3D Printable Trismus Treatment Device

Initial Design Report Template

Team (Pictured left to right)

[Cassina Olson – Logistics Manager and Co-Testing Engineer]

[Nathan Bastidas – Project Manager and Co-Testing Engineer]

[Carter Rhoades – Manufacturing Engineer and Co-CAD Engineer]

[Shilo Bailey – Financial Manager and Co-CAD Engineer]

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Project Sponsor(s): Dr. Rebecca Bartlett, Carolyn Abraham

Faculty Advisor: Dr. Tim Becker

Instructor: Dr. Carson Pete

DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

EXECUTIVE SUMMARY

The Mechanical Engineering program at NAU is intended to be finished strong through a final capstone project that combines aspects from students' coursework through their college career. The project assigned to group 5 is to design a device to assist with relieving symptoms of trismus (lockjaw) in various levels of severity. This project is important due to the high price of current commercial devices and the lack of cheaper and professional alternatives. The scope of this project plays a large part in the challenge of the project itself, as the resulting design must be fully manufacturable via fusion deposition manufacturing or FDM. A more commonly used term for this is 3D printing. This is a process where plastic is melted through a moving extruder that builds each part in layers, like a motorized hot glue gun. This process is essential to our client for two reasons, the device can be mass produced cheaply and by any clinician with a 3D printer. The Trismus Capstone team aims to design a 3D printable and open-source device intended to help relieve trismus symptoms via the active stretching of the jaw, where other solutions have been either inaccessible or too expensive for practical use. The timeline for this project will span two semesters of coursework, where the first semester is used for initial design and prototyping, and the second for iterative design and more intensive prototyping. On a smaller timescale, the trismus group hopes to have a functional prototype made by the end of the month at the time of writing. The first milestone the trismus team hopes to complete is to have a fully detailed CAD package made of the first prototype to start the device's manufacturing process. The Design selected involves a leverage-based design, where a compliant spring provides active resistance to the jaw's natural closing motion and a graded surface to indicate jaw strain and the bite force of the patient. The design processes the trismus group has used involved the use of various decision-making tools including QFDs, HoQs, Decision matrices, and extensive literature review on related topics. The results of these processes have been noted throughout this document. Overall, the team is on track to submit their final deliverables on time and at a level of quality that is acceptable. The team's main challenge so far has been to select materials suitable for this task, and this was resolved where a suitable plastic (PETG) was selected for its strength and nontoxic makeup. In conclusion, this report will give an overview of the Trismus team’s engineering process as a work in progress and discuss their results. This project's future looks successful, as so far, the team has effectively communicated ideas and their process internally and provided quality ideas within their concept generation and decision phases.

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1 BACKGROUND

This project aims to develop a cost-effective, 3D-printable device to aid physical therapists in treating patients with Trismus, a condition caused by neck and throat cancer that limits jaw mobility.

Key Features:

- **Affordable and Accessible:** The device is designed for easy 3D printing in doctor's offices, with a production cost under $50. Open-source design files will further increase accessibility.
- **Multi-functional:** The device measures both mouth opening distance and bite force, providing valuable data for monitoring progress and tailoring physical therapy.
- **Safe for Use:** Patient safety is prioritized through careful material selection and design to minimize risks of injury.

Project Success:

Success hinges on the device's ability to:

- Withstand expected bite force without breaking.
- Clearly indicate the amount of bite force applied.
- Comfortably fit within a limited mouth opening range.

1.1 Project Description

This project aims to develop a cost-effective 3D printable device to aid with physical therapy for neck and throat cancer patients diagnosed with Trismus. Trismus, or lockjaw, reduces a person's maximum mouth opening (MMO) which can impact a patient's quality of life by limiting the type of food they can consume and affecting their speech. The primary focus of this project was to create an accessible device readily available for 3D printing and assembly in any doctor's office, with a 'low' production cost but following further discussions with the clients, the project scope was expanded to encompass additional functionalities:

- **Measurement of Mouth Opening:** The device now incorporates a mechanism to quantify the patient's jaw opening distance during physical therapy sessions. This data can be crucial in monitoring progress and tailoring treatment plans.
- **Bite Force Measurement:** The ability to measure bite force remains a core function. Quantifying bite force can potentially provide valuable insights for physical therapists, allowing for more targeted interventions and improved treatment outcomes. This would also prevent excessive force from being applied to the teeth and jaw.

The budget for this project was not clearly defined at the beginning until after the first client meeting when the client stated they would like the device to cost less than $50 to manufacture. Based on this customer requirement the budget was then expanded to $200 - $300 to ensure an adequate amount of 3D printer filament would be enough to produce several prototypes and send to the client for review and feedback.

1.2 Deliverables

This project aims to produce a multi-functional device that addresses the needs of physical

therapists in evaluating and treating jaw-related conditions. The key deliverables are:

Core Functionality:

- **Successful Prototype and Manufacturable Device:** A functional prototype that can be readily manufactured using 3D printing technology. The design should prioritize printability and use materials compatible with most 3D printers found in doctor's offices or clinics.
- **Safe for Use:** The device must be designed with the patient's safety in mind. Materials and construction should minimize any risks of injury to the mouth, teeth, or jaws during use.

Measurement Capabilities:

- **Measure Mouth Opening:** The device should incorporate a mechanism to accurately measure the distance a patient can open their mouth. This data is valuable for monitoring progress in physical therapy for jaw mobility.
- **Visually Quantify Bite Force:** The device should provide a clear and easy-to-interpret visual indication of the bite force applied by the patient. This functionality allows therapists to assess jaw strength and tailor treatment plans accordingly.

Cost and Accessibility:

- **Cost-Effective Production:** The design should be optimized for 3D printing with materials that keep the production cost under $50 per device. This affordability makes the device accessible for a wider range of healthcare providers.
- **Open-Source Design:** The design will be available to any doctor or healthcare provider as an open-source design. A patent for the device will be considered to prevent 'unsafe' alternations or modifications that could harm the patient and a patent would prevent 'selling' of the device.

Success Metrics

This section outlines the success criteria for the device's ability to withstand bite force, visually quantify the force applied, and fit within the specified mouth opening range.

1. **Bite Withstanding Capability:**

- **Success Definition:** The design must successfully resist the maximum bite force expected of a patient while preventing excessive force from being applied to the patient's jaw and teeth.
- **Assessment Method:**
    - Testing: We will conduct bite force tests using a standardized bite force testing machine or a calibrated surrogate bite apparatus.
    - Calculations: The maximum expected bite force will be determined through research on the maximum bite force of a person. The design will be subjected to a force exceeding this value by a pre-determined safety factor.
    - Design Requirements: The design materials and structure must be able to handle the calculated force without permanent deformation or failure.

2. **Visual Bite Force Quantification:**

- **Success Definition:** The design should incorporate a visual indicator that allows for the clear and measurable assessment of the applied bite force.
- **Assessment Method:**
    - Testing: Prototypes will be tested with varying bite forces to observe the visual indicator's response.
    - Calculations: A correlation will be established between the visual indicator's response and the applied bite force through calibration with a force or pressure testing machine.
    - Design Requirements: The visual indicator should provide a clear and quantifiable response that is easily interpretable by the user. This response could involve a color change, deformation gauge, or other measurable signal.

3. **Mouth Opening Accommodation:**

- **Success Definition:** The design must comfortably fit within the patient's mouth opening range of approximately 5-6 mm.
- **Assessment Method:**
    - Testing: Physical prototypes will be tested by placing them within a mold or model replicating human jaw and mouth opening.
    - Design Requirements: The design dimensions must ensure it can be placed within the specified mouth opening range without causing discomfort or hindering the patient’s movement.

Overall Project Success:

The project will be considered successful if all three criteria are met. The design should effectively resist the target bite force, provide a clear visual indication of the force applied, and comfortably fit within the designated mouth opening range.

2 REQUIREMENTS

Our team must meet the client's needs through the requirements they provided (CRs) and quantifiable engineering requirements (ERs) based on the client's needs for project success. Based upon these ERs, a House of Quality (HoQ) will be constructed as a decision-making tool to inform the teams engineering process and decision making.

2.1 Customer Requirements (CRs)

- Cost Effective: The device should be cheaper than alternative devices
- Safe: The Device must not cause harm to its operator or itself during operation
- Open Source: Provide a full instructional suite to assist in-house reproduction of the design
- Produceable Soley via 3D Printing: Design must be able to be FDM printed, relevant 3D printing design considerations must be accounted for (Max overhang angles, Material use, etc.)
- Adaptive: The device should be able to accommodate various patient cases with varying severity

2.2 Engineering Requirements (ERs)

- Target Price: Each unit (Total of all materials and electrical costs per device) costs less than $50
- Safe: All Aspects of design are within acceptable material strength requirements as well as nontoxic (Binary 1 = acceptable)
- Printable: All parts are manufactured Via FDM (Binary 1 = acceptable)
- Adaptive: Device can accommodate a 25mm incisor gap (Target fit a 6mm gap extreme cases)

2.3 House of Quality (HoQ) And Quality Function Deployment (QFD)

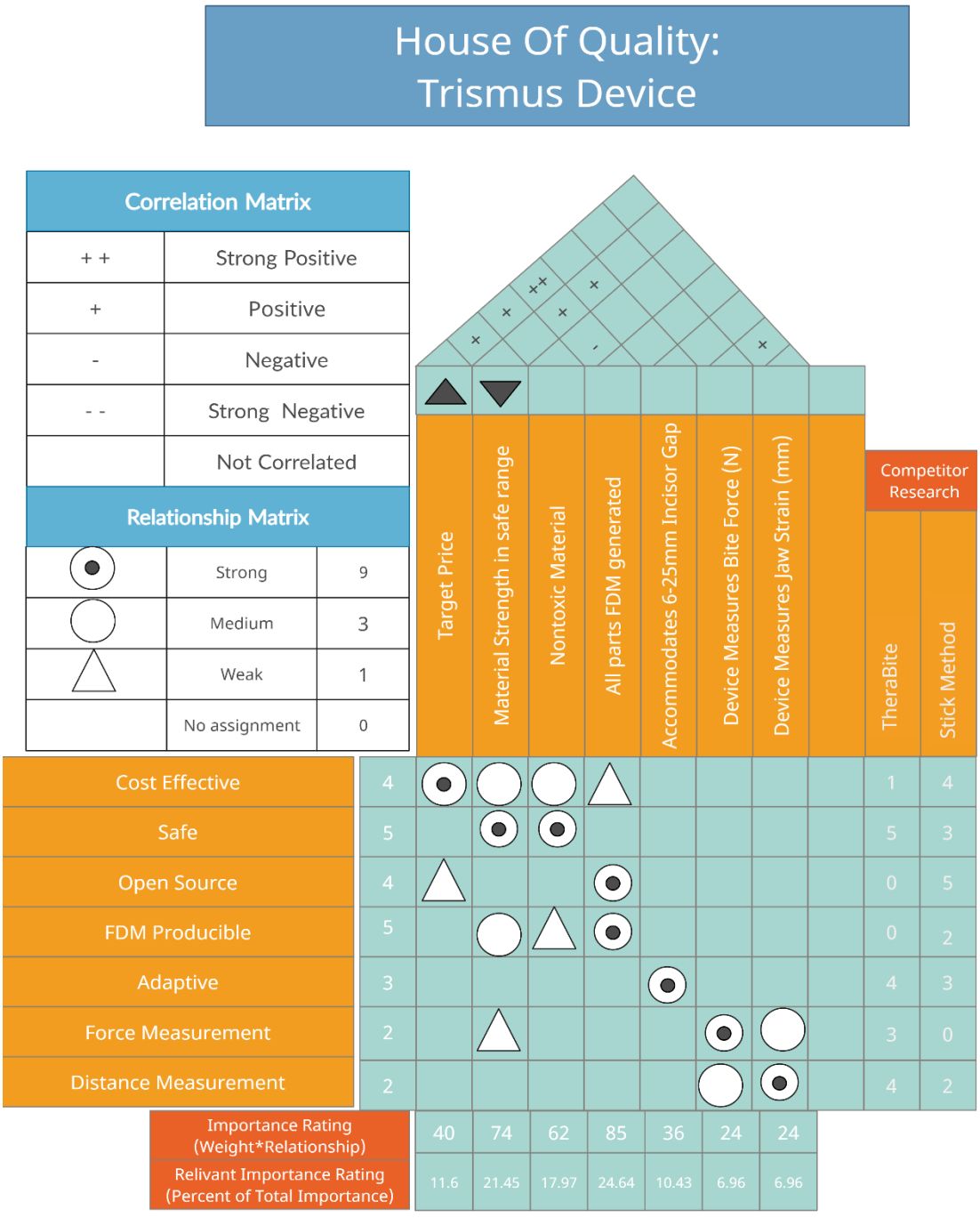


Fig [1] House of Quality for Trismus Device

QFD

Quality Function Deployment

Project title:	Trismus Device	Technical Requirements (Weights 1: Low, 3: Med., 9: High)								
Project Team:	Team #5: Trismus	Fast 3D-Printing Speed	Modular / Adaptable to different insicor gaps	Durable	Producable via 3D Printing	Follows Project Guidelines/Requirements	Weighted Score			
Date:	2/5/2024							Competitors		
	Customer Weights (1: low, 5: high)							Therabite	Orastretch	Clinician Device
								Competitive evaluation (1: low, 5: high)		
								Competitor rating 1	Competitor rating 2	Competitor rating 3
Cost Effective (PPU < $50)	4	3	1		9		52	1	2	5
Open Source (Provide Full Instructional Suite for reproduction)	5	3	1		9		65	1	3	4
Safe (Cause no harm to operator or itself)	4			9	1	3	52	5	4	2
Technical Requirement Units		**hrs**	**in.**	**MPa**	**%**	**N/A**	169			
Technical importance score		27	9	36	85	12	100%			
	Importance %	16%	5%	21%	50%	7%				
	Priorities rank	**3**	**5**	**2**	**1**	**4**				

Fig [2] Quality Function Deployment Table

3 Research Within Your Design Space

3.1 Benchmarking

The team identified three systems currently used in modern-day Trismus treatment. System #1 is the TheraBite Jaw Motion Rehabilitation System by CranioRehab. This device is among some of the most common devices used in modern-day Trismus treatment. This system is designed with various features, including various bite pads and a wide range of motion in mechanical opening. The major issue with this device that our client acknowledged was its price and accessibility to the common patient. Priced at $579.99 per unit, this device is generally paid for out of pocket rather than being covered by the patient's insurance. Many insurance companies do not cover any portion of the device's cost, leaving the total payment to the patient.

The second system is the UNIQUE Trismus device, priced at $24 per unit. This device is far more affordable, with the downside being that the device is, reportedly, extremely painful for patients to use. Our client highlighted the fact that the two major reasons that many patients do not continue with their long-term treatment is either due to financial costs (with regards to the affordability of the device or the treatment itself) and/or the potential pain that comes from the treatment or device itself.

Finally, the third system is an in-house Trismus device. This device is normally created by the clinician themselves and is usually comprised of various tongue depressors taped together to create a sort of spacer between the upper and lower jaw. Multiple tongue depressors would be added over time to increase the space between the two jaws, stretching the muscles over their treatment. Though extremely cost effective, this form of treatment could also be considered painful over time and is generally the most varied in terms of results.

[Describe System-level benchmarking identifying at least three systems that you consider state-of-the-art. Describe all other sub-system-level benchmarking. Cite each benchmarked system/sub-system per IEEE citation style.]

3.2 Literature Review

[Create an annotated bibliography of your references for the project. This is simply the reference title followed by a paragraph summarizing the material in the reference and how it applies to your project. Cite each reference per IEEE citation style. Separate sections per student along with their name (Example: 3.2.1 John Doe). At this point you should have ***7+ references per student****.]*

3.2.1 Shilo Bailey

Exercise Intervention for the Treatment of Trismus in Head and Neck Cancer – A Prospective Two-Year Follow-up Study [1]

A study investigated if structured exercises with jaw mobilizing devices would improve mouth opening and quality of life in head and neck cancer patients who experience limited jaw opening (trismus) as a side effect of radiotherapy. Patients who exercised showed significantly better improvement in mouth opening and reported fewer trismus-related symptoms and better overall quality of life after two years compared to a control group, suggesting this exercise program to be an effective long-term treatment for trismus in these patients.

Trismus Therapy Devices: A Systematic Review [3]

A two-year study showed that head and neck cancer patients who did structured exercises with jaw mobilizing devices after radiation treatment had significantly better long-term jaw opening and fewer symptoms like trouble eating and speaking compared to patients who didn't exercise. This suggests these exercises can be a valuable treatment for radiation-induced jaw limitations, improving patients' quality of life.

Mobilization regimens for the prevention of jaw hypomobility in the radiated patient: A comparison of three techniques [2]

Researchers compared jaw exercises with tongue depressors or a Therabite device to improve jaw mobility in radiated head and neck cancer patients. After ten weeks, the Therabite group showed significantly greater improvement and continued to gain mobility throughout the study, while the other groups plateaued after four weeks. Patients using Therabite also reported feeling more in control and compliant with the exercises, suggesting it may be a more effective treatment for radiation-induced jaw limitations.

Feasibility study of intensive intervention using novel trismus device during adjuvant radiation for head and neck cancer: RestorabiteTM [4]

This pilot study investigated a new 3D-printed jaw stretching device called RestorabiteTM for patients with head and neck cancer who experience limited jaw opening (trismus) after surgery and before radiation therapy. The device applies a regulated force to improve jaw mobility and patients were followed for 6 months. The study showed good patient adherence, significant improvement in jaw opening, and improved quality of life. Future studies will explore improving adherence during radiation and determine the optimal force for individual patients.

3.2.2 Nathan Bastidas

Biomaterials: An Introduction to Materials in Medicine [5]

This textbook highlights different materials in the biomedical field, primarily in the fields of implants and medicinal use. This, pair alongside the next source, give the team a great deal of knowledge that can be applied towards what materials we will be using for this project.

Biomaterials: An Introduction [6]

This additional textbook focuses on the biocompatibility of various materials, degradation and science. The source focuses on the major materials (ceramics, metals, and polymers) in a biomedical context, highlighting the various uses of these different materials and their strengths and weaknesses in their application. For this project, the chapters focusing on polymers are the most important, as many 3D printing filaments are considered polymers of some kind.

ISO Standards of Medical Devices [10]

The medical article displays the various categories of the ISO safety standards and how biomedical devices are classified under such a system. These safety standards give our team clear insight into how meticulous we must be when designing this product in order to have a device that will not cause any harm or biological damage to the patient.

Materials and applications of 3D printing technology in Dentistry: An Overview [11]

This document highlights the current state of 3D printing with regards to dental procedures and products. As our device deals with the inside of the human mouth, some details regarding the landscape of 3D

printing with regards to the mouth could help provide some examples of different compatible materials to use.

Designing biomaterials for 3D printing [12]

This research paper details 3D printable biomaterials that can be used for a wide variety of manufacturing situations. As one of our most prominent objectives is for the device to not cause any long term harm (either through ingestion of toxic materials or potential contamination of the inside of the patient's mouth), seeing what biocompatible, 3D printable materials exist will allow us to complete that objective.

Biocompatible 3D resins for medical devices [13]

Similar to the previous source, this document gives us additional references regarding different 3D printing material that is considered biocompatible. However, this article focuses more on biocompatible resins rather than more common type known as filaments.

Siraya Tech Blu-Tough Resin [14]

This manufacturer's website gives the team technical data regarding an on-the-market product that we can use to print out our device. Siraya's Blu-Tough resin has gone through the ISO Standards to be considered a biocompatible material used in 3D resin printing.

3.2.3 Cassina Olson

The Design and Manufacture of Medical Devices [18]

This book chapter cites a few commonly used biomedical materials and their biocompatibility in humans as tested. It further explains the qualities that constitute a biomedical device versus a device interacted with by humans regularly and where people may posit to draw a line between them. It references the FDA for device classification and uses these guidelines as a basis for class 2 and class 3 medical devices.

Classify Your Medical Device [1]

This FDA source provides the specific qualities and requirements for a medical device to be classified as class 1, 2, or 3. This source defines class 1 devices as noninvasive, non-surgical, temporary, and containing no bioactive components. Under this system, the trismus device is considered a class 1 device alongside Band-Aids and gauze wrappings.

Trismus in Head and Neck Oncology: A Systematic Review [20]

This paper shows the effects of radiation on certain muscle groups and joints in the mandibular area. It continues to express the strains within the mouth and how to combat muscle strain and varying upper neck muscle losses from radiation.

The Degree and Time-Course Assessment of Radiation-Induced Trismus Occurring After Radiotherapy for Nasopharyngeal Cancer [21]

This book chapter analyzes the severity of trismus after different times in which the patient was exposed to radiation therapy and whether surgery was involved/required for the cancer cells/tumor. It further explored the possibility of beginning trismus treatment early and the effects of this on keeping patients from ever experiencing trismus symptoms that limit opening to under 6mm (about 0.24 in).

Mandibular Sites Prone to Fracture: Analysis of 174 Cases in a Nigerian Tertiary Hospital [22]

This experimental finding shows the sites in the jaw that fractured most often with forced mouth opening movement. This study is centered on people of African descent and provides a more ethnically inclusive basis for trismus treatment.

Evaluation of Jawbone Density and Morphology in Bruxers Using Panoramic Radiography [23]

This online source shows the findings of how bruxism may affect the jaw and tooth structure in a patient. These were conclusive because bruxism leaves a patient's dentin exposed and causes micro fractures that may greatly decrease the appropriate pressure for application on the mouth during trismus treatment.

Comparative Study of Mechanical Properties of Dental Restorative Materials and Dental Hard Tissues in Compressive Loads [24]

This source displays the findings of compressive experimental trials on various dental layers and popular dental replacement materials such as fillers, veneers, and crowns. Often, filling materials can weaken the integrity of the tooth and may cause concern for the applied pressure on a tooth during trismus treatment.

3.2.4 Carter Rhoades

Fatigue Analysis of FDM Materials [15]

This source provides an overview of fatigue in 3D printed materials

Biocompatible 3D printing resins for medical applications: A review of marketed intended use, biocompatibility certification, and post-processing guidance [16]

This source provides an overview of a biocompatible variant of SLA resin

Special materials used in FDM Rapid Prototyping Technology Application [17]

This Source provides an overview of various specialty or uncommon 3D printer materials.

3.3 Mathematical Modeling

3.3.1 Jaw Muscle — Shilo Bailey

Assumptions:

- Maximum 'bite' force is "produced at horizontal and vertical joint force directions",[].
- Temporomandibular Joins is a simple lever model
- Average Jaw Weight:
    - Head Wt = 10 – 11 lbs, []
    - Jaw is approximately 20% of head weight/maws
    - Assumed Jaw Wt = 2lbs
- Maximum Bite Force: F = 275lbf or 1.22kN, []
- For Patients with 0 – 5 mm mouth opening can be considered as static

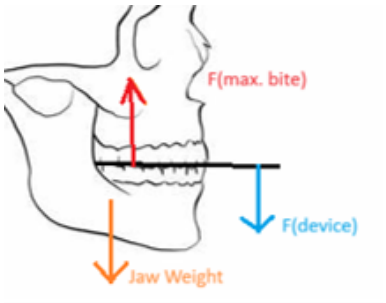
Equation Used: Static Equilibrium, $\sum F_y = 0$

$$\sum F_y = F_{\max bite} - W_{jaw} - F_{device} = 0$$

$$F_{device} = F_{\max bite} - W_{jaw} = F_{\max bite} - m_{jaw} * g$$

$$F_{device} = 275lbf - 2lbs * 32.1\frac{ft}{s^2}$$

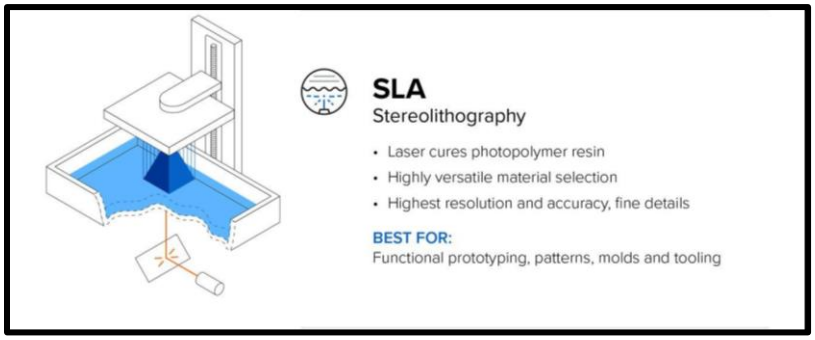
$$F_{device} = 210.8lbf = 937N$$

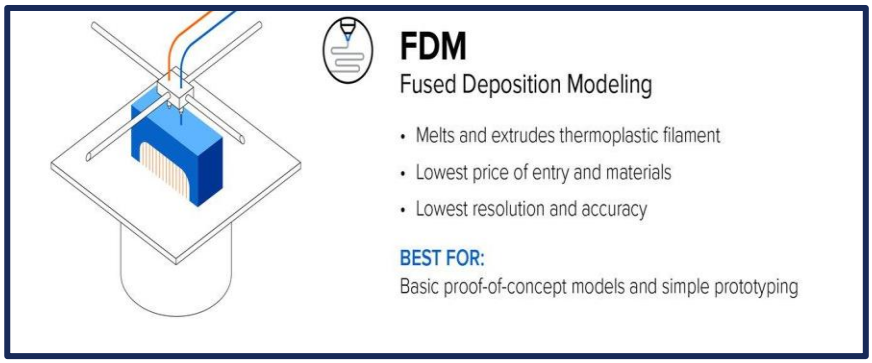


3.3.2 3D Printing and Manufacturing — Nathan Bastidas

Assumptions:

- Printer used: Creality Ender 3
- Slicer Software: UltiMaker Cura
- Two Forms of printing: SLA & FDM





Equation used: Max Printing Speed and Flow Rate Equation

$$Max\ Recommended\ Print\ Speed = \frac{Flow\ Rate\ Max}{(Height\ Layer * Extrudtion\ Width)}$$

$$Flow\ Rate = \frac{Nozzle\ Size}{(Height\ Layer * Print\ Speed)}$$

3.3.3 Dental Stresses — Cassina Olson

The following formulas were used in MATLAB to define the ideal dental stress range to not fracture

patients' teeth and jaws by applying too much pressure, but also not delay recovery by applying too little pressure. The first calculates pressure from the force applied and the surface area while accounting for bone density and tooth area. The second calculates tooth fracture propagation for preexisting conditions while maintaining progress with the device. The graph below these formulas demonstrates the stress and strain differences of compromised tooth layers as well as popular tooth material replacements so that the team may understand how these affect the integrity of the tooth with opening force pressure applied. From there, range assumptions were made to provide the most accurate ideal pressure for application. The results show a graph with the best range of pressure for the incisors and a separate graph with the best range of pressure for the molars as these may change with tooth decay and remaining teeth locations.

$$P = \frac{F}{A} \qquad P_F = CTRd^{1/2}$$

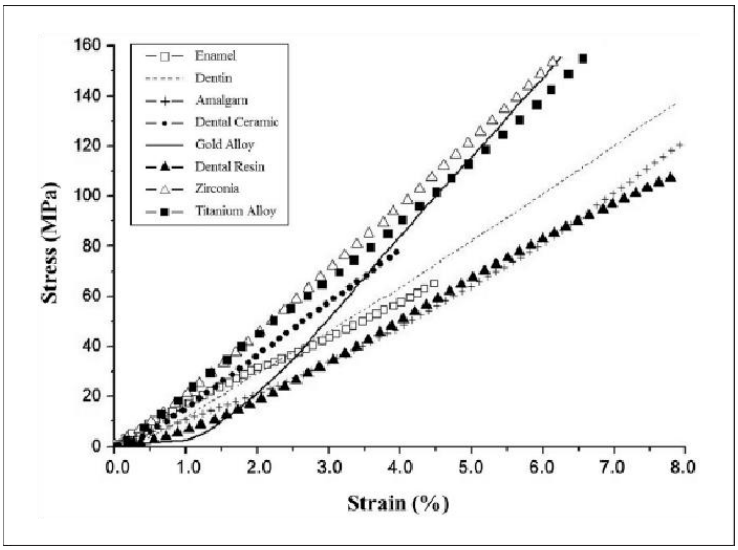


Fig [3.1] A Chart of Compromised Dental Layers and Popular Tooth Replacement Materials

Assumptions:

1) Patients have compromised bone density due to radiation treatment of the upper body.
2) The force applied on the jaws/molars exceeds that of the incisors
3) All patients are of adult facial stature, being over the age of 15 with a minimum mouth surface area of 175.55 mm (about 6.91 in) and a maximum mouth surface area of 182.75 mm (about 7.19 in).
4) The average surface area of a tooth is about 24mm^2 with half and quarter sizes scaling to 12 mm^2 and 6 mm^2 respectively.

The suggested range of applied pressures will be calculated and shown when the number of teeth is input into the sample size MATLAB code shown below with results.

```
% Collected Data
INC = 57:0.01:83; %pounds of force by incisors
JM = 108:0.01:150; %pounds of force by jaw/molars
STPetit = 175.55; %mm^2 mouth area for petite jaw
STAV = 178.85; %mm^2 mouth area for average jaw
STLRG = 182.75; %mm^2 mouth area for large jaw
TT = 739; %mm^2 average full mouth tooth area
Quadrant = 168; %mm^2 average one quadrant tooth area
Onetooth = 24; %mm^2 average one tooth

initial = input ("type 1 for full teeth, 2 for Half Teeth, 3 for one
Quadrant Teeth, 4 for No teeth, or 5 for special area")
if initial == 1
Incisor_Pressure = INC*TT;
Molar_Pressure = JM*TT;
disp ('Incisor Pressure')
disp (Incisor_Pressure)
disp('Jaw/Molar Pressure')
disp (Molar_Pressure)
disp ('average Incisor Pressure')
x = mean(Incisor_Pressure)
disp ('average Molar Pressure')
y = mean(Molar_Pressure)
```

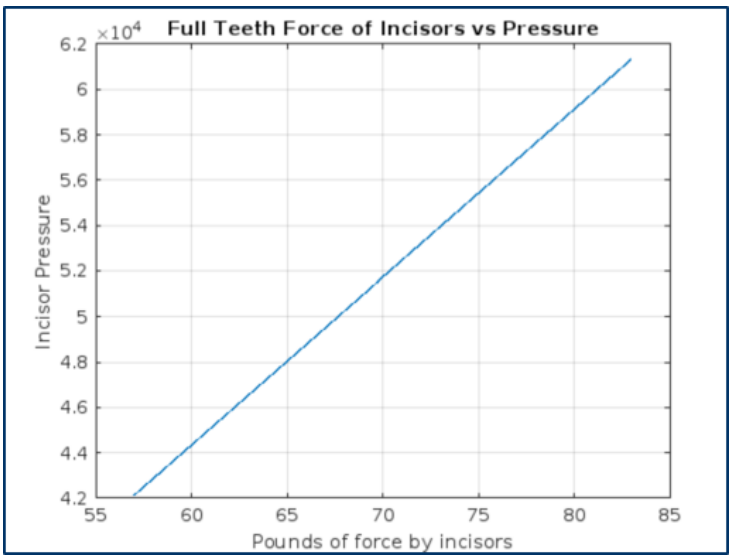


Fig [3.2] Nominal Pressure Range on Incisors for a Patient with Full Teeth

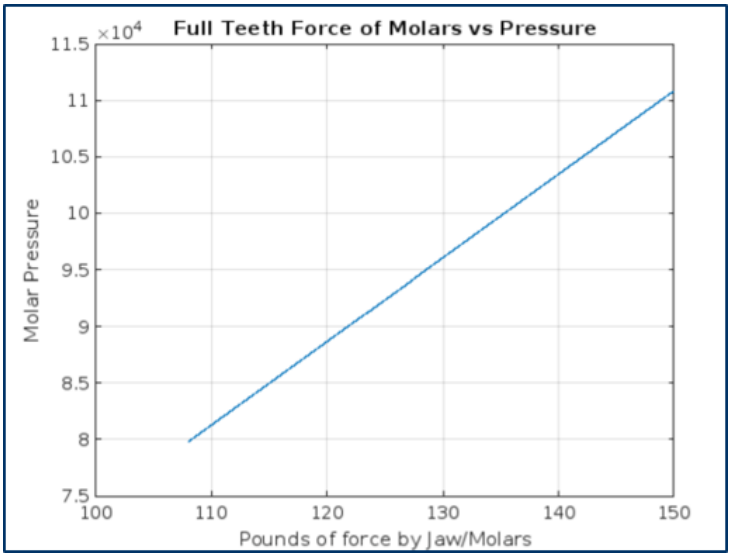
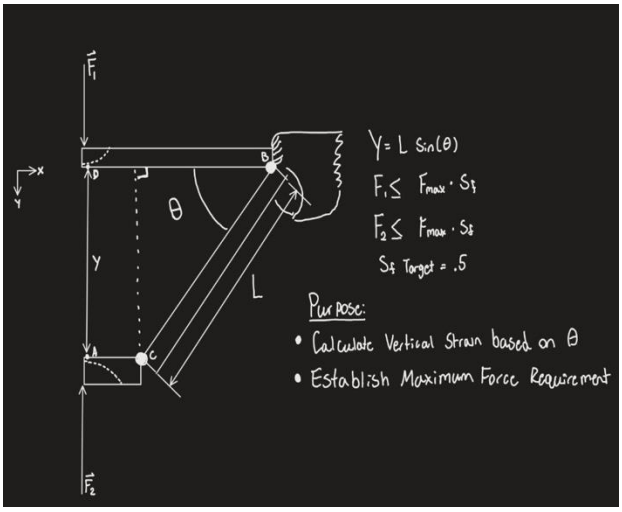


Fig [3.3] Nominal Pressure Range on Molars for a Patient with Full Teeth

3.3.4 Mechanical Lever Properties — Carter Rhoades



Relevant Variables:

Y= Vertical Displacement

Θ = Lever Angle

L = Lever Length

F_1= Force Applied to top Teeth

F_2 = Force Applied to Bottom Teeth

Mb= Moment of point B (Fulcrum)

Relevant Equations:

① Y= L*Sin(Θ)

② Mb = F_2*(L*Cos(Θ))

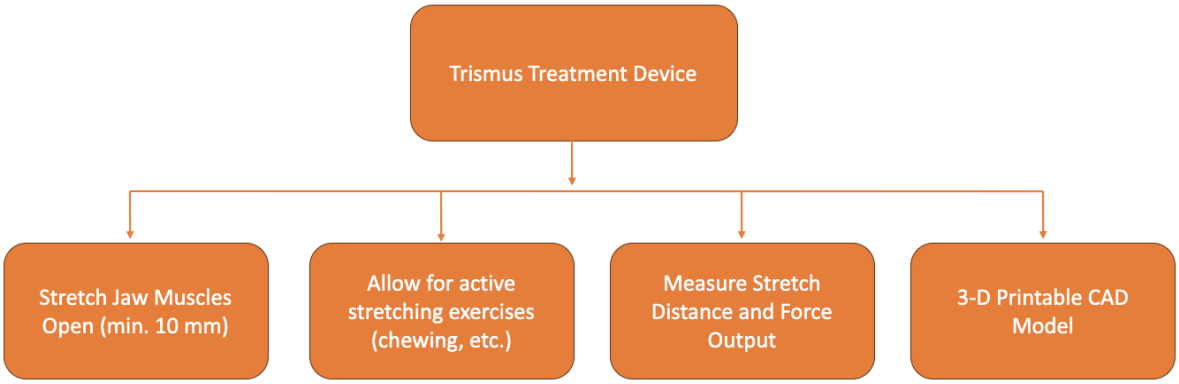
③ ΣFx = 0 (Device Stays Fixed)

④ ΣFy = 0 (Device Stays Fixed)

4 Design Concepts

4.1 Functional Decomposition

The following decomposition charts express the necessary customer and engineering requirements for the proposed trismus device. This figure displays the initial four main requirements set by trismus sponsor, Dr. Bartlett, for the team create a concept base from.



Stretch Jaw Muscles

The first requirement is to stretch patients' jaw muscles open to a minimum of 10mm (about 0.39 in) safely and with minimal fracture to the jaw and teeth as many patients may have lower bone density or weakened structural support in and around the jaw due to radiation.

Active and Passive Stretching

The second requirement is to create a singular device that can provide active and passive stretching, meaning that the device can force open a jaw, but also be altered easily to a state in which the patient can freely bite down and apply pressure to the device in a compliant mode. This will allow for the rebuilding of muscle and can contribute to a quicker recovery with regular use.

Measurements

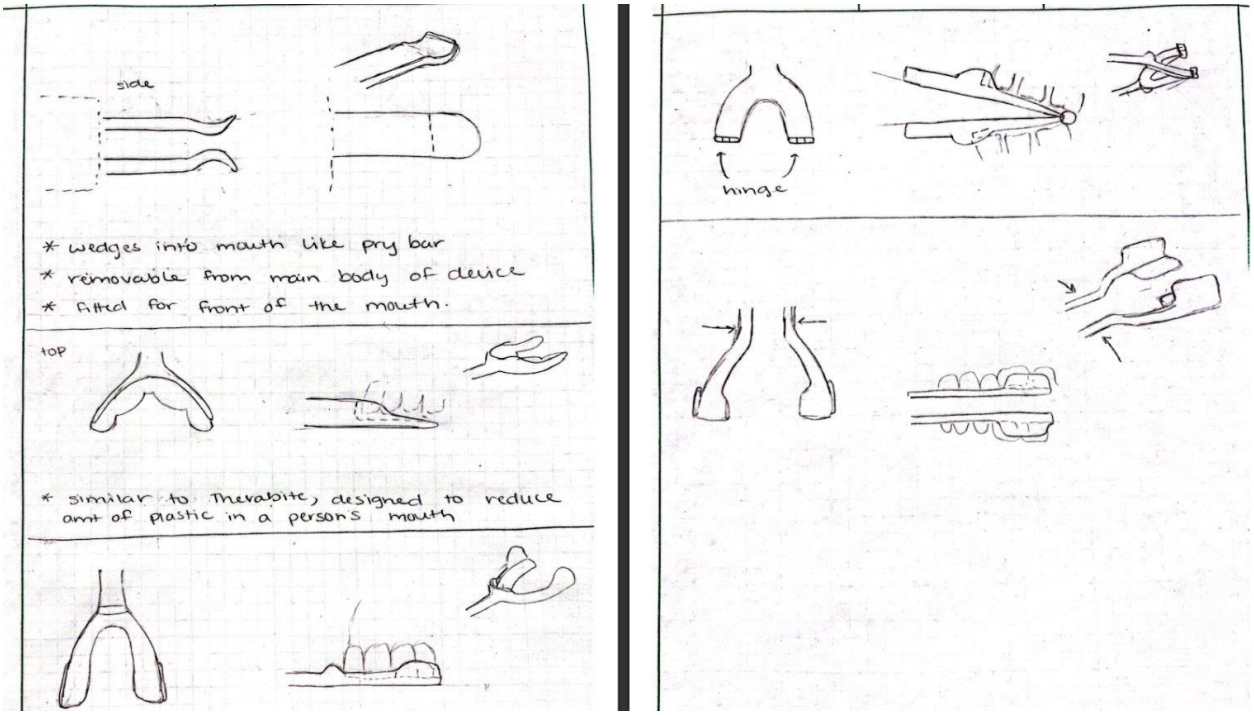
The third requirement allows for doctors to measure the recovery speed and maintain an optimum pressure on the device to not fracture any part of the patients' mouths and not delay recovery for fear of fracture. The stretch distance measurement apparatus is also intended to show the patients' progress in an outpatient setting for easily readable results and safe self-administration.

3D Printable CAD

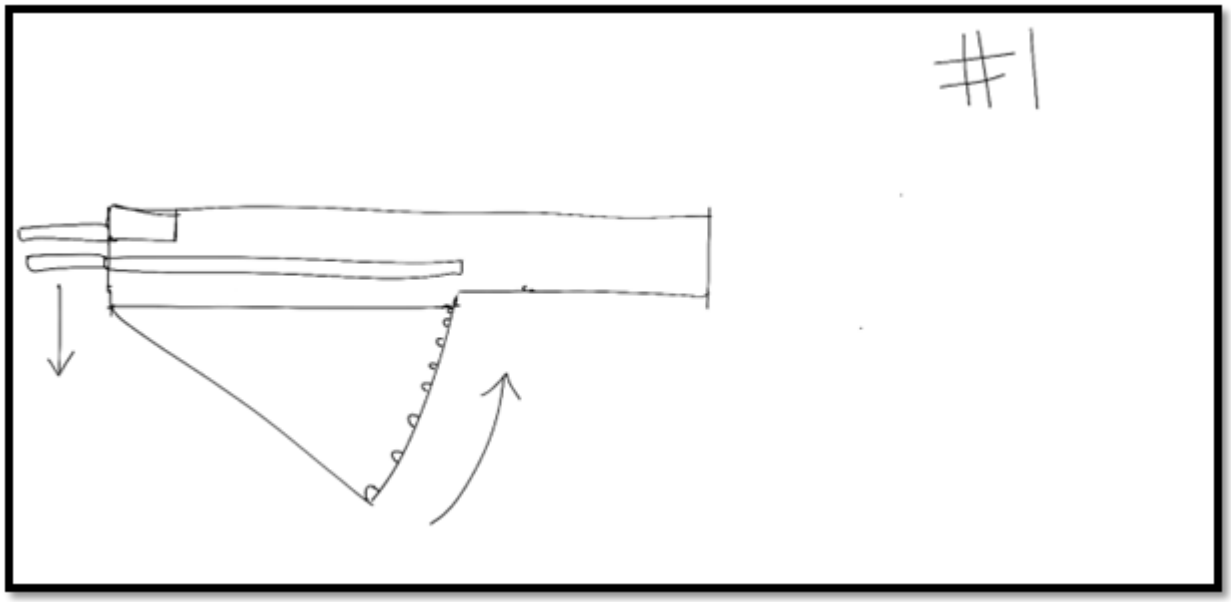
The final portion expresses both a sponsor and engineering requirement as the entire file to print this device must be accessible and easy to import for printing in a medical facility. The CAD package must have few to no risks to a medical professional, be easily assembled, and present no medical or health risks to the patient, including, but not limited to device fracture, gouging, and choking.

4.2 Concept Generation

4.2.1 Mouthpiece — Shilo Bailey

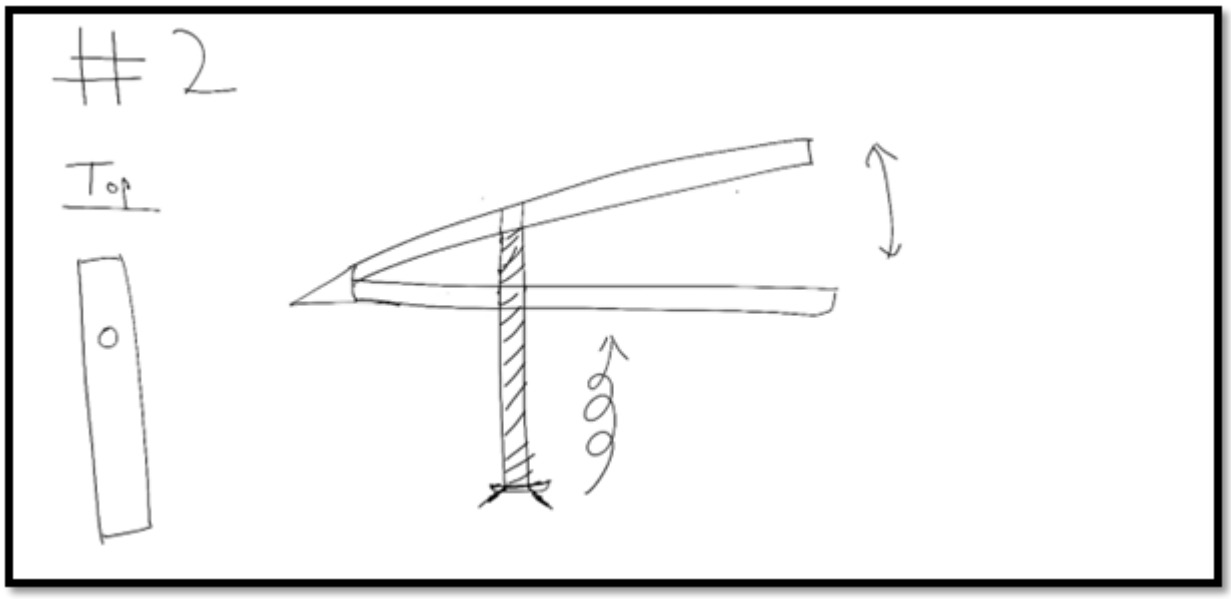


4.2.2 Mechanical Designs — Nathan Bastidas

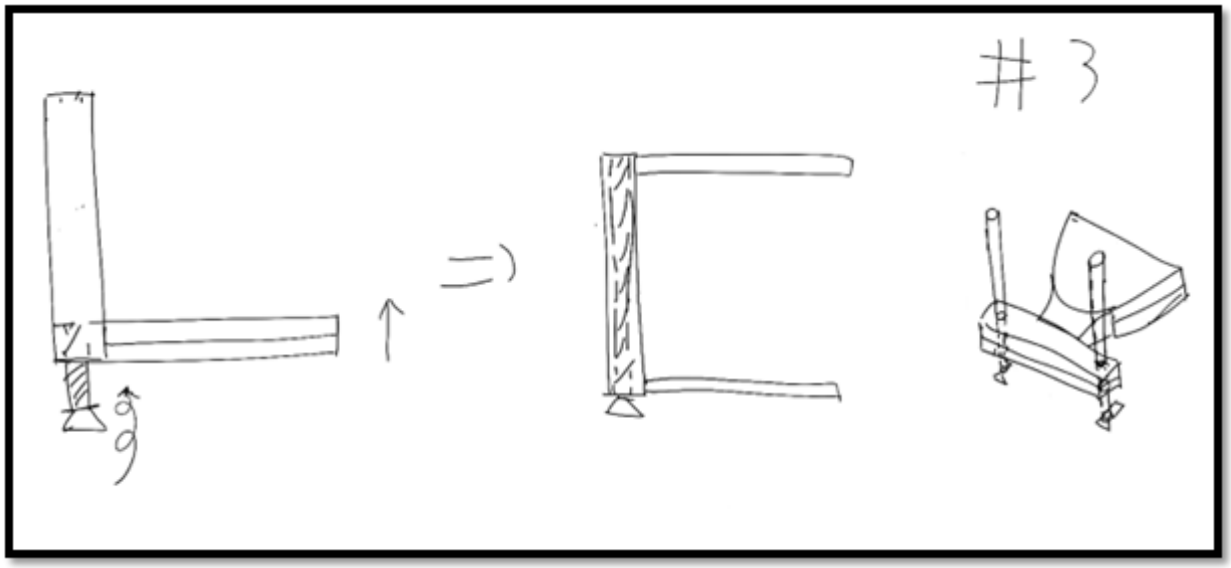


Design #1: A squeeze-lever type mechanism with various grooves made on the side of the lever. As the lever is pressed into the device with a squeezing hand gesture, the bottom mouthpiece will click into place inside the groove, locking the bottom mouthpiece at a new distance. Each groove is designed to increase in space over time, that way the device naturally locks at a specified

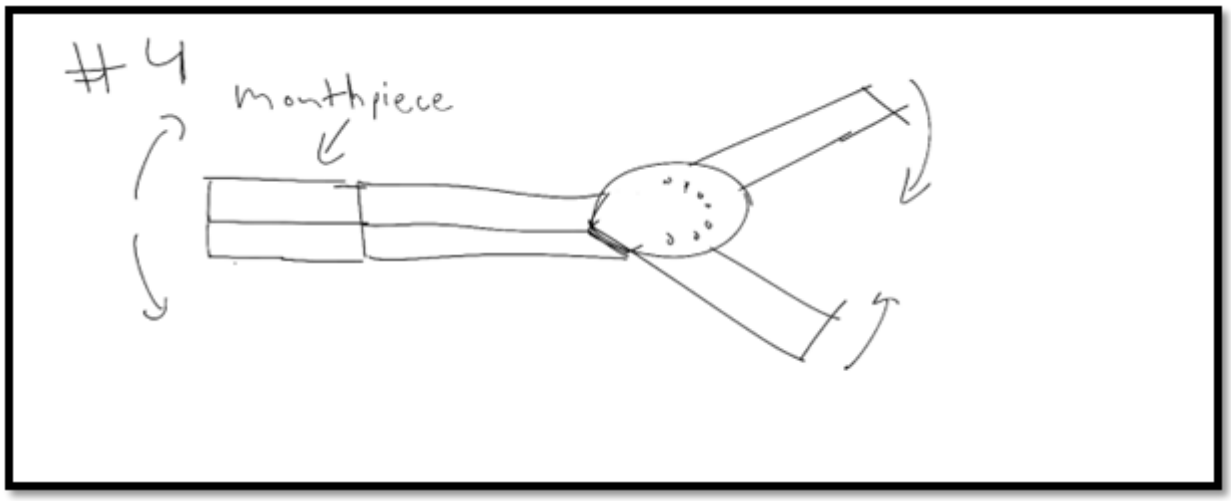
distance but has enough wiggle room between each groove to actively chew against the device for active stretching exercises.



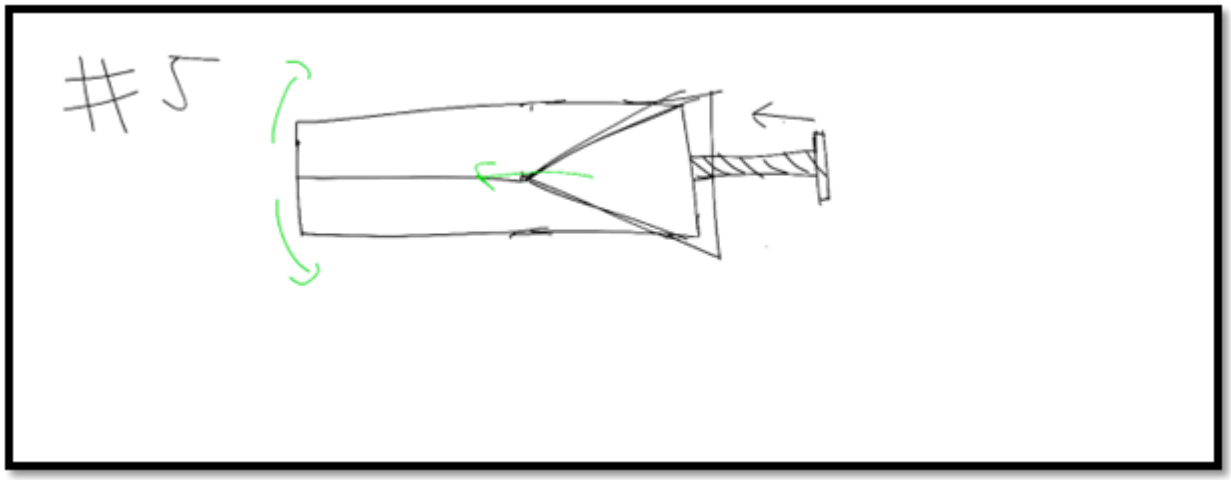
Design #2: This design utilizes a single screw point that can be adjusted manually by turning the knob on the bottom of the device. As it is turned, it causes the two mouthpieces to separate at an angle, allowing for a potentially greater spread. With this design, it could be modified to be more spring-like in nature, allowing for an easier time blending active and passive stretching exercises.



Design #3: Similar to design #2, this design uses two screw points that elevate part of the mouthguard, similar to an elevating platform. This design could be utilized for patients that have different levels of stretching for each side of their jaw.

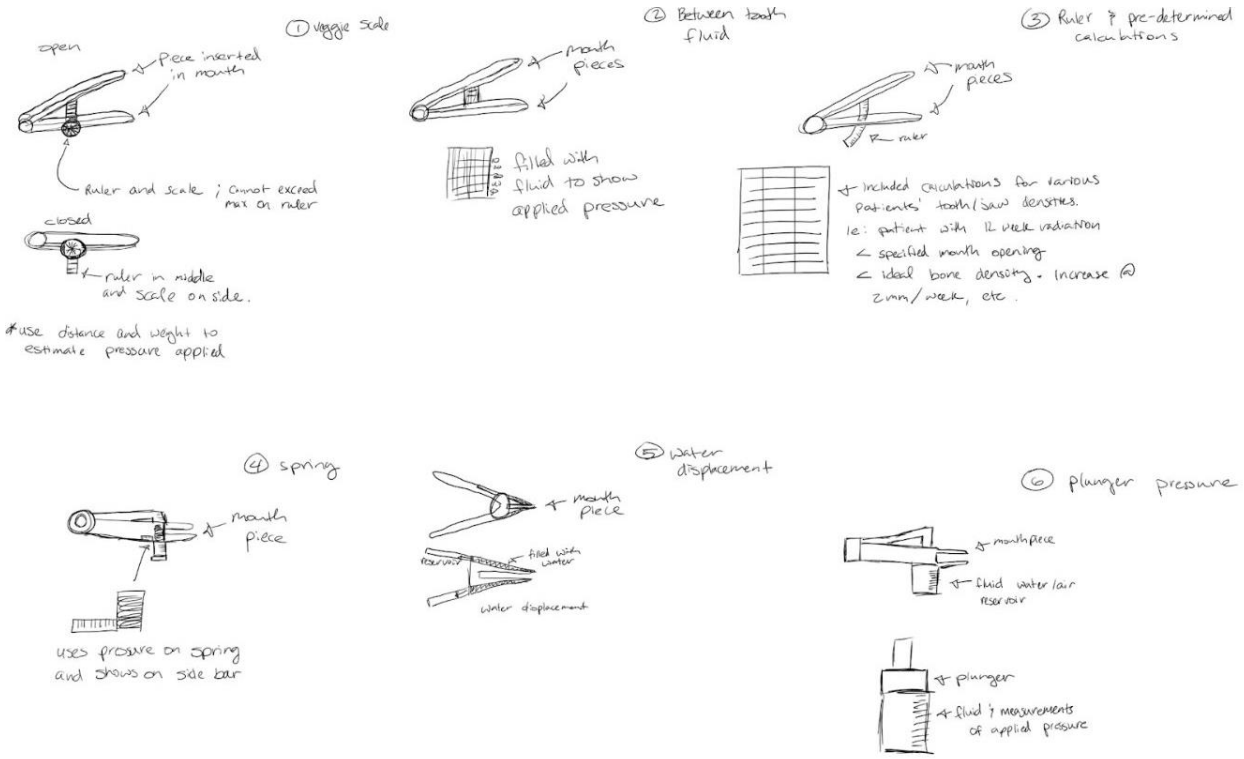


Design #4: This design uses a scissor-type mechanism to open the jaw. Each half of the mouthpiece would be linked to one part of the handle, allowing for a scissoring motion. In the center would be an adjustable lock, like design #1 where different grooves of varying distances would be able to lock the device in place for passive stretching over time.



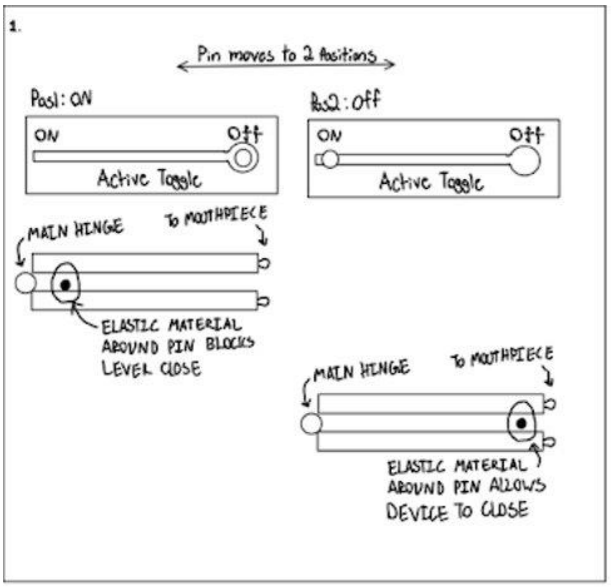
Design #5: The most unique variant, design #5 utilizes a single screw point on the back end of the device that is linked to a triangular wedge that rests between the two mouthpieces. At rest, the wedge sits flush with the two pieces. In use, the screw in the back can be turned, pushing the wedge forward between the two mouthpieces, causing them to spread.

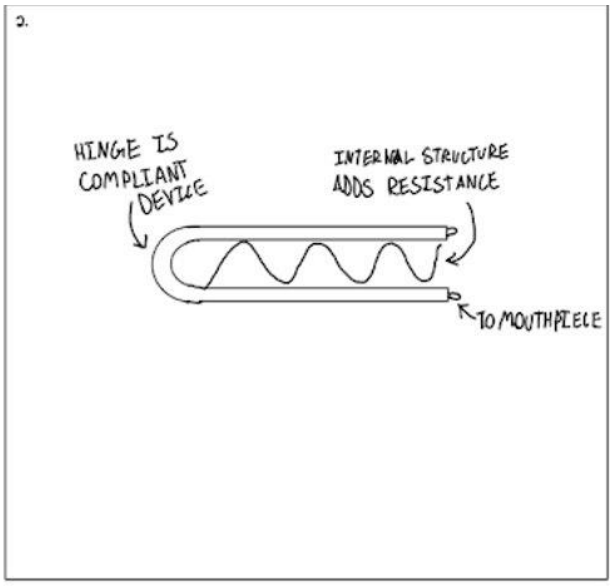
4.2.3 Pressure Measurements — Cassina Olson

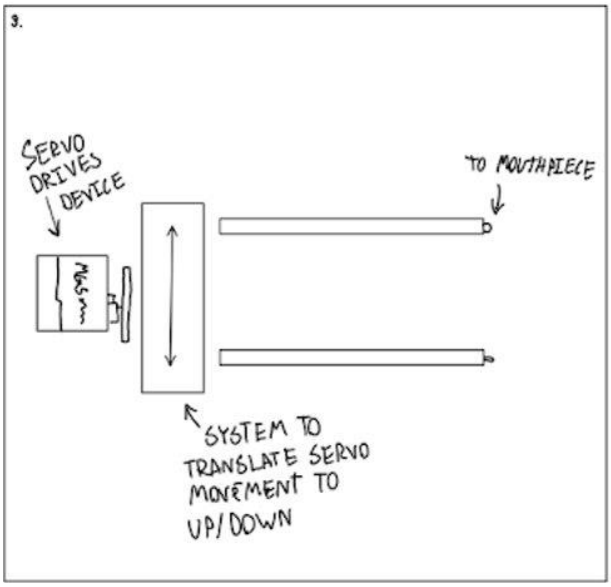


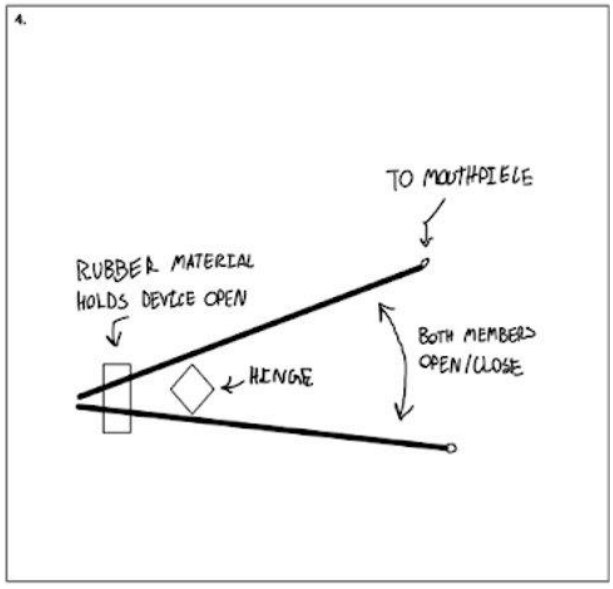
The first design shows pressure measurements through a purchased part that measures weight. This is like a veggie scale and would require a separate ruler to measure the mouth stretch distance. The second design has a tube filled with liquid and as the device is compressed, it will show the amount of pressure applied but may break under the strength of the jaw. The third design only incorporates a ruler and premade measurements based on different preset charts which is easier in design but provides no actual solution for pressure measurements. The fourth design uses a spring to measure the pressure applied to the device from the mouth which will be difficult to design and include but would achieve precise pressure measurements. The fifth design uses silicone pads filled with water and a reservoir to measure pressure by water displacement which will work well, but tap water may contain contaminants, so the consumer must purchase distilled water to fill the reservoir. The sixth and final design incorporates both parts of the second design into one single part. The plunger pushes down on the fluid and as the plunger gets further down, the more pressure is shown to be applied. The markings on the outside of the plunger also indicate distance and force. The only issue is that it may be difficult to incorporate different styles of the device such as one that separates at the mouthpiece.

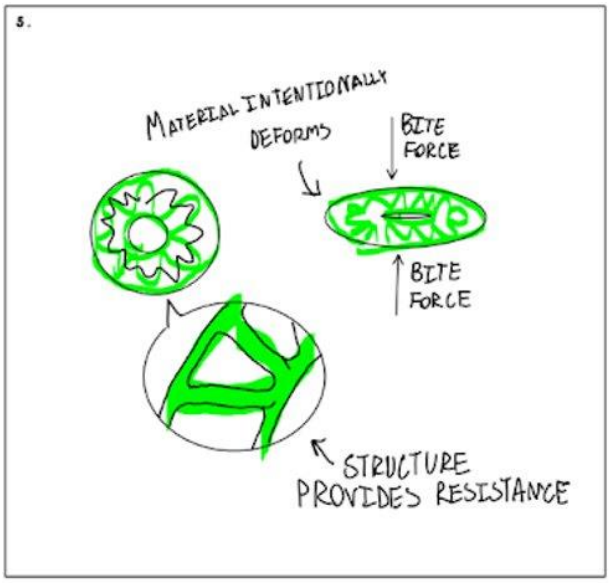
4.2.4 Shell Material and Active Resistance Systems — Carter Rhodes

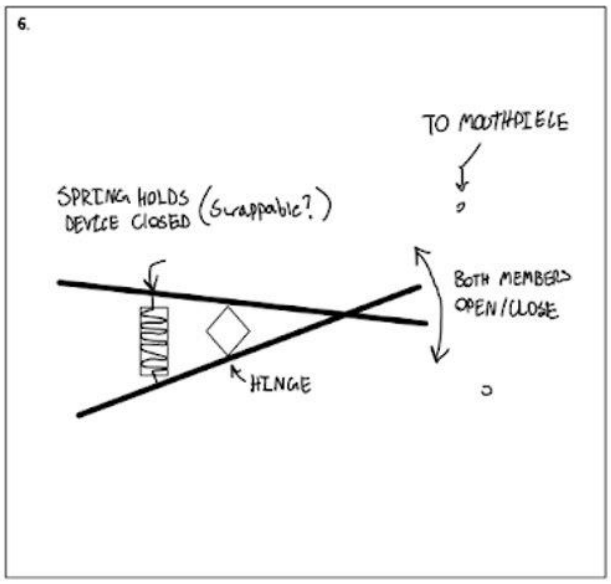

1.
Pin moves to 2 positions
Pos1: ON
Pos2: Off
ON
Off
Active Toggle
ON
Off
Active Toggle
MAIN HINGE
To MOUTHPIECE
ELASTIC MATERIAL AROUND PIN BLOCKS LEVER CLOSE
MAIN HINGE
To MOUTHPIECE
ELASTIC MATERIAL AROUND PIN ALLOWS DEVICE TO CLOSE

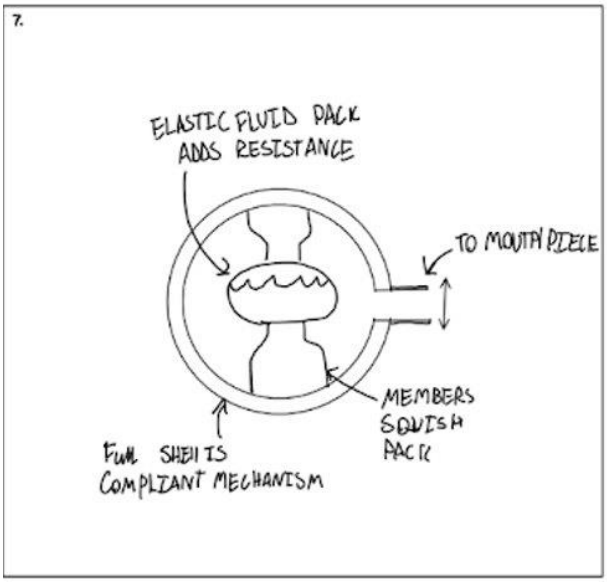

2.
HINGE IS COMPLIANT DEVICE
INTERNAL STRUCTURE ADDS RESISTANCE
TO MOUTHPIECE


3.
SERVO DRIVES DEVICE
TO MOUTHPIECE
SYSTEM TO TRANSLATE SERVO MOVEMENT TO UP/DOWN


4.
TO MOUTHPIECE
RUBBER MATERIAL HOLDS DEVICE OPEN
HINGE
BOTH MEMBERS OPEN/CLOSE







4.2.

1 "ToggleSwitch":

Pro: Easy actuation of active resistance.

Con: Requires multi-material printer or non-printed material for soft resistance around printed pin.

2 "InternalSpring":

Pro: Compliant spring printed with device.

Con: No active resistance actuation.

3 "ServoControlled":

Pro: Precise resistance force control.

Con: Disqualified as class 2 device (Requires electronics).

4 "BandResistance":

Pro: Simple design with toggleable resistance (Removable elastic).

Con: May require non-printed, albeit cheap, parts.

5 "ChewingGum":

Pro: Useful solely for jaw exercise.

Con: Requires separate device for active resistance.

6 "CompliantSpring":

Pro: Swappable Compliant Springs change resistance by geometric design.

Con: More parts needed as well as multiple materials due to variable compliant spring types.

7 "WaterOrb":

Pro: Device is inherently strong due to geometry.

Con: Maintaining water-tightness of internal fluid pack may be challenging with FDM printing. 4.2.4

[Show and describe all applicable top-level and sub-system-level concepts. All other concepts that were filtered out early in the process can go into the appendix. Discuss initial pros and cons of each concept.]

4.3 Selection Criteria

The selection criteria include cost as it must be under $50 to produce each device, ease of printability as quantifiable by the number of times a reprint must occur or how many of and how often the 3D printer parts must be replaced, and safety as defined by strength testing able to withstand 1.5 times estimated average applied pressure and body safe printing materials as defined by the FDA or other regulatory administrations. The force measurement aspect must show an accuracy within 1mm (about 0.04 in) of measurement and 5psi of pressure for the device which can be seen and adjusted through testing.

While calculations from testing have not been processed, the MATLAB code from section 3 intakes the average surface area of a human mouth while accounting for present teeth, varying bone densities, and potential unaddressed dental issues to output the nominal range of pressure to be applied to the patients' mouth. Success is defined by testing for the accuracy of the nominal range as determined by lack of fracture and patient comfort.

Ease of printability is classified as having to remove or destroy equal or less than 1 in 10 consecutively printed and assembled apparatuses. It is also quantified as having to replace 1 or fewer parts of the 3D printer for every 10 fully printed devices and base structures.

Cost is defined as less than $50 per printed device. This does not account for misprints, printer failures, the cost of a 3D printer, or labor costs to print and assemble. It is only constituted of the cost of printing filament and one nozzle replacement for every 10 full device prints.

4.4 Concept Selection

Using the above criteria, the following decision matrix was created, giving each requirement a weight and rating each design against a current competitor to see which design captures all of the design requirements best. As shown, the TheraBite brand trismus device failed in cost, printability and force measurements

which ranked higher in weight, giving it a score of 2.55 when weighted and leaving much to be desired which the team took to create a better fit. Based on the ratings and multiplied weights, alternative design 5 excelled with a weighted score of 7.5. The next best options were alternate design 1 with a weighted score of 6.5 and design 3 with an equal weighted score. However, the team looked to create a version that included each of the best aspects from each model to create a device that would, in theory, rank a full 10 when weighted.

Criteria	Weight	Current Solution :TheraBite		Alternate Design 1	
		Rating (0-10)	Weighted Rating	Rating (0-10)	Weighted Rating
Cost (Lower cost scores higher)	30%	1	0.3	7	2.1
Printability	15%	0	0	6	0.9
Print In Place	5%	0	0	8	0.4
Safe	20%	5	1	5	1
Open Source	5%	0	0	9	0.45
Adaptability	10%	8	0.8	6	0.6
Force Measurement?	15%	3	0.45	7	1.05
Total Percentage:	100%	Total Option A:	2.55	Total Option B:	6.5

Alternate Design 2		Alternate Design 3		Alternate Design 4		Alternate Design 5	
Rating (0-10)	Weighted Rating	Rating (0-10)	Weighted Rating	Rating (0-10)	Weighted Rating	Rating (0-10)	Weighted Rating
6	1.8	7	2.1	4	1.2	9	2.7
5	0.75	6	0.9	5	0.75	8	1.2
3	0.15	2	0.1	2	0.1	7	0.35
5	1	5	1	5	1	5	1
8	0.4	8	0.4	5	0.25	9	0.45
7	0.7	8	0.8	6	0.6	6	0.6
6	0.9	8	1.2	3	0.45	8	1.2
Total Option C:	5.7	Total Option D:	6.5	Total Option E:	4.35	Total Option F:	7.5

Best Fit: Design #5

Top 5 Combinations (More on page 2)

System:	Pressure Measurement	Mouth Piece	Active Resistance	Mechanical	Drafter:
Alt Design 1	Ruled Measurements	PryBar	RubberBand	SqueezeLever	NAT
Alt Design 2	Plunger Pressure	MouthGuard	TogglePin	SingleScrew	CAS
Alt Design 3	Spring Force	Molar-Anchored	Spring	DoubleScrew	SHI
Alt Design 4	Water Displacement	MouthGuard	FullCompliant(#7)	ScissorMechanism	CTR
Alt Design 5	Leverage Device	PryBar	TogglePin	Wedge	CTR

Fig [4.3.1] Concept Selection Decision Matrix

Alternative Designs for Remodel

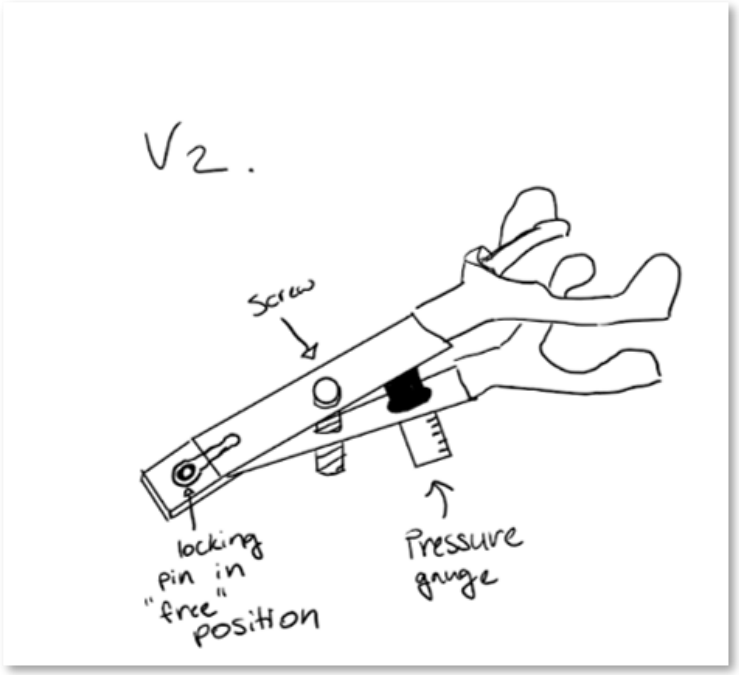


Fig [4.3.2] Alternative Design 2

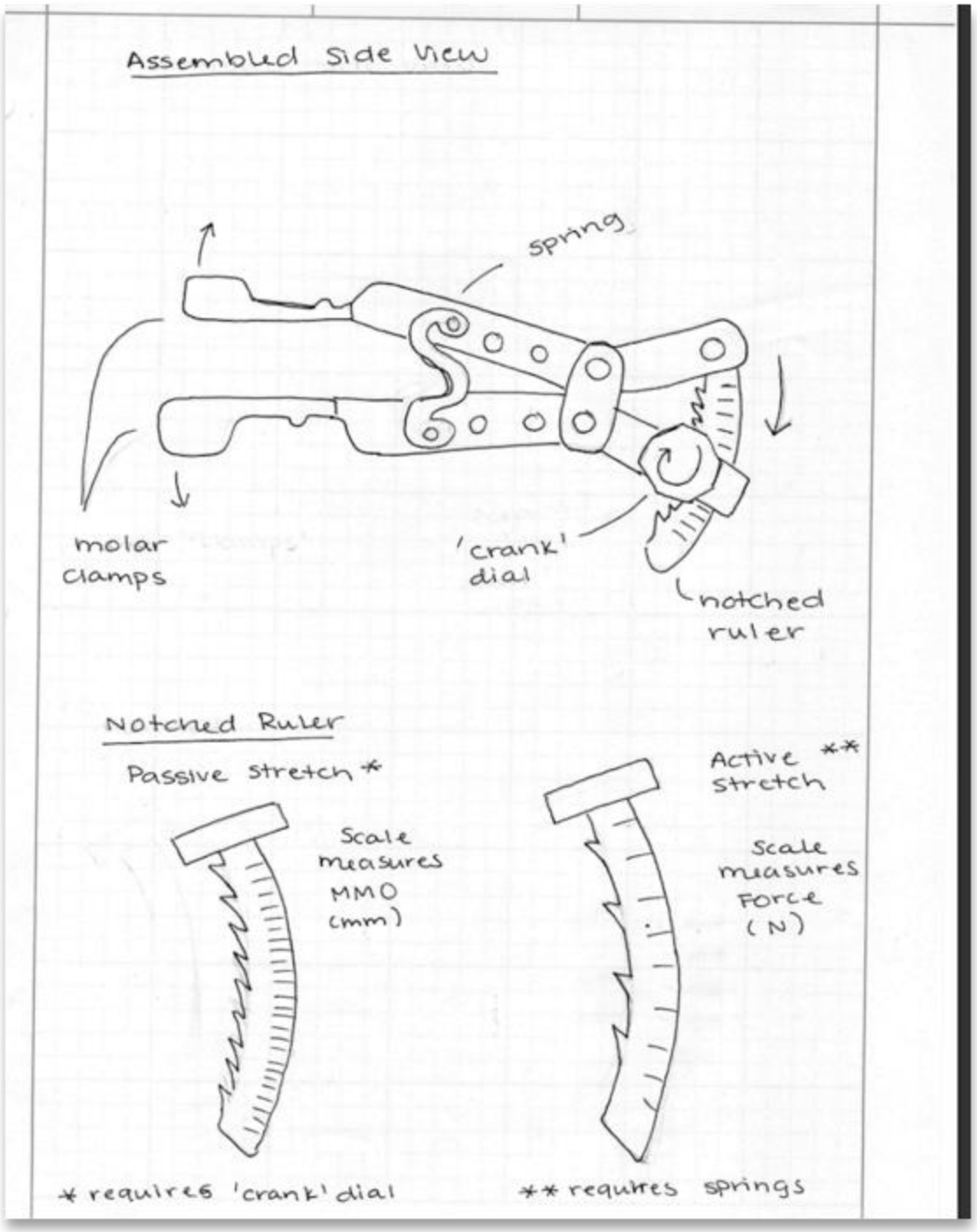


Fig [4.3.3] Alternative Design 3

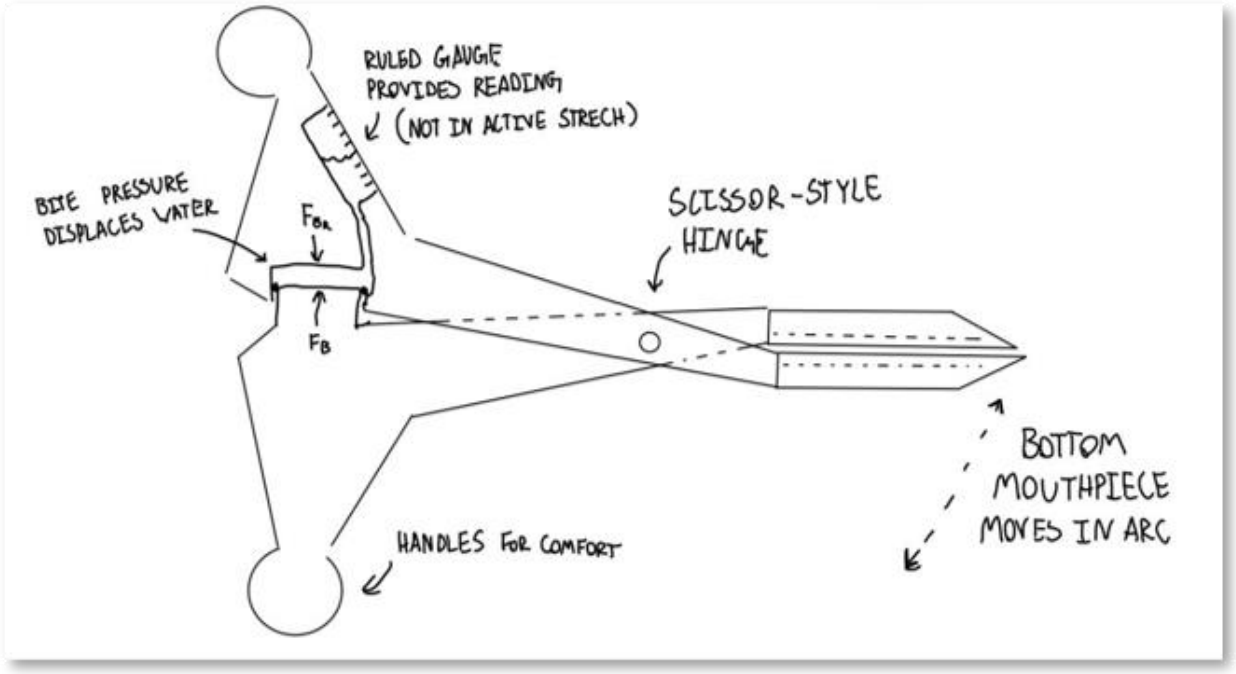


Fig [4.3.4] Alternative Design 5

Current CAD

Using the body of alternative design 3, the hinge of alternative design 5, and the pressure system of alternative design 2, the team created a CAD design to display the concept design to best fit all client needs and engineering requirements. Each of the following figures depicts the final design and the location of major subsystems related to the design requirements. This features a notched ruler with turning device to control the rate of applied pressure, jaw piece with tabs and gaps for molar reach, and compliant spring to provide active resistance training for the patient to reach a minimum threshold of 10mm (about 0.39 in) more speedily and build jaw muscle again.

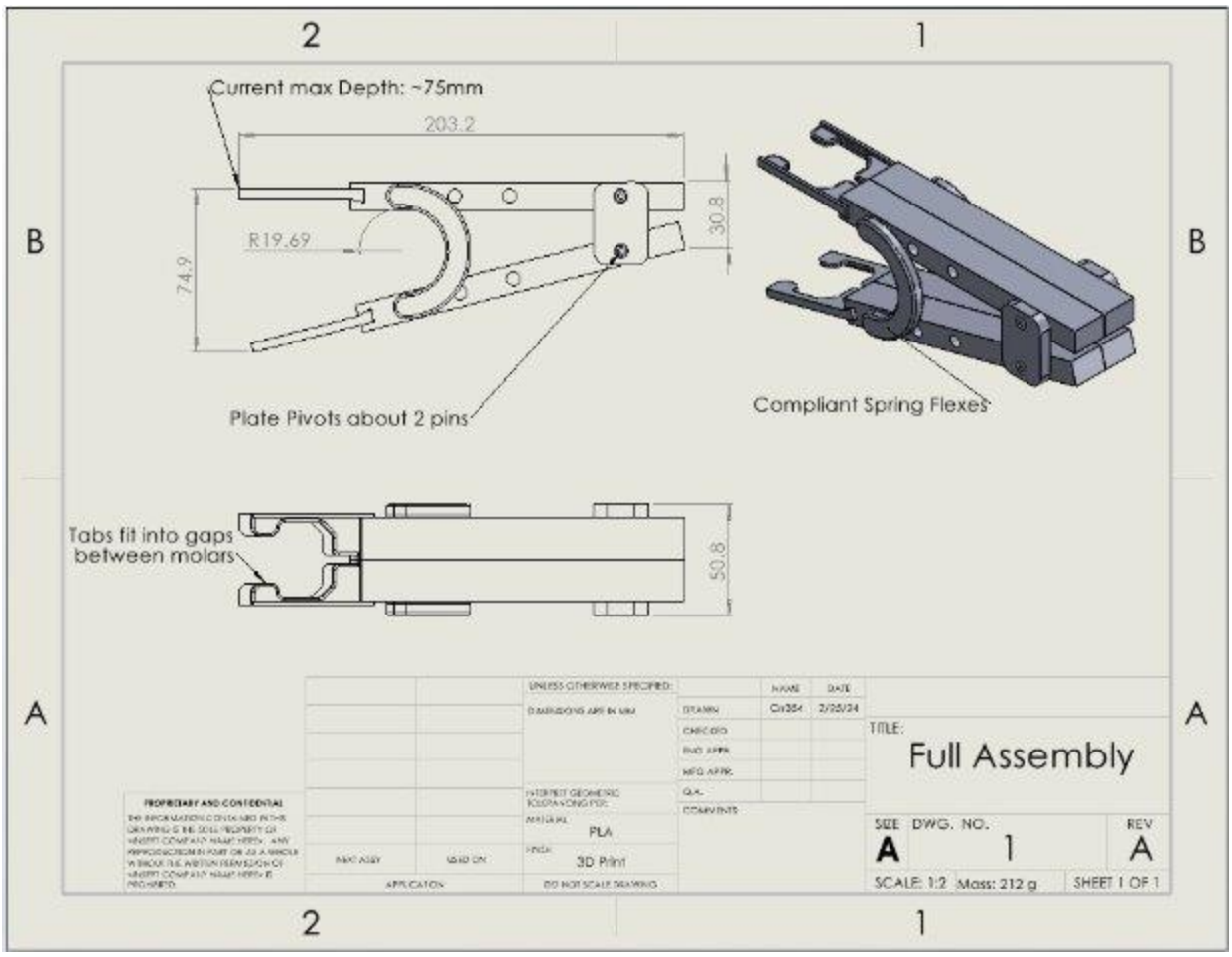


Fig [4.4.1] CAD Mouthpiece and Compliant Spring

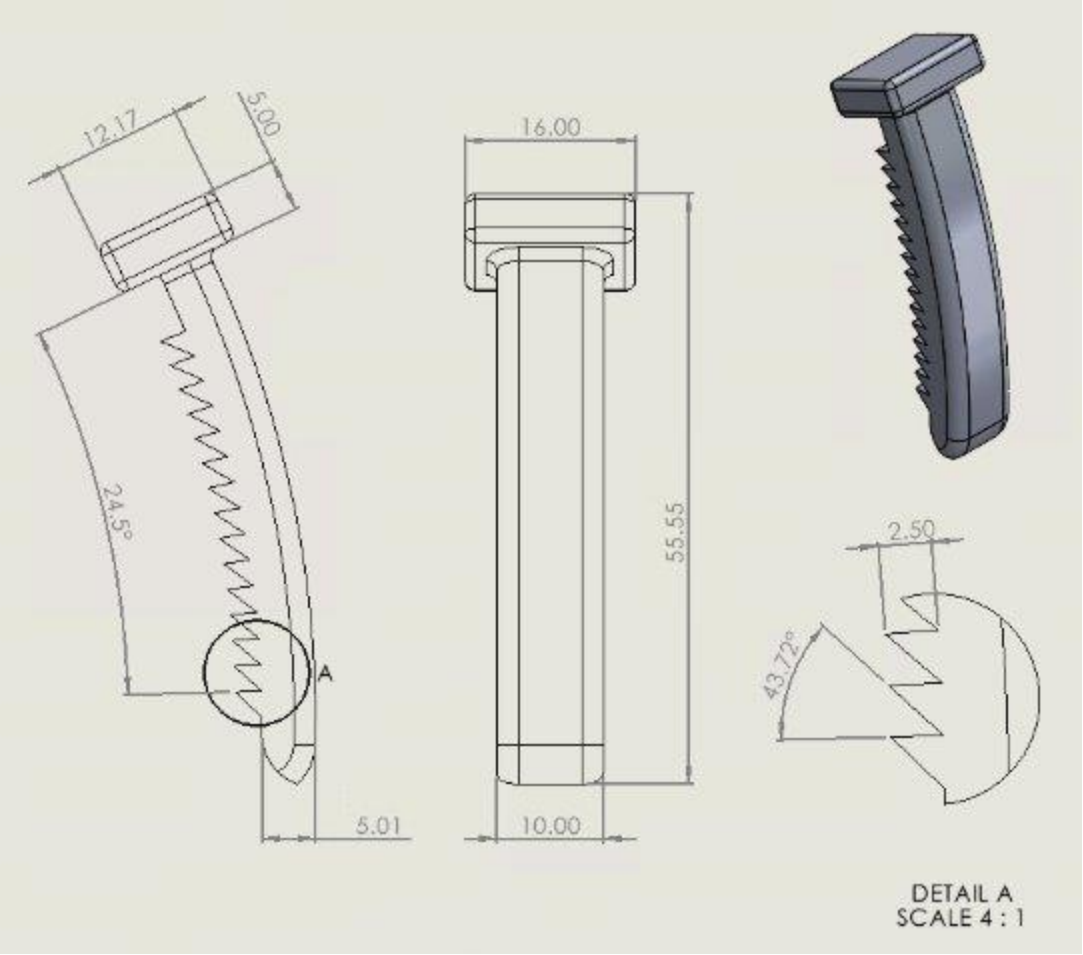


Fig [4.4.2] Subsystem of Applied Force and Measurement Ruler in Millimeters

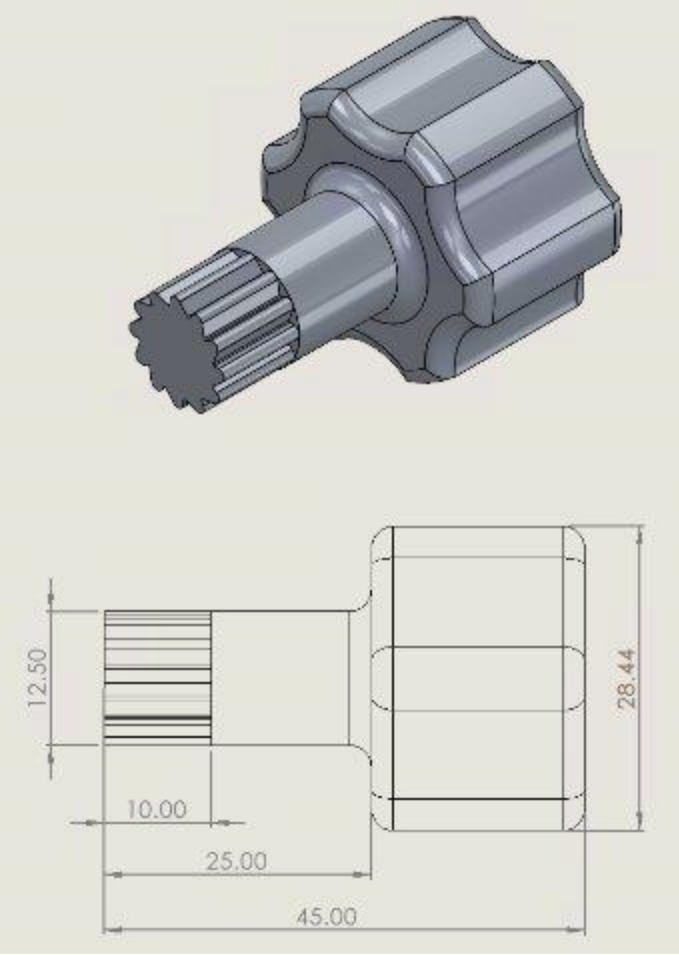


Fig [4.4.3] Subsystem of Applied Force and Movement Control

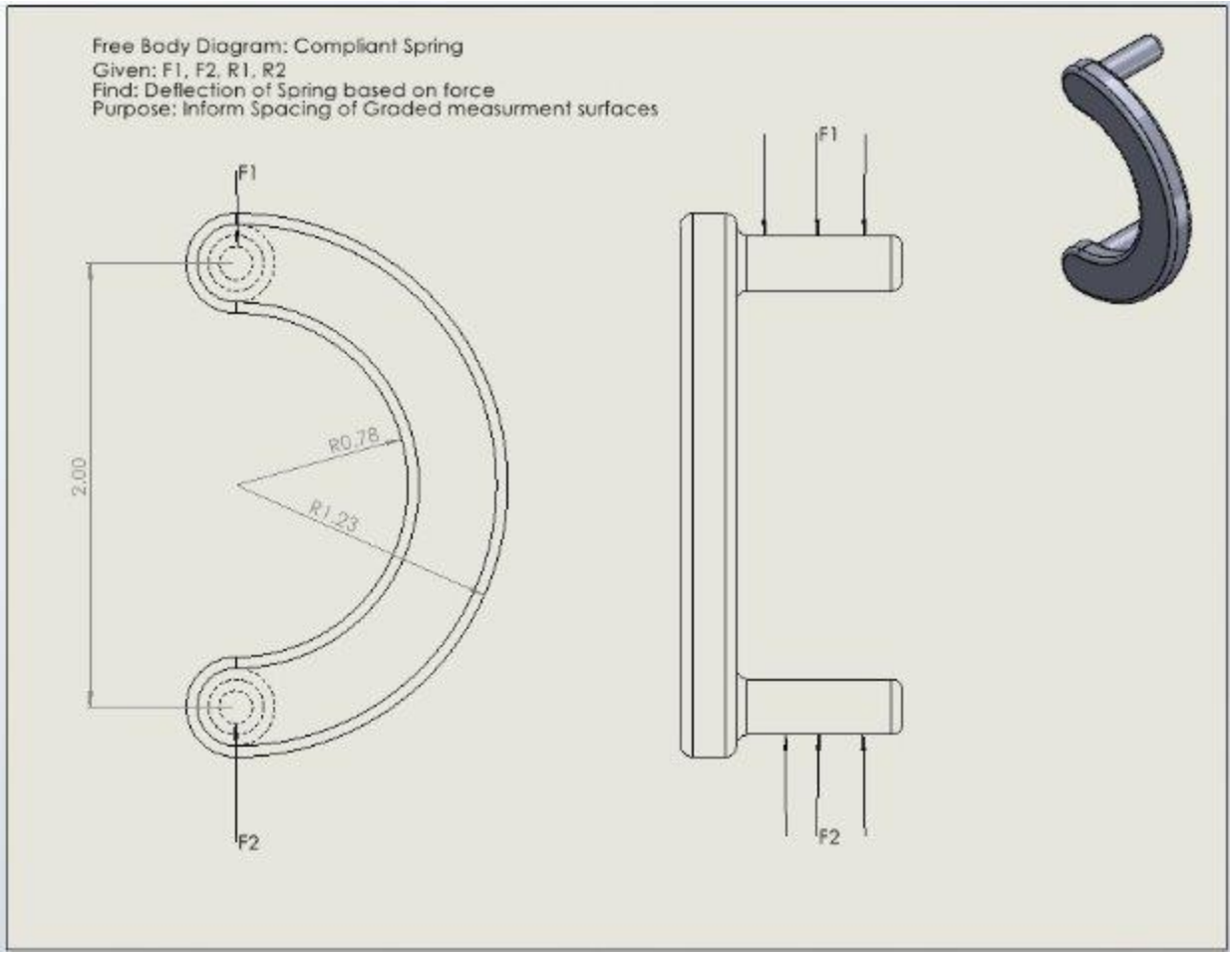


Fig [4.4.4] Subsystem of Active Resistance with Compliant Spring

5 CONCLUSIONS

The Trismus treatment device is designed with Dr. Rebecca Bartlett and Carolyn Abraham from Dignity Health Phoenix. This device is to be entirely 3D printed, allowing for easy replication and reproduction of the design, safe (with regards to material use and strength tolerances) for the patient and the device, and have each unit cost $50 or less to produce.

Our current solution is to utilize PETG filament to print out the entire CAD package and publish the files and instructions alongside a full report of the device. This way, clinicians across the United States can find this article with the included files and instructions and be able to replicate it with relative ease for their patients.

REFERENCES

[Include here all references cited, following the reference style described in the syllabus. There should only be one Reference list in this report, so all individual section or subsection reference lists must be compiled here with the main report references. If you wish to include a bibliography, which lists not only references cited but other relevant literature, include it as an Appendix.]

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