3D Printable Trismus Treatment Device

Conceptual Design Report

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DISCLAIMER

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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. This form of printing is one of the most common forms used in 3D printing machines, making it an easy start for someone who is not experienced with 3D printers. 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 and passive 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 their second prototype made by the end of the month at the time of writing. The current milestone the Trismus team hopes to complete is to have a fully functional device that can be used for initial testing. 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 working with the PETG material in the printing process due to its more specific printing requirements. 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:

The device will be considered as successful based on its 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. Two rolls of PETG filament have been purchased so far for prototyping and additional roll of filament (PCTG) will be purchased since the material was suggested by Travis and will be considered for printing and testing will be conducted on both.

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 while meeting all course requirements and deliverables for the Capstone Class (ME 476C).

1.2.1 ME 476C Key Deliverables

Deliverables for ME 476C are based on successfully identifying and meeting client needs while practicing professionalism through submission of required documents and assignments such as presentations 1 – 3, report 1, and this report. Additional course deliverables includes; maintaining a Gantt chart for project progress, submitting weekly timesheets, conducting client meetings on a weekly basis, building a prototype, and a technical analysis of the device. These deliverables allow our team to practice utilizing all material learned from previous classes and apply them to this project to ensure that we hold the necessary skills and knowledge to design and implement a quality product our client would approve of.

1.2.2 Client Key Deliverables

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.

1.3 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.

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.

1. **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.

2. **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.

From the previous report, our quantifiable engineering requirements (ERs) and customer requirements (CRs) have not changed in any significant way. Instead, this report will focus more on how our team is planning on fulfilling these requirements.

2.1 Customer Requirements (CRs)

Cost Effective: The device should be cheaper than alternative devices, with a price per unit of less than $50 USD. Currently, the full assembly cost is $1.98 (based on the cost of material expended during the printing process).

Safe: The Device must not cause harm to its operator or itself during operation. Research into ISO safety standards for medical devices has influenced some design revisions, ensuring safe operation of the device under normal conditions as well as purposely designed fail safes in case of improper use.

Open Source: Provide a full instructional suite to assist in-house reproduction of the design. Alongside the medical journal of this device, a full CAD assembly suite will be included with instructions (both image and links to videos on the internet) on how to properly set up the 3D printer, slicer software, printing process, and overall device assembly. Included in this instruction document is a list of modifiable tolerances of each device part, as well as recommended and tested materials for use in creating the device. A general disclaimer will be included to discourage further modification of the device outside of its safety standards.

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.). Current material testing is focusing on PETG and PCTG. Both materials are commonly used in biomedical industries, as well as commercial printing of objects that would come into contact with the human body, such as water bottles. PCTG appears to be the more practical material to use, as it does not require any special enclosure for printing and is a more refined version (mechanically) of PETG.

Adaptive: The device should be able to accommodate various patient cases with varying severity of Trismus, as well as various dental shapes and incisor openings. Currently, the team is devising various swappable mouthpieces that can adapt to different oral shapes, incisor openings, as well as teeth count in a patient.

2.2 Engineering Requirements (ERs)

Target Price: Each unit (Total of all materials and electrical costs per device) costs less than $50 USD.

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, as well as without any additional enclosures or materials outside of the filament and 3D FDM printer (Binary 1 = acceptable).

Adaptive: Device can accommodate a 25mm incisor gap (Target fit a 6mm gap extreme cases). Current testing shows a minimum of 6mm gap being the smallest accommodable size for the device.

2.3 House of Quality (HoQ)

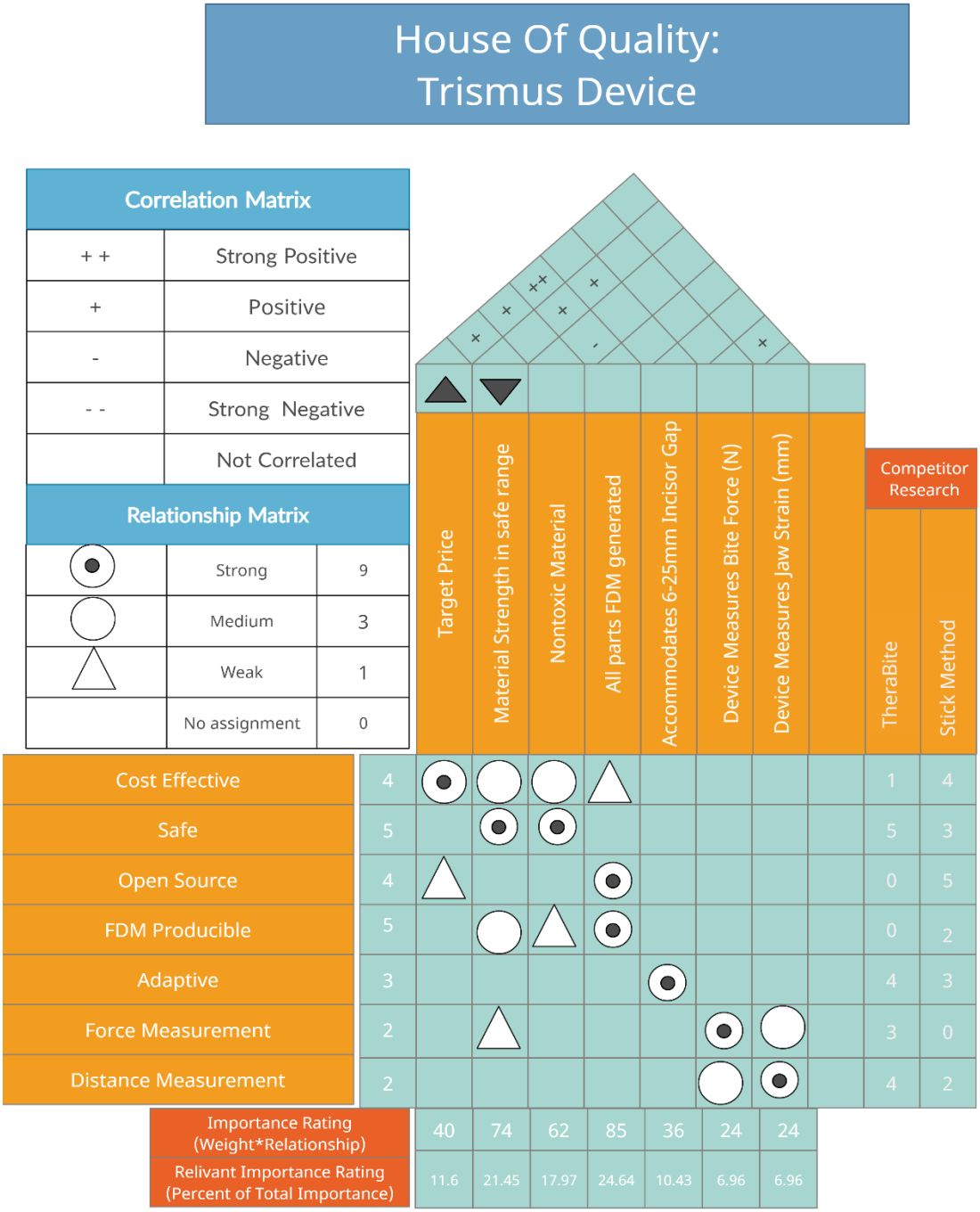
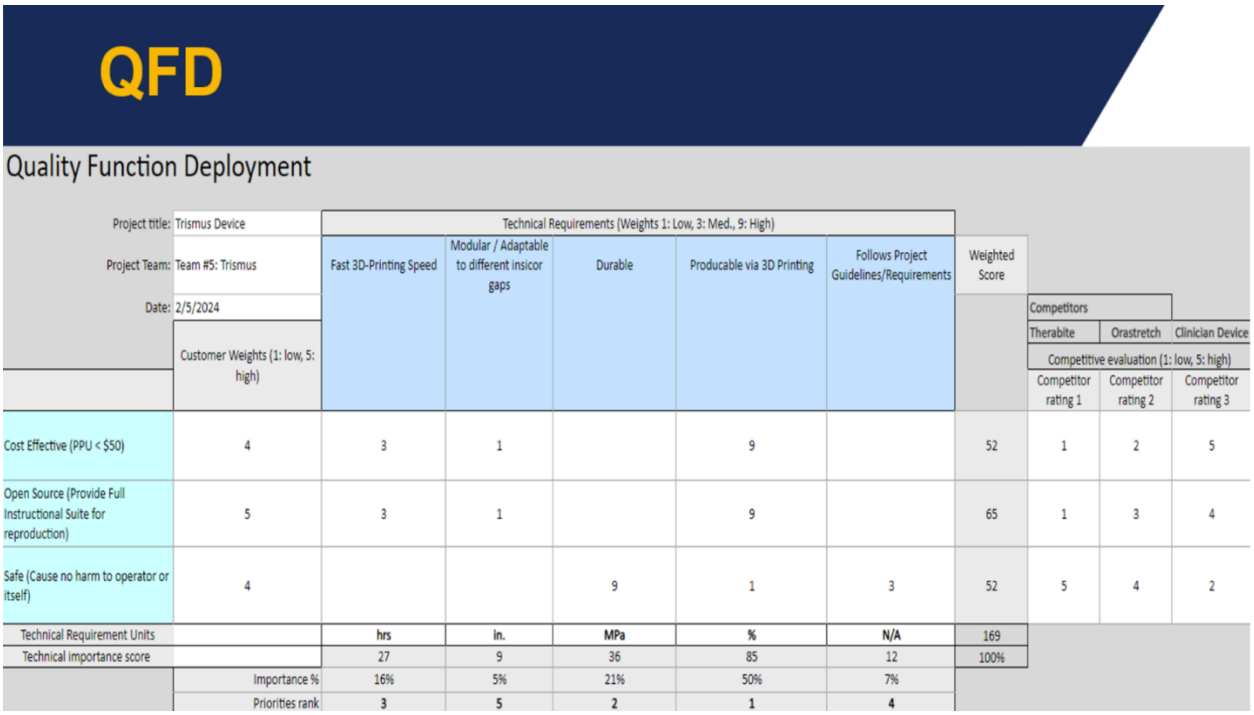


Fig [2.3.1] House of Quality for Trismus Device



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	Competitors		
Date:	2/5/2024							Therabite	Orastretch	Clinician Device
	Customer Weights (1: low, 5: high)							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 [2.3.2] House of Quality for Trismus Device

3 Research Within Your Design Space

3.1 Benchmarking

To determine the viability of this product, the team considered 3 state-of-the-art systems within the design. These include the use of a compliant spring, nondigital pressure readings, and an entirely 3D printable design. The compliant spring [Fig 3.1.1] is benchmarked by withstanding a maximum of 200N (found by maximum bite force of a healthy mouth) [cite] of downward force and a FMEA design to fracture within 50N above this maximum. Testing for proof of these results will be done by crush tests and dummy tests where the device is inserted in a false jaw to simulate a harsh bite.

The nondigital pressure readings [Fig 3.1.2] are benchmarked by their accuracy within 5N (found from manufacturing suggestions) [1] to determine the force applied by the jaw on the device. Testing for proof of this will include showing that measured applied pressure is equivalent to device readings over the product's lifetime to determine accuracy changes over time and when the device is no longer viable.

The entirely 3D printable design [Fig 3.1.3] is benchmarked by both the safety of the materials used and the need for any consumer of the device to need any additional part that cannot be printed. The device must be easily assembled, by viable long enough to offset production costs, and require little to no outside tools or materials to function properly. Benchmarking for this will include blind assembly from instruction, lifetime use quality assurance testing, and material testing to confirm the accuracy of provided mechanical properties. [2]

Subsystems within the design include the mouthpiece mechanism and the turn dial to open the device. These are benchmarked by their use in tandem and accuracy in increasing the distance between the two mouth pieces by 1mm per turn as defined by a click. [3.1.4]

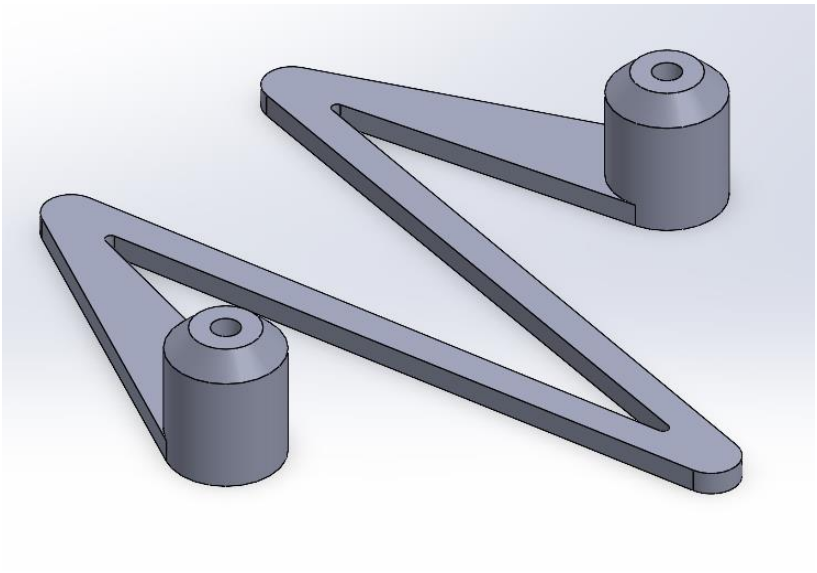


Fig 3.1.1: Compliant Spring

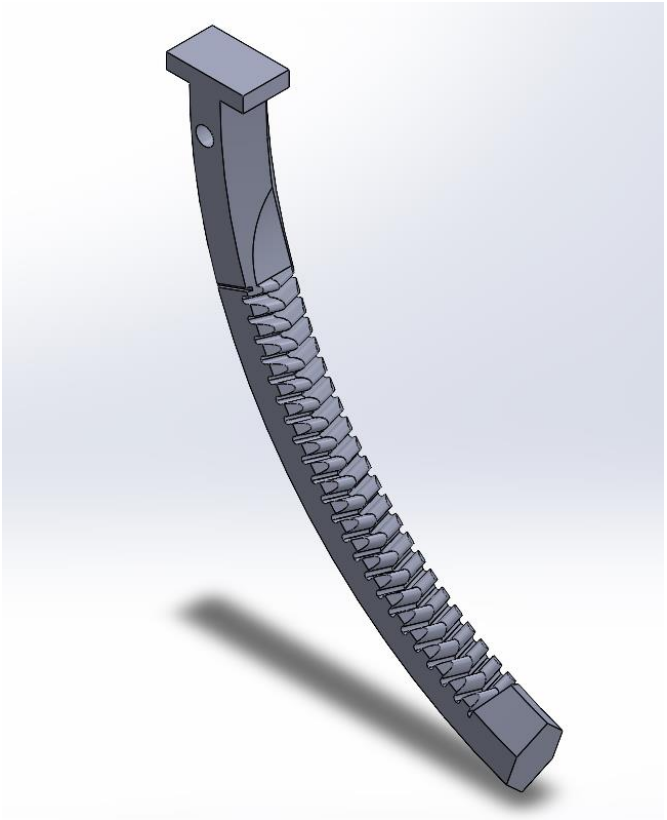


Fig 3.1.2: Pressure Reader/Ruler

Fig 3.1.3: 3D Printed Model of Full Device

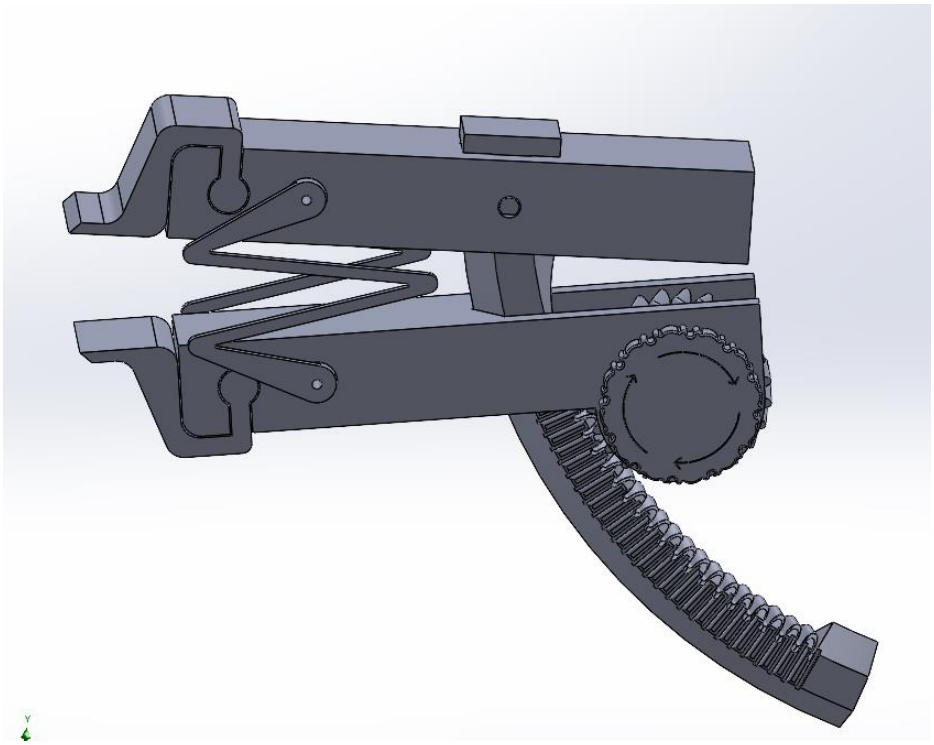


Fig 3.1.4: Full CAD of Apparatus (Turn Dial)

3.2 Literature Review

3.2.1 Shilo Bailey

Exercise Intervention for the Treatment of Trismus in Head and Neck Cancer – A Prospective Two-Year Follow-up Study [3]

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 [4]

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 [5]

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 [6]

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.

Regulatory mechanisms of jaw bone and tooth development [7]

Development in jaw muscle pathways and nerves is crucial for proper jaw function. Disruptions in these pathways can lead to conditions such as trismus, characterized by restricted mouth opening. Understanding and addressing these disruptions are essential for managing trismus and maintaining oral health.

New Approaches to Enhanced Remineralization of Tooth Enamel [8]

Restoring natural materials in teeth is essential for preserving their structural integrity and function. However, the process can alter the tooth's original properties, potentially affecting the amount of pressure required for biting and chewing.

Tooth Enamel and Its Dynamic Protein Matrix [9]

The effects of root repair on teeth are pivotal for ensuring long-term dental health. Severe trismus can impede proper healing or cause disruptions in the repair process, potentially compromising the integrity and stability of the tooth.

Tooth enamel remineralization [10]

The process of teeth remineralization is essential for maintaining their strength and resilience against decay. Trismus can disrupt this process and cause further oral issues, such as cavities and unnecessary enamel erosion.

Organic Matrix of Tooth Enamel [11]

Disruptions to oral hygiene caused by trismus can cause injury or potentially destroy the natural matrix of teeth. This is particularly bad for patients with diabetes or a naturally acidic mouth.

Abiotic tooth enamel [12]

Trismus directly affects the abiotic enamel restorations and may cause longevity issues with healthy teeth. Patients with weak or unhealthy teeth may lose them due to the lack of repair that can occur during trismus.

3.2.2 Nathan Bastidas

Biomaterials: An Introduction to Materials in Medicine [13]

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 [14]

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 [15]

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 [16]

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 [17]

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 [18]

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 [2]

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.

Kinetics of Ternary Co-polycondensation for High-Performance PCTG Copolyester with Ester Interchange, Polycondensation, and Mass Transfer [19]

This report details the intricacies of PCTG, as well as it's direct comparisons to PETG. Additionally, the report discusses the chemical composition of PCTG, and it's effects on the material properties.

Balanced strength and toughness improvement in polylactide (PLA)/poly(1,4-cyclohexylene dimethylene terephthalate glycol) (PCTG) blends using various compatibilizers [20]

The report discusses the initial differences between PLA and PCTG as materials, detailing the potential blend of the two improving various mechanical properties of the material, such as tensile strength and elasticity.

Overview of Materials for PETG Copolyester [21]

This technical sheet gives average data for PETG material used in 3D printing. This data is collected from various manufacturers, with all the listed values being the mean of the different manufacturers' material properties. With this, our team can find an estimated strength of the device.

3.2.3 Cassina Olson

The Design and Manufacture of Medical Devices [1]

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 [22]

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 [23]

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 [24]

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 [25]

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 [26]

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 [27]

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.

Comparison of Mechanical Property and Role Between Enamel and Dentin in the Human Teeth [28]

This scientific literature describes the different aspects and materials of the tooth and jaw and popular substitutions in dentistry that may alter the necessary pressure needed for a patient regarding the trismus device. From this, the team can consider testing hydroxyapatite as it is the most common substance in teeth/bones and replacements.

Adverse Effects of Orthodontic Treatment: A Clinical Perspective [29]

This research was conducted to determine the effects of orthodontic trauma on patients with varying backgrounds such as those with preexisting trauma, missing teeth, and genetic predisposition. These findings may result in the team needing to alter the mouthpiece or add a different design for the mouthpiece in addition to the original ones. People with these predispositions may have tooth or jaw fracturing, tooth movement within the mouth, and in some cases, pain with decalcification or enamel loss.

Potential Health Impact of Microplastics: A Review of Environmental Distribution, Human Exposure, and Toxic Effects [30]

This peer reviewed article considers the effects of different plastics within the mouth and how microplastics affect humans. This thorough article outlines plastics that are safer for humans and compares those to plastics that a person should rarely, if ever, be in contact with. This will inform the team of which materials to use if the material needed is unavailable or unsuccessful.

3.2.4 Carter Rhoades

Fatigue Analysis of FDM Materials [31]

This source provides an overview of fatigue in 3D printed materials. The information in this article is

useful because it helps us determine how long each part might last, as well as some considerations to lessen the effect of fatigue on 3D printed objects.

Biocompatible 3D printing resins for medical applications: A review of marketed intended use, biocompatibility certification, and post-processing guidance [32]

This source provides an overview of a biocompatible variant of SLA resin, its uses, and how to process parts out of the printing area. This may prove useful for our project if we require the use of SLA printed mouthpieces that conform to a scan of the patient's mouth.

Special materials used in FDM Rapid Prototyping Technology Application [33]

This Source provides an overview of various specialty or uncommon 3D printer materials. Some materials may be stronger than others but significantly harder to print, thisa source explains the various tradeoffs between various filaments.

Trismus [34]

This source discusses the broader Trismus condition. It explains the causes, the physical symptoms, including musculature nomenclature, and treatment of this affliction. This is useful for our project because it discusses the main ailment we want to treat.

Persistent trismus following mandibular third molar extraction and its management: A case report and literature review [35]

The study talks about a patient who suffered from trismus 45 days after a tooth extraction. They received treatment and the article explains this in detail. This is relevant to our project because it explains possible treatments and implies potential design considerations.

A Preliminary Report on the Efficacy of a Dynamic Jaw Opening Device (Dynasplint Trismus System) as Part of the Multimodal Treatment of Trismus in Patients With Head and Neck Cancer [36]

This source explains the Dynasplint system and its process. It concludes by establishing the functionality of the treatment with final treatment results. This is useful for our project because it demonstrates a good benchmark process to compare our device to in terms of MID.

Trismus: Etiology, Differential Diagnosis and Treatment [37]

One more article that discusses the overall condition of trismus, and its treatments, This is a useful tool to use for our project to reference the symptoms of trismus.

Treating trismus with dynamic splinting: A cohort, case series [38]

Explained a case study of 40 participants who used the DTS system to improve their symptoms of trismus after cancer related trauma. This article is useful because it explains the functionality of a preexisting design.

TheraBite exercises to treat trismus secondary to head and neck cancer [39]

This source evaluates the effect of TheraBite exercises on mouth opening and to analyze factors influencing this effect in a patient record evaluation. This is a useful benchmark for our results to compare to.

Prediction of post-treatment trismus in head and neck cancer patients [40]

This article provides an overview of a study done on trismus patients quality of life vs a healthy control group. This is based on a variety of factors to quantify the patient’s quality of life. This may help us to inform our HOQ quantitative values for abstract concepts such as comfort.

3.3 Mathematical Modeling

3.3.1 Maximum Bite Force Calculations - 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

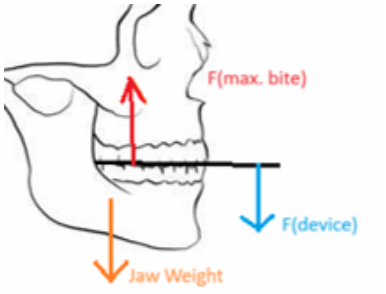
Equation Used: Static Equilibrium, $\sum F_y = 0$

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

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

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

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



3.3.2 Manufacturing and 3D Printing - Nathan Bastidas

System 1: Initial Theoretical Print Speed and Process:

With various assumptions made during this project's initial planning process, which will be discussed further in this initial entry, we found a mathematical formula to help predict the time necessary to print out our device. As the Trismus Treatment device must be fully 3D printed, a swifter print time will allow clients more time to produce more units for their patients over time. In terms of software various slicers, programs designed to convert 3D models into printable instructions, were considered for this project. For our initial modeling, we settled on using Ultimaker Cura as our slicer software. A Creality Ender 3 was set as the printer inside the software, as that is one of the most affordable and accessible printers in the current market. Finally, considering the choice of an Ender 3 as our printer, FDM printing was chosen as the printing format due to its low price of entry and relative simplicity for those who have no experience in 3D printing.

Additionally, the following mechanical properties were assumed for generic PETG [21]:

- Chemical Resistance (FDA-Compliant)
- Yield Strength: ~47.9 - 52.9 MPa

- Tensile Strength: ~60-66 MPa
- Density: ~1.26e3 - 1.28e3 kg/m^3
- Avg. Print Speed: 60-80 mm/s

With these values, we were able to estimate an average print time of ~17 hours/assembly with the following equations.

- $MaxSpeed_{Rec.} = (Flow\ Rate_{Max})/(Height_{Layer} * Extrusion_{Width})$
- $Flow\ Rate = Nozzle\ Size\ (mm) \cdot (Height_{Layer} \cdot print\ Speed)$

System 2: Updated Printing Procedures with Known Variables:

With our first set of materials purchased, we were able to secure data given by the manufacturer to gain a more accurate timeframe for manufacturing. PETG from Polymaker's Polylite line was purchased and used for material testing and our initial prototypes. The following data was given to us by the manufacturer:

- Youngs Modulus: 2.17 GPa
- Tensile Strength (XY): 51 MPa
- Tensile Strength (Z): 43 MPa
- Density: 1.25 g/cm^3
- Avg. Print Speed: 30-50 mm/s
- Bending Strength (XY: 3-Point Test): 70 MPa
- Bending Modulus: 1.899 GPa

Using our initial equations, as well as printer and slicer assumptions, we were able to estimate that with a 20% infill with this material, we would be at roughly ~11 hours / assembly.

3.3.3 Pressure Measurements in MATLAB - Cassina Olson

System 1: General Pressure in MATLAB

Using the pressure from a fully toothed mouth [cite], dividing by the number of teeth [cite], and multiplying each tooth by a ratio for pressure differences experienced by each tooth [cite], the following graphs were yielded, showing the minimum force needed to open a mouth starting at 0.6mm (about 0.02 in). These were separated by molar and incisor pressures as the calculation findings differed by a wide margin. The first set of photos show a typical person with full teeth present, and the second set of photos show a person missing 75% of teeth in the mouth. These findings confirm that, without teeth, patients will need less pressure applied to the mouth to safely undergo treatment.

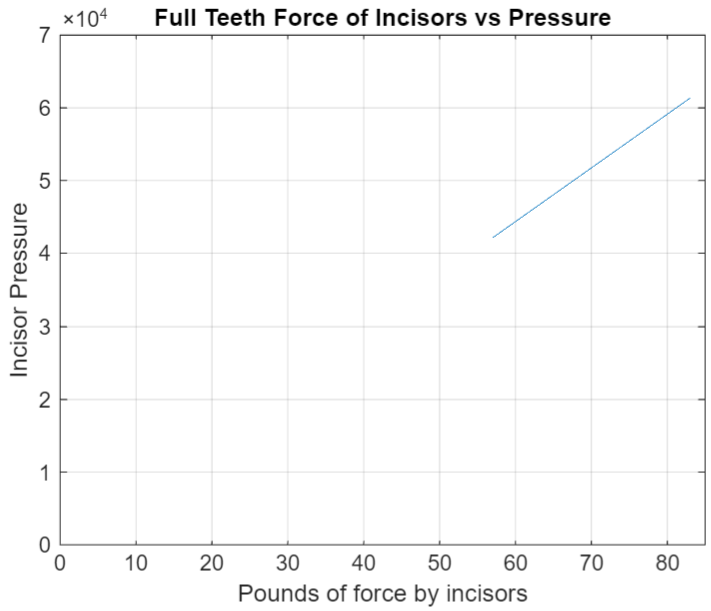


Fig 3.3.3.1: Full Teeth Incisors v Pressure

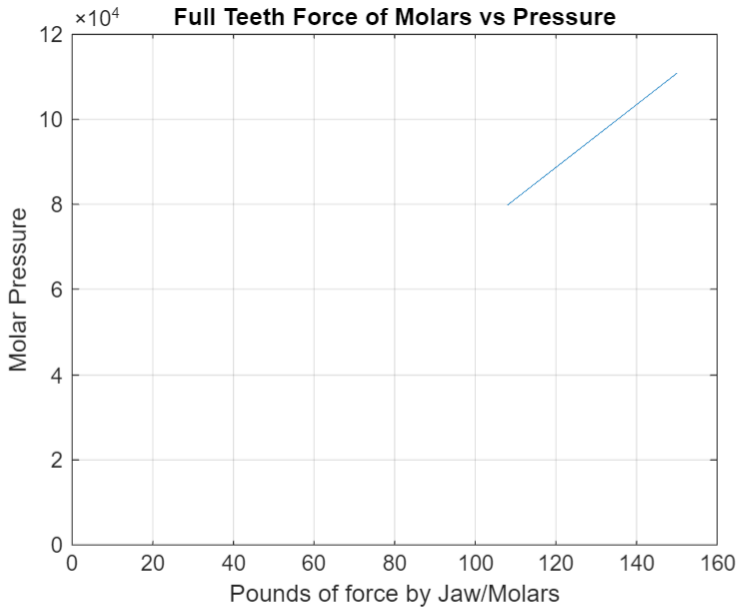


Figure 3.3.3.2: Full Teeth Molars v Pressure

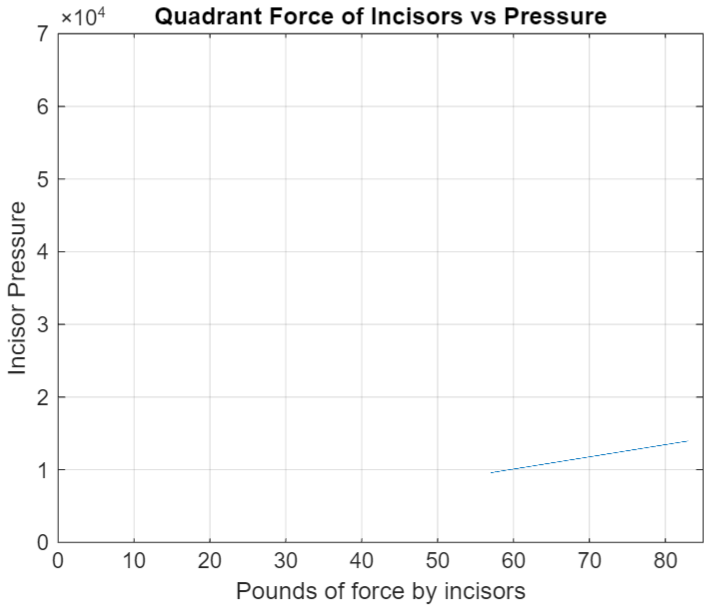


Figure 3.3.3.3: Quadrant Teeth Incisors v Pressure

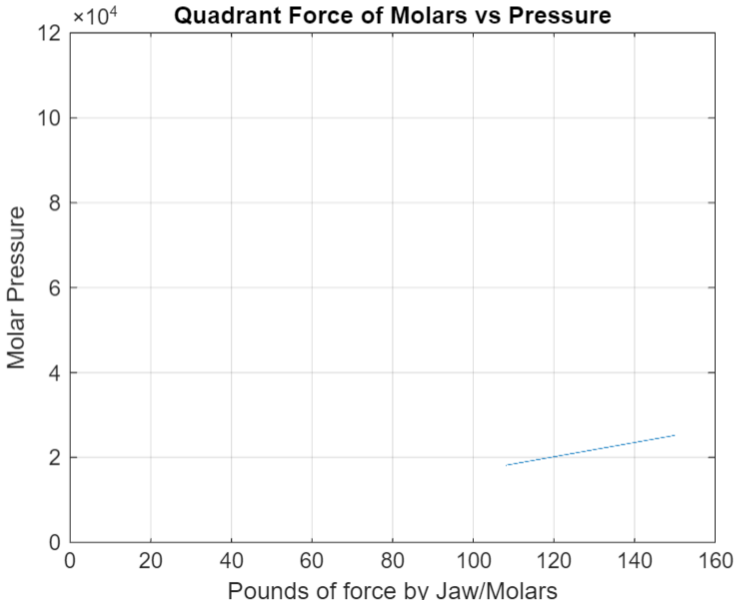


Figure 3.3.3.4: Quadrant Teeth Molars v Pressure

System 2: Pressure Mapping in MATLAB/Simulink

Using the same procedure and metrics as above, but with a remodeled compression map, the following graph was yielded. This represents an ideal patient with a full mouth of teeth as the front mouthpiece applies pressure to the front teeth only. The second map shows what the pressure map may look like with an updated, mouthguard-like mouthpiece that utilizes the back teeth rather than the front teeth for pressure

application. The second map shows the areas with the most stress as highlighted in yellow, with the molars bearing the most pressure and the front teeth (or lack of teeth) bearing the least. As the mouth was designed as a sinusoidal function in MATLAB, there is excess data shown which may benefit the team to see what a bite that is too large or small for the apparatus would endure during treatment.

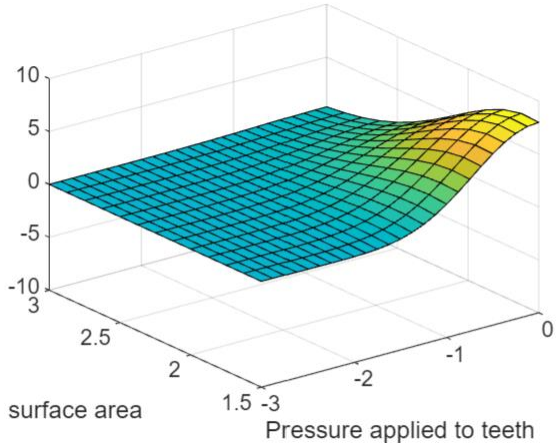


Fig 3.3.3.5: Frontal Bite Mouthguard as Surface Plot for Pressure

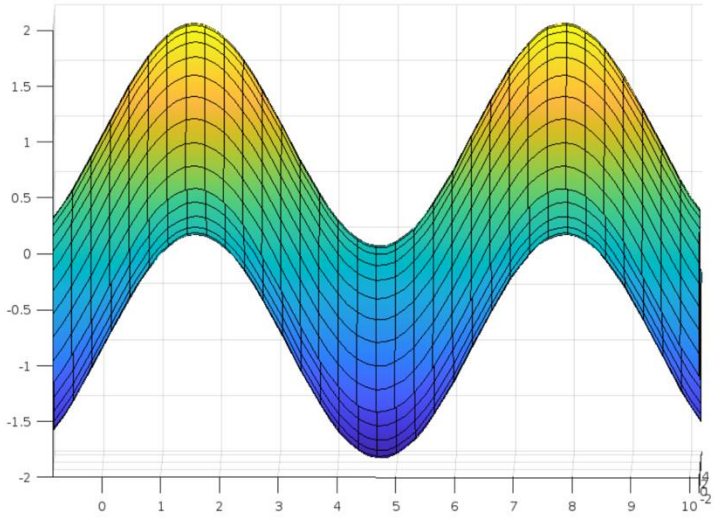


Fig 3.3.3.6: Side Bite Mouthguard as Surface Plot for Pressure

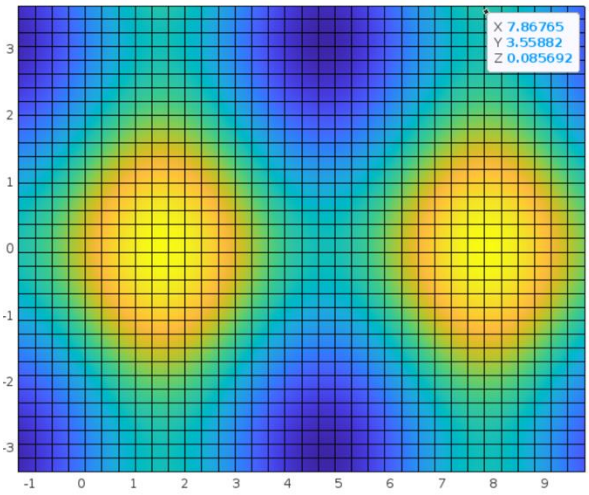


Fig 3.3.3.7: Side Bite Mouthguard as colormap for Pressure

Equations used:

- $Force = mass \cdot area$
- $[X, Y, Z] = sphere$

(Core MATLAB code to model the mouth as a sphere that ends in two sinusoidal curves to show pressure changes)

3.3.4 SolidWorks Compliant Spring Simulation - Carter Rhoades

This Is a mathematical model of the Top portion of the device. The static simulation is done in SolidWorks and is testing the deformation of the Compliant Spring. The program uses FEA to complete its assessment. This simulation was performed under the worst stress conditions, where the max bite force of the average human, 305N, was applied to the top and bottom mouthpieces. This was done to see the maximum possible displacement of the spring in context of the greater design. The result of this Simulation implies that the Spring needs to possess more bending points to spread out the load.

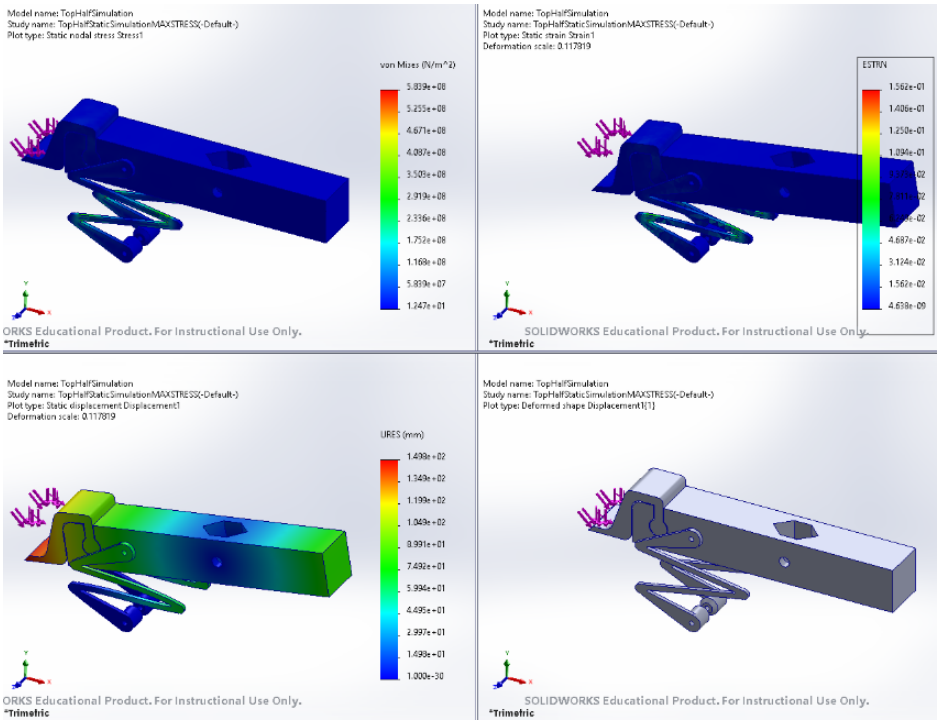


Fig 3.3.4.1 Static simulation of top half of deice under maximum force

4 Design Concepts

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.

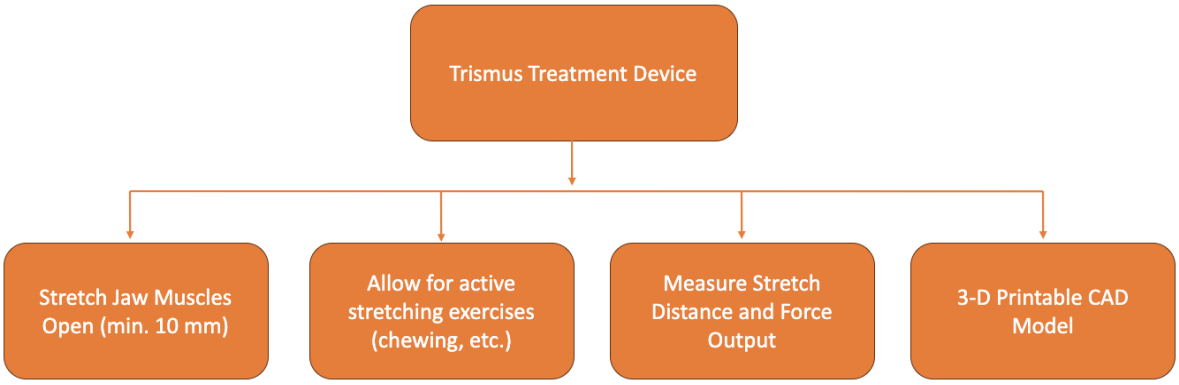


Figure 4.1: Trismus Decomposition Chart

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

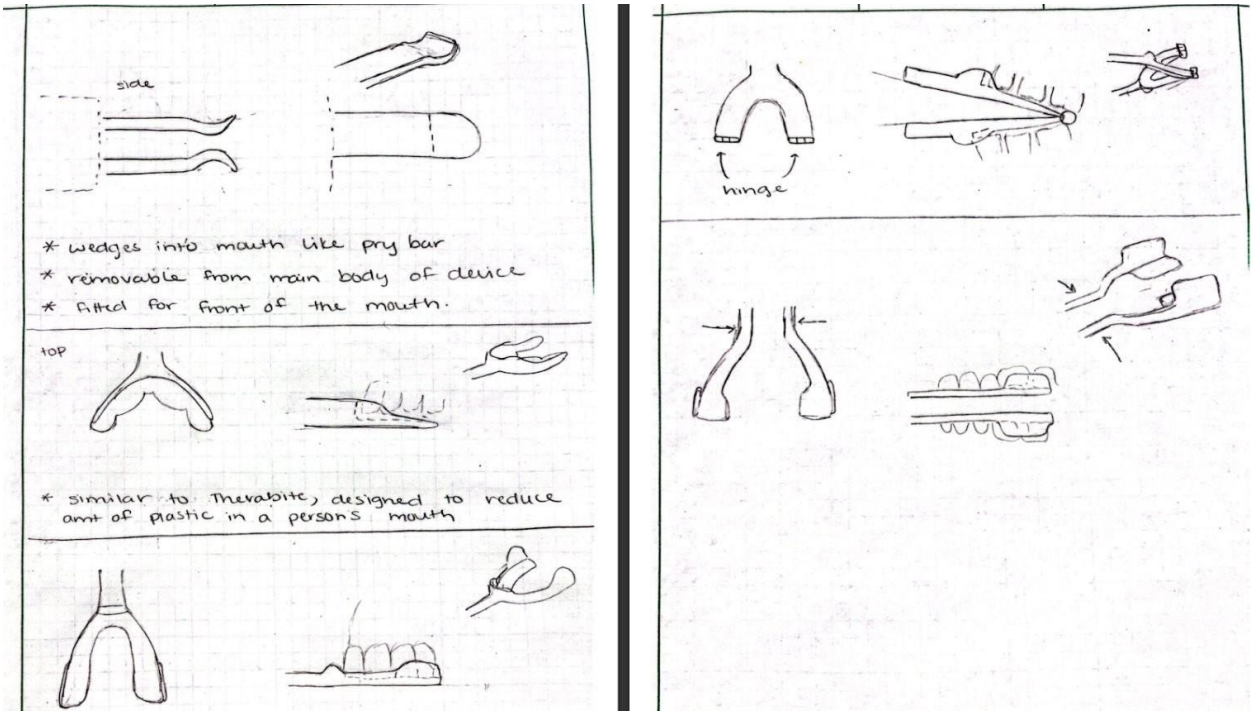
The third requirement allows for doctors to measure the recovery speed and maintain an optimum pressure on the device to not fracture any part of the patients' mouths and not delay recovery for fear of fracture. The stretch distance measurement apparatus is also intended to show the patients' progress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

3D Printable CAD

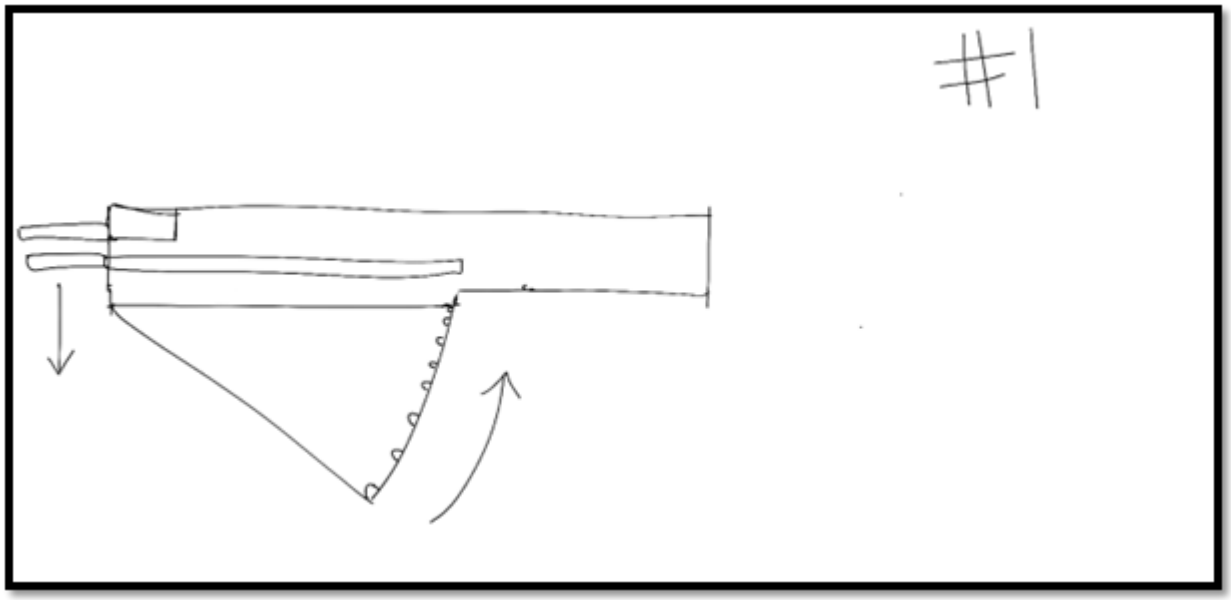
The final portion expresses both a sponsor and engineering requirement as the entire file to print this device must be accessible and easy to import for printing in a medical facility. The CAD package must have few to no risks to a medical professional, be easily assembled, and present no medical or health risks to the patient, including device fracture, gouging, and choking.

4.1 Concept Generation

4.2.1 Mouthpiece — Shilo Bailey

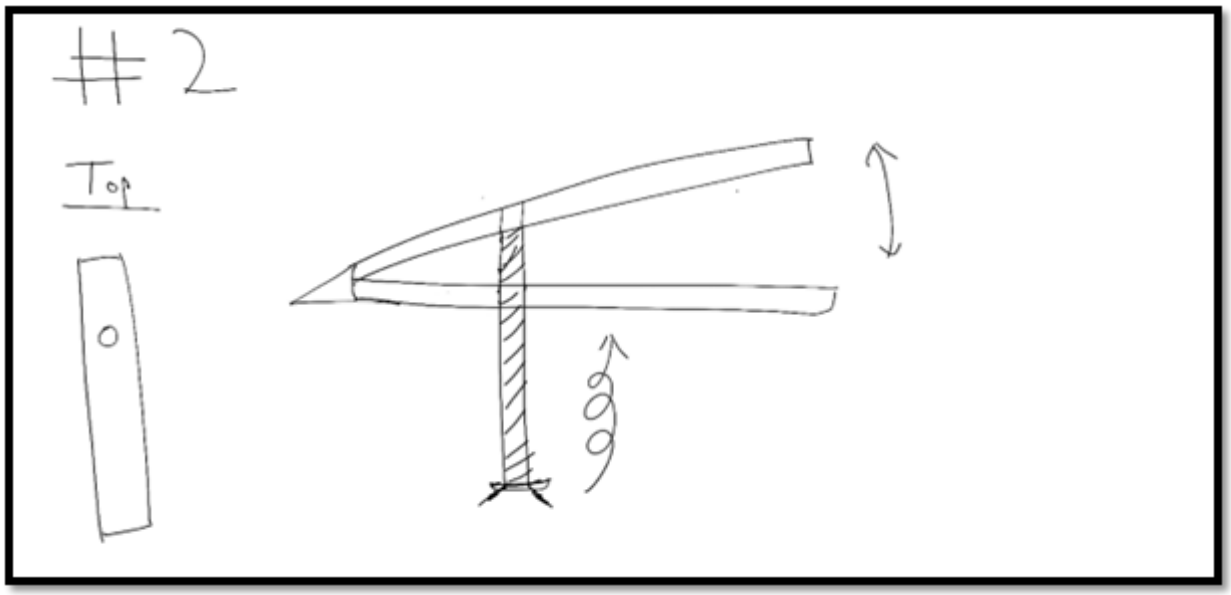


4.2.2 Mechanical Designs — Nathan Bastidas

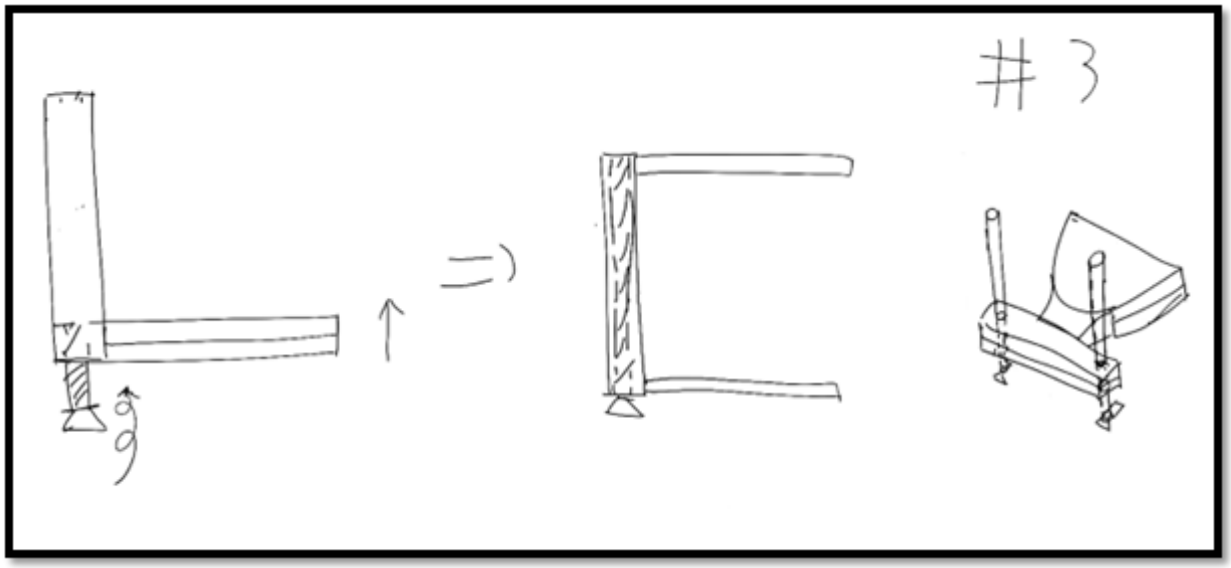


Design #1: A squeeze-lever type mechanism with various grooves made on the side of the lever. As the lever is pressed into the device with a squeezing hand gesture, the bottom mouthpiece will click into place inside the groove, locking the bottom mouthpiece at a new distance. Each groove is designed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

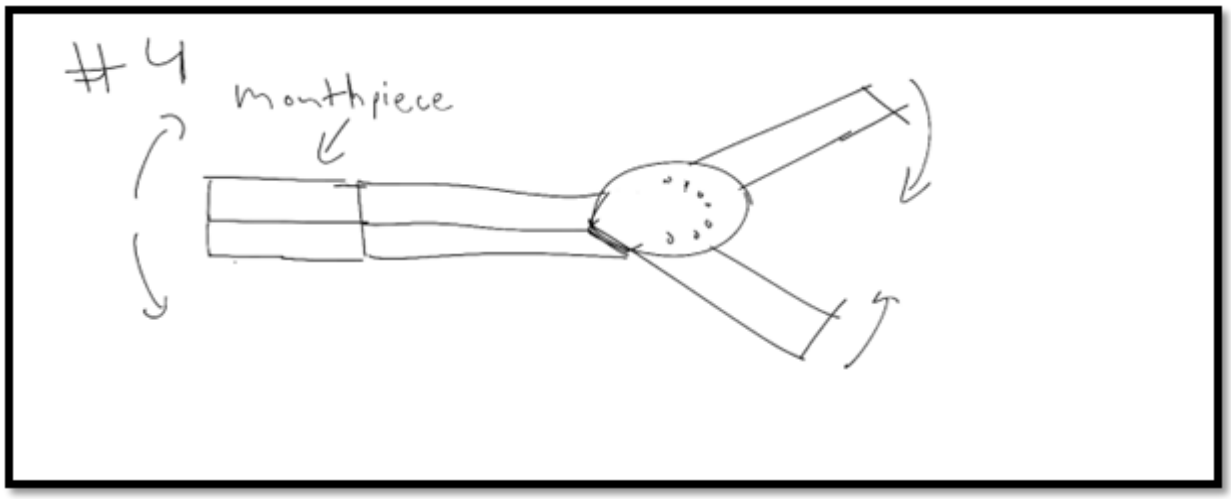
distance but has enough wiggle room between each groove to actively chew against the device for active stretching exercises.



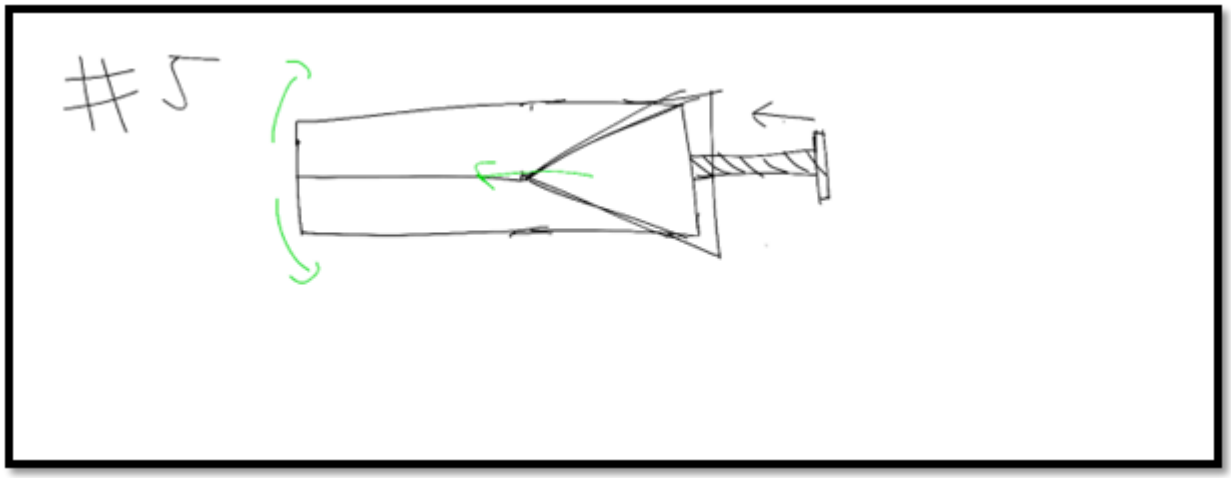
Design #2: This design utilizes a single screw point that can be adjusted manually by turning the knob on the bottom of the device. As it is turned, it causes the two mouthpieces to separate at an angle, allowing for a potentially greater spread. With this design, it could be modified to be more spring-like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

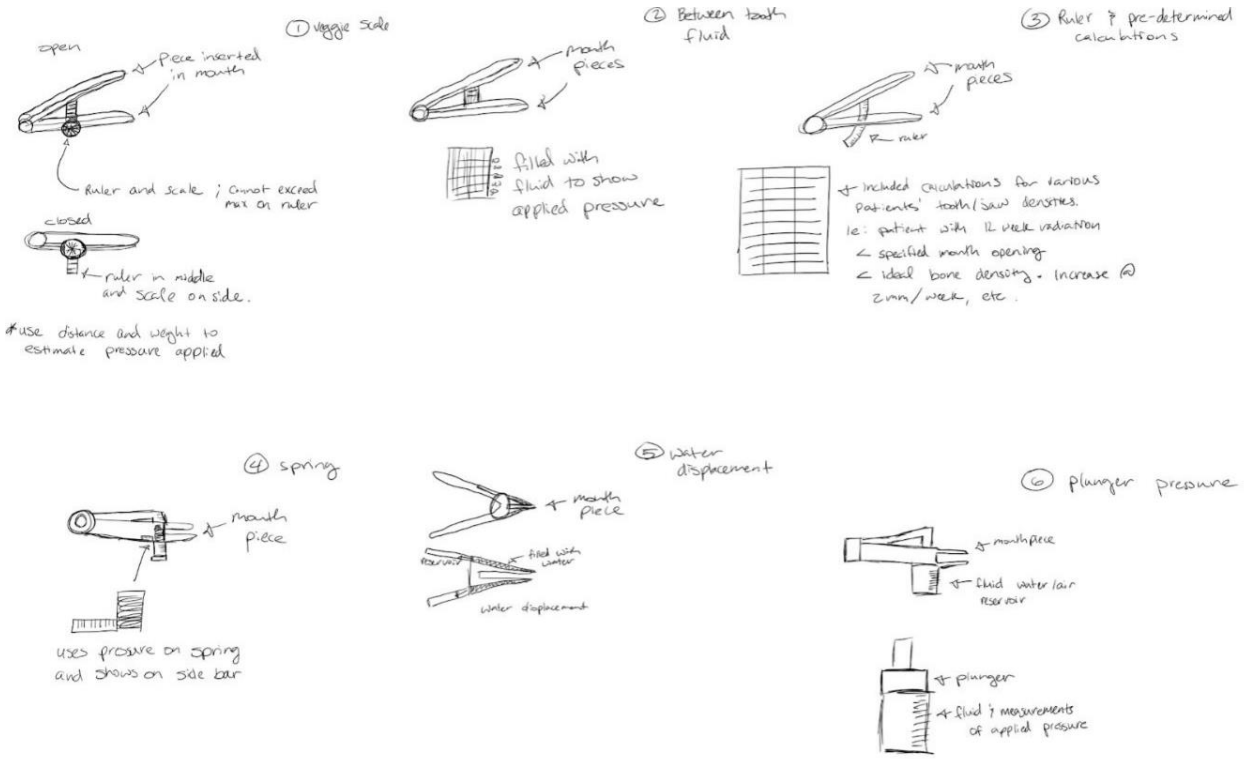


Design #4: This design uses a scissor-type mechanism to open the jaw. Each half of the mouthpiece would be linked to one part of the handle, allowing for a scissoring motion. In the center would be an adjustable lock, like design #1 where different grooves of varying distances would be able to lock the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



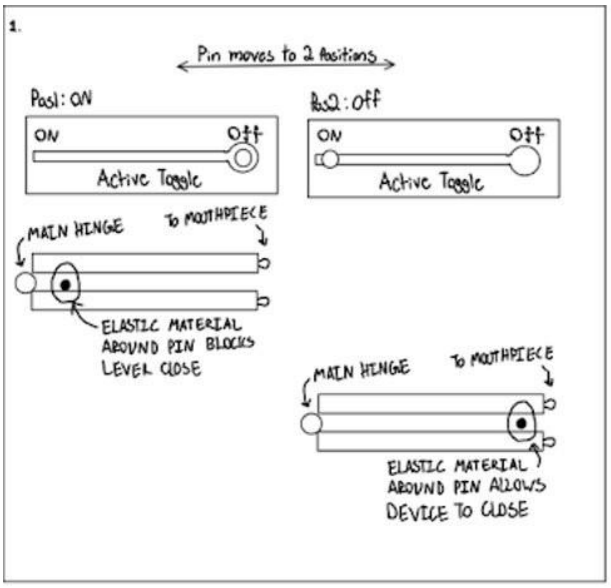
Design #5: The most unique variant, design #5 utilizes a single screw point on the back end of the device that is linked to a triangular wedge that rests between the two mouthpieces. At rest, the wedge sits flush with the two pieces. In use, the screw in the back can be turned, pushing the wedge forward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

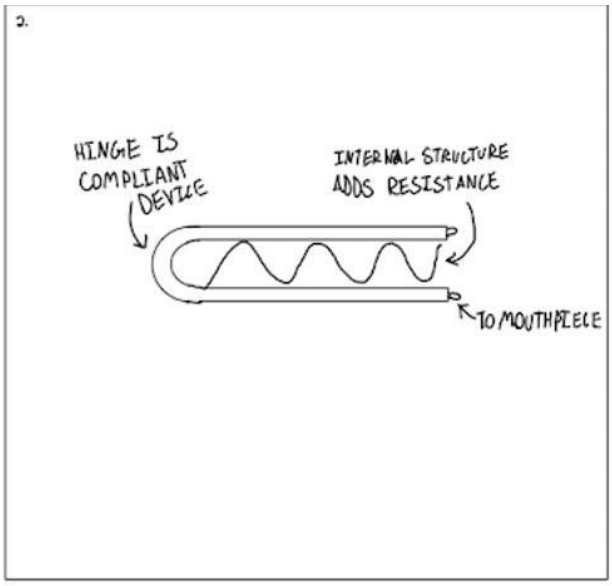
4.2.3 Pressure Measurements — Cassina Olson

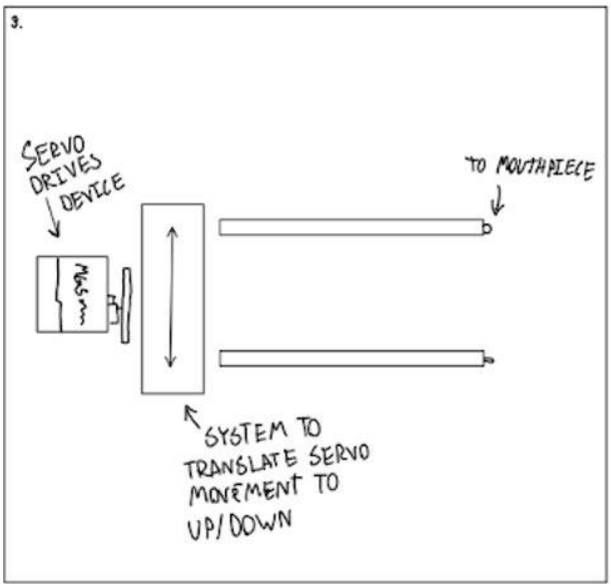


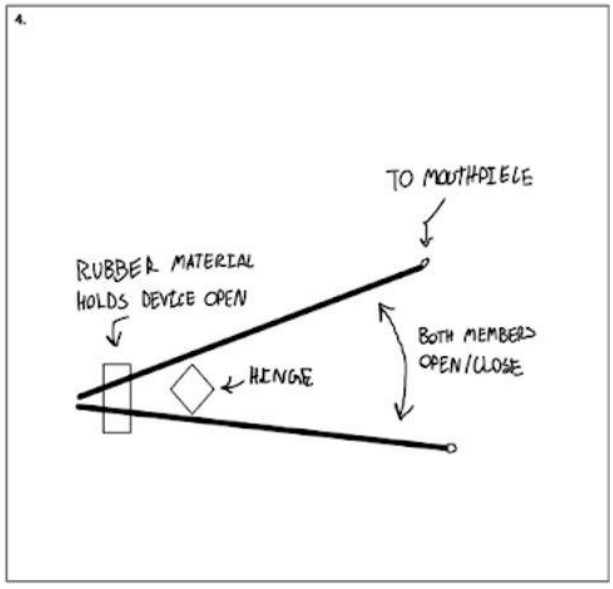
The first design shows pressure measurements through a purchased part that measures weight. This is like a veggie scale and would require a separate ruler to measure the mouth stretch distance. The second design has a tube filled with liquid and as the device is compressed, it will show the amount of 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.

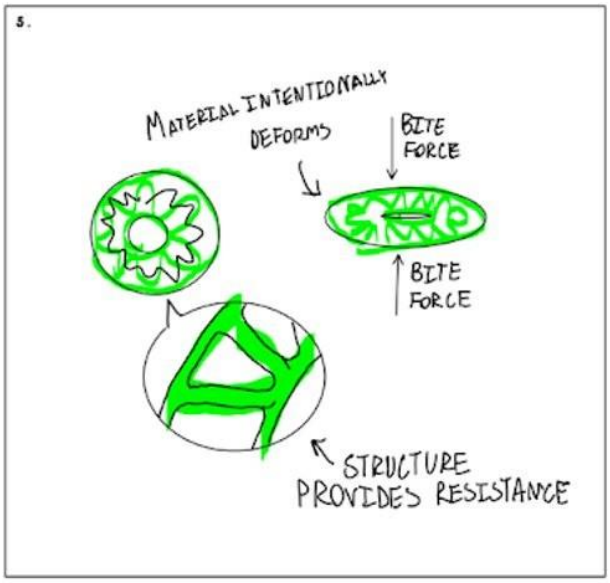
4.2.4 Shell Material and Active Resistance Systems — Carter Rhodes

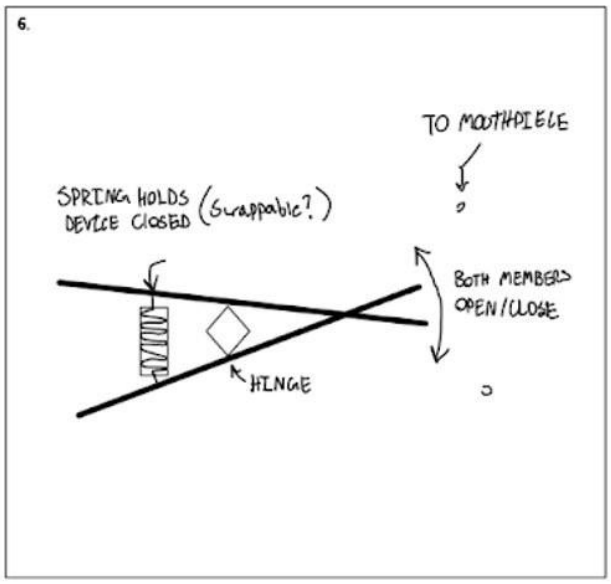

1.
Pin moves to 2 positions
Pos1: ON
Pos2: Off
ON
Off
Active Toggle
ON
Off
Active Toggle
MAIN HINGE
To MOUTHPIECE
ELASTIC MATERIAL
ABOUND PIN BLOCKS
LEVER CLOSE
MAIN HINGE
To MOUTHPIECE
ELASTIC MATERIAL
ABOUND PIN ALLOWS
DEVICE TO CLOSE

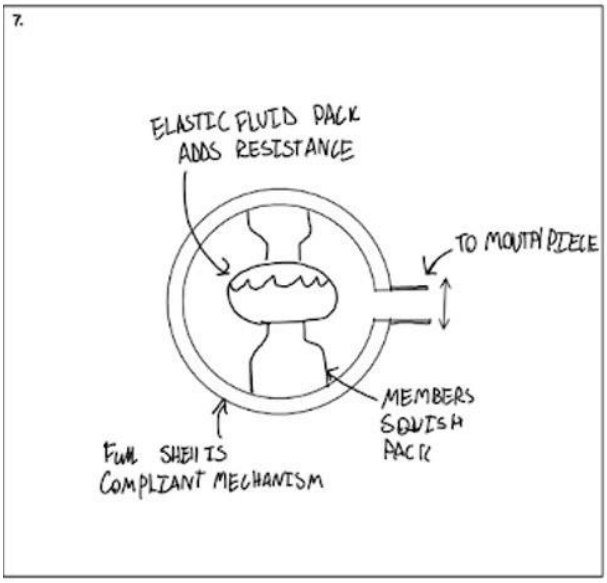

2.
HINGE IS
COMPLIANT
DEVICE
INTERNAL STRUCTURE
ADDS RESISTANCE
TO MOUTHPIECE


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.

4.2.2 "InternalSpring":

Pro: Compliant spring printed with device.

Con: No active resistance actuation.

4.2.3 "ServoControlled":

Pro: Precise resistance force control.

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

4.2.4 "BandResistance":

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

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

4.2.5 "ChewingGum":

Pro: Useful solely for jaw exercise.

Con: Requires separate device for active resistance.

4.2.6 "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.

4.2.7 "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 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.

4.3 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 Decision Matrix

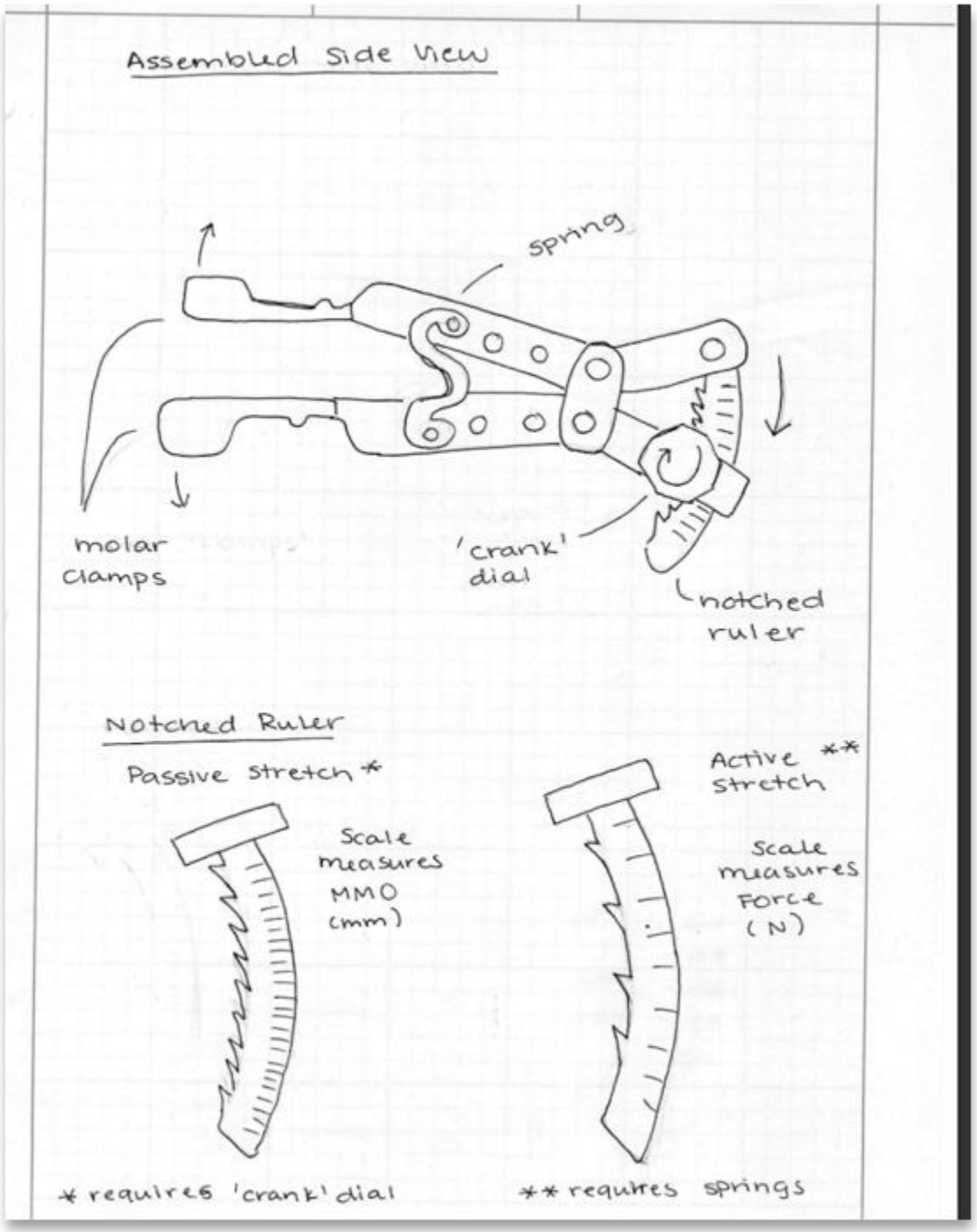


Fig 4.3.2: Selected Design (Alternative Design 3)

5 Schedule and Budget

5.1 Schedule

Below is the current Gantt Chart as of 4/25/2024 showing completed and current deliverables, most deliverable components are assigned based on each member's role.

The Team Charter required all team members to work collaboratively and create a charter that would outline the team's rules to ensure all deliverables are completed and to enforce the importance of communication between team members.

Team Charter				
Clarify Expectations and Sign	Shilo Bailey	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Nathan Bastidas	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Cassina Olson	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Carter Rhoades	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Team	100%	1/25/24	1/26/24

Fig 5.1.1: Team Charter Gantt

Presentation 1 required the team to begin reviewing journal articles for benchmarking, identify customer and engineering requirements, create a QFD based on the requirements, and begin mathematical modeling.

Presentation 1				
Budget/TVM/IVP	Shilo Bailey	100%	1/29/24	2/5/24
QFD / Format	Nathan Bastidas	100%	1/29/24	2/5/24
Intro/hook/problem/benchmark/	Cassina Olson	100%	1/29/24	2/5/24
C and E requirements/ scheduling	Carter Rhoades	100%	1/29/24	2/5/24
Lit reviews; mathematical modelling	Team	100%	1/29/24	2/5/24

Fig 5.1.2: Presentation 1 Gantt

For Presentation 2 the team completed concept generation and evaluations which were then presented to the client for review and approval. Engineering calculations were also completed to identify components of the device which would be used to quantify the bite force applied to the device and measure the mouth opening.

Presentation 2				
Suite of Potential Solutions	Team	100%	2/12/24	2/26/24
BoM/Concept Eval.	Nathan Bastidas	100%	2/12/24	2/26/24
Intro/project desc./concept generation	Cassina Olson	100%	2/12/24	2/26/24
Engineering Calculations/CAD (Spring,Body)	Carter Rhoades	100%	2/12/24	2/26/24
Schedule/Budget/CAD (Ruler, Mouth Guard)	Shilo Bailey	100%	2/12/24	2/26/24

Fig 5.1.3: Presentation 2 Gantt

For Report 1, all previous deliverables were gathered and formatted into a report and each chapter was delegated to a team member for completion.

Report 1				
Ch 1	Shilo Bailey	100%	2/24/24	3/16/24
Ch 3	Nathan Bastidas	100%	2/24/24	3/16/24
Ch 4	Cassina Olson	100%	2/24/24	3/16/24
Ch 2	Carter Rhoades	100%	2/24/24	3/16/24
Lit reviews; mathematical modelling	Team	100%	2/24/24	3/16/24

Fig 5.1.4: Report 1 Gantt

For the Website Check, each team member uploaded deliverables and documents for each delegated portion of the website and ensured it was accessible via desktop and mobile devices.

Website Check 1				
Documents	Shilo Bailey	100%	2/23/24	3/15/24
Project Description	Nathan Bastidas	100%	2/23/24	3/15/24
Gallery	Cassina Olson	100%	2/23/24	3/15/24
About Us	Carter Rhoades	100%	2/23/24	3/15/24
Pictures	Team	100%	2/23/24	3/15/24

Fig 5.1.5: Website Check 1 Gantt

The Analytical Analysis Memo required the team to analyze different components for the device ranging from material properties to stresses applied to the jaw. All analyses were then compiled into a memo.

Analytical Analysis Memo				
Jaw Stresses	Shilo Bailey	100%	3/1/24	3/22/24
Material Stress	Nathan Bastidas	100%	3/1/24	3/22/24
Dental	Cassina Olson	100%	3/1/24	3/22/24
Lever Tolerances	Carter Rhoades	100%	3/1/24	3/22/24
Formatting	Team	100%	3/1/24	3/22/24

Fig 5.1.6: Analytical Analysis Memo Gantt

For Presentation 3, the team continued to move forward with the design process and began 3D printing the 1st prototype after discussing design concepts and concerns with the client. A demonstration of the 1st prototype was conducted in class after the presentation was completed.

Presentation 3/1st Prototype				
Schedule & Budget / CAD Model	Shilo Bailey	100%	3/11/24	4/1/24

Design Requirements / Engineering	Nathan Bastidas	100%	3/11/24	4/1/24
Design Validation / Project Description	Cassina Olson	100%	3/11/24	4/1/24
Design Description / CAD Model	Carter Rhoades	100%	3/11/24	4/1/24
Come up with FMEA ideas	Team	100%	3/11/24	4/1/24

Fig 5.1.7: Presentation 3/ 1st Prototype Gantt

For Report 2, all previous deliverables were gathered and formatted into a report and each report component was delegated to a team member for completion.

Report 2				
Schedule & Budget / Background	Shilo Bailey	100%	4/2/24	4/23/24
Requirements / Conclusions	Nathan Bastidas	80%	4/2/24	4/23/24
Research Within Design Space	Cassina Olson	0%	4/2/24	4/23/24
Design Concepts / Design Validation	Carter Rhoades	0%	4/2/24	4/23/24
References, Appendices	Team	0%	4/2/24	4/23/24

Fig 5.1.8: Report 2 Gantt

The Final CAD/BOM will include SolidWorks parts and drawings of each component of the device and be compiled into a Bill of Materials.

Final CAD/BOM				
Mechanics of Notched Ruler	Shilo Bailey	0%	4/5/24	4/26/24
Molar Mouthpiece	Nathan Bastidas	0%	4/5/24	4/26/24
Molar Mouthpiece	Cassina Olson	0%	4/5/24	4/26/24
Mechanics of Notched Ruler	Carter Rhoades	0%	4/5/24	4/26/24

Submission / Drawings	Team	0%	4/5/24	4/26/24

Fig 5.1.9: Final CAD/BOM Gantt

The 2nd prototype demonstration will be completed by 4/29/24 and each team member will discuss their delegated component of the device.

2nd Prototype Demo				
Explain Notched Ruler	Shilo Bailey	0%	4/8/24	4/29/24
Explain Mouthpiece	Nathan Bastidas	0%	4/8/24	4/29/24
Explain Mouthpiece	Cassina Olson	0%	4/8/24	4/29/24
Explain Compliant Spring	Carter Rhoades	0%	4/8/24	4/29/24
Task	Team	0%	4/8/24	4/29/24

Fig 5.1.10: 2nd Prototype Demo Gantt

The Project Management memo/report will be completed by 5/3/24 and each team member will complete their delegated component.

Project Management				
Purchasing Plan	Shilo Bailey	0%	4/12/24	5/3/24
Reflection	Nathan Bastidas	0%	4/12/24	5/3/24
Gantt Chart	Cassina Olson	0%	4/12/24	5/3/24
Manufacturing Plan	Carter Rhoades	0%	4/12/24	5/3/24
Formatting	Team	0%	4/12/24	5/3/24

Fig 5.1.11: Project Management Gantt

Website Check 2 will be completed by all team members before the end of the semester to ensure that all documents and deliverables from the semester are showcased on the Capstone Trismus website.

Website Check 2				
Add more	Shilo Bailey	0%	4/14/24	5/5/24
Submit	Nathan Bastidas	0%	4/14/24	5/5/24
Add more	Cassina Olson	0%	4/14/24	5/5/24
Add more	Carter Rhoades	0%	4/14/24	5/5/24
Add more	Team	0%	4/14/24	5/5/24

Fig 5.1.12: Website Check 2 Gantt

A full Gantt Chart for the 2024 Spring Semester can be found in Appendix A.

Below is a draft of the Gantt chart for ME486C including main deliverables and tentative due dates. The Gantt chart will be updated as more information regarding deliverables is provided.

TASK	ASSIGNED TO	PROGRESS	START	END
Project Management				
	Shilo Bailey	0%	1/25/24	8/28/24
	Nathan Bastidas	0%	1/25/24	8/28/24
	Cassina Olson	0%	1/25/24	8/28/24
	Carter Rhoades	0%	1/25/24	8/28/24
	Team	0%	1/25/24	8/28/24
Engineering Calculations				
	Shilo Bailey	0%	8/28/24	9/4/24
	Nathan Bastidas	0%	8/28/24	9/4/24
	Cassina Olson	0%	8/28/24	9/4/24
	Carter Rhoades	0%	8/28/24	9/4/24
	Team	0%	8/28/24	9/4/24
Website Check 1				
	Team	0%	9/25/24	10/9/24
	Nathan Bastidas	0%	9/25/24	10/9/24
	Cassina Olson	0%	9/25/24	10/9/24

	Carter Rhoades	0%	9/25/24	10/9/24
	Shilo Bailey	0%	9/25/24	10/9/24
Finalized Testing Plan				
	Shilo Bailey	0%	10/9/24	10/30/24
	Nathan Bastidas	0%	10/9/24	10/30/24
	Cassina Olson	0%	10/9/24	10/30/24
	Carter Rhoades	0%	10/9/24	10/30/24
	Team	0%	10/9/24	10/30/24
Final CAD Packet				
	Shilo Bailey	0%	10/30/24	11/20/24
	Nathan Bastidas	0%	10/30/24	11/20/24
	Cassina Olson	0%	10/30/24	11/20/24
	Carter Rhoades	0%	10/30/24	11/20/24
	Team	0%	10/30/24	11/20/24
Final Report & Final Website Check				
	Shilo Bailey	0%	11/6/24	11/27/24
	Nathan Bastidas	0%	11/6/24	11/27/24
	Cassina Olson	0%	11/6/24	11/27/24
	Carter Rhoades	0%	11/6/24	11/27/24
	Team	0%	11/6/24	11/27/24
Client Handoff				
	Shilo Bailey	0%	11/20/24	12/11/24
	Nathan Bastidas	0%	11/20/24	12/11/24
	Cassina Olson	0%	11/20/24	12/11/24
	Carter Rhoades	0%	11/20/24	12/11/24
	Team	0%	11/20/24	12/11/24

Fig 5.1.13: Full Gantt Chart

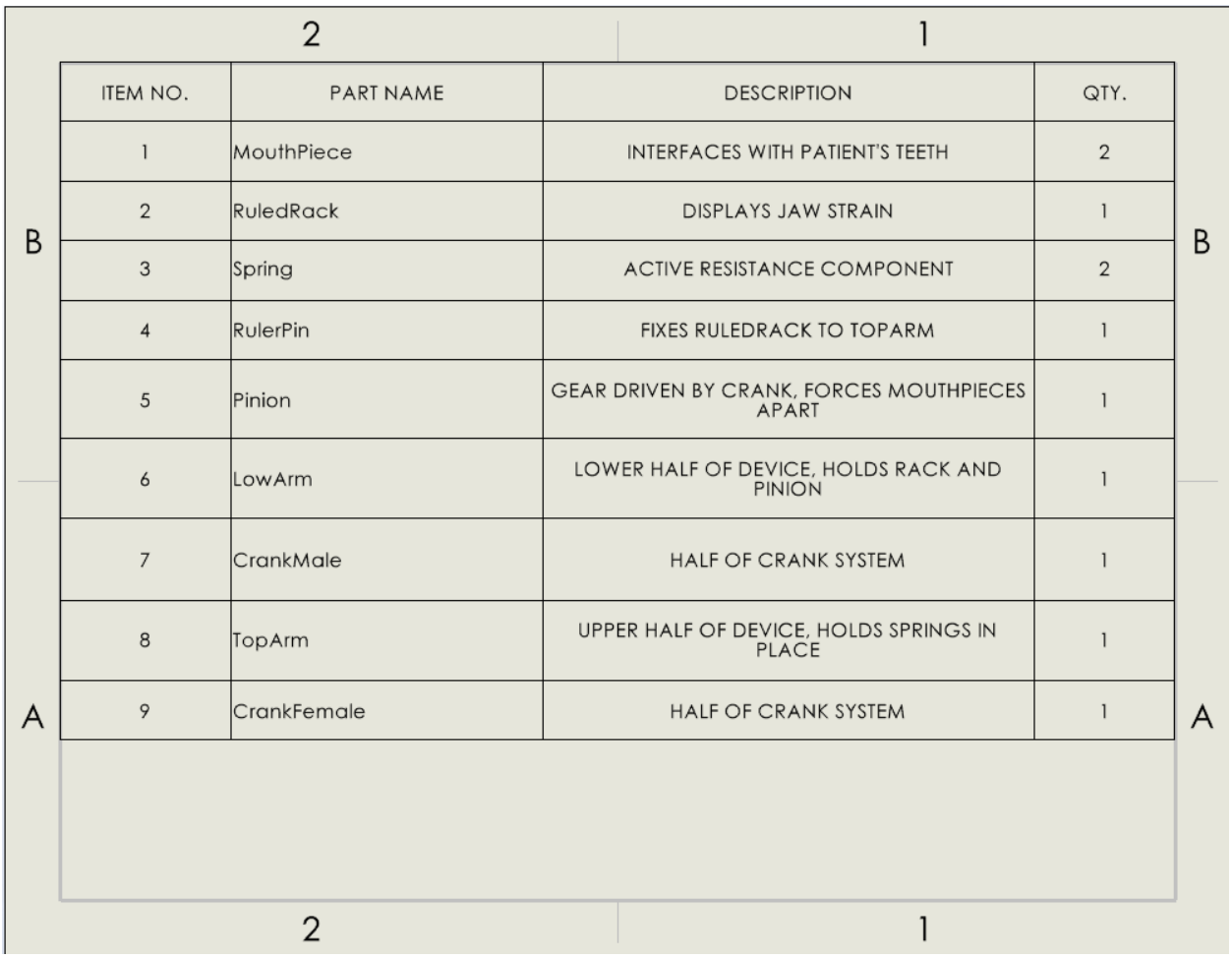
5.2 Budget

At the start of the project, a definitive amount for the budget was not made clear until the first client meeting where Carolyn Abraham stated that one of the device's requirements was to cost less than $50 to 3D print. Based on this customer requirement we estimated that a budget of $200 - $300 was needed to buy 3D printer filament for prototyping and small-scale manufacturing so we requested $200 from the Communication & Speech Disorder (CSD) department at NAU and was approved. The team also decided to donate and fundraise at least $100 which will be used as an emergency fund in case filament or other material is needed at the last minute.

Budget Components	Type	Cost
Allocated	Funds from CSD Department	$200
Fundraising	Team Donations	$100
Expenses	Printer Filament (PETG x2)	(- $50)
	Printer Filament (PCTG x1)	(-$61)
Total Spent		$111
Remaining		$199

Table (1): Trismus Spring Budget

5.3 Bill of Materials (BoM)



ITEM NO.	PART NAME	DESCRIPTION	QTY.
1	MouthPiece	INTERFACES WITH PATIENT'S TEETH	2
2	RuledRack	DISPLAYS JAW STRAIN	1
3	Spring	ACTIVE RESISTANCE COMPONENT	2
4	RulerPin	FIXES RULEDRACK TO TOPARM	1
5	Pinion	GEAR DRIVEN BY CRANK, FORCES MOUTHPIECES APART	1
6	LowArm	LOWER HALF OF DEVICE, HOLDS RACK AND PINION	1
7	CrankMale	HALF OF CRANK SYSTEM	1
8	TopArm	UPPER HALF OF DEVICE, HOLDS SPRINGS IN PLACE	1
9	CrankFemale	HALF OF CRANK SYSTEM	1

Fig 5.3.1: Final Bill of Materials

6 Design Validation and Initial Prototyping

6.1 Failure Modes and Effects Analysis (FMEA)

FAILURE MODE AND EFFECTS ANALYSIS

Item: Trismus Device | Responsibility: Team Trismus | FMEA number: Unknown
Model: Current | Prepared by: Team Trismus | Page : 1 of 1
Core Team: Team Trismus | FMEA Date (Orig): 3/31/24 | Rev: 1

Process/ Function/ Item	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/ Mechanism(s) of Failure	Occur	Current Process Controls	Detec	RPN	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
												Actions Taken	Sev	Occ	Det	RPN
Compliant Spring	Too strong/weak	Cannot press down on the device/ Spring Fracture	7	C	Improper machine set up /Improper assembly /Improper tolerances	0	Operator training and instructions	0	0	Create training guide and directions / Consider a stopping point or device failure upon reaching a particular pressure amount	Testing and manufacturing managers. Completion goal at second prototype	Instruction planning and testing tolerances	7	0	0	0
Pressure Measuring Tool	Locking / Fracture	False measurements / injure patient / device user	5	U	Improper machine set up	0	None	0	0	Create training guide and directions / Design Considerations	Testing and manufacturing managers. Completion goal at second prototype	Instruction planning and testing tolerances	5	0	0	0
Handle Pressing Down	Fracture	Injure patient / device user	7	U	Improper machining / improper assembly	0	None	0	0	Consider a stopping point or device failure upon reaching a particular pressure amount	Testing and manufacturing managers. Completion goal at second prototype	Instruction planning and testing tolerances	7	0	0	0
Mouthpiece	Locking	Injure patient / fear	9	H	Improper machine set up /Improper assembly /Improper tolerances	0	None	0	0	Operator training and instructions	Testing and manufacturing managers. Completion goal at second prototype	Instruction planning and testing tolerances	9	0	0	0
Grip Comfort	Locking / Fracture	Skin abrasions / injure device user	4	U	Improper machining / improper assembly	0	None	0	0	Design considerations / multiple designs for comfort	Testing and manufacturing managers. Completion goal at second prototype	Testing tolerances andusre feedback	4	0	0	0
Mouthpiece Comfort	Excessive size / subpar size	Skin abrasions / injure device user	5	U	Improper machining / improper assembly	0	None	0	0	Design considerations / multiple designs for comfort	Testing and manufacturing managers. Completion goal at second prototype	Testing tolerances andusre feedback	5	0	0	0
3D Printing filament too thin/thick	fracture / inability to use device	Cannot assemble / Injure Patient	5	C	Improper machine set up	0	None	0	0	Operator training and instructions	Testing and manufacturing managers. Completion goal at second prototype	Instruction planning and testing tolerances	5	0	0	0

Fig 6.1: FMEA Chart

6.2 Initial Prototyping

6.2a

Fig 6.2.1: Initial Prototype #1

Goal: Generally, Inform physical scale of Manufacturing Method

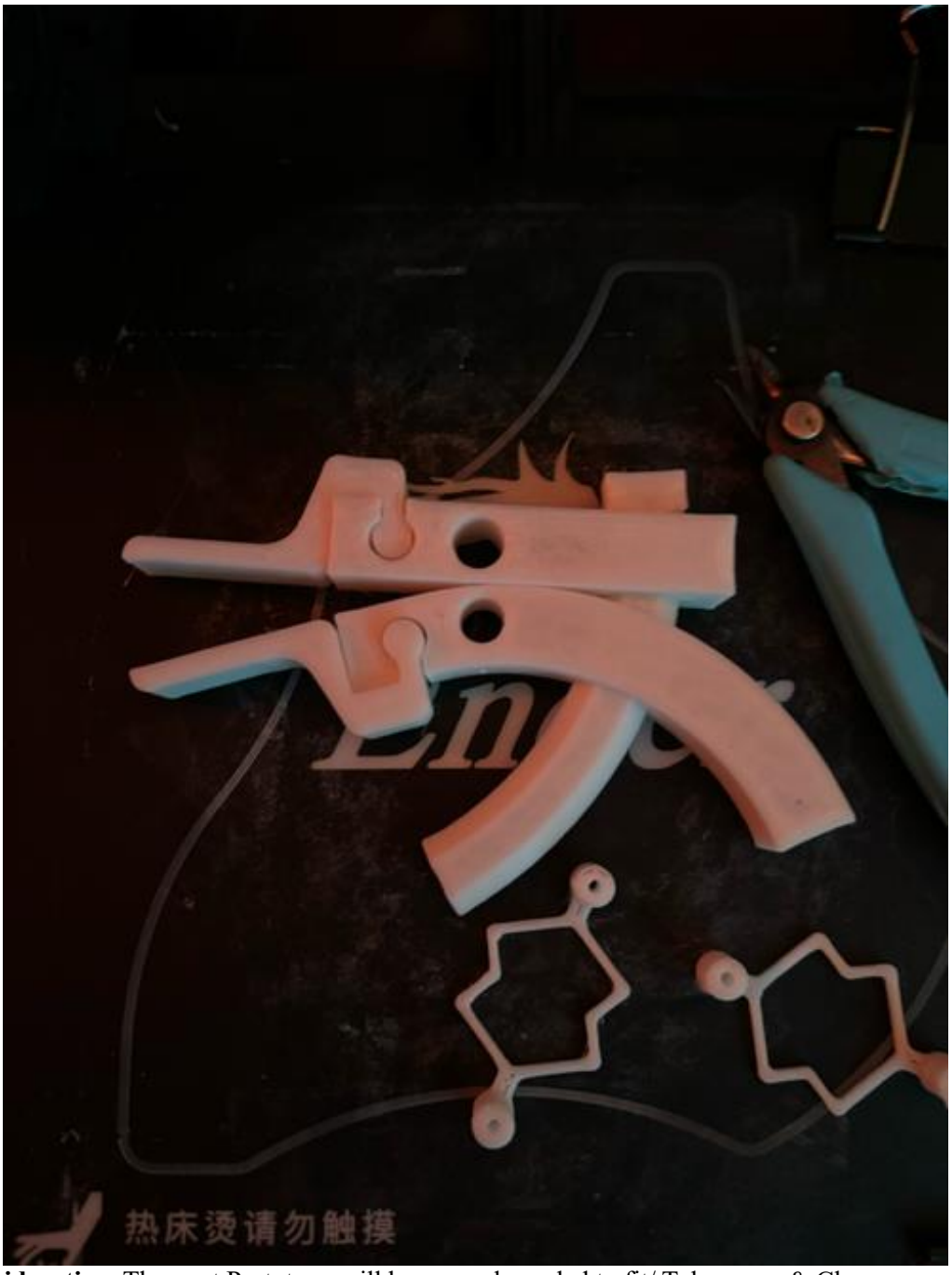
Answer: Parts of the design are not scaled together correctly and do not fit together

Design Consideration: The next Prototype will be properly scaled to fit/ Tolerances & Clearances must be considered

6.2b

Fig 6.2.2: Initial Prototype #2

Goal: Ensure new clearances and motion within device are functioning correctly



Answer: The spring does not deform in a repeatable way or fit into the device, The ruled surface is oriented incorrectly, The Structure of the device appears stable

Design Consideration: The next Prototype will be properly scaled to fit/ Tolerances & Clearances

6.2c

Fig 6.2.3: Initial Prototype #3

Goal: Test motion of new ruled surface, full size prototype to determine ergonomics

Answer: Motion theoretically works well, print quality provides unwanted resistance to movement. New spring design deforms in a predictable way. The ruler now stays in place during operation. The Mouthpieces are mounted vertically to reduce printing overhangs.

Design Consideration: The next version will have a straight arm for both the top and bottom members to increase printability, the next design will also include a system to forcefully separate the mouthpieces via rack and pinion on the ruler. Via Client feedback, the mouthpieces will also be changed to be larger.

6.3 Other Engineering Calculations

SOLIDWORKS integrated FEA Simulation:

Various tests have been performed using this tool to determine stress risers in geometry and a safety factor for each part may be calculated from these results as well. The figure shown displays the results of a simulation of the max bite forces applied to the top half of the system to determine proper displacement of the compliant 3D printed spring..

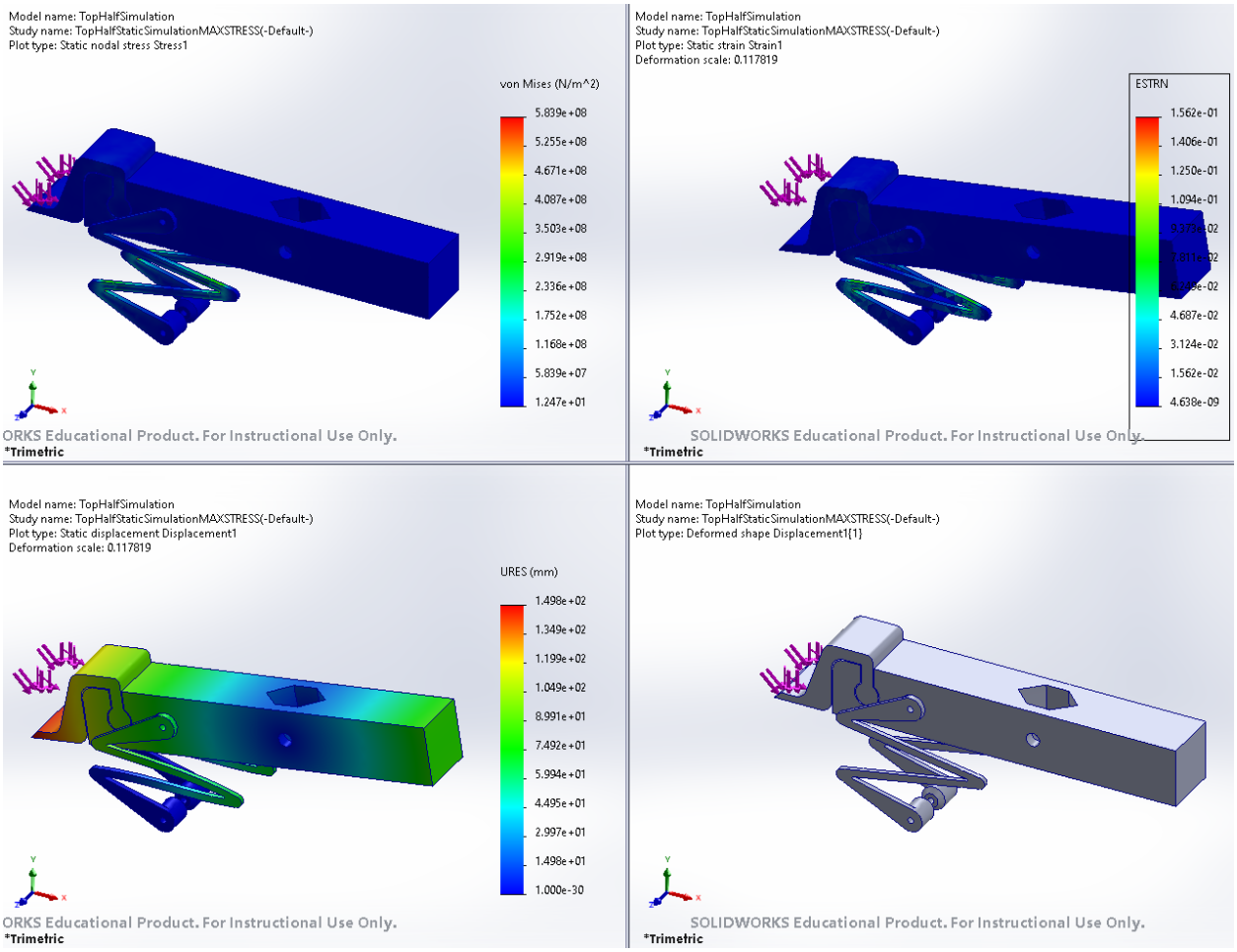


Fig 6.3.1: SolidWorks Static Loading of Compliant Spring

6.4 Future Testing Potential

The future of our projects testing involves testing and verifying our manufacturing materials, this will be done via standardized geometry in a test vice (EG Dog bone Tensile Tests, Sheet Tests, etc.)

6.4a:

Materials and Safety – Vigorous safety measures must be taken due to the nature of our design. We plan to test the material properties of various digital and physical representations of our materials to ensure all parts are under operational loads based on a safety factor.

6.4b:

Functionality – The other testing procedures will provide direct feedback on the device's operation. This will utilize a physical model of a human skull and jaw to test motion and tweak geometry to improve ergonomics.

7 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. The device must be able to measure incisor displacement and force application from the jaw to the device. With these features, clinicians and researchers will be able to replicate an affordable device for patient research and treatment.

Our current solution is to utilize PETG/PCTG 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. The provided instructions will showcase how to set up a 3D printer, materials necessary, printing instructions, assembly instructions, and part tolerances and materials tested to be considered safe in this device's use. A disclaimer stating that further modification of the device beyond its intended and tested tolerances is at the risk of the clinician/researcher and not the designers will be added to encourage safe use.

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9 APPENDICES

[Use Appendices to include lengthy technical details or other content that would otherwise break up the text of the main body of the report.]

9.1 Appendix A: Spring Semester Gantt Chart

Trismus Project

Company

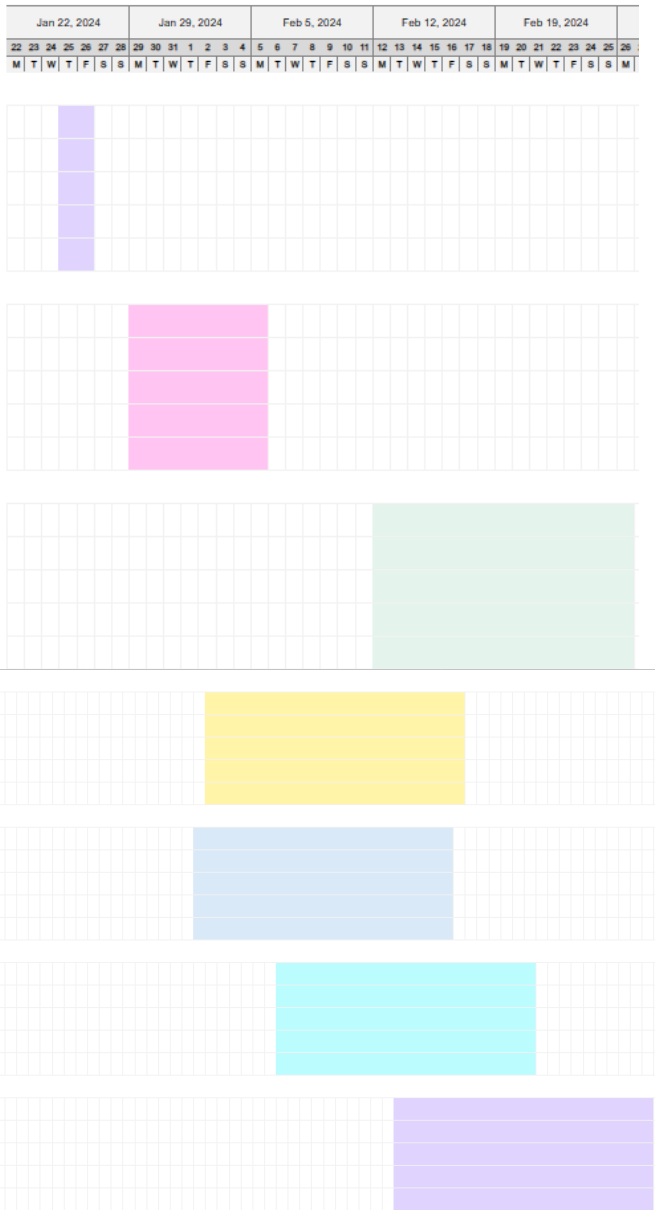
Individual assignments not included

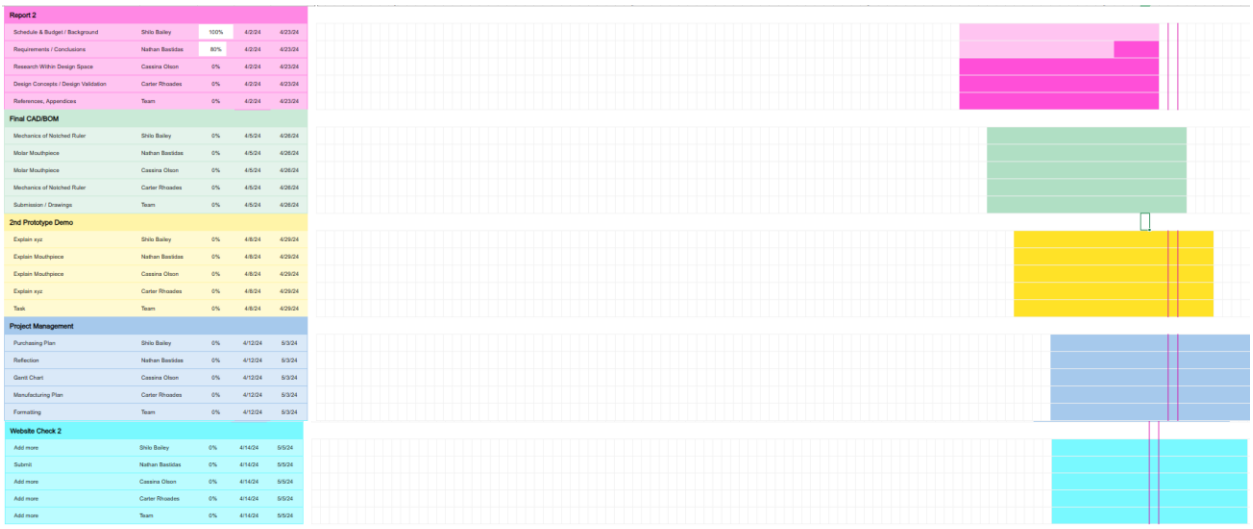
Shilo Bailey, Nathan Bastidas, Cassina Olson, Carter Rhoades

Project start: Thu, 1/25/2024

Display week: 1

TASK	ASSIGNED TO	PROGRESS	START	END
Team Charter				
Clarify Expectations and Sign	Shilo Bailey	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Nathan Bastidas	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Cassina Olson	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Carter Rhoades	100%	1/25/24	1/26/24
Clarify Expectations and Sign	Team	100%	1/25/24	1/26/24
Presentation 1				
Budget/TVM/IVP	Shilo Bailey	100%	1/29/24	2/5/24
QFD / Format	Nathan Bastidas	100%	1/29/24	2/5/24
Intro/hook/problem/benchmark/	Cassina Olson	100%	1/29/24	2/5/24
C and E requirements/ scheduling	Carter Rhoades	100%	1/29/24	2/5/24
Lit reviews; mathematical modelling	Team	100%	1/29/24	2/5/24
Presentation 2				
Suite of Potential Solutions	Team	100%	2/12/24	2/26/24
BoM/Concept Eval.	Nathan Bastidas	100%	2/12/24	2/26/24
Intro/project desc./concept generation	Cassina Olson	100%	2/12/24	2/26/24
Engineering Calculations/CAD (Spring,Body)	Carter Rhoades	100%	2/12/24	2/26/24
Schedule/Budget/CAD (Ruler, Mouth Guard)	Shilo Bailey	100%	2/12/24	2/26/24
Report 1				
Ch 1	Shilo Bailey	100%	2/24/24	3/16/24
Ch 3	Nathan Bastidas	100%	2/24/24	3/16/24
Ch 4	Cassina Olson	100%	2/24/24	3/16/24
Ch 2	Carter Rhoades	100%	2/24/24	3/16/24
Lit reviews; mathematical modelling	Team	100%	2/24/24	3/16/24
Website Check 1				
Documents	Shilo Bailey	100%	2/23/24	3/15/24
Project Description	Nathan Bastidas	100%	2/23/24	3/15/24
Gallery	Cassina Olson	100%	2/23/24	3/15/24
About Us	Carter Rhoades	100%	2/23/24	3/15/24
Pictures	Team	100%	2/23/24	3/15/24
Analytical Analysis Memo				
Jaw Stresses	Shilo Bailey	100%	3/1/24	3/22/24
Material Stress	Nathan Bastidas	100%	3/1/24	3/22/24
Dental	Cassina Olson	100%	3/1/24	3/22/24
Lever Tolerances	Carter Rhoades	100%	3/1/24	3/22/24
Formatting	Team	100%	3/1/24	3/22/24
Presentation 3/1st Prototype				
Schedule & Budget / CAD Model	Shilo Bailey	100%	3/11/24	4/1/24
Design Requirements / Engineering	Nathan Bastidas	100%	3/11/24	4/1/24
Design Validation / Project Description	Cassina Olson	100%	3/11/24	4/1/24
Design Description / CAD Model	Carter Rhoades	100%	3/11/24	4/1/24
Come up with FMEA ideas	Team	100%	3/11/24	4/1/24





Report 2				
Schedule & Budget / Background	Shilo Bailey	100%	4/2/24	4/23/24
Requirements / Conclusions	Nathan Basildas	80%	4/2/24	4/23/24
Research Within Design Space	Cassina Olson	0%	4/2/24	4/23/24
Design Concepts / Design Validation	Carter Rhoades	0%	4/2/24	4/23/24
References, Appendices	Team	0%	4/2/24	4/23/24
Final CAD/BOM				
Mechanics of Notched Ruler	Shilo Bailey	0%	4/5/24	4/26/24
Molar Mouthpiece	Nathan Basildas	0%	4/5/24	4/26/24
Molar Mouthpiece	Cassina Olson	0%	4/5/24	4/26/24
Mechanics of Notched Ruler	Carter Rhoades	0%	4/5/24	4/26/24
Submission / Drawings	Team	0%	4/5/24	4/26/24
2nd Prototype Demo				
Explain xyz	Shilo Bailey	0%	4/8/24	4/29/24
Explain Mouthpiece	Nathan Basildas	0%	4/8/24	4/29/24
Explain Mouthpiece	Cassina Olson	0%	4/8/24	4/29/24
Explain xyz	Carter Rhoades	0%	4/8/24	4/29/24
Task	Team	0%	4/8/24	4/29/24
Project Management				
Purchasing Plan	Shilo Bailey	0%	4/12/24	5/3/24
Reflection	Nathan Basildas	0%	4/12/24	5/3/24
Gantt Chart	Cassina Olson	0%	4/12/24	5/3/24
Manufacturing Plan	Carter Rhoades	0%	4/12/24	5/3/24
Formatting	Team	0%	4/12/24	5/3/24
Website Check 2				
Add more	Shilo Bailey	0%	4/14/24	5/5/24
Submit	Nathan Basildas	0%	4/14/24	5/5/24
Add more	Cassina Olson	0%	4/14/24	5/5/24
Add more	Carter Rhoades	0%	4/14/24	5/5/24
Add more	Team	0%	4/14/24	5/5/24

9.2 Appendix B: Descriptive Title