

ELLE HEIMER - Oct 25, 2024, 11:38 AM CDT

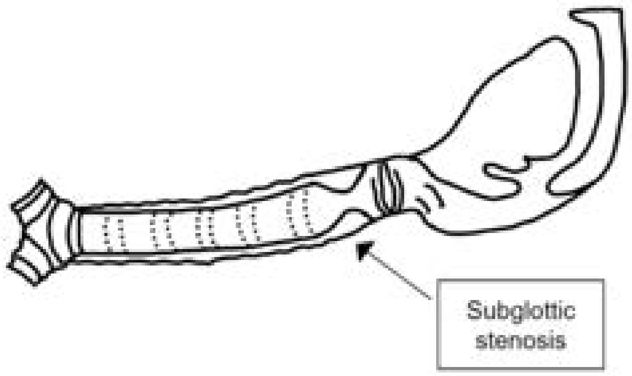


Download

Screenshot_2024-10-09_165159.png (59.1 kB) Modular adjustable airway trainer with replaceable anatomy from larynx to bronchus. Patient specific anatomy will be printed from scans.

2024/10/1: Design #3 Patient-Specific Modular Airway Drawing

ELLE HEIMER - Oct 25, 2024, 11:39 AM CDT



Download

Screenshot_2024-10-11_092943.png (88.8 kB) Individual, patient-specific airway created from scans that become .stl files to be 3D printed. The airway will represent specific pathologies for intubation training.

2024/11/15 - Tong Lecture: Tasso

ELLE HEIMER - Nov 15, 2024, 12:52 PM CST

Title: Tong Lecture: Tasso

Date: 11/15/2024

Content by: Elle

Present: All of BME

Goals: Learn about the journey of a business

Content:

Speakers: Dr. Erwin Berthier, PhD and Dr. Ben Cassavant, PhD

Tasso: allows for painless blood diagnostic collection at home

Over 10 billion blood draws every year in the US

    7,000 different types of tests

Started by: Blood draws in clinic are a hassle, inspired by the fact everything can be delivered to your home

-began prototyping (painless, easy, simple)

- used Law & Entrepreneurship Clinic

- found various funding opportunities: SBIR grants

    - wrote a crazy amount of grants to submit (DARPA, NIH)

    - got $150,000 grant

- kill your product when needed

- took 10 years of development

-developed tamper-proof security case to solve the chain-of-custody problem

    - big for athletes

-drowning in a sea of possibilities (the everything problem)

-look for labels in the FDA that already exist

-just go for an idea if you have one

Conclusions/action items: N/A

2024/10/8 - RADIUS Lab DICOM files

ELLE HEIMER - Dec 04, 2024, 4:52 PM CST

Title: RADIUS Lab DICOM

Date: 10/8/2024

Present: Elle, Jack, Dr. Schroeder

Goals: Find deidentified scans for use in 3D printing

Content by: Elle

Content:

Recieved possible NIH repository of deidentified scans (head and neck scan below):

https://3d.nih.gov/entries/3DPX-004646

Communication from Dr. Schoeder's collegue:

Jeffrey Kanne, MD

"Here are some trachea cases for your project. The RADIUS lab at UW should be able to get you anonymized DICOM data for your simulation project"

https://radiology.wisc.edu/research/services/medical-imaging-research-support/image-analysis/

1756999 - diffuse tracheal wall thickening (probably ulcerative colitis)

3527545 - perforated trachea (and esophagus) after instrumentation

1470766 - relapsing polychondritis

50045801 - sarcoidosis with tracheal involvement

3751237 - focal tracheal stenosis

1560388 - extrinsic tracheal compression from metastatic squamous cell carcinoma of the trachea

2516833 - granulomatosis with polyangiitis (9/1/2020 CT)

3396425 - variant tracheal bronchus

1778603 - tracheal stenosis

3746160 - squamous cell carcinoma of the trachea

1664190 - esophageal carcinoma invading the trachea

3655550 - blunt tracheal injury

3584945 - tracheal stenosis after resection of adenoid cystic carcioma

3015076 - penetrating tracheal injury

2749705 - progressive tracheal stenosis

2496509 - tracheal stenosis from aortic and subclavian artery aneurysm

3048069 - left isomerism with complete tracheal rings.

- Dr.Schroeder believed many of these scans were not going to be terribly useful as many are very complicated traumas or previous surgeries

-we can start with tracheal stenosis from aortic and subclavian artery aneurysm

and

extrinsic tracheal compression from metastatic squamous cell carcinoma of the trachea

Conclusions/action items:

We now have two possible sets of scan databases that we can pull from. Now we have to submit a scan request form to the RADIUS lab for the 2 scans mentioned. We must keep searching for ways to obtain scans that are open-mouthed.

2024/11/14 - Scan Retrieval + RADIUS Lab Communication

ELLE HEIMER - Dec 04, 2024, 5:02 PM CST

Title: RADIUS Lab Communication

Date: 11/14/2024

Present: Elle, Jack, Dr. Schroeder

Goals: Receive approval from RADIUS lab for scans

Content by: Elle

Content:

- sent attached request form to RADIUS lab

-received communication back that the lab requests IRB approval and consent forms:

Dr. Schroeder had previously reached out to the IRB and they said this project was not research, and therefore they(the IRB) does not have a role of oversight for this.

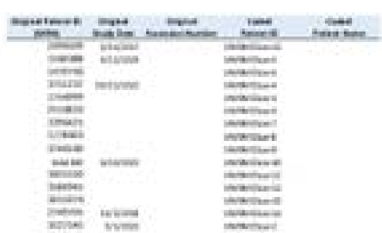
Dr. Schroeder's suggestion: may be best to just focus on the creation of a normal "proof of concept" model that utilizes the open-source scan

- Luke Schepers, PhD suggested open-source software called ITK-snap that allows you to do segmentations and export an STL file for printing

Conclusions/action items:

We now have to continue our own search for usable scans. We will look into the ITK-snap software. Additionally, we will continue to consider how we could combine mulitple scans in order to get a model with an open mouth.

ELLE HEIMER - Dec 04, 2024, 5:03 PM CST



Download

UWBMEAirwayTrainers-Data-Template-for-Research-Image-Requests.xlsx_-_Sheet1.pdf (29.2 kB)

9/12/2024 - 3D Printed Biomimetic Rabbit Airway Simulation Model for Nasotracheal Intubation Training

MAIWAND TARAZI - Dec 11, 2024, 2:49 PM CST

Title: 3D Printed Biomimetic Rabbit Airway Simulation Model for Nasotracheal Intubation Training

Date: November 26th, 2020

Content by: Maiwand Tarazi

Present: N/A

Goals: Learn potential model to examine animal anatomical features via intubation technique.

Search Term: N/A

Link: https://www.frontiersin.org/journals/veterinary-science/articles/10.3389/fvets.2020.587524/full

Citation:

[1] G. Oberoi et al., "3D printed biomimetic rabbit airway simulation model for nasotracheal intubation training," Frontiers, https://www.frontiersin.org/journals/veterinary-science/articles/10.3389/fvets.2020.587524/full (accessed Sep. 13, 2024).

Content:

- Rabbit intubation is risky due to anatomical features.

- Objective: Create a 3D-printed rabbit airway model for training.

- Data: Two rabbit heads scanned with μCT, micro-MRI, and CBCT.

- 3D models printed using polyjet technology.

- Results: 93% accuracy (μCT), 97% (CBCT); good visual/tactile feedback.

- Conclusion: Low-cost model aids veterinary intubation training.

Conclusions/action items: The low cost model of airway trainer aids in intubation training on animals. This research needs to applied at the clinical setting to examine its effects, for future use.

9/26/2024 - Airway biomechanics and pressure analysis

MAIWAND TARAZI - Sep 26, 2024, 5:03 PM CDT

Title: Mechanical properties of the Upper Airway

Date: September 11, 2013

Content by: Maiwand Tarazi

Present: N/A

Goals: Understand the general biomechanics of different airway components (nose, mouth, larynx, pharynx, glottis, etc.) to understand critical features that must be maintained when building a trainer, replicating the anatomy.

Search Term: Airway biomechanics

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3770742/

Citation:

[1] K. P. Strohl, J. P. Butler, and A. Malhotra, “Mechanical Properties of the Upper Airway,” *Comprehensive Physiology*, vol. 2, no. 3, pp. 1853–1872, Jul. 2012, doi: https://doi.org/10.1002/cphy.c110053.

Content:

- Airway resistance typically ranges from 0.2-0.5 L/s; Rohrer’s equation models pressure drop and airflow but lacks compliance considerations.
- Airflow can be laminar or turbulent; allergic rhinitis affects airflow dynamics, while OSA patients exhibit negative effort dependence.
- Nasal resistance increases in the supine position; airflow becomes turbulent above 30 L/min; the pharynx is compliant and can collapse during sleep.
- The larynx functions as a valve, resisting collapse; its dysfunction affects overall airway resistance.
- Upper airway mechanics involve resistance, compliance, and flow transitions; current models like Rohrer’s equation need enhancements to address non-linear dynamics and compliance effects.
- The valve characteristic of the larynx is important for simulating airflow through it

Conclusions/action items: This paper provided very detailed information regrading the upper airway mechanics. Important take aways from this study are that pressure differentials are central in airflow dynamics. So, when building an airway trainer calculations must be made to make sure pressure differences are regulated/maintained. In terms of the larynx (a component we may need to simulate) its important to not design it as a "straight tube". Rather, designing it like a valve is more reflective of its function in the airway region.

9/26/2024 - Multimaterial airway trainer model

MAIWAND TARAZI - Sep 26, 2024, 6:08 PM CDT

Title: Multi-material three dimensional printed models for simulation of bronchoscopy

Date: June 27, 2019

Content by: Maiwand Tarazi

Present: N/A

Goals: Learn about existing and/or potential materials that can be used to create airway trainers to possibly use in creating a better designed airway trainer.

Search Term: Airway trainer materials and methods

Link: https://link.springer.com/article/10.1186/s12909-019-1677-9

Citation:

[1] B. H. K. Ho *et al.*, "Multi-material three dimensional printed models for simulation of bronchoscopy," *BMC Medical Education*, vol. 19, no. 1, Jun. 2019, doi: https://doi.org/10.1186/s12909-019-1677-9.

Content:

- Study granted institutional review board approval (IRB-2017-05-052) to evaluate three patient-specific 3D printed airway models by expert respiratory physicians using a structured questionnaire.
- CT scans from patients with various conditions were processed to create printable .stl files, with models featuring:
    - Tracheal Wall: Custom mix of plastic (FullCure RGD851, VeroMagenta) and rubber (FullCure 930, TangoPlus), Shore hardness D40-D60.
    - Tumor: Fully rubber (FullCure FLX930, TangoPlus).
    - Support resin (FullCure 705) required post-processing for residue removal.
- Participants evaluated the models after training on a standard endoscopic trainer, using a ten-item Likert scale questionnaire. Results indicated high reliability (Cronbach's alpha = 0.83) with positive feedback on anatomical accuracy, though texture and color were noted as areas for improvement.
- The study demonstrates that multi-material 3D printed airway models can effectively serve as training tools for bronchoscopy, with recommendations for enhanced realism in future designs.

Conclusions/action items: This study provides possible materials (photopolymer RGD851 for 3D printing, FLX930 rubber material, resin fibers, etc.) to create a novel airway trainer that can reflect accurate airway anatomy. The results of the study indicated that the trainers provided high accuracy with airway anatomy. These materials can be put into our design and may prove useful, but more testing in the future.

10/11/2024 - Measuring shore hardness of material using a durometer

MAIWAND TARAZI - Oct 11, 2024, 1:07 AM CDT

Title: What is a Durometer - Elastomer and Plastic Hardness

Content by: Maiwand Tarazi

Present: N/A

Goals: Understand how to measure shore hardness using a tool called the Durometer.

Search Term: Shore hardness measurement

Link:

https://www.industrialspec.com/about-us/blog/detail/what-is-durometer-elastomer-and-plastic-hardness

Citation:

[1] S. W. ISM, “What is Durometer? – Elastomer and Plastic Hardness,” *www.industrialspec.com*. https://www.industrialspec.com/about-us/blog/detail/what-is-durometer-elastomer-and-plastic-hardness

Content:

- The durometer is a standardized way to measure the hardness (Shore Hardness) of materials like rubber and plastics

- measurement scales range from 0 to 100 but no durometer "unit" exists

- in general, a higher durometer elastomer is harder than a lower durometer elastomer

- for most rubber materials, Shore durometer numbers are usually provided as either Shore A or Shore D

- hardness or material hardness is a material's resistance to being penetrated or permanently indented

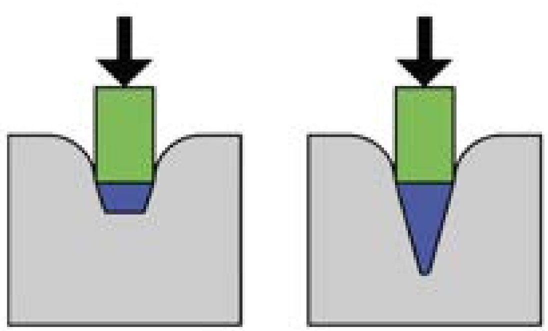


Figure 3
The Shore durometer hardness test

Conclusions/action items: After development of our trainer anatomy our team can consult materials testing labs in the School of Engineering to test the Shore Hardness of the material. Testing is critical to ensure that our product has biomechanical properties which reflect that of real airway anatomy.

10/11/2024 - Measuring Young's Modulus using an Atomic Force Microscope (AFM)

MAIWAND TARAZI - Oct 11, 2024, 1:30 AM CDT

Title: How do you measure Young's Modulus with an AFM?

Content by: Maiwand Tarazi

Present: N/A

Goals: Understand Young's Modulus and how to measure it using an AFM.

Search Term: Measuring Young's Modulus

Link: https://afm.oxinst.com/outreach/how-do-you-measure-youngs-modulus-with-an-afm

Citation:

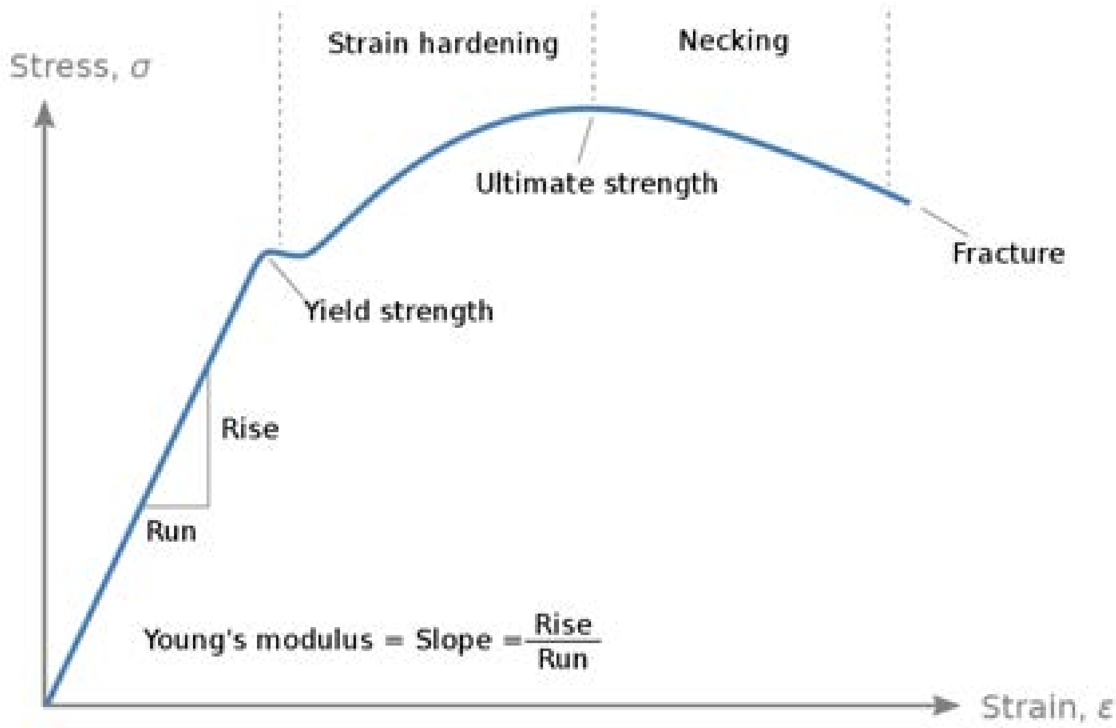
[1] an AFM, “How do you measure Young’s Modulus with an AFM?,” *Oxford Instruments*, 2023. https://afm.oxinst.com/outreach/how-do-you-measure-youngs-modulus-with-an-afm

Content:

- The AFM is uniquely capable of measuring the Young's Modulus (often called the Elastic Modulus) with nanoscale lateral resolution. It can do this for a wide range of materials, from single molecules, through rubbers and polymers, to ceramics and metals

- elastic modulus is an umbrella term that refers to how much a sample is physically deformed (strained) when applying an external stress

(Young's Modulus = E = Stress/ Strain)



- The atomic force microscope is an instrument that "feels" the topography and various properties of of surfaces by means of a microscopic physical probe

- This probe consists of a mounting substrate with an extended cantilever and a sharp tip that points downward from the free end towards the sample

- The changes in force between the tip and sample can be measured where deformations provide values corresponding to the Young's Modulus

Conclusions/action items: Having learned a new way to measure Young's Modulus our team should visit a materials testing lab at the College of Engineering after development of airway anatomy. While there are many potential ways to measure this metric knowing this method is great as it's widely used in the literature.

9/19/2024 - 3D Printed Circothyrotomy Task Trainer

MAIWAND TARAZI - Sep 19, 2024, 5:08 PM CDT

Title: A Novel Approach to Emergency Airway Simulation Using a 3D-printed Circothyrotomy Task Trainer

Date: July 1st, 2021

Content by: Maiwand Tarazi

Present: N/A

Goals: Understand novel approach to building this airway trainer. What insight can be taken for our approach in airway trainer engineering.

Search Term: Novel airway trainer model

Link:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8491648/

Citation:

[1] “A Novel Approach to Emergency Airway Simulation Using a 3D-printed Cricothyrotomy Task Trainer,” *Journal of Education in Perioperative Medicine*, vol. 23, no. 3, Sep. 2021, doi: https://doi.org/10.46374/volxxiii_issue3_sims.

Content:

- Circrothyrotomy is an invasive airway access technique on the emergency pathway of the difficult airway

- To perform these procedures on real people, much practice is needed and it usually performed on airway trainers extensively

- This paper attempted to follow a novel approach in developing a 3D printed that is noninferior (better) to pig tracheas which are often used in circothyrotomy procedures

- the 3D printed trainers were made from silicone "skin" pads, acrylic paint, mesh fabric, and ecoflex gel (layer).

Conclusions/action items: When tested, the 3D printed airway trainers performed better than pig tracheas. The study discusses that the airway trainers were built to reflect the anatomy of a human being rather than a pig which led to better medical student performances, operating on the 3D model. This research is helpful to our research as it provides a list of possible materials what we can use to make our model.

9/19/2024 - Low Cost 3D Printed Airway Model

MAIWAND TARAZI - Sep 19, 2024, 1:49 PM CDT

MARIBEL GLODOWSKI - Sep 13, 2024, 11:47 AM CDT

Title: Development and Assessment of a Low-Cost 3D-Printed Airway Model for Bronchoscopy Simulation Training

Date: July 2016

Content by: Maiwand Tarazi

Present: N/A

Goals: Compare existing low-cost airway trainer model to what our team needs to build as per client instructions. How is it better, how is it the same?

Search Term: 3D printed airway trainer

Link:
https://journals.lww.com/bronchology/FullText/2016/07000/Development_and_Assessment_of_a_Low_Cost.15.aspx

Citation:

[1] *Intensive Care Unit, “Development and assessment of a low-cost 3D-printed airway... : Journal of Bronchology & Interventional Pulmonology,” LWW, https://journals.lww.com/bronchology/FullText/2016/07000/Development_and_Assessment_of_a_Low_Cost.15.aspx (accessed Sep. 19, 2024).

Content:

- Premise was to develop a low-cost, 3D-printed model for bronchoscopy training.

- Apprenticeship model causes complications and patient discomfort; virtual simulators are costly.

- Made with ABS/HIPS filament for about $AUD 40, accurately replicates lower airway anatomy and bronchoscopy haptics.

- In terms of pros the trainer is inexpensive, easily reproducible, allows unlimited training opportunities.

- In terms of limitations the trainer lacks upper airway simulation; could be paired with an upper airway mannequin.

- Training for advanced bronchoscope procedures and skill assessment.

- For future research, determine its role in structured training and cognitive skill development.

Conclusions/action items: While this model proposed is very cheap which can be good for widespread use, it has limitations in terms of the materials it uses. The materials they use are cheap and do not reflect the complex anatomy in the airway region (which they targeted). Our project, due to client demands, should utilize more exotic material which reflects the true nature of the endotracheal region. This can provide a more accurate display of anatomy and thus might be a better model, especially for the clinical setting.

10/5/2024 - Laredal Airway Trainer Model

MAIWAND TARAZI - Dec 11, 2024, 2:35 PM CST

Title: Laredal Airway Trainer Model

Date: 10/5/2024

Content by: Maiwand Tarazi

Present: N/A

Goals: Understand the pros and cons of the Laredel model given that its a popular model used by clinicians to practice test intubations

Search Term: Airway trainers used in hospitals

Link: https://laerdal.com/distributors/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/

Citation:

[1] "Laerdal Airway Management Trainer | Laerdal Medical," *Laerdal Medical*, 2024. https://laerdal.com/distributors/products/skills-proficiency/airway-management-trainers/laerdal-airway-management-trainer/ (accessed Dec. 11, 2024).

Content:

Model used by many physicians in the U.S. and worldwide to practice test intubations

- Cost: $3,000 average --> quite expensive

- Presents generic, healthy airway anatomy for physicians to operate on (what would happen in a real operation where a patient had an abnormality?)

- How do the materials the trainer is made from reflect the the true properties of a patient (skin durability, pressure, etc.) --> variability in this may cause unreliable intubation conditions

Conclusions/action items: The current popular Laredal model seen above is used in hospitals/clinics around the country and the world. Although effective, it does reflect the variable nature of patient specific anatomy (patient pathologies, abnormalities, etc.). This is problematic especially for cases where patients show up with abnormalities where physicians have not seen before. Creating a trainer which can reflect this complex anatomy to improve on this aspect is critical for adequate intubation training.

10/7/2024 - Ambu Airway Trainer

MAIWAND TARAZI - Dec 11, 2024, 2:49 PM CST

Title: Competing design --> Ambu Airway Trainer

Date: 10/7/2024

Content by: Maiwand Tarazi

Present: Competing airway trainer design

Goals: Understand the pros and cons of this current trainer. Use cons as a way to create a novel trainer which improves on this design.

Content:

The Ambu Airway Management Trainer is designed to train all modern airway management techniques.This makes it possible to train the placement of Orotracheal tubes, Laryngeal Masks, Combitube™, Nasotracheal tubes, Nasopharyngeal tubes, Endotracheal tubes and Guedel airways.

The Ambu Airway Management Trainer is easy to clean and can be easy be maintained. All parts can easy be accessed without the need of tools.

The Ambu Airway Management Trainer gives an accurate simulation of mouth, nostrils, teeth, tongue, pharynx, larynx, epiglottis, vocal cords, trachea, oesophagus and lungs. Realistic lifting and tilting of head gives you the right feel. It has a realistic movement of the head, cervical spine and jaw simulate relevant anatomical changes during intubation.

The Ambu Airway Management Trainer has also included an electronically tooth sensor that indicates when too much force is applied to the upper teeth.

It is recommended to use the following sizes when training with the Airway Management Trainer:

- Endotracheal tube 8 mm
- Nasotracheal tube 7 mm
- Laryngeal mask, sizes 3 and 4

Conclusions/action items: Likewise to the Laredal mode, this Ambu Airway Trainer presents generic, healthy airway anatomy for physicians. And while currently effective, it may not be representative of the complex and variable nature of patient specific anatomy. Thus, creating a novel trainer which can improve on this design (design to account for variability) will be necessary for a better model. In addition, observing the material of the trainer is important, the novel trainer needs to reflect the true nature of the skin and tissue of the patient.

11/15/2024 - Final Head and Neck CT Scans (Dicom file)

MAIWAND TARAZI - Nov 15, 2024, 4:23 PM CST

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

Title: Head and Neck CT scans

Date: 11/15/2024

Content by: Maiwand Tarazi

Present: Final collection of head and neck CTs for modeling anatomical outline

Goals: With these head and neck CTs, create an anatomical outline (uploading these files into 3D slicer or advanced softwares --from Synopsis, Limbus, etc.)

Content:

Conclusions/action items: With the dicom files I found, I was able to upload them into a DICOM uploading software. The DICOM software was able to show these images above. The First image is a CT scan of the ending of the neck down to the chest. The important part of the chest scan is the bronchiole imaging (small "lines" that can be seen in the lungs). These bronchioles make modeling the anatomy more complete (usual scans are hollow and don't show the complete structure.) With these scans, hopefully, we can use 3D slicing software, including advanced software from companies such as Synopsis and Limbus to create detailed imaging outlines.

11/15/2024 - Current software ideas

MAIWAND TARAZI - Nov 15, 2024, 4:42 PM CST

MAIWAND TARAZI - Nov 15, 2024, 4:49 PM CST

Title: Current segmentation software ideas/strategy

Date: 11/15/2024

Content by: Maiwand Tarazi

Present: Current CT scan segmentation software ideas.

Goals: Obtain a software from a company (Limbus, Synopsis, TotalSegmentor, etc.) to obtain accurate segments of the CT scans.

Content:

- Update as of today, Limbus reached back to Elle stating that they cannot offer their product to us. Currently on waiting from both Synopsis (who I reached out to) for a free 30 day trial using their software and TotalSegmentator.

Conclusions/action items: Wait for a response from Synopsis and TotalSegmentator. If no response or rejection, make due with Democratize 3D to create segments of the CT scans.

11/15/2024 - Initial CT Scan segmentation software update

MAIWAND TARAZI - Nov 15, 2024, 5:01 PM CST

Title: Initial CT Scan segmentation software update

Date: 11/15/2024

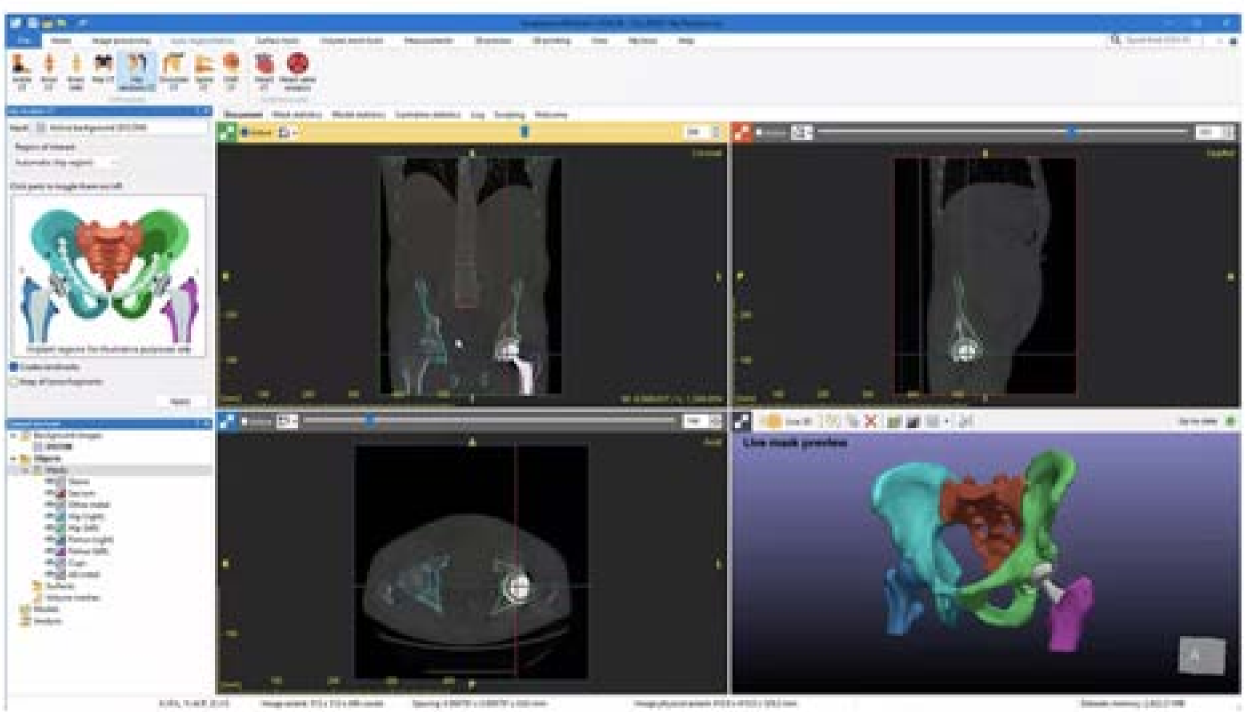
Content by: Maiwand Tarazi

Present: Strategies (softwares) the team plan on using to segment CT scans.

Goals: Reach out to segmentation software companies: Limbus, Synopsis, and TotalSegmentator to obtain a free trial of their services. Ideally, we need just one good response (can use their tech) so we can proceed to segment the CT head-neck scans that we found.

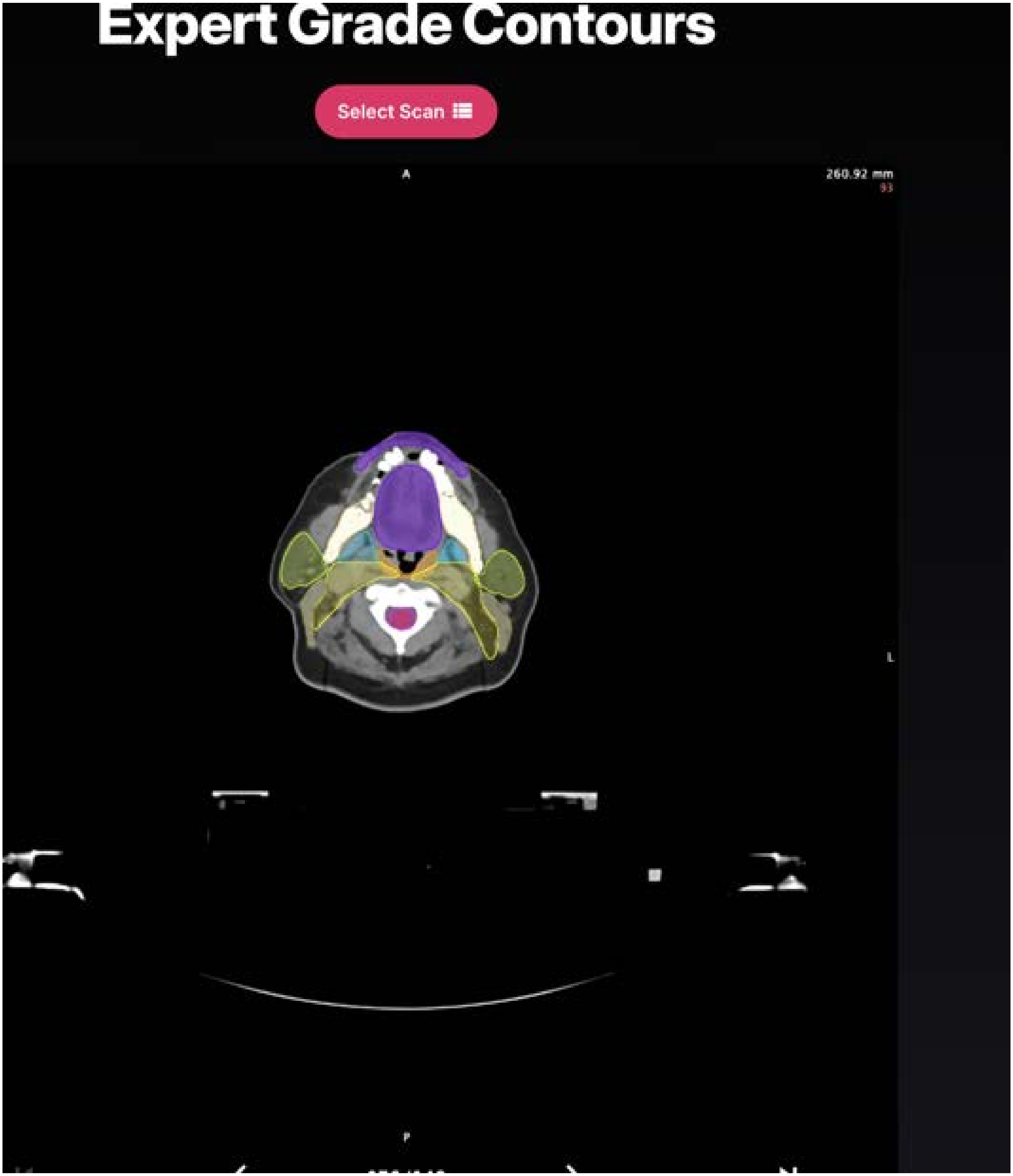
Content:

- Synopsis: Simpleware ScanIP is a flagship software by Synopsys for 3D image processing, segmentation, and visualization of data for medical imaging (CT, MRI) or industrial scans.



The AI-powered Simpleware Hip Revision CT tool.

Limbus: These tools can be adapted for limbus segmentation if the imaging modality is compatible (e.g slit-lamp, OCT, or photographic images)



Conclusions/action items: Hopefully one of these software companies reach back to us to enable a free trial of their tech. This will help us segment our CT scans.

11/15/2024 - MediData: Alternative to democratize 3D

MAIWAND TARAZI - Nov 15, 2024, 5:39 PM CST

Title: MediData: Alternative to democratize 3D

Date: 11/15/2024

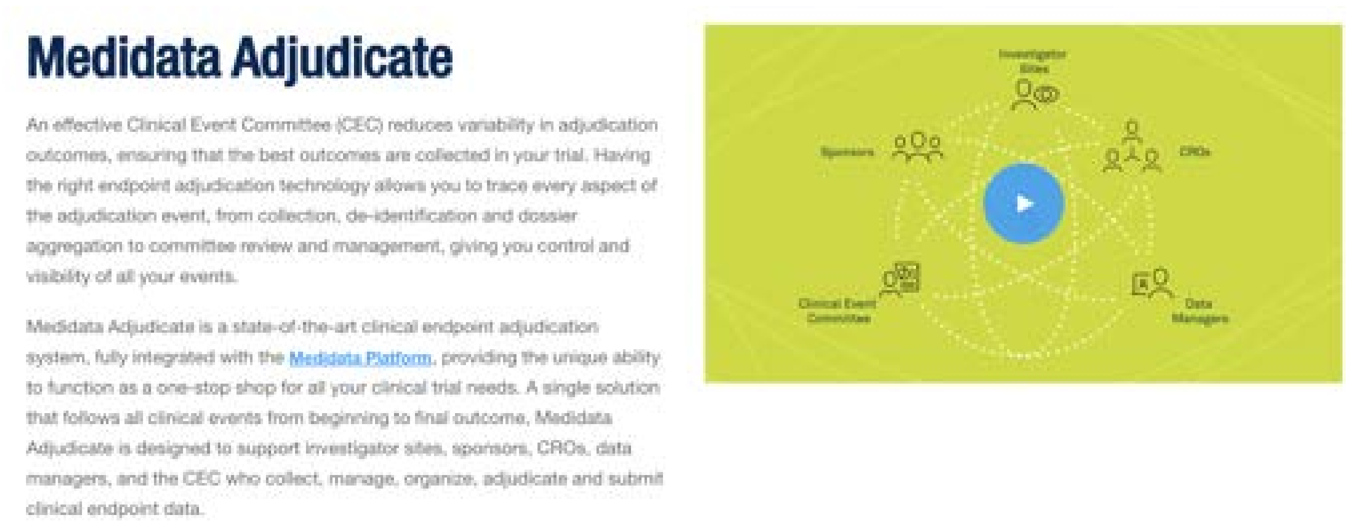
Content by: Maiwand Tarazi

Present: Potential segmentation software alternative to Democratize 3D.

Goals: See if MediData can be used to segment our CT scans.

Content:

MediData by Dassault Systems: Medidata specializes in cloud-based solutions for clinical trials, including tools for analyzing medical imaging like CT scans. Their imaging platform supports workflows for clinical trials by enabling secure storage, management, and analysis or imaging data, including segmentation and quantitive assessment.



Conclusions/action items: Reach out to MediData to see if we can use their medical segmentation software.

11/15/2024 - Segmentation Start: Democratize 3D

MAIWAND TARAZI - Nov 15, 2024, 5:17 PM CST

Title: Segmentation Idea Start: Democratize 3D

Date: 11/15/2024

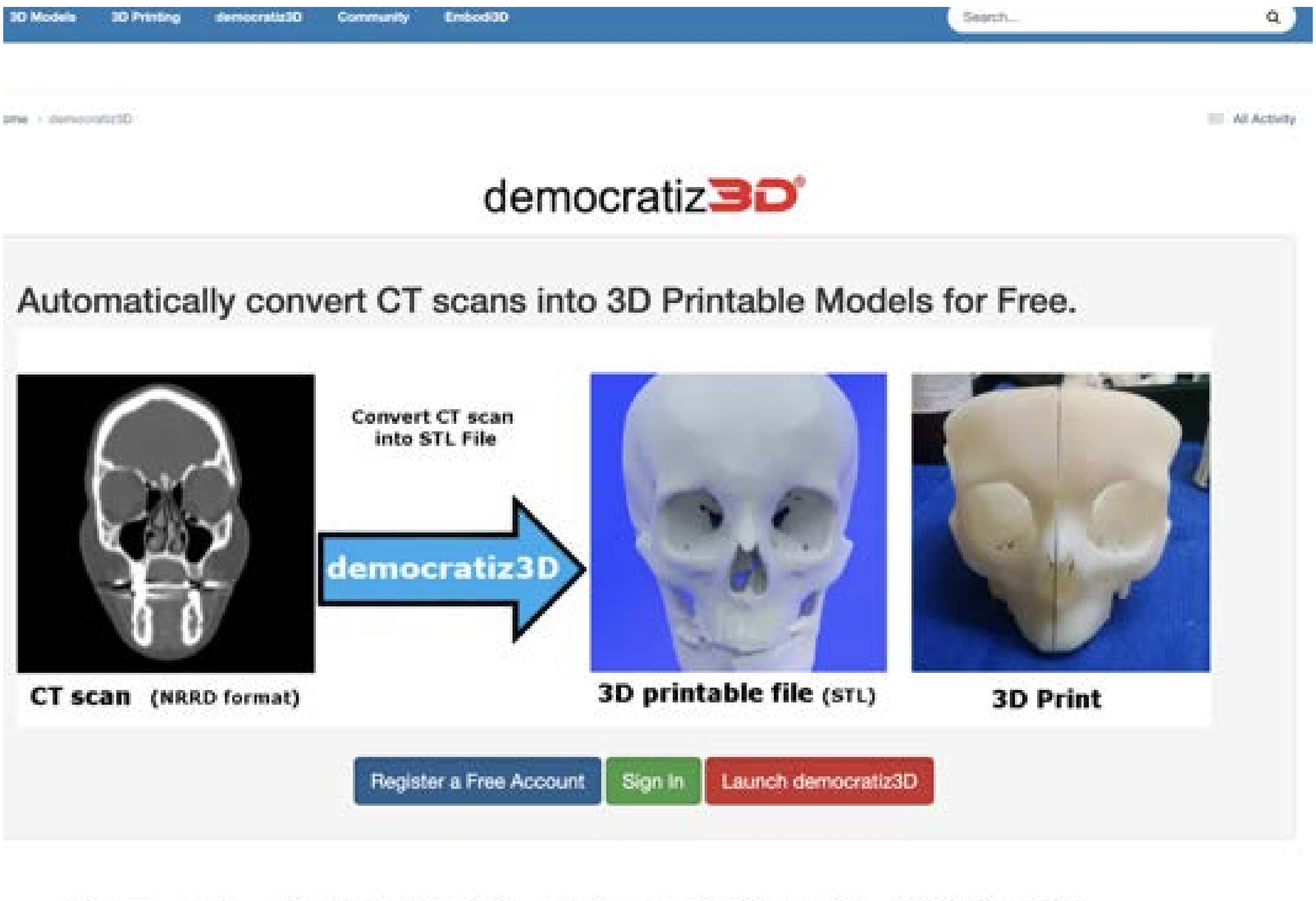
Content by: Maiwand Tarazi

Present: First CT scan segmentation software: Democratize 3D

Goals: Play with Democratize 3D to see if it can adequately segment CT head-neck scans.

Content:

Democratize 3D: To segment CT scans, democratizing 3D enables wider access to free or low-cost tools like 3D slicer and ITK-Snap which provide manual and automated segmentation features. AI frameworks like MONAI and nnU-Net simplify the process with pre-trained models, while cloud platforms like Google Colab allow segmentation without expensive hardware, making CT analysis more accessible to researchers and clinicians.



Conclusions/action items: Play with democratize 3d to get segments of the CT scans we obtain. Big thing to consider with democratize is: can it produce segmented scans that are whole and not hollow (show lung/airway anatomy like bronchioles for example.). If this software is not necessarily useful, we can look for other softwares to do the job.

11/20/2024 - Building of Jaw Component of Trainer

MAIWAND TARAZI - Dec 08, 2024, 11:31 PM CST

MAIWAND TARAZI - Dec 11, 2024, 1:49 PM CST

Title: Building of Jaw Component of Trainer

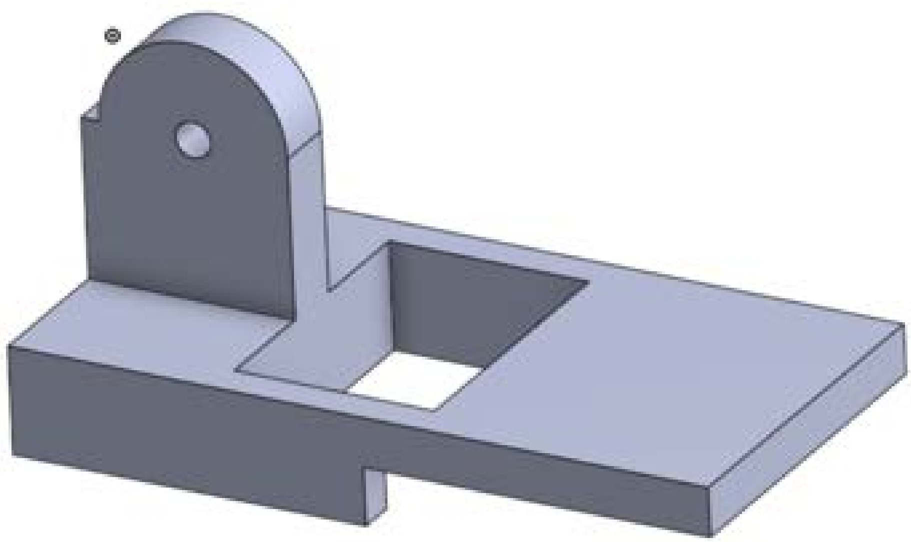
Date: 11/8/2024

Content by: Maiwand Tarazi

Present: Simulated model of the jaw component

Goals: Present detailed imagery of the components. Understand mechanics of the component.

Content:



Conclusions/action items: This component is the jaw. This will be attached (via pin connections) to our base later on. The exact shape of this component is imperative as it fits neatly with the designed base. The hole (on the top) was measured precisely to ensure proper fitting with the base component. That is, the base and jaw connection "force" must be strong to ensure a consolidated final prototype. This caution also connects to how this jaw component reflects a good model of a real jaw. Now, the hinge component must be made to proceed.

11/20/2024 - Building of Torsional Springs

MAIWAND TARAZI - Dec 11, 2024, 1:50 PM CST

Title: Building of Torsional Springs for Airway Trainer

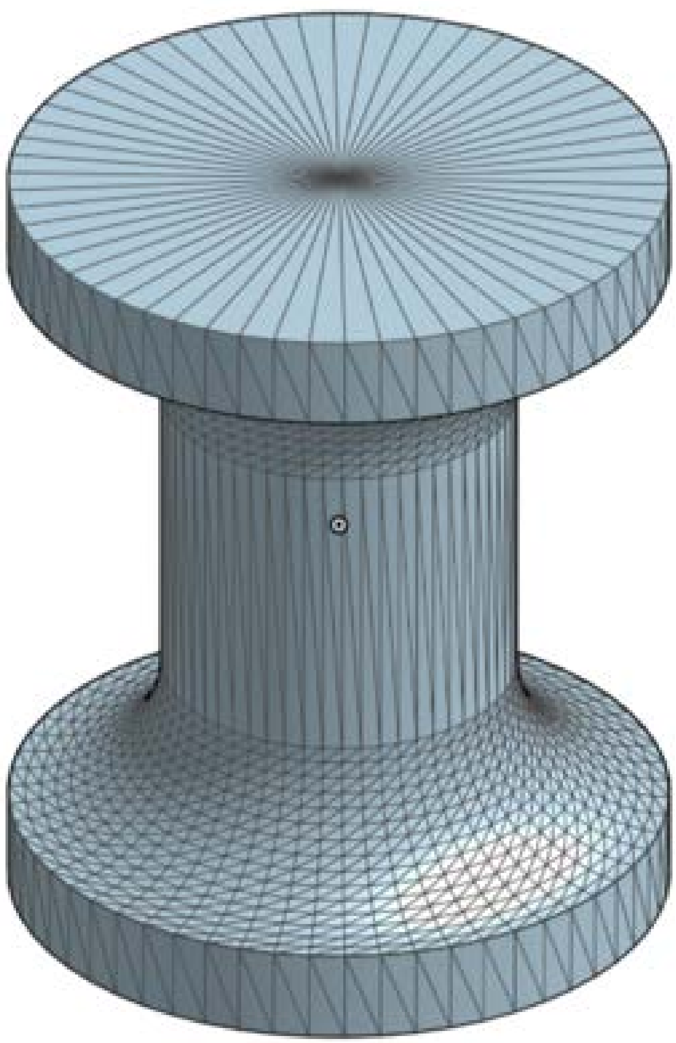
Date: 11/20/2024

Content by: Maiwand Tarazi

Present: Torsional springs built for airway trainer prototype

Goals: Present the design for the torsional springs as well as understand the theory of why it was used (constructed specifically).

Content:



- Torsional spring component seen above was made via 3D printing a the maker space. This component was made such that it can induce a moment (rotation about its axis) which can then enable rotating of the lower jaw component which is also attached to the trainer.

Conclusions/action items: The torsional spring seen above is very important to wrap up our trainer base design. Its structure is conducive to moment generation about its axis of symmetry which is important as its placement on the trainer will allow the lower jaw element of our trainer to rotate as well. Having said this, these torsional springs were printed multiple times (6 in total) which will be tested and placed in junction points between the jaw components and the base itself.

11/21/2024 - Building of Hinge Component of Airway Trainer

MAIWAND TARAZI - Dec 11, 2024, 1:50 PM CST

Title: Building of Hinge Component of Airway Trainer

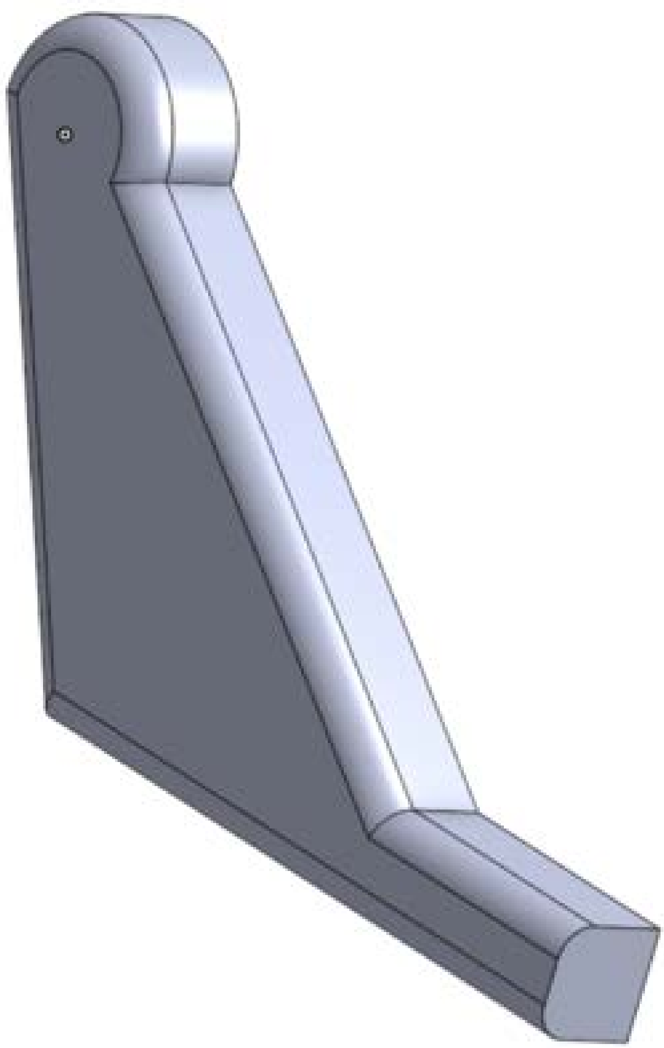
Date: 11/21/2024

Content by: Maiwand Tarazi

Present: Built hinge for airway trainer as well as the theory behind its design.

Goals: Present an image of the built hinge component for the airway trainer as well as the theory behind the design.

Content:



Conclusions/action items: Above is an image of the simulated hinge component. This hinge is vital to our design as it enables rotation (moment about) of the lower jaw component. The hinge (along with a pair or torsional springs) will enable adequate but limited (27-50 flexion angle) of the jaw component. This will reflect the real physiology of the anatomy which is important to make this design as accurate as possible.

11/26/2024 - 3D printed Airway Mold

MAIWAND TARAZI - Dec 11, 2024, 1:48 PM CST

Title: 3D Printed Trachea Mold

Date: 12/26/2024

Content by: Maiwand Tarazi

Present: Team-built trachea mold make at the maker space

Goals: Present built 3D mold for bookkeeping progress throughout semester.

Content:

Conclusions/action items: This mold was built (3D printed) at the maker space and highlights the complex and dynamic nature of airway anatomy. The main trachea component can be seen in the middle as the "tube". Spiraling components on the sides represent tissue build on the side of the trachea which highlights that of real patient anatomy.

11/28/2024 - CT Scans resolved

MAIWAND TARAZI - Dec 11, 2024, 2:52 PM CST

Title: CT Scan Issue Resolved

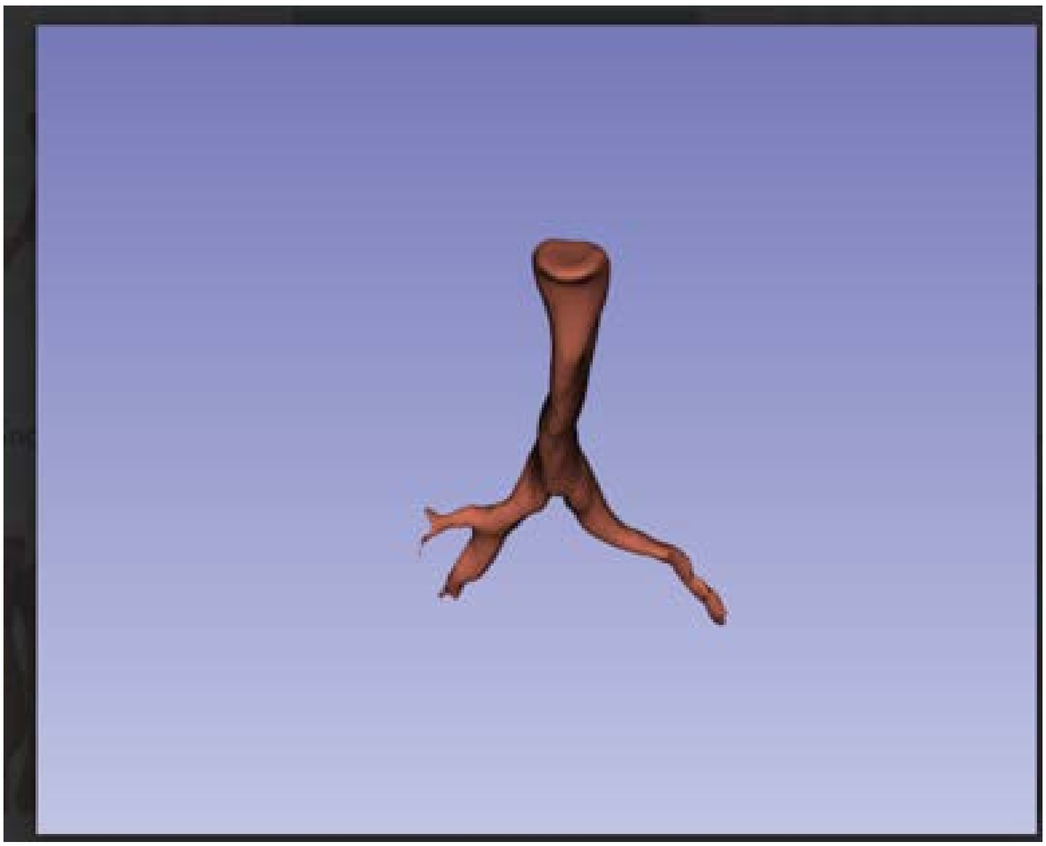
Date: 11/28/2024

Content by: Maiwand Tarazi and Ilia

Present: Potential solution to lack of obtaining accurate CT scans from UW - School of Medicine and Public Health. Since we were not able to obtain these scans we were able to ask Ilia's sister for some sample scans to utilize. Below on this entry are results of segmentation analysis on these scans.

Goals: Present potential CT scans from Illia's Sister who works at GE Healthcare

Content:



Conclusions/action items: These images are results of 3D slicing scans provided to us by Ilia's sister. These scans were imperative for our group as they provided us the anatomical frameworks seen above. Further segmentation of these scans will be required to get a more detailed analysis and accurate anatomy for the trainer.

12/5/2024 - Trainer Base Assembly: Final Prototype

MAIWAND TARAZI - Dec 05, 2024, 10:58 PM CST

MAIWAND TARAZI - Dec 05, 2024, 11:20 PM CST

Title: Trainer Base Build: Final

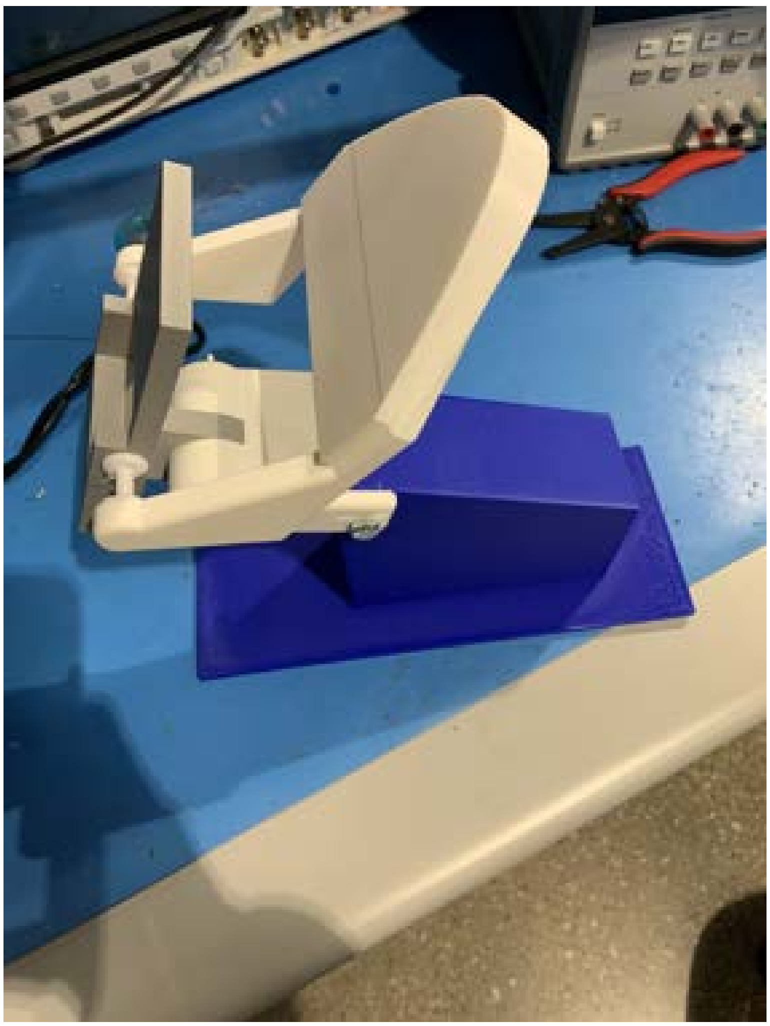
Date: 12/5/2024

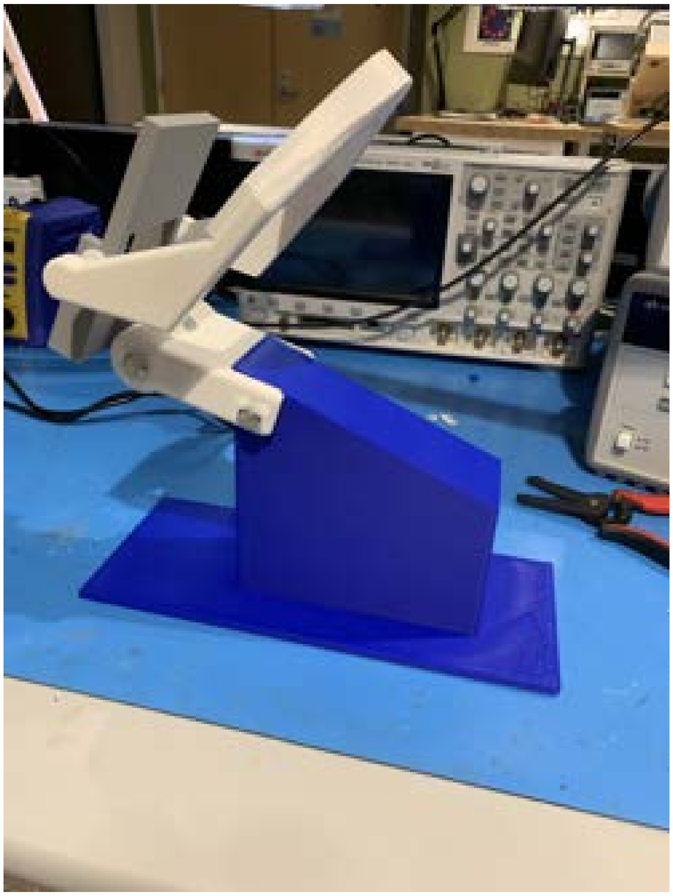
Content by: Maiwand Tarazi

Present: Final base model for team's airway trainer

Goals: Present the final base design built.

Content:





Conclusions/action items: At the maker space Nathan and I assembled the base. Specifically we screwed the blue base stage to the white lower jaw component as seen in the image (side view) above. Lastly via superglue and point attachments we connected the gray upper jaw component to the white lower jaw component. This is a major accomplishment for our team as we now have a completed prototype base ready prior to final deliverables.

12/11/2024 - Failed Prints at Makerspace (Reflection and Future Considerations)

MAIWAND TARAZI - Dec 11, 2024, 1:51 PM CST

Title: Failed 3D Prints at the Makerspace (Reflection and Future Considerations)

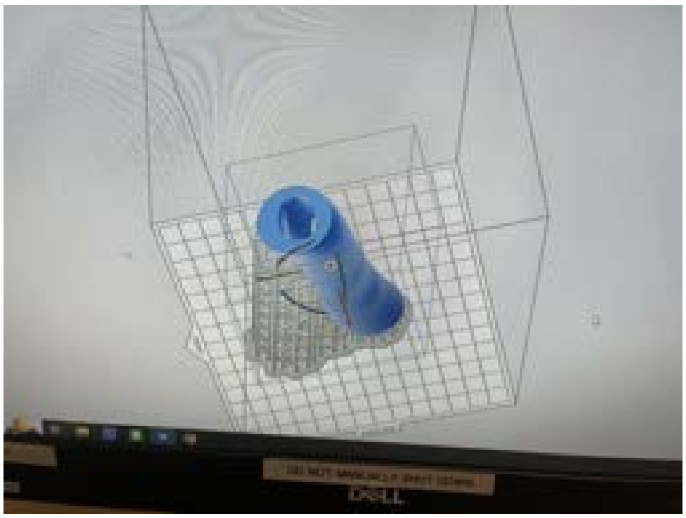
Date: 12/11/2024

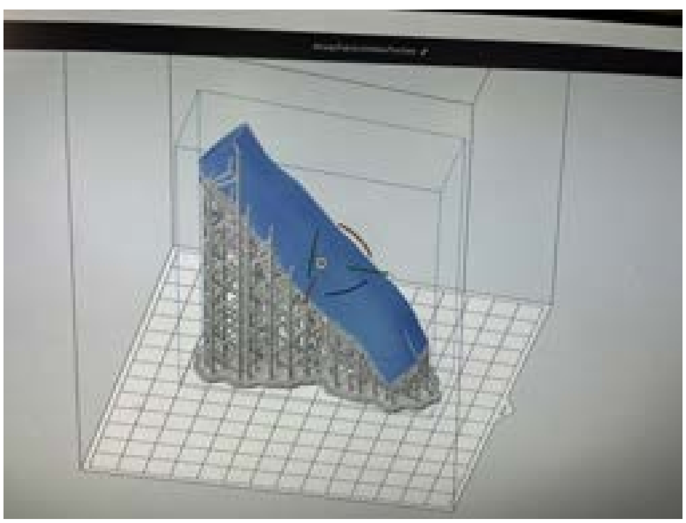
Content by: Maiwand Tarazi

Present: Images of failed prints throughout the semester

Goals: Present the failed prints and understanding why they failed for future reference in future design courses requiring prints at Makerspace.

Content:





The above images show the initial solidworks-slicer models for the trachea airway component of the trainer. The last image shows the failed results received at the Makerspace. The fundamental reason why these models did not print correctly is due to incorrect dimensions inputted on Solidworks. We did not complete adequate research on what dimension values (and forces) would support the trachea structure.

Conclusions/action items: The images above provide a failed print which occurred this semester. The reason of the failed result is due to incorrect measurements and not accounting for forces acting on the printed pieces. In the future, before printing, we should throughly measure dimensions of the piece being made to make sure it will print correctly. This is especially important as each print does impact our budget as the semester progresses.

12/11/2024 - Future Work (alternate ideas for creating a novel airway trainer)

MAIWAND TARAZI - Dec 11, 2024, 1:41 PM CST

Title: Future work (alternative ideas for creating a novel airway trainer)

Date: 12/11/2024

Content by: Maiwand Tarazi

Present: Alternative methods for creating a novel airway trainer.

Goals: Introduce alternate ways to proceed with the airway design.

Content:

- One major method is directly collaborating with the UW-School of Medicine and Public health. This means having a project which directly involves the medical school. Because our project was "sponsored" by the medical school we were given directions as to what to do (problem statement from client). We did not receive scans from the hospital which we could use for segmentation models which was a big issue for our group. These scans would've been great, especially if we received them in the early stages of the semester. This is a major alternate idea to creating this trainer. Another idea, could be direct collaboration with a medical company in the Madison area to provide us adequate technology (autosegmentation) to make more direct help to help us reach better results. While our group did create a great final prototype we know that we could make some more improvements that could take a level higher where use in the clinical setting may be a possibility.

Conclusions/action items: Our group's project design was encountered with a variety of issues. The main issue seen was the lack of access to accurate CT scans which we hoped to get from the hospital to use for segmentation. In addition, out group did not have authorization for advanced autosegmentation softwares to segment said CT scans. If possible, direct collaboration with the UW-School of Medicine and Public Health or a medical company in the Madison area would help the team get access to reliable CT scans from anatomical imaging and advanced autosegmentation software to create our design. This is the major future work to consider for this project if continued in future semesters.

9/11/2024 - Lecture 1

MAIWAND TARAZI - Sep 11, 2024, 2:08 PM CDT

Title: Lecture 1

Date: 9/11/2024

Content by: Maiwand Tarazi

Present: lecture 1 details

Goals:

Content:

Job search tips:

- Keep track of what you do; ECS tracking sheet =

ECS.wisc.edu/trackingsheet

- Quality of source matters - Handshake, Linkedin, Indeed,

- Connect before you are a candidate; use your people

- Applying is step 1; a follow up is required (2-3 weeks)

- It takes time

Resume Tips

- Tailor your resume to the position; quick changes

- Create balance; show a full picture of your experience

- Build resume on Microsoft word; do not use google docs

Cover Letter Tips

- ALWAYS based on the job posting

- custom to each job

Career Fair Advice for BME

- Identify your purpose; more than just an internship

- Looking beyond the obvious; overlap with other disciplines

- Research the employer; feedback from our partners

- Develop your "valued added" statement

- Fall Engineering Career Fair; Sept 16-19; look for BME, EE, and ME

Conclusions/action items:

Received great advice on how to reach out to companies.

9/18/2024 - Lecture 2

MAIWAND TARAZI - Sep 18, 2024, 2:00 PM CDT

Title: Exploring your Leadership Style

Date: 9/18/2024

Content by: Maiwand Tarazi

Present: lecture details from week 2

Goals:

- Talk about:

- Leadership

- Leadership styles in BME

Content:

- Anatomy of a good leader:

- Self awareness; understand your strengths and weaknesses

- Vision; provide direction and purpose, set goals

- Styles:

- Power model; leadership = power

Thought process: someone has to take control here, and it should be me; being in control is the most important thing

- Servant Leadership: it's not about me and my needs, the needs of my followers is the most important

- Authentic leadership: "by being my genuine self, I will gain and build trust"; building esteem and self-awareness

- People Oriented Leader: The glue that holds the team together; you get to know everyone as individuals

- Process-Oriented Leader: Sets the pace for the team; willing to work alongside everyone

- Thought-Oriented Leader: Sees the big picture and anticipates the future

- Impact-Oriented Leader: You set the bar high and push for excellent performance

- Leadership doesn't require a particular job title; Leading others starts with leading yourself

- Self assess: what you enjoy, what you're good at, and what drives you

- Observe and reflect: What are tasks and experiences that give you a sense of accomplishment?

- Seek out feedback: Others may be able to identify your strengths

- Team Goal: Ideally, our team will be very organized in the time management while building our designs. In order to facilitate this, I will help the team be organized with due dates that we must meet to ensure that all components are done in a timely matter.

Conclusions/action items:

Continue to be a leader in design project and improve on areas that I'm weak on.

9/25/2024 - Lecture 3

MAIWAND TARAZI - Sep 25, 2024, 2:05 PM CDT

Title: BME Advising Session Part II: Fall Post Graduate Planning

Date: 9/25/2024

Content by: Maiwand Tarazi

Present: Lecture details

Goals: Advice to plan out future after BME degree

Content:

- Use your undergraduate experience to "build a story"

- Do your homework - never too late

- Think about letter writers or references early - 3 strong ones

- School: prepare for MCAT or GRE summer before senior year

- Writing your story: make sure personal statement or cover letter is clear and concise

- General: Start with what you want to do - thesis statement, personal statement: show a reasonable idea of what, defend your plan with your life experiences, CV to some extent in paragraph form

- Doctoral, PHd = desire to be an independent researcher, write research grants, work in academia

- MS is a stepping stone for further education: rewrite your story, will make you more desirable as it may fill gaps in your resume and provide you more experiences; really powerful if you add industry experience

- Research MS Option: for those continuing on for a Phd here; can be funded as RA/TA/PA; Thesis required

- Accelerated Program Option: coursework only, independent study/research is allowed; funding

- Biomedical Innovation, Design, and Entereorenurship: project based, project required; partnership with business school

- Applying for BME accelerated MS program: Applying online, pay fee and submit; need at least a 3.0 overall/3.0 in the last 60 credits

- Explorer opportunities and interests: MEng, MS in global health, MS in other engineering, similar to advice earlier and for Phd programs later

- Doctoral degree (Phd) Additional Advice: Follow your passion, who is working in that area?, network, conferences, utilize your lab PI here at Madison = collaborators; Build your resume/ CV

- PhD application process: Apply early and list names - must do rolling review, generally > 3.5 GPA and 75%tile quantitive GRE

- Medical School (MD) advice: premed advising (check with them), must take chem 344 & 345, two semesters of physics, two semesters of english, biochem 501, can be satisfied with BME 128 credits

- Research is required, Volunteer (clinical setting desired), shadow physicians, patient contact time, build relationships = letter writers, use your design experiences, requirements vary by degree

Conclusions/action items: Continue to plan out future after BME degree

10/2/2024 - Lecture 4

MAIWAND TARAZI - Oct 02, 2024, 2:01 PM CDT

Title: Near Peer Mentoring

Date: 10/2/2024

Content by: Maiwand Tarazi

Present: Lecture details

Goals: Discuss the mentoring process in BME 300

Content:

- Why are we peer mentoring:

- Additional instructional and emotional support for students

- Peer mentors are more approachable, mentees are more willing to work

Transferrable Skills

- Leadership

- Communication

- Active listening

- Study practices

- self awareness

General Benefits of Mentoring

- increased self-esteem/confidence

- increased patience

- build positive habits

- foster personal growth

- help identify gaps in your own knowledge

- sense of accomplishment

What does it mean to be a good mentor?:

- Building trust

- Psychological safety

- Reliability

- Support/Enthusiasm

- Being available

- Transparent

- Humanizing their challenges: be the coach

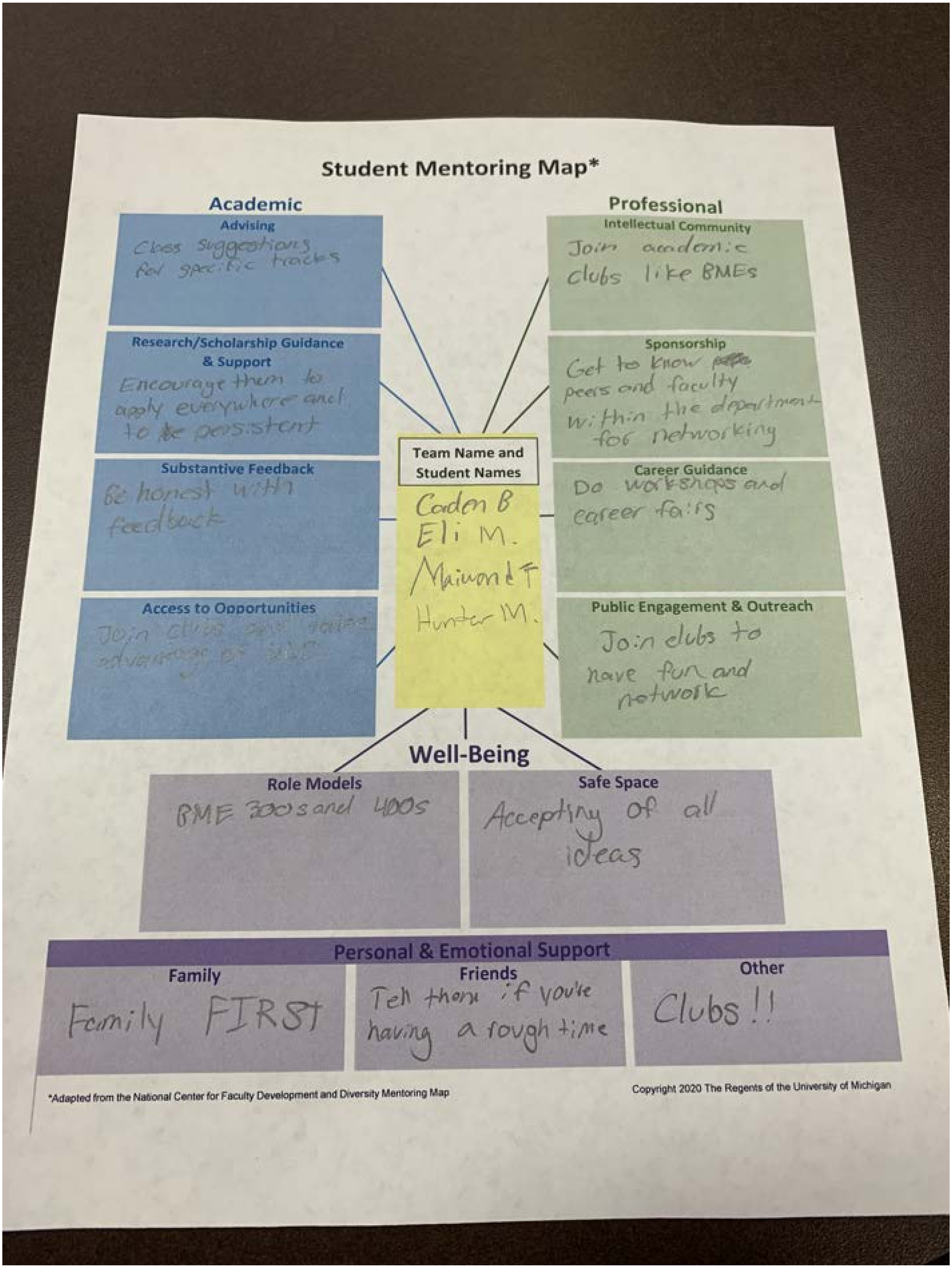
- Good Listening

Listening effectively

- Get rid of distractions
- Stop talking
- Act like you're interested
- Look at the other person
- Get the main idea
- Ask questions

What do you wish you knew in BME 200

Mentor Map:


Student Mentoring Map*
Academic
Advising
Class suggestions for specific tracks
Research/Scholarship Guidance & Support
Encourage them to apply everywhere and to be persistent
Substantive Feedback
Be honest with feedback
Access to Opportunities
Professional
Intellectual Community
Join academic clubs like BMEs
Sponsorship
Get to know peers and faculty within the department for networking
Career Guidance
Do workshops and career fairs
Public Engagement & Outreach
Join clubs to have fun and network
Team Name and Student Names
Caden B
Eli M.
Maiwand F
Hunter M.
Well-Being
Role Models
BME 300s and 400s
Safe Space
Accepting of all ideas
Personal & Emotional Support
Family
Family FIRST
Friends
Tell them if you're having a rough time
Other
Clubs!!
*Adapted from the National Center for Faculty Development and Diversity Mentoring Map
Copyright 2020 The Regents of the University of Michigan

Conclusions/action items: Continue to find new ways to mentor students in BME 200.

10/9/2024 - Lecture 5

MAIWAND TARAZI - Oct 09, 2024, 1:59 PM CDT

Title: Lecture 5

Date: 10/9/2024

Content by: Maiwand Tarazi

Present: lecture details

Goals: Learn ways to make engineering more sustainable and apply it to design projects

Content:

Sustainable Engineering

- In 1987, the United Nations Brundtland Commission defined sustainability as "meting the needs of the present without compromising the ability of future generations to meet their own needs"

- Circular Economy: keeping things recycled, which keeps it in the "economy"; the circular economy attempts to keep things out of land fills

- Increasing nutrients in water can lead to Eutrification (often occurs in lakes and streams)

- Life cycle assessment: look at materials in how they are made, distributed, used, and as waste --> coca cola did the first life cycle assessment

Conclusions/action items: Use these sustainability tips in the design project.

10/16/2024 - Lecture 6

MAIWAND TARAZI - Oct 16, 2024, 2:05 PM CDT

Title: Introduction to WARF, IP, Disclosing and Licensing

Date: 10/16/2024

Content by: Maiwand Tarazi

Present: lecture details

Goals: Learn about the WARF foundation and patenting at UW-Madison.

Content:

- WARF Mission: to support scientific research within the UW-Madison community by providing financial support, actively managing assets, and moving innovations to the marketplace for a financial return and global impact.

- Vision: Enable University of Wisconsin-Madison research to solve the world's problems

- Technology transfer: moving research results from campus out into the market. WARF works at this interface to facilitate securing IP rights and commercial licenses

- Examples include: intellectual property licenses, industry sponsored research, consulting arrangements, fee for service

- Intellectual property overview: four types which include patents, copyrights, trademarks, and trade secrets other WARF IPs include biomaterials, techniques, and data

- Overview of non-patent IP: Copyrights -->

- Protection for creative works that are expressed in a tangible medium; a wide range of subject matter, including software code

- Trademarks: protection for names, marks, logos, dress, etc.

- Trade secrets: can be used to protect anything of value, protection is good so long as the concept is not generally known

- Patents Generally:

- A patent is a property right, granted by a governmental agency; patent holder has right to exclude others from making, using, selling, or importing the claimed invention

- There are three different types of U.S. patents: Design, Plant, Utility

- Utility patents: issued for the invention of a new and useful process, machine, manufacture, or composition of matter; a quid pro quo with the USPTO

- patent examiners are scientists hired and trained by the USPTO to review patent applications for these requirements

- Disclosing an innovation to WARF:

- describe the innovation, identify its advantages and potential applications, name contributors, and provide funding and public disclosure details

- Meeting with WARF:

- discuss the innovation in more detail

- ask questions about WARF and patenting processes

- discuss next steps

- WARF bases its decision on accepting an innovation into our portfolio on: IP considerations and licensing considerations

- Marketing and Licensing: Licensing the IP is the next step in transferring the technology

- Market Analysis: market status - established, emerging, new

- License negotiation: type and terms and consideration

- Ongoing: technology development, enforcement, amendment, termination

- Value of licensing: benefits to the company -->

- reduced R and D costs, improved time to market, opportunity to enter new markets and expand your community quickly, new features or products provide additional revenue opportunities

- Determining the value-->

- technology application, key selling points, technology trends, market size, industry standards

- AI and IP: can AI invent? --> No; inventor must be a natural person, conception --> but, AI may assist in inventing under Pannu factors

Conclusions/action items: Be aware of the patenting rules and intellectual property while working on design projects.

10/23/2024 - Lecture 7

MAIWAND TARAZI - Oct 23, 2024, 2:03 PM CDT

Title: Do I need an IRB?

Date: 10/23/2024

Content by: Maiwand Tarazi

Present: lecture details

Goals: Learn about the IRB and its application in the BME design projects.

Content:

- IRB origin:

unethical research --> ethical principles --> human research regulations

- includes many infamous studies

- Belmont principles: respect for persons, beneficence, and justice

- regulations for protection of human "subjects"

- IRB was instituted by common rule and FDA regulations

- UW Madison IRBs include minimal risk research IRB and the health sciences IRB serves UW-Madison, UW health affiliates, and the Madison VA hospital

- Multi-site studies required to use single IRB

- Does my design project need an IRB? --> Is it research under the Common Rule?

- Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

- Does it involve human subjects?

- A human subject means a living individual about whom an investigator conducts research

- Is it human research under FDA device regs? --> device: intended for use in diagnosis, treatment, or prevention of disease, or that affects structure or function of the body

- Research/clinical investigation = involves one or more subjects to determine device safety or effectiveness

- Subject = individual on whom or on whose specimen an investigational device s used or as a control in an investigation

- How to prepare for IRB review:

- complete required training for researchers through CITI

- complete annual outside activities reports

- Develop your research plan:

- identify appropriate principal investigator and study team

- collect preliminary (non-human) data and background info

- develop a research question and steps to answer it

- PBA components:

- protocol document: details study aims, rationale, procedures, device info, and analysis plan

- details eligibility, recruitment, informed consent process, participate protections

Conclusions/action items: Consider the IRB process while working in design projects.

10/30/2023 - Lecture 8

MAIWAND TARAZI - Oct 30, 2024, 2:07 PM CDT

Title: Navigating FDA Device Requirements

Date: 10/30/2024

Content by: Maiwand Tarazi

Present: lecture details

Goals: Discuss FDA regulated oversight program overview and ICTR IND/IDE consultations service discussion

Content:

- Defining a medical device: anything that is intended to improve the health of the body which is not a drug or a biologic

- Traditional Medical Devices: MRI machines, drug infusers

- Non-traditional medical devices: fitbit watches, software, AI, machine learning, etc.

- Device Classification Overview: Class I, Class II, Class III

- General Controls, Special Controls, Premarket Approval

- General controls: registration and listing, adverse event reporting, general labeling

- Special controls: performance standards, special labeling requirements, post-market surveillance, potential data requirements

- premarket approval: data to show safety and effectiveness

- Class I Devices: low level risk, basic regulatory requirements, self-registration an listing with the FDA

- Class II Devices: higher risk than Class I, must follow general and special controls which can include performance standards and post market surveillance, submission of a 510(k) application to show substantial equivalence may be exempt

- Class III Devices: high risk level, sustain or support life, implanted or potential for unreasonable risk. must follow general controls and additional stringent requirements, such as clinical trials to demonstrate safety and efficacy. PMA submission, which involves a comprehensive FDA review safety and effectiveness data before marketing

- Market submission types: Premarket approval and De novo classification (novel devices, no legally marketed predicate)

- How to Classify a Medical Device:

- Product Code: device defintion and classification, submission type, GMP requirements, recognized consensus standards

- Key points for Classification: depends on the intended use and indications for use, where indications for use may affect safety or effectiveness, then may be new intended use

Conclusions/action items: Be considerate of the FDA regulations while working on design projects.

11/6/2024 - Lecture 9

MAIWAND TARAZI - Nov 06, 2024, 2:06 PM CST

Title: Regulatory Strategy: The Framework Guiding Advanced Therapeutic Product Development

Date: 11/6/2024

Content by: Maiwand Tarazi

Present: lecture details

Goals: Understand the overall structure of the FDA, including the framework of laws, regulations, and guidances for advanced therapeutics

Content:

- Genome Editing: Target precise genome locus and delete, insert, or change existing sequences

- Gene Delivery: Transfer molecular tools and assembled gene systems into the cell

- Cell Therapy: Use expanded cells to transfer medicinal bioactivity to regenerate tissue

- Dramatic implications: 351 vs 361 products

- 361 type products are low risk (safe) type products that do not need very much regulations

- Conversely, 351 type product are regulated as drugs/and or biologics (more regulations)

- Product Development Life Cycle: "Each stage of the product development cycle faces its own risks and challenges, and proper management of these risks is vital for successful commercialization. It's extremely important to be able to distinguish between studies that are "on the critical path" vs "good research projects"

- A Target Product Profile (TPP) is your product vision; patient identification: indication; patient benefits: efficacy profile; patient risks: safety profile; is it medically and commercially compelling

- Considerations when Developing a 351-regulated CGT: time is very important in this process, it's important to manage to make sure all processes (nonclinical, quality, clinical, and regulatory) are completed

- Quality management system implementation: a system that documents policies, processes, internal rules, procedures, and other records to ensure consistent quality

- Career options within a Regulated Environment: Chemistry, Manufacturing, Controls --> Characteristics and Analytics, Process Development, Manufacturing Development, and Gene Delivery

Conclusions/action items: While working on design projects, keep in mind the guiding framework of advanced therapeutic development.

11/13/2024 - Lecture 10

MAIWAND TARAZI - Nov 13, 2024, 2:01 PM CST

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

Title: Medical Device Innovation: From Prototype to Commercial Clinical Use

Date: 11/13/2024

Content by: Maiwand Tarazi

Present: lecture details

Goals: Go over the medical device process including how devices are introduced by new ideas, testing the devices with human subjects, FDA regulatory process to name a few.

Content:

Medical Device Process at a Glance:

1. Innovation idea and development

2. Human testing data acquisition with IRB oversight

3. FDA regulatory process

4. Reimbursement of financial incentive

5. sales

Regulatory Pathways for Medical devices --> as follows:

Breakthrough Devices Program

- Formerly expedited access program

- timely access to medical devices for life threatening or irreversibly debilitating diseases

General steps from approval to adoption:

Clinical studies --> FDA approval --> CPT codes --> CMS National insurance decisions --> Standards of practices --> National regional buying groups --> Regional/Local hospitals --> Hospital/IDN value analytics groups --> product evaluations --> Regional/just in time distribution --> Product implementation

Workflow: Patient Care Pathway as a Starting Point

Materials --> Clinician --> Patient --> RN, PharmD

- Observing who your stakeholders are is very important to know how the technology may be used

For example: National Clinical Oversight: FDA, Clinical Advisory Groups, International Clinical Societies

Value Based HealthCare

- If we define value more broadly as improving patient outcomes while making it more affordable to deliver those outcomes, there is a wider range of possibilities for product developers, providers and payers to collaborate, and signs of progress are easier to find.

Trickle-Down Influence for New Technology: National Policy, Standards of clinical practice guidelines --> Health system and provider --> Payor

Value Drivers to Discover:

- Economic: Money, Staff time, Resources, Waste, Metrics

- Clinical: Improve outcomes, Reduce risk, Reduce complications, Shorten length of stay, Solve "issues"

- Mission impact: Patient Satisfaction, Academic leadership, Innovation in care

--> Evidence more compelling than "hand-waving" benefit assumptions

Who buys, Pays and gets Reimbursed: It depends

Key Terms to Uncover Payment:

- CMS Centers for Medicare and Medicaid Services

- DRG Diagnostic Related Groups

- CPT Current procedural code

- ICD 10 International categorization of diseases

- GPO Group purchasing organization

- IDN integrated delivery networks

- Payer Mix

--> Existence of codes do not equal financially favorable

Conclusions/action items: While working on design project, be considerate of these rules and regulations in the medical device process.

11/15/2024 - Tong Lecture

MAIWAND TARAZI - Nov 15, 2024, 12:50 PM CST

Title: Tong BME Distinguished Entrepreneur Lecture

Date: 11/15/2024

Content by: Maiwand Tarazi

Present: Discussion details from Dr. Berthier and Dr. Casavant regarding their contributions to Biomedical engineering.

Goals: Learn about the BME pathways that Dr.s Berthier and Casavant took and how they shaped their careers in biomecal tehcnology, creating the company Tasso, Inc.

Content:

Tasso company

Originally making 60k a year

Spent money prototyping, even if they lost

Eventually, they asked for help because they - LAW and Entrepreneurship at UW Madison

Got scrappy with funding opportunities

Wrote as many grants as he could with the limited resources they had

They got one 150K grant and paid back credit card debt

Minority and health disparities

Sometimes just having an idea is great in America because there are so many resources that push

Sometimes changing the technology is good but you have to be careful in a way because killing products affects process

10 billion blood tests are done a year

they do steroid tests for many sports

They need a dry blood sample for one person, then they can maybe scale

Scaling up - derisking technology, lots of new concepts - continual iteration

Quality, culture, and HR

- cancelling cash flow due to pandemic lead to them slowing things down.

Covid antibodies

focusing on all the small things once at a time, quality is always the most important thing in heath. Don't take the low road because your reputation is on the line

Who can figure out how to get it done.

They had a great product that would grow and it did.

Regulatory strategy- This

They had a class II iVD and it would take 18 months to

Read the labels - it's easy to over-analyze what regulators say they "want" to do

if you have an idea just go for it, you will maniefest the hours of work and figuring out. There will always be walls, innovate - think new and creatively

Have a cool name - Tasso(badger in Italian)

Conclusions/action items: Hearing the backgrounds of both Dr. Berthier and Casavant show that careers in BME are vast and often take trial and error (especially in the entrepreneurship case). Keep exploring different BME career paths.

11/20/2024 - Lecture 11

MAIWAND TARAZI - Dec 10, 2024, 11:19 AM CST

Title: How New Product Development Works in the Medical Device Industry

Date: 11/20/2024

Content by: Maiwand Tarazi

Present: Lecture details

Goals: Learn more about how new product developments in the medical device industry

Content:

- New Prdocut Development
  - This process is highly regulated
  - Pretty expensive
  - Competitve
  - Requires lots of resources
- Strategy for sustaining NPDs
  - Define how the business will sustain itself over the next 3-5 years
  - Define which product categories to develop, sustain, and eliminate
  - Select and prioritize projects to support over next 1-3 years
  - Allocate budget and resources based on project prioritization
- Types of NPD projects
  - Line extensions
  - Product improvements
  - New to world
  - New to company
- Managing NPD: Stage-gate process
  - Stage 0 - Ideation
    - Choose area of opportunity
    - Review market trends and/or competitive threats (existing intellectual property and more)
    - Conduct primary and secondary research
    - Identify customer unmet needs
    - Create high-level, "Back of the napkin" ideas
  - Stage 1 - Exploration
    - Define problem to be solved and customer requirements - Define the problem statement
    - Review, refine, and screen list of ideas from Stage 0 for exploration
    - Create concepts for 8-10 ideas
    - Develop high-level business case (market size, value proposition, etc.)
    - Conduct preliminary technical scouting and intellectual property landscaping
  - Stage 2 - Concept Development
    - Based on customer interviews and use-case assessments, down-select from 8-10 to 2-3 to **1 leading concept**
    - Develop robust business case including market opportunity, initial forecast, and projected expenses
    - Conduct comprehensive IP examination
    - Next Gate review is "go/no go" business decision
  - Stage 3 - Design Development

    - Move to functional prototype
    - Continue iterate design process including initial testing and reviews with customers
    - Confirm regulatory pathway
    - Begin formal **Design Control** documentation
      - Mandatory for FDA Class 2 & 3 and almost all EMA devices
      - Includes **documentation** of customer needs, design requirements, design inputs/outputs, testing, and design reviews
      - Tightly aligned with Risk Management
      - Protype -> test -> evaluate -> (Cycle)
  - Stage 4 - Design Confirmation
    - Conduct extensive verification and validation testing
    - Finalize product and component drawings/models
    - Accelerate manufacturing process development along with plans for quality control
    - "freeze" design at the end of this stage
    - Submit Regulatory documentation, e.g. FDA 510(k)
  - Stage 5 - Design Transfer & Commercialization
    - Complete any remaining testing
    - Make final design changes
    - Build molds, assembly/test equipment
    - Create Instruction for Use (IFU) and user manuals
    - Develop service plan and resources
    - Finalize go-to-market strategy and start limited release (if applicable)
  - Launch - Post-Market Surveillance
    - Regulatory agencies expect that companies are monitoring and documenting customer complaints and field issues post-launch
    - Companies continuously track customer and salesforce feedback via interviews and surveys
    - On a 4-6 month cadence, project teams report out to stakeholders:
      - Account sales
      - Business and regulatory issues observe
      - Complaints
      - Product and porcess improvement opportunities
  - Different Phases like "The Cloud", "The Funnel", and "The Tunnel"
  - Several steps and questions asked to ensure the NPD is needed
    - Mitigates financial risks, reduces chances of failure
- Case Study
  - Suction chambers and systems streamlined work
    - Integrated system within machine to get rid of waste instead of having to manually dump canisters
- Summary
  - Medical device development is an expensive, complex, and highly collaborative effort
  - Having limited resources, most businesses have instituted processes like Stage-Gate to reduce risk and increase probability of success
  - Good product design and development is necessary for commercial success

Conclusions/action items:

Keep these points in mind and work on product development with a more wholistic view.

9/13/2024 - Client Meeting 1

MAIWAND TARAZI - Sep 13, 2024, 11:31 AM CDT

Title: Client Meeting

Date: 9/13/2024

Content by: Maiwand Tarazi

Present: Client meeting details

Goals: Get to know our client and to get acquainted with the premise of project. Ask questions to clarify aim.

Content:

- Dr. Schroder provided us a detailed model of the region of the throat (larynx) we will focus on. Let us test out tools to examine the airway region.

- In terms of logistics, he provided us a budget of approximately $750. He stated that the main physiological concern we should be addressing in developing is obesity and how it affects airway dynamics.

- Vision for the project is a swappable anatomy of an airway trainer to give residents as much practice possible; enable experience of variety of anatomy environments; if at all possible (last goal) is to create a patient-specific model to test on prior to surgery

- Dr. Schroder's main concerns about current airway trainer devices are there inability to replicate specific anatomy, lack of lubriacation; in addition some trainers are too stiff which do not reflect the true nature of real procedures

Conclusions/action items:

Investigate DICOM files that we were advised to look at. Additionally, find material that can replicate airway anatomy, like fleshy bits with flexibility (minimize stiffness). We will continue communicating with Dr. Schroder to see if he has any 'sacrificial model' manakins that we can use a test airway trainers on.

10/11/2024 - Client Meeting 2

MAIWAND TARAZI - Dec 11, 2024, 1:52 PM CST

Title: Client Meeting 2

Date: 10/11/2024

Content by: Maiwand Tarazi

Present: Client meeting details including questions asked to Dr. Schroder and updates provided to him.

Goals: Acquaint our client with our current progress and ask him regarding current doubts we have.

Content:

Project Updates:

- Show the presentation
- Design matrices
- Plan moving forward
    - Using existing makerspace resin to print a test piece and see if this will work
- Updated project scope and goals
    - Make an anatomically accurate airway (tongue and down) out of a material that represents anatomical mechanics
    - THEN try and make a functioning airway if possible

Questions:

- Dept wants to purchase everything themselves, but will they be able to reimburse Makerspace costs where it has to be billed to a wiscard or credit card?

Conclusions/action items: The project has made significant progress, with updated goals focusing on creating an anatomically accurate airway prototype using materials that mimic anatomical mechanics. The immediate next step involves testing the feasibility of using the existing Makerspace resin to print a test piece. Moving forward, the team plans to refine the design matrices and finalize the project scope based on the test results. Additionally, clarification is needed on whether the department can reimburse Makerspace expenses billed to a Wiscard or credit card.

9/12/2024 - Human Airway Research

Ilia Mikhailenko - Sep 12, 2024, 11:31 AM CDT

Title: Research on the Human Airway

Date: 9/12/2024

Content by: Ilia M

Present: N/A

Goals: To discover more on the biology/physiology of the human airway path and how we can work towards 3D printing airway trainers

Search Term: human airway biology/physiology

Link: https://www.frontiersin.org/journals/veterinary-science/articles/10.3389/fvets.2020.587524/full

Citation:

Oberoi, Gunpreet, et al. "3D Printed Biomimetic Rabbit Airway Simulation Model for Nasotracheal Intubation Training." *Frontiers*, Frontiers, 22 Oct. 2020, www.frontiersin.org/journals/veterinary-science/articles/10.3389/fvets.2020.587524/full.

Content:

- Animal specimens are very convenient for learning more about human anatomy (rabbits have a very similar airway path)
- Current models include animal specimens, simulations, and virtual reality, each with issues (cost, toxicity, accessibility)
- Models for airway trainers have been created through additive manufacturing, which uses CT/MRI data and offers a more humane alternative. A drawback of these is that current models lack realistic human anatomy
- Looking to work toward developing a realistic, cost-effective rabbit nasotracheal simulation model using advanced 3D printing. This would enhance training, reduce live animal use, and address ethical and financial concerns.

Conclusions/action items: Our team should keep this all in mind when meeting with our client tomorrow and discussing the important features that an airway trainer should possess as well as the basic anatomy of an airway trainer and how we plan to recreate it.

9/18/2024 - Airway Materials Research

Ilia Mikhailenko - Sep 20, 2024, 12:52 PM CDT

Title: Research on the Airway Materials

Date: 9/18/2024

Content by: Ilia M

Present: N/A

Goals: To discover more on the materials used in current airway designs

Link: https://www.medicalexpo.com/medical-manufacturer/silicone-training-manikin-61076.html.

Citation:

Silicone Training Manikin - All Medical Device Manufacturers. https://www.medicalexpo.com/medical-manufacturer/silicone-training-manikin-61076.html. Accessed 15 Sept. 2024.

Content:

- Silicone: Ideal for flexible and realistic lung, skin, and airway texture
- Plastic/resin: for rigid components like teeth, trachea, and bone structures.
- Latex: Soft, elastic material for simulating tissues such as the tongue and pharynx.
- Synthetic fluids: Used to simulate bodily fluids in vomiting
- Electronic sensors: Embedded to provide feedback to trainees on airway management actions

Conclusions/action items: The team should consider this information when choosing the materials to use for various parts of the future design.

9/26/2024 - Mechanical Properties of the Airway Tree

Ilia Mikhailenko - Sep 27, 2024, 10:29 AM CDT

Title: Mechanical properties of the airway tree: heterogeneous and anisotropic pseudoelastic and viscoelastic tissue responses

Date: 9/26/2024

Content by: Ilia Mikhailenko

Present: N/A

Goals:

Search Term: Human airway mechanics

Link: https://journals.physiology.org/doi/full/10.1152/japplphysiol.00090.2018

Citation:

M. Eskandari, A. L. Arvayo, and M. E. Levenston, "Mechanical properties of the airway tree: heterogeneous and anisotropic pseudoelastic and viscoelastic tissue responses," *Journal of Applied Physiology*, vol. 125, no. 3, pp. 878–888, Sep. 2018, doi: 10.1152/japplphysiol.00090.2018.

Content:

- Study states that lung disease is a major issue but, despite this, airway mechanics are not well understood. Lack of specific data forces computational models to use trachea data, overlooking time-dependent, viscoelastic airway behaviors.

- Mechanical properties of various airways were measured. This gives us measurements that we can seek to replicated

- Specimens were tested from trachea, large bronchi, small bronchi in axial and circumferential orientations

- Results of the experiment provide a basis for airway models to better predict lung disease and injury/pathology outcomes. This is very advanced though (most likely not actually super useful to us).

Conclusions/action items:

This article provides the group with specific measurements of human cadavers that we seek to replicate in order to establish anatomically accurate sizes for the circumference and length of various regions in the trachea. The other parts of the study which discuss predicting airway pathology are unfortunately not very helpful to us as our design will likely not achieve this level of complexity. However, a positive of the experiment is that we will be able to evaluate the scans our client sends us to see if they are similar to the expected measurements - the amount of variance we see in the scan to the expected measurement can also serve as a metric to determine how difficult the intubation will be.

Ilia Mikhailenko - Sep 27, 2024, 10:20 AM CDT

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10/3/2024 - Difficult Airway Statistics and Information

Ilia Mikhailenko - Oct 11, 2024, 12:15 PM CDT

Title: Difficult Airway Statistics and Info

Date: 10/3/2024

Content by: Ilia M

Present: N/A

Goals: Learn more about the frequency of airway issues and why airway trainers are important

Search Term: annual abnormal airway cases

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10362894/

Citation:

Maguire, Samantha, et al. “Endotracheal Intubation of Difficult Airways in Emergency Settings: A Guide for Innovators.” Medical Devices (Auckland, N.Z.), vol. 16, July 2023, pp. 183–99. PubMed Central, https://doi.org/10.2147/MDER.S419715.

Content:

- 400,000 people in U.S. intubated in emergency setting every year

- Approximately 12.7% of emergency intubations are unsuccessful on the first attempt

- An inability to intubate on the 1st attempt is linked to a greater chance of adverse events, which could include oxygen desaturation, aspiration (vomiting), trauma to soft tissue, dysrhythmia, hypotension, and cardiac arrest

- Difficult airways (defined and identified based on a clinical metric) occur in 30% of emergency department patients and significantly impair the ability to intubate

- A DSE >2–2.5 cm is a predictor of difficult laryngoscopy

Conclusions/action items: I am responsible for creating the background and problem statement slides on our group's preliminary slideshow as well as the motivation and problem statement in our preliminary design report, and the statistics and information provided in this article give me a solid scholarly backing to help me introduce and discuss our problem. I need to discuss why airway trainers and, thus, airway management, is important and a relevant medical problem that we should be concerned with, and the statistics provided here allow me to do this. Moving forward, I need to create introductory slides for our slideshow, and practice presenting them, and also begin writing the motivation and problem statement.

10/8/2024 - Further Information Concerning the Importance of Airway Management

Ilia Mikhailenko - Oct 11, 2024, 12:30 PM CDT

Title: More information regarding the advancement of airway trainers

Date: 10/10/2024

Content by: Ilia M

Present: N/A

Goals: Learn about advancements in airway management/trainers

Search Term: New airway trainer technologies

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9726337/

Citation:

Vasconcelos Pereira, Ana, et al. "New Technologies in Airway Management: A Review." *Medicine*, vol. 101, no. 48, Dec. 2022, p. e32084. *PubMed Central*, https://doi.org/10.1097/MD.0000000000032084.

Close Delete Edit

Content:

- Major complications of airway management occurred at a rate of 46.3 per million cases during general anesthesia

- Other possible avenues used for airway management: trainees being teleguided, use of AI in airway management and training, or even point-of-care ultrasound in airway management

- Measuring the distance from the skin to the epiglottis (DSE) is one of the most studied index tests to predict difficult direct laryngoscopy

- A DSE greater than 2–2.5 cm is a predictor of difficult laryngoscopy

- In a group studied that used telemedicine, they had an intubation success rate of 96%, versus the control group's success rate being just 72%, with the former group also taking significantly less time to intubate (difference of 94.3 seconds).

Conclusions/action items: As I mentioned in the previous note, I am responsible for writing our group's preliminary slideshow as well as the motivation and problem statement in our preliminary design report. Everything accumulated here is meant to be used as information for me to better introduce the significance of our problem.

action items

1. Write problem statement and motivation in report

2. Conduct further research if necessary

9/15/2024 Nasco Life/form Airway Trainer

Title: Nasco Life/form Airway Trainer
Date: 9/15

Content by: Ilia

Present: n/a

Goals: Explore the build and various features of the Nasco Life/form Airway Trainer to gain a better understanding of existing airway trainers

Search Term: Airway trainers

Link: https://anatomywarehouse.com/airway-management-trainer-simulator-with-head-a-101496?utm_term=&utm_campaign=NX_NTM_Search_DSA_All+Pages&utm_source=adwords&utm_medium=ppc&hsa_acc=1764114649&hsa_cam=8237727060
19959388920&hsa_kw=&hsa_mt=&hsa_net=adwords&hsa_ver=3&gad_source=1&gclid=Cj0KCQiApNW6BhD5ARIsACmEbkU2P8omoMr5GsLrtQZG3r2-6

Citation:
“Nasco Life/form® Airway Management Trainer,” Nasco Healthcare. Accessed: Sept. 15, 2024. [Online]. Available: https://www.nascohealthcare.com/produ

Content:
- Nasco Life/form Airway Management Trainer is a practical option for simulation training due to the following

Key features:

- Realistic tongue, teeth, and airway structures that allow for intubation practice

- Handles oral and nasal intubation with feedback. Also allows specific challenges to be faced by the trainee, such as a swollen tongue and airway blockage

- Trainer has a modular design made up of replaceable parts which allows for extended use

Pros: The airway structures are accessible, enabling study and material analysis. The trainer is durable and also adaptable to the specific needs of the trai

Cons: The trainer acks advanced features like simulated vomit or laryngospasm that can be found in competing Laerdal models. Also, while the trainer is g
functions

Conclusions/action items:
The Nasco Life/form Airway Trainer presents a solid alternative to the Laerdal model, particularly for applications requiring modularity and replaceable com
feedback for trainees when facing situations including swollen tongues and blockages. However, it lacks advanced features like simulated vomit or laryngos
and material analysis. Need to discuss with Dr. Schroeder to see if this trainer's features align better with his target for the project.

Action Items:

1) Discuss with Dr. Schroeder to see if this is the kind of model he thinks our group should model our design after

2) Look into other trainers so that we can provide Dr. Schroeder with a wide array of options regarding possible designs

Ilia Mikhailenko - Dec 08, 2024, 9:22 PM CST

Download

lifeform-lifeform-adult-airway-management-trainer-head-only__37967.jpg (148 kB)

9/18/2024 - Nasco Adult Airway Trainer

Ilia Mikhailenko - Dec 08, 2024, 9:22 PM CST

Title: Nasco Adult Airway Trainer

Date: 9/18/20124

Content by: Ilia Mikhailenko

Present: N/A

Goals: Learn more about existing airway trainers already on the market and the aspects of their design that we can incorporate into ours as well as areas where we can improve.

Content:

Size: 0.81 m x 0.63 m x 0.30 m

Weight: 19 kg

- This design has a detailed representation of human anatomy, including: Sculpted alveolar sacs, bronchial tree, blood vessels, and flexible lungs, interior main bronchus and oral/nasal pharyngeal spaces as well as others
- Simulates complex airway condition with breakout teeth, tongue edema, and laryngospasm
- Has an anatomical stomach that swells with esophageal intubation or excessive pressure during BVM use
- Simulates vomiting for realistic training scenarios
- Excellent for multitasking and challenging airway management training

Adult Airway Management Trainer [SKU: 101-501]

Conclusions/action items: This is a strong design and the team has a lot to learn from the features it provides. The design has lungs visible to any trainee who may be using it and this is how the team plans to construct the design this semester, making the upper thoracic portion detachable from the rest of the model. This differs from the Nasco Life/form airway trainer because it has a full upper body as opposed to just a head and trachea.

9/18/2024 - Ambu Airway Trainer

Ilia Mikhailenko - Sep 18, 2024, 5:47 PM CDT

Title: Nasco Adult Airway Trainer

Date: 9/18/20124

Content by: Ilia Mikhailenko

Present: N/A

Goals: Learn more about existing airway trainers already on the market and the aspects of their design that we can incorporate into ours as well as areas where we can improve.

Content:

Size: 0.50 m x 0.25 m x 0.31 m

Weight: 5 kg

- Open left side of the head allows for supervision of airway activity, which is helped by a transparent pharynx and trachea
- Supports airway training for orotracheal tubes, laryngeal masks, nasotracheal tubes, and endotracheal tubes
- Internal features are easily accessible without the need for tools due to the hole in the side
- An electronic tooth sensor detects and signals when excessive force is applied to upper teeth. The sensitivity is modifiable

Conclusions/action items: This is a strong design and the team can learn much from its advanced features. The design's hole in the side of the head allows for greater visibility for spectating participants, and allows one to better visualize the airway anatomy as a whole. These factors should definitely be considered when designing this project's final product.

9/26/2024 - Additive Manufacturing with Liquid Latex

Ilia Mikhailenko - Sep 27, 2024, 10:53 AM CDT

Title: Additive Manufacturing with Liquid Latex

Date: 9/26/2024

Content by: Ilia Mikhailenko

Present: N/A

Goals: Evaluate a possible option for 3D printing using latex

Search Term: latex 3D printing options

Link:

https://www.liebertpub.com/doi/full/10.1089/3dp.2018.0062

Citation:

Quetzeri-Santiago, Miguel A., et al. "Additive Manufacturing with Liquid Latex and Recycled End-of-Life Rubber." *3D Printing and Additive Manufacturing*, vol. 6, no. 3, June 2019, pp. 149–57. *DOI.org (Crossref)*, https://doi.org/10.1089/3dp.2018.0062

Content:

- Injection molding is the current predominant processing method, offering low cost and high speed but lacking customization and flexibility.

- A more versatile manufacturing technique is through additive manufacturing, and the study sought to develop an approach using a "drop-on-demand" (DoD) system (is this something we could possibly use?)

- This printing system can handle both high viscosity and high solid content (60 wt. percentage).

- DoD allows for a reliable and precise printing pattern. Is innovative because it mixes with micronized rubber powder from recycled tires (10 wt. percentage) - (any way to access this?)

- Experimental results showed that product stiffness remains the same, but maximum elongation reduces (750% to 430%) with this method

- Potential for complex elastomer structures (is this what our model is considered to be?)

Conclusions/action items:

This paper gives our team another possible avenue to go down with 3D printing. At the time I am writing this, I do not know how feasible this is as I am not aware what kind of 3D printing technology we have available to us and if additive manufacturing with a DoD system is one of them. The interesting part of this study that could prove fruitful to us is that this type of 3D printing can handle both high viscous and solid content. As mentioned in my Mechanical Properties of an Airway research, airways have both viscous and

elastic properties to them, so this is an interesting possibility for mimicking these. My next steps are to check in with my team at the meeting and see if this is a realistic possibility.

9/26/2024 - Emergence of 3D Printing in Airway Training

Ilia Mikhailenko - Oct 02, 2024, 1:23 PM CDT

Title: Emergence of 3D Printing in Airway Training

Date: 9/26/2024

Content by: Ilia Mikhailenko

Present: N/A

Goals: Analyze existing methods for 3D printing airway trainers, and opportunities for improvement in this field

Search Term: 3D printing airway trainersr

Link: https://www.ijohs.com/article/doi/10.54531/FWBG1538

Citation:

Picton, Graham. *The Emerging Role of 3D Printing in Airway Training: A Narrative Review*. Nov. 2022. *www.ijohs.com*, https://doi.org/10.54531/FWBG1538.

Content:

- 3D printing is becoming increasingly common in treating possible medical scenarios.

- This is common for a normal airway anatomy, and overall a very versatile tool but underutilized in the area of creating representations of complex patient pathologies

- The current major barrier in making this is a lack of technical skill - understanding how to design a model well enough that can actually be used for pre-procedure practice

- Cited 7 sources regarding past 3D printing projects in the medical field

Conclusions/action items:

This article provides backing for the legitimacy of our project. The source states that 3D printing has been virtually exhausted in the field of normal airways and that this is an extremely competitive market. However, there is immense potential in the area of unique and challenging airway pathology, and now further research must be done to see how others have done this in the past, in areas involving airway, and some that do not.

Action item: Use links to research more into other pathology-specific 3D printing projects

10/14/2024 - Connecting Head to Pathology with Magnets and Hinge

Ilia Mikhailenko - Nov 07, 2024, 10:28 PM CST

Title: Magnet Design

Date: 10/14/2024

Content by: Ilia

Present: N/A

Goals: Explore the idea of using a magnet as a connection mechanism between the trainer head and the pathological component

Content:

- Would allow for a clean and simple connection between the two main components of our design. Easy to remove and reattach

- How and where would we incorporate these magnets into the pathological component? Could account for magnet space in the 3D model, or possibly drill something

- Would we be able to make this connection strong enough so that airway management can be practiced without the airway moving around, but not so strong that the pieces are extremely difficult to swap out?

- The hinge joint would let the head to rotate back and forth, which allows trainees to practice the head-tilt chin-lift maneuver

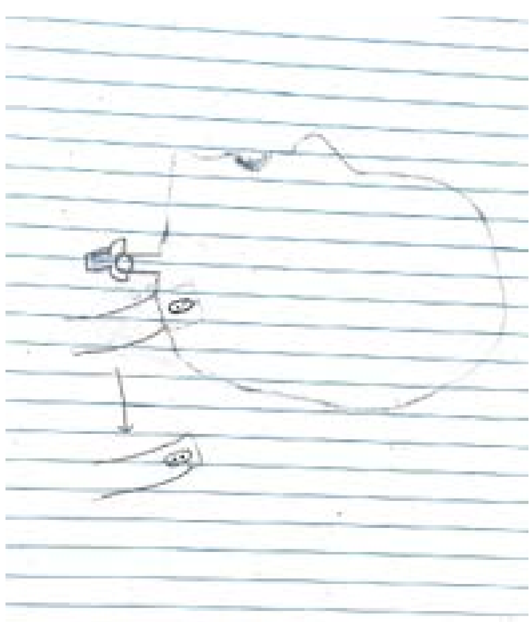
Conclusions/action items: As mentioned above, magnets have the potential to give a simple and straightforward connection mechanism between the head and pathology components in our design. I need to further discuss with the pathology group how this magnet piece would fit into their printed pathology, and also look into existing trainer designs to see where the magnet in the head-piece could be placed. In addition, I need to further research what types of magnets would be possible for this, which includes their cost, design, and compatibility with our materials. In addition, I also need to look into the dimensions of the hinge for it be strong enough to support the head but not excessively bulky.

1. Consider how to implement space for a magnet into 3D pathology design

2. Research cost and what specific magnets would be used

3. Further research on dimensions of hinge to be strong enough be not too bulky

Ilia Mikhailenko - Oct 18, 2024, 12:14 PM CDT



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10/21/2024 - Disassembly of Airway Trainer Head

Ilia Mikhailenko - Nov 28, 2024, 4:24 PM CST

Ilia Mikhailenko - Nov 29, 2024, 1:39 PM CST

Title: Disassembly and Analysis of AIRSIM Airway Trainer

Date: 10/21/2024

Content by: Ilia

Present: Jack, Nathan

Goals: To gain insights into the design and functionality of a working airway trainer

Content:

- A few members of our team met in the Makerspace to disassemble a functioning airway trainer so that we could study its internal structure and gather data to guide us through our design process
- During the process, we focused on measuring critical aspects such as the flexibility, material composition, and how different components were assembled to enable realistic movement and durability. A link to the spreadsheet containing the measurement is provided here: https://docs.google.com/spreadsheets/d/1Zk9Bi0IAWbyRvm_wMJg8iQ2VE3GOsMY8mFaaDvKmmWQ/edit?usp=sharing
- We also documented this visually by taking lots of pictures of the disassembly process, highlighting the key components and mechanisms we aim to replicate or improve upon. The link to these photos is provided here: https://drive.google.com/drive/folders/1mcmNiKdi2ZTvwKA4ZIBhMb4pI5KVmE40?usp=drive_link
- Observations included the varying stiffness of materials used in different regions (e.g., softer materials in the airway vs. firmer components for structural support) and how these contributed to the trainer's functionality

Conclusions/Action Items: Our team disassembled a functioning airway trainer in the Makerspace to study its internal structure and gather measurements, focusing on flexibility, material composition, and assembly for realistic movement and durability. We documented the process with a spreadsheet of measurements (link here) and photos of key components and mechanisms (link here). Observations, such as the use of softer materials in the airway and firmer ones for structural support, will help guide our design improvements.

1. Organize and analyze the photos taken during disassembly for future reference and inclusion in our design documentation.
2. Compile and review the measurements obtained, particularly focusing on how flexibility and material choice affect performance.
3. Begin brainstorming how these findings can be incorporated into our design, noting areas where improvements could be made.
4. Check in with the subgroup responsible for material sourcing to discuss potential materials that could mimic or enhance the features observed.

10/31/2024 - Initial Model of Base

Ilia Mikhailenko - Nov 07, 2024, 10:59 PM CST

Title: Base 3D Model

Date: 10/31/2024

Content by: Ilia

Present: N/A

Goals: Design and model the base that our airway trainer will rest on

Content:

- Current base dimensions are 30 cm x 12 cm x 1 cm for the bottom prism, and 5 cm x 12 cm for the raised triangular vertical cross-section

- There is also a 2 cm slit created running all the way down through the raised triangular portion that will allow us to secure the airway trainer to the base via a looping mechanism

- Would it be better to remove the ridge and instead seal something onto the raised triangular portion? It would be difficult to reach down and under the base every time you want to detach a pathology from the trainer

- Is the angle of the triangular portion similar to that of a descending human trachea? Would need to get measurements of existing mannequins to verify whether or not this is true

Conclusions/action items: As mentioned above, I have modeled a base in SolidWorks and its dimensions are outlined above. I have also attached the file below. It has a slit running through the the elevated portion which we are currently planning to utilize in order to attach the novel pathological portion to the airway trainer and the overall design - however, I am not certain this is the best idea. It has a distinct flaw in requiring the trainee to reach under the base every single time they want to swap out one pathology for another, which is inconvenient. More thought must be given to this to determine if there is a better way. I also need to look into measuring the angle tracheal elevation on currently used trainers to make sure that what I have will be anatomically accurate when the pathology is attached.

1. Reach out to team to determine if this design is best or if the slit should be changed for something else

2. Measure angle of existing airway's trachea

3. Look into material for 3D printing this base

Ilia Mikhailenko - Nov 07, 2024, 10:33 PM CST

Download

Part1.AirwayBase.SLDPRT (81.6 kB)

11/7/2024 - 2nd Model of Base

Ilia Mikhailenko - Nov 08, 2024, 10:24 AM CST

Title: Base 3D Model

Date: 11/7/2024

Content by: Ilia

Present: N/A

Goals: Update the initial model for the base design

Content:

- Base dimensions have remained 30 cm x 12 cm x 1 cm for the bottom prism, and 5 cm x 12 cm for the raised triangular vertical cross-section

- After careful consideration, our group has decided to move forward with the velcro design because of its ease of use and implementation. Need to look into specific velcros and determine which specific one our group will be using

- Due to this, the slit that initially ran through the raised triangular portion is no longer necessary and has been removed, with the raised portion is now being completely solid

- Still need to determine if the angle of the triangular portion similar to that of a descending human trachea - measurements of existing mannequins needed

- What material would be best for 3D - printing? I am thinking possibly PLA?

Conclusions/action items: I updated the initial model for the base design - the general dimension were maintained, but the slit I initially had was removed due to a redesign regarding our attachment mechanism which will now involve velcro. I have also attached the file below. The velcro will be laid flat on the elevated portion of the trainer - the specific type of velcro is still yet to be finalized, but our group is leaning toward recloseable fastener. I still need dive deeper into what the angle tracheal elevation on existing trainers is to compare that to mine. Anatomical accuracy is crucial to give trainee's working with this airway trainer a realistic simulation of human airway management. Now that our base model is very close to finalized, I need to conduct further research regarding material - I am thinking of using PLA but need to hear my group's thoughts on this.

1. Decide on velcro that we will use for attachment

2. Measure angle of an existing airway trainer's trachea

3. Look into material for 3D printing this base - check in with group to see if PLA is valid or if they have other suggestions

Ilia Mikhailenko - Nov 08, 2024, 10:24 AM CST

Download

Part1.AirwayBase_updated.SLDPRT (91.2 kB)

11/7/2024 - Velcro: Candidate for an Attachment Mechanism Between the Base and Pathology

Ilia Mikhailenko - Nov 08, 2024, 12:29 PM CST

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

Title: Selection of Velcro for Base to Airway Attachment

Date: 11/7/2024

Content by: Ilia M

Present: N/A

Goals: To record the specific kind of velcro we have decided to use in our design

Content:

- This velcro has interlocking mushroom shaped heads that provide a secure, reliable, and durable connection which can be repeatedly opened and closed multiple times, meeting the needs of our trainer model

- Low surface energy acrylic adhesive bonds well to a variety of substrates

- The fastener secures with an audible snap that indicates to the user it has been properly closed

- How much velcro would be needed? Need to decide on a length with team and order as soon as possible so that it can be tested in our prototype

- Link to velcro: https://www.amazon.com/3M-Dual-Lock-Reclosable-Fastener/dp/B007OXK330?sr=8-8

Conclusions/action items:

Our group is very likely likely leaning towards velcro for our method of attachment between the base and the swappable pathological component of the airway. More specifically, we are very attracted to this specific kind of velcro which I have linked above due to the factors I have listed, which can be summarized as a versatile and reusable bonding mechanism that informs the user when it has been secured correctly. In order to really finalize this decision, our group needs to create a design matrix including all the most favorable methods of attachment - however, velcro definitely seems to be the strongest candidate. If velcro comes out on top in the design matrix, we will need to order it afterwards.

1. Determine how swappable pathology component will attach and be secured to the head of the trainer

2. Determine how much of this velcro is needed

3. Create a design matrix for attachment of pathology to base component

11/14/2024 - Brainstorming Different Methods to Secure Base to Surface

Ilia Mikhailenko - Nov 29, 2024, 2:07 PM CST

Title: Exploring Methods to Secure Airway Trainer on Surface

Date: 11/14/2024

Content by: Ilia

Present: N/A

Goals: To brainstorm and evaluate potential methods for securing our airway trainer to the surface it will rest on, ensuring stability during use.

Content:

During our meeting, we briefly discussed various methods to keep the airway trainer secured while it is being used. This is some brainstorming work I've done for the trainer - with my ideas I mainly prioritize stability, ease of use, and adaptability to different surfaces. I don't have any points system, but this may be required in the future with some sort of design matrix.

Ideas:

- **Suction Cups:**
  - Pros: Effective on smooth surfaces - easy to apply and remove without damage to surface
  - Cons: Limited to specific surface types and may lose effectiveness if the surface isn't ideal (for suction cups to be most effective, surface should be fairly clean or flat)
- **Clamp Mechanism:**
  - Pros: Provides a firm grip and works well on tables or edges - also capable of adapting to a variety of surface thicknesses
  - Cons: Requires a sturdy edge to attach and can't be used on the ground, which is a common location for airway management
- **Weighted Base:**
  - Pros: Adds stability without relying on the type of surface that airway management is occurring on or other accessory attachments
  - Cons: Would increase the overall weight of the trainer and would likely decrease portability
- **Rubberized Base with Anti-Slip Pads:**
  - Pros: Simple, lightweight, and effective on most surfaces without damaging them.
  - Cons: May still shift slightly during use, especially on high-friction procedures.
- **Combination:**
  - Could combine several of these together to maximize the positives and minimize the downsides

I'll need to discuss these methods with my group and possibly organize to determine which one we will move forward with.

Conclusions/Action Items: I brainstormed ways to secure the airway trainer during use, focusing on stability, ease of use, and surface adaptability. Ideas I came up with included suction cups (great for smooth surfaces but limited elsewhere), clamps (good for table edges but not the ground), a weighted base (stable but less portable), and a rubberized base with anti-slip pads (lightweight but may still shift). Which one is best is largely dependent on what surfaces the trainer will be used on. A combination of these might be the best option, and I'll discuss these ideas with the group to decide on the best approach.

1. Get feedback from group on which methods they like/don't like
2. Determine which surfaces the airway trainer will most commonly be used on to narrow down options
3. Possibly create a design matrix to see which of the methods would be most effective

11/14/2024 - Makerspace Inquiry Regarding the Rendering of a Mannequin's head

Ilia Mikhailenko - Nov 14, 2024, 9:26 PM CST

Title: Makerspace Inquiry Regarding the Rendering of a Mannequin's head

Date: 11/14/2024

Content by: Ilia M

Present: Maribel, Nathan

Goals: To better understand how to go about creating a scan of the a human head which we can use in our airway

Content:

- Our subgroup that has been working on designing the base visited the makerspace to inquire with the experienced staff there about their recommendations for going about printing a scan of a human-like head

- Our initial plan was to render the head of a physical airway trainer which our group has been studying and researching. We were deciding between several cutting-edge tools available in the makerspace and were looking to check in with users more familiar with the technology.

- Pete, the guy we talked to, mentioned how, although what we were planning to was technically a feasible option, it would likely be very long and tedious due to the amount of time necessary to get a complete scan of such a complex feature and then conduct all the post-processing to allow the software to have a proper representation of what we are looking for

- Instead, Pete recommended we simply search for an STL file of a human head online and work to edit and print that, as this would circumvent much of the long and arduous process described up above.

- Our group searched online and quickly located a file we think will be useful. However, we weren't entirely sure how to edit it or how much of the head we will actually need. The entire piece will definitely not be necessary as we need to the printed model to have an open mouth, but we will check in with the other subgroup to confirm this and also ask for modeling advice, as this has been a focal point of their subproject and they may be able to provide us with valuable insight.

Conclusions/action items:

Our subgroup initially planned to 3D scan and print a human-like head based on a physical airway trainer, but after consulting with staff at the makerspace, we learned the process would be too time-consuming and complex. Instead, we were advised to find an online STL file of a human head, which we did. We are now coordinating with the other subgroup to refine the file and ensure it fits our project requirements, particularly ensuring the model has an open mouth so that it can be used to practice intubation.

1. Determine how much of the STL head is needed for a 3D print

2. Figure out how we can edit the file to achieve this desired amount

3. Check in with other subgroup to accomplish above tasks

11/21/2024 - Continued Analysis of Airway Trainer Headpiece

Ilia Mikhailenko - Nov 28, 2024, 3:54 PM CST

Title: Continued Analysis of Airway Trainer Headpiece

Date: 11/21/2024

Content by: Ilia Mikhailenko

Present: Jack, Maribel, Nathan, Maiwand

Goals: To better understand the mechanics of a functioning airway trainer headpiece, and, specifically, to analyze the rubber surrounding specific screws on the airway trainer

Content:

- Our subgroup, which is focused on creating a base and functional "head" component that the 3D-printed scans would be able to attach to, conducted a detailed inspection of the functioning airway trainer headpiece, and in the process noticed certain rubber components around screws in the trainer's head
- The purpose of these rubber pieces was initially unclear, as they do not seem to play any important role in securing the screws or maintaining structural integrity
- However, after deliberation several potential functions were proposed for the rubber, including:
    1. Vibration dampening (reduced wear and tear that may arise from vibrations during repeated use)
    2. Prevents over-tightening (could act as a barrier preventing excessive tightening, which would possibly damage the trainer)
    3. User safety (rubber is much softer than the hard screws beneath, and could just be a precautionary measure preventing users from cutting themselves when using the trainer)

- We discussed these possibilities with our subgroup and decided to investigate further by consulting our the other subgroup to hear their thoughts
- Additionally, it was later noted that similar designs often incorporate rubber for ergonomic reasons, which might also apply here

Conclusions/Action Items:

While the rubber components around the screws on the airway trainer headpiece initially seemed unnecessary, our group identified several reasonable purposes that they may have, such as vibration dampening, preventing over-tightening, or enhancing user safety. To better understand their role, we plan to consult the other subgroup for clarification as well as a second opinion on what we have assessed. This investigation could provide valuable insights for designing our own functional head component.

1. Research whether the rubber serves a specific manufacturer-intended function
2. Possibly conduct a brief experiment testing if removing the rubber affects the headpiece's stability or functionality in any way

3. Check with the other subgroup for their insights on the screws to see if they have any thoughts different from ours

4. Document findings and decide whether to replicate this feature in future airway trainer modifications.

11/15/2024 - Tong Distinguished Lecture - Tasso, Inc.

Ilia Mikhailenko - Nov 16, 2024, 12:15 PM CST

Title: Tong Distinguished Lecture - Tasso, Inc.

Date: 9/5/2016

Content by: Ilia M

Present: N/A

Goals: Hear from former Badger BME's about their journey in starting a BME company from the ground up

Content:

- Tasso CEO's and co-founders

- Ben: Rejected from every graduate program - begged professors to let him help them to get his foot in door

- Irwin: low grades, worked hard and knocked on doors

- Noticed inadequacies and areas for improvement in the blood-drawing process

- Theorized that blood collection could happen in the home, with the at-home delivery system we live in

- Scraped together anything they could to somehow draw blood - had zero entrepreneurial knowledge/experience

- Submitted grants to lots of organizations - got $150K which kickstarted the business

- Technology evolved over time: $25 model to $150K grant

- Little known about capillaries - did more research and made a transformative discovery regarding their anatomy and physiology

- Focused in on one problem - didn't try to tackle everything at once

- When scaling a business, quality is key. Need to hold to your reputation

Conclusions/action items:

Tasso’s co-founders, Ben and Irwin, overcame significant early challenges, including rejections and a lack of entrepreneurial experience, by persistence and hard work. They identified inefficiencies in traditional blood-drawing methods and envisioned an at-home drawing system. Starting with minimal resources, they secured a $150K grant that helped develop their technology, making key discoveries about capillary anatomy along the way. By focusing on one problem at a time and maintaining a commitment to quality, they successfully scaled their business and built a strong reputation. This story provides a phenomenal example for a simple idea can transform many, many lives

11/22/2024 - Reaching Out to GE Healthcare for Airway Scan

Ilia Mikhailenko - Nov 28, 2024, 4:11 PM CST

Title: Reaching out to GE Healthcare for Airway Scan

Date: 11/28/2024

Content by: Ilia

Present: Jack

Goals: To attempt to obtain an airway scan from a new source that we haven't tried yet (GE Healthcare)

Content:

- A big stall in our project has been our inability to procure an airway scan. In an attempt to help out with this issue, I reached out to my sister, who works at GE Healthcare, to try to leverage her expertise and network and get a useable airway scan.
- My sister, Katya, connected us with one of her coworkers, who specializes in medical imaging and was willing to help with identifying and sharing a relevant scan with us
- The scan we were sent is a trauma including the chest, upper body, and head, which gives anatomical details necessary for our airway trainer model. The mouth is open, which is very important for our scan as a closed mouth airway would be impossible to intubate.
- Her coworker mentioned that while the scan would be provided, we may need to perform some preprocessing to make the file compatible with our modeling tools. He also suggested a few software options we could use to manage the high-resolution data efficiently.
- We will follow up after receiving the scan to update whether or not this was successful.

Conclusions/Action Items:

To help move our project forward, I reached out to my sister, Katya, at GE Healthcare, and she connected us with a coworker who provided a trauma scan of the chest, upper body, and head with an open mouth—perfect for our airway trainer model. While the scan meets our needs, we may need to preprocess the file to ensure it’s compatible with our modeling tools. We’ll test it out and follow up soon to share if it works as intended!

1. Wait for the scan from GE Healthcare and ensure it's compatible with our slicing and modeling software
2. Research preprocessing steps and confirm access to the tools suggested
3. Begin slicing and modeling the scan once all technical aspects are addressed

11/27/2024 - Update on GE Healthcare Airway Scan

Ilia Mikhailenko - Nov 29, 2024, 2:58 PM CST

Title: Update on Airway Scan from GE Healthcare

Date: 11/28/2024

Content by: Ilia

Present: N/A

Goals: Follow up on the airway scan received from GE Healthcare

Content:

- The airway scan, delivered as a zipped file via Shared Spaces, has been sent to me from Nate Spry, an employee of GE Healthcare
- I shared the file with Jack, who forwarded it to Srihari who plans to analyze it
- The scan includes a trauma model of the chest, upper body, and head, with an open mouth, which is a critical feature for our airway trainer. Srihari will review the file to assess its quality, anatomical accuracy, compatibility with our modeling and slicing software, and anything else he finds important
- Initial concerns include whether the resolution and format will allow smooth preprocessing and whether modifications will be required to isolate the airway.
- If usable, the scan may need segmenting or simplification to streamline printing and avoid issues with resolution or file size.
- We may need to find preprocessing tools for handling medical imaging formats like DICOM to STL conversion

Conclusions/Action Items:

We received a zipped airway scan from Nate Spry at GE Healthcare, which has been shared with Srihari who will evaluate it. The scan includes a trauma model with an open mouth, critical for our airway trainer, but Srihari will evaluate its overall quality and compatibility with our project and the tools we have available to us. If usable, the scan may require segmentation or simplification, and we may need tools to convert medical imaging formats like DICOM to STL.

Action items:

1. Wait for Srihari's feedback on the scan
2. Research preprocessing steps and software for managing trauma scans
3. Prepare to segment and slice the scan, if necessary

11/29/2024 - Struggles with Printing in Makerspace

Ilia Mikhailenko - Nov 29, 2024, 2:43 PM CST

Title: Struggles with Printing in Makerspace

Date: 11/21

Content by: Ilia

Present: N/A

Goals: Summarize key insights from Makerspace staff regarding challenges printing models

Content:

- Two models were created by Jack: a cylinder with a negative airway for anatomical accuracy and a thin soft tissue model offset by 0.4mm, the maximum achievable in OnShape without collisions.
- The first printing attempt failed due to a combination of orientation, thickness, and material issues, specifically with FormLabs 50A resin.
- After consulting people in the Makerspace, Jack spent an extended period of time there attempting to manually painting supports to optimize printability, but the aforementioned resin's limitations mean the print may still result in failure
- Makerspace staff noted the thin sections and resin properties make it unlikely that the print will be successful
- A peer at the makerspace experienced in printing flexible heart models suggested segmenting the design into multiple pieces to improve success rates. This idea will need to be explored further

Conclusions/Action Items:
The challenges associated with 50A resin may prevent successful printing of the full model despite Jack's and the rest of our group's efforts. We will need to explore segmenting the current model we have into smaller parts and will reach out to Makerspace Fab Fellows for assistance with slicing as needed. I wasn't directly involved in this process but it has been a fairly major roadblock and due to this I thought it was worth noting in my section of the notebook.

12/10/2024 - Tensile Testing of Type IV Dogbone Samples

Ilia Mikhailenko - Dec 11, 2024, 10:54 AM CST

Title: Tensile Testing of Type IV Dogbone Samples

Date: 12/10/2024

Content by: Ilia

Present: Jack and Nathan

Goals: Conduct tensile testing of Type IV dogbone samples to evaluate material properties

Content:

- Collected force-displacement data for Type IV dogbone samples.

- Recorded constants: gauge length and cross-sectional area for each sample.

- Processed raw data in Matlab to produce stress vs. strain graphs

- Calculated Young's Modulus from the linear region of stress vs. strain graphs (will need to include in final report)

- Measured Young's Modulus: 0.91 MPa (datasheet value was1.59 MPa) with a standard deviation of 0.109 MPa

- Variability observed due to post-print support removal, which sometimes damaged the samples (need to look into ways to circumvent this)

- Pictures displaying the testing process (a dogbone with the printing support structure as well as a dogbone in the MTS machine) have been included below

Conclusions/Action Items:

To summarize the data we collected, there is force-displacement data for Type IV dogbone samples (including constants such as gauge length and cross-sectional area). The raw data were processed using MATLAB to generate stress vs. strain graphs, from which Young's Modulus was calculated to be 0.91 MPa with a standard dev of 0.109 MPa (compared to the datasheet value of 1.59 MPa). The variation seen in our results was likely due to the minor damage caused during the removal of 3D-printing supports. The pictures below demonstrate the process we took. Overall, our prototype was able to sustain the testing reasonably well - however there is definitely room for improvement which can be found in using more durable materials or different post-processing methods that would strengthen our trainer

Action items/things to consider:

1. Look into 3D-printing methods that avoid support structures to reduce damage to dogbones

2. Possibly conduct further testing to refine the accuracy of the YM

4. Explore different materials or post-processing methods to see if there better options for material properties

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Ilia Mikhailenko - Dec 10, 2024, 11:31 PM CST

DATA

Download

SampleWithSupports_1_.HEIC (1.54 MB)

Ilia Mikhailenko - Dec 10, 2024, 11:32 PM CST

Download

IMG_4499.HEIC (2.09 MB)

12/10/2024 - FEA testing and results

Ilia Mikhailenko - Dec 11, 2024, 10:47 AM CST

Title: Finite Element Analysis (FEA) Testing Results

Date: 12/10/2024

Content by: Ilia

Present: Jack, Maribel, Nathan, Maiwand

Goals: Assess the structural integrity of our prototype under simulated loading conditions using FEA

Content:

- Factor of Safety threshold was set at 5, so anything lower than 5 was considered a structural failure

- FEA tests were done by applying a force to the right area, top area, and both right and top areas of each part simultaneously

- Tests were done on the base piece, neck hinge, bottom jaw, and top jaw

- Base piece and neck hinge passed all three FEA tests!

- Top and bottom jaw were not as successful, failing under 1) Simultaneous 63 N force applied to top and right sections and 2) 63 N force applied only to the top area.

- Do these tests above need to be ran again to confirm validity?

- All info listed above will need to be included in the final report

Conclusions/Action Items:

The main goal of this testing was to determine whether the airway trainer parts could withstand forces similar to those exerted during intubation, the highest of which are around 63 N. Using SOLIDWORKS FEA software, a 63 N was applied to the top, right, and combined areas of the base, including the bottom jaw, top jaw, neck hinge, and base piece. The base piece and neck hinge passed all tests, while the top and bottom jaws failed when a 63 N force was applied to the top or both top and right sections. Further testing may be required to confirm results, and all findings will be included in the final report.

Action items/things to consider:

- Consider using a different material to reinforce jaw components to so it can withstand forces above 63 N

- Possibly re-run FEA tests to confirm results if time permits

- Document FEA results for future reference

12/10/2024 - Neck Hinge Range of Motion Testing and Results

Ilia Mikhailenko - Dec 11, 2024, 10:45 AM CST

Title: Airway Trainer Range of Motion Evaluation

Date: 12/10/2024

Content by: Ilia

Present: Jack, Maribel, Nathan, Maiwand

Goals: Ensure the airway trainer accurately represents the range of motion necessary for realistic intubation simulation.

Content:

- Flexion (head moving toward the chest) and extension (head moving upward) are both needed in intubation with extension being more important because it opens the human airway and is a common part of airway management

- Inaccurate flexion and extension can decrease how realistic the trainer is and potentially lead to unsafe training practices.

- The airsim trainer provided by the client was used to gather reference values for flexion and extension. Maximum flexion of the AirSim was 50 degrees and extension was recorded at 45 degrees (initial values)

- However, it was found that screws were missing from the trainer, meaning the numbers we gathered may have been inaccurate. The trainer's range of motion values may need to be adjusted to accurately reflect what is used in commercially-available airway trainers

- Our trainer's neck hinge piece had a flexion recorded at 55 degrees, which actually exceeded that of the airsim. However, the extension was not quite as up to par and was only 27 degrees. Our design may need to be reevaluated to determine why the extension is lacking and how it can be improved

Conclusion/Action Items:

The goal of this testing was to ensure that our airway trainer’s range of motion in the neck hinge accurately simulates human head movement during intubation, which we verified by comparing it to the airsim trainer, an airway managment trainer popular on the market. The airsim trainer provided a reference but had a hyperextension issue caused by missing screws, which needs to be addressed. Our trainer's range of motion may need to see improvement from its current 27 degrees of extension to avoid unrealistic training scenarios. Overall, while there is room for improvement its current range of motion appears to be satisfactory to be used for practicing intubation.

Next Steps:

1. Look into ways to improve the range of our trainer's head extension and bring it closer to the 45 degrees seen in the airsim

2. Possibly retest the airsim trainer to confirm accurate range of motion with correctly fitted screws

3. look into how to improve our own trainer's flexion to meet the standard set by the airsim

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.

USE THIS 2014/11/03-Template

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

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

2014/11/03 - Research Template

MARIBEL GLODOWSKI - Sep 13, 2024, 11:47 AM CDT

Title:

Date:

Content by:

Present: N/A

Goals:

Search Term:

Link:

Citation:

Content:

Conclusions/action items: