Trismus Treatment Device

ME 476C

Team Members:

Shilo Bailey, Nathan Bastidas, Cassina Olson, Carter Rhoades

NAU NORTHERN ARIZONA UNIVERSITY

Project Description

The Trismus Treatment Team:

<u>Primary Sponsors:</u>

- Dr. Rebecca Bartlett
- Carolyn Abraham from Dignity Health

<u>Advisors/Collaborators:</u>

- Dr. Timothy Becker
- Communication Sciences and Disorder (CSD) students

<u>Main Goal:</u> Create more affordable devices to open tighter jaws without causing pain.

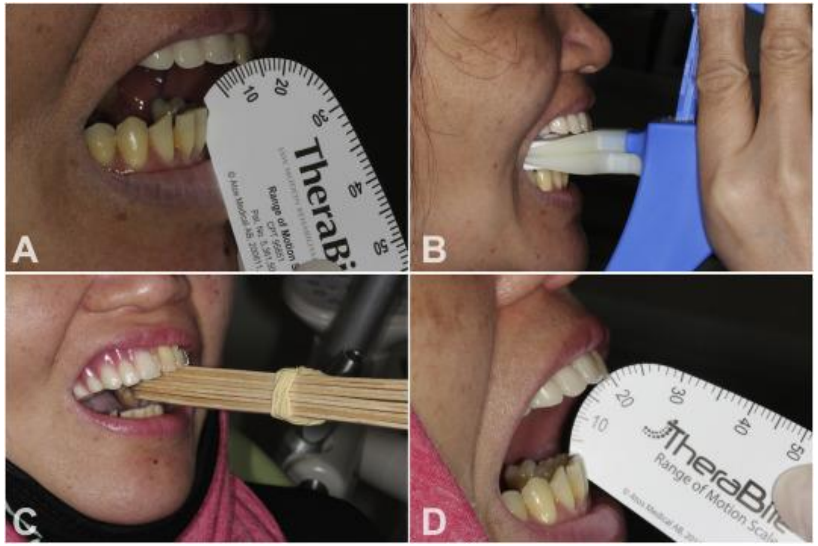


Fig. 1 - Science Direct V16 I1 doi.org

Background & Benchmarking

Background

Cancer treatments such as radiation can result in muscle spasms that tighten the jaw to a point known as 'lock jaw' where people cannot eat or drink independently.

Most products are either incredibly expensive or improvised at the doctor's office with tongue depressors, which can be extremely painful.

Background & Benchmarking

Benchmarking

TheraBite: $579.99

- Adjustable with replacement bite pads

UNIQUE: $24

- Extremely painful but more affordable

In house Trismus Device

- Non-reusable but nearly free
- Created by clinician

Fig 2 - Therabite

Fig 3 - In-house Trismus

Fig 4 - UNIQUE Trismus

Customer Requirements

Requirement	Explanation
Cost Effective	Target price is < $50/Unit
Safe	The Device must not cause harm to its operator or itself
Open Source	Provide a full instructional suite to assist in-house reproduction of the design
Produceable via 3D Printing	Design must utilize additive manufacturing technology, relevant design considerations must be accounted for (Max overhang angles, Material use, etc.)
Adaptive	Can accommodate patients with small incisor gaps (<25mm gap)

Goal:
Create a trismus treatment device that is affordable, safe, easily accessible, and versatile enough to accommodate diverse patient profiles.

Table I: Customer Requirements

Engineering Requirements

Cost-Effective	Each unit < $50 to generate	The total cost of all parts of the device must be less than $50
Safe	Safety Rating	We will use various properties within our system to generate this (Max Force output, average teeth strength, etc.)
Open Source	Y/N	The device's design must be open to distribution without restriction to any qualified clinician
Produceable via 3D Printing	Percentage of parts that are producible vs purchased hardware	Two categories will be calculated, purchased cost and material cost. The goal is to have 80% of the cost resultant of 3D printing expenditure.
Adaptability	# of operable sizes	The size of the device must accommodate a wide range of patient types and mouth shapes

Table II: Engineering Requirements

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		
								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**				

Table III: QFD

Literature Review: pt 1 (Shilo)

- [1] Nina Pauli, Ulrika Svensson, Therese Karlsson & Caterina Finizia (2016) “Exercise intervention for the treatment of trismus in head and neck cancer – a prospective two-year follow-up study,” Acta Oncologica, 55:6, 686-692, DOI: 10.3109/0284186X.2015.1133928

- [2] Charters E, Dunn M, Cheng K, Aung V, Mukherjee P, Froggatt C, Dusseldorp JR, Clark JR, “Trismus therapy devices: A systematic review,” Oral Oncology, Volume 126, 2022, 105728, ISSN 1368-8375, https://doi.org/10.1016/j.oraloncology.2022.105728. Accessed February 3, 2024

- [3] Daniel Buchbinder, Robert B. Currivan, Andrew J. Kaplan, Mark L. Urken, “Mobilization regimens for the prevention of jaw hypomobility in the radiated patient: A comparison of three techniques,” Journal of Oral and Maxillofacial Surgery, Volume 51, Issue 8, 1993, Pages 863-867, ISSN 0278-2391, https://doi.org/10.1016/S0278-2391(10)80104-1.

- [4] Emma Charters, Jamie Loy, Raymond Wu, Kai Cheng, Masako Dunn, Sarah Davies, Jonathan Clark, “Feasibility study of intensive intervention using novel trismus device during adjuvant radiation for head and neck cancer: RestorabiteTM,” Oral Oncology, Volume 146, 2023, 106558, ISSN 1368-8375, https://doi.org/10.1016/j.oraloncology.2023.106558.

Literature Review: pt 2 (Nathan)

- [6] J. B. Park and R. S. Lakes, *Biomaterials: An Introduction*. New York, NY: Springer, 2010.
    - Textbook that focuses on biocompatibility of materials, as well as material degradation and material science.

- [7] D. Dharavath and R. Maddi, “ISO standards of Medical Devices,” World Journal of Current Medical and Pharmaceutical Research, https://wjcmpr.com/index.php/journal/article/view/213 (accessed Feb. 4, 2024).
    - Journal that discusses the ISO Standards regarding biomedical device safety and qualifications.

- [8] M. Jeong et al., “Materials and applications of 3D printing technology in Dentistry: An overview,” MDPI, https://www.mdpi.com/2304-6767/12/1/1 (accessed Feb. 4, 2024).
    - Current overview regarding 3D printing materials in dental applications.

- [9] “Biocompatible 3D resins for medical devices,” 3Dresyns, https://www.3dresyns.com/pages/bio-compatible-3dresyns (accessed Feb. 4, 2024).
    - 3Dresyn is a company that advertises a monomer-free biocompatible 3D resin for medical devices.

Literature Review: pt 3 (Cassina)

- [10] J. P. Davim, *The design and manufacture of medical devices*. Ch 1. Cambridge: Woodhead Publishing Ltd, 2012.
    - This book chapter cites a few commonly used biomedical materials and their biocompatibility

- [11] Center for Devices and Radiological Health, "Classify Your Medical Device," U.S. Food and Drug Administration, Jul. 02, 2020. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
    - This resource provides the specific qualities and requirements for a medical device to be classifies as class 1, 2, or 3. We are making a class 1 device.

- [15] P. U. Dijkstra, W. W. I. Kalk, and J. L. N. Roodenburg, "Trismus in head and neck oncology: a systematic review," Oral Oncology, vol. 40, no. 9, pp. 879–889, Oct. 2004, doi: https://doi.org/10.1016/j.oraloncology.2004.04.003.
    - This paper shows the effects of radiation on certain muscle groups and joints in the mandibular area.

- [16] C.-J. Wang, E.-Y. Huang, H.-C. Hsu, H.-C. Chen, F.-M. Fang, and C.-Y. Hsiung, "The Degree and Time-Course Assessment of Radiation-Induced Trismus Occurring After Radiotherapy for Nasopharyngeal Cancer," The Laryngoscope, vol. 115, no. 8, pp. 1458–1460, Aug. 2005, doi: https://doi.org/10.1097/01.mlg.0000171019.80351.46.
    - This book chapter analyzes the severity of trismus after different times in which the patient was exposed to radiation therapy and whether or not surgery was involved/required for the cancer cells/tumor.

Literature Review: pt 4 (Carter)

[17] J. Lee and A. Huang, "Fatigue Analysis of FDM Materials," *Rapid Prototyping Journal*, vol. 19, no. 4, pp. 291–299, Jun. 2013. doi:10.1108/13552541311323290

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

[18] C. Guttridge, A. Shannon, A. O'Sullivan, K. J. O'Sullivan, and L. W. O'Sullivan, "Biocompatible 3D printing resins for medical applications: A review of marketed intended use, biocompatibility certification, and post-processing guidance," *Annals of 3D Printed Medicine*, vol. 5, p. 100044, Mar. 2022. doi:10.1016/j.stlm.2021.100044

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

[19] L. Novakova-Marcincinova, J. Novak-Marcincin, J. Barna, and J. Torok, "Special materials used in FDM Rapid Prototyping Technology Application," *2012 IEEE 16th International Conference on Intelligent Engineering Systems (INES)*, Jun. 2012. doi:10.1109/ines.2012.6249805

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

Mathematical Modeling - Muscle

Assumptions:

- Maximum 'bite' force is "produced at horizontal and vertical joint force directions", [20].
- Temporomandibular Joint is a simple lever model
- Average Jaw Weight:
  - Head Wt = 10 – 11lbs [21]
  - Jaw is approx. 20% of head weight/mass
  - Assumed Jaw Wt = 2lbs
- Maximum Bite Force: F = 275lbf or 1.22kN [22]
- For patients with 0mm of mouth opening, the jaw would be static.

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

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

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

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

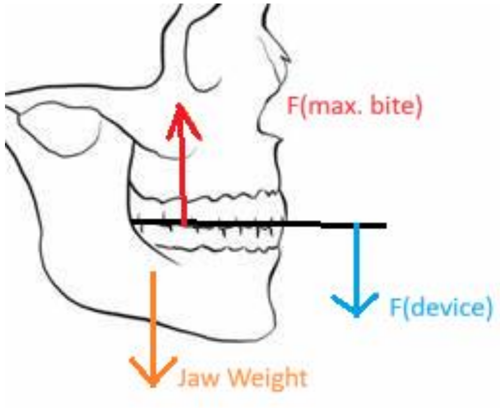


Fig 5 – Jaw Bite Forces

Equations

Static Equilibrium - $\sum F_y = 0$

[20] T.M.G.J. van Eijden, E.M. Klok, W.A. Weijs, J.H. Koolstra, "Mechanical capabilities of the human jaw muscles studied with a mathematical model, Archives of Oral Biology," Volume 33, Issue 11, 1988, Pages 819-826, ISSN 0003-9969, https://doi.org/10.1016/0003-9969(88)90106-9. (accessed Feb. 4, 2024)
[21] "How Much Does the Human Head Weigh? (Answered) | Measuringly," Aug. 10, 2023. https://measuringly.com/how-much-does-human-head-weigh/
[22] E. D. Excellence, "How Powerful Is the Jaw? | How Jaw Pain Can Affect Oral Health," *Eastgate Dental Excellence*, Jan. 31, 2022. https://eastgatedentalexcellence.com/blog/the-human-jaw-and-how-it-affects-your-oral-health/ (accessed Feb. 4, 2024).

Mathematical Modeling – Manufacturing

Equations, Engineering Tools

- 3D Printer Slicers (Chitubox, Cura, Ideamaker)
- 3D Printing Equation (General)
  - **$\text{Max Speed}_{Rec.} = (\text{Flow Rate}_{Max}) / (\text{Height}_{Layer} * \text{Extrusion Width})$**
- **Flow Rate Equation:**
  - **$\text{Flow Rate} = \text{Nozzle Size (mm)} \times (\text{Height}_{Layer} * \text{Print Speed})$**

Example:

$\text{Max Speed}_{Rec.} = (13\ mm^3/s) / (0.2\ mm * 0.6\ mm)$

$\text{Max Speed}_{Rec.} = 108\ mm/s$

Fig 6 – SLA Printing

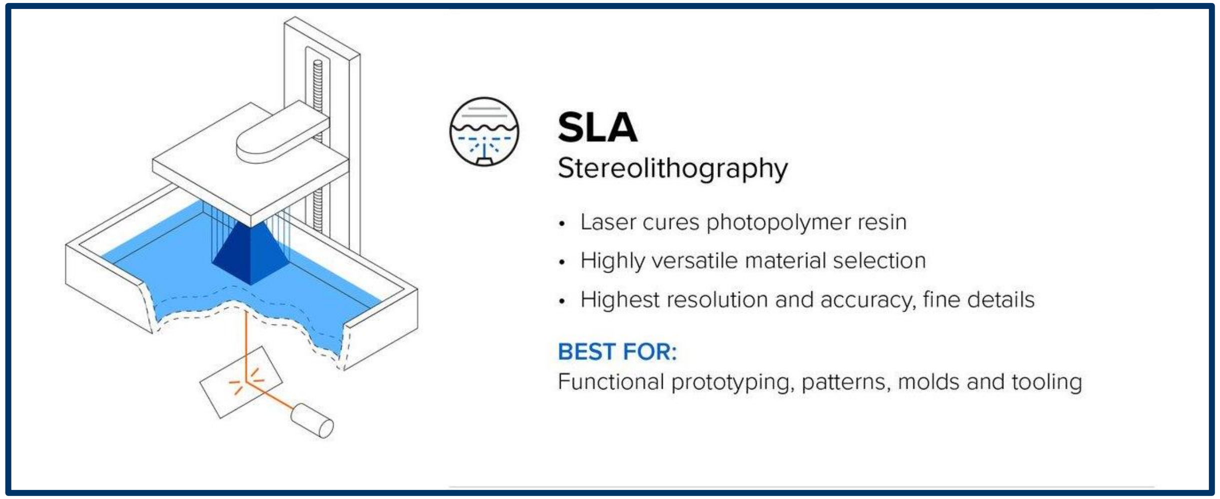
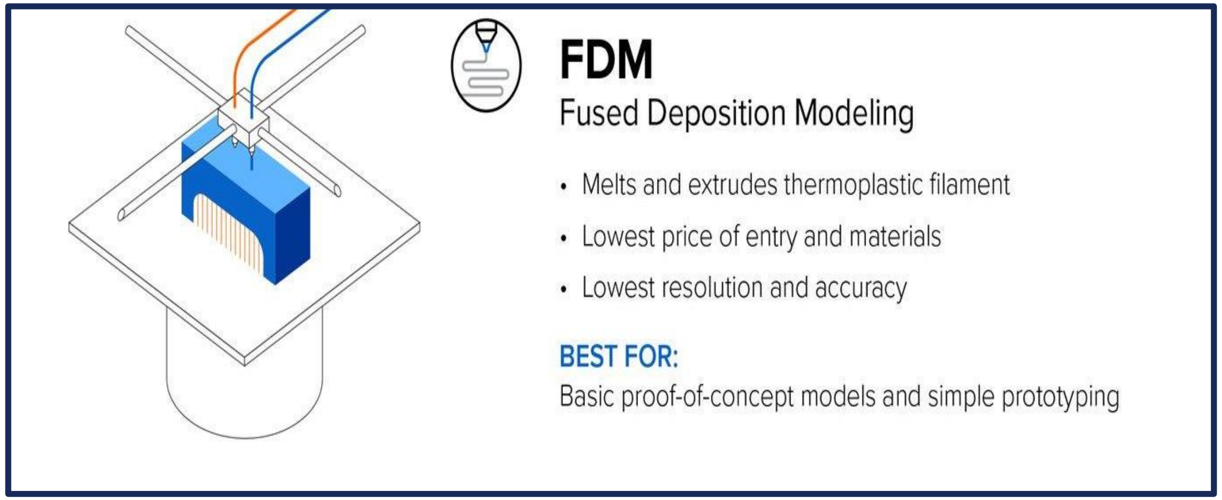


Fig 7 – FDM Printing



Mathematical Modeling - Dental

1. Equations

Pressure and Tooth Fracture Propagation

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

2. Engineering Tools

Compression force testers, Radial compression force testers, Online pressure simulator

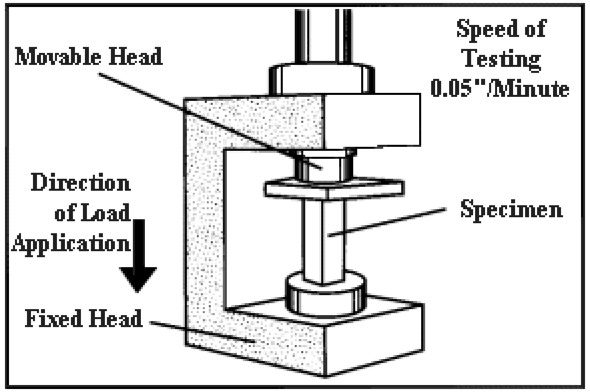


Fig 8 – Compression Test Machine

3. Example (No Teeth vs Teeth)

Max Pressure from source: 44.6 –74.4 Kg/m^2.

F = 230 – 251 N
L = 16.44cm--19.33cm W = 0.71cm--1.10cm
A = 11.67cm^2—21.26cm^2
P = 197 kPa – 108 kPa

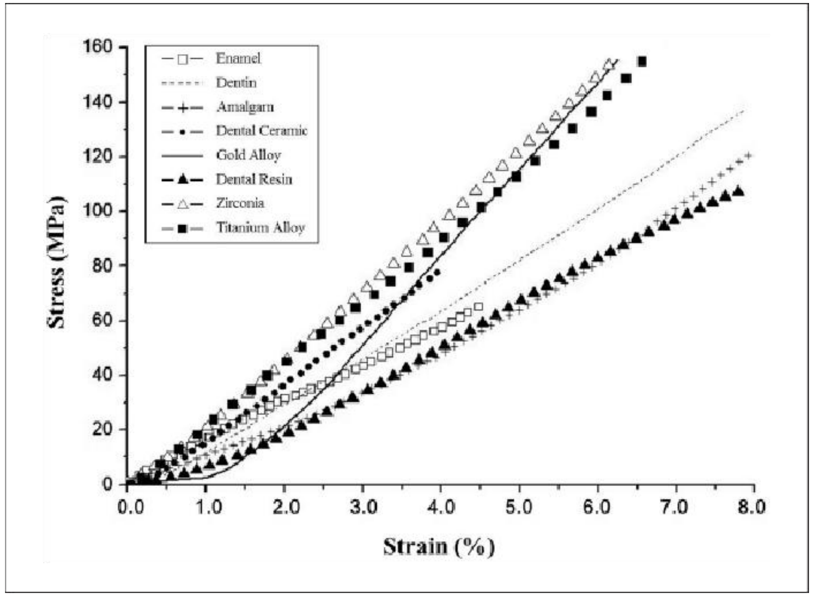
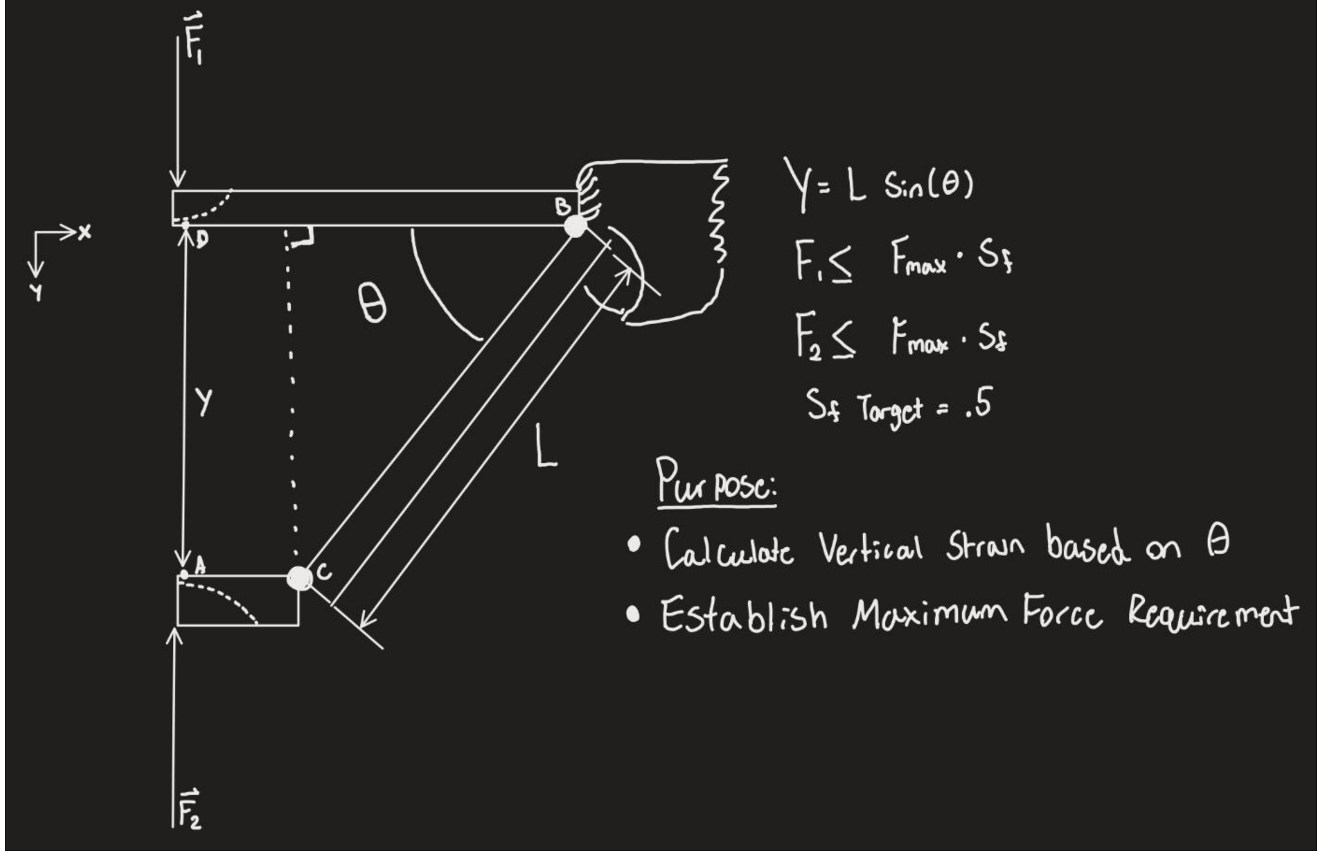


Fig 9 – Dental Restorative Stress-Strain Graph

[23] C. E. Anyanechi and B. D. Saheeb, "Mandibular sites prone to fracture: analysis of 174 cases in a Nigerian tertiary hospital," Ghana medical journal, vol. 45, no. 3, pp. 111–4, 2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3266144/#:~:text=Functional%20processes%20such%20as%20the
[24] Chun, Keyoung & Lee, Jong. (2014). Comparative study of mechanical properties of dental restorative materials and dental hard tissues in compressive loads. Journal of dental biomechanics.
[25] MatWeb, "Compressive Strength Testing of Plastics," www.matweb.com. https://www.matweb.com/reference/compressivestrength.aspx

Mathematical Modeling - Lever Properties

Model Of Potential Device



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)

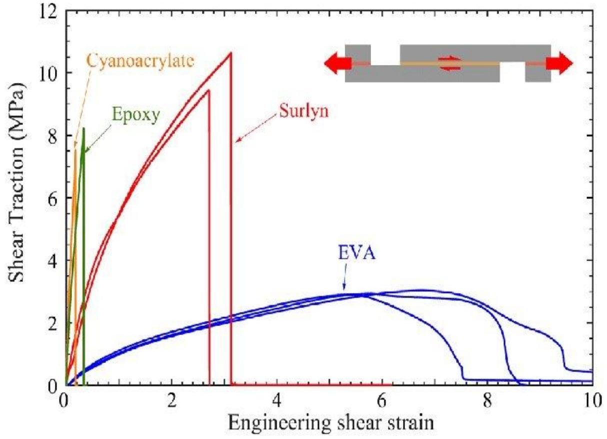
Relevant Equations:

① Y=L*Sin(Θ)

② Mb = F_2*(L*Cos(Θ))

③ ΣFx = 0 (Device Stays Fixed)

④ΣFy = 0 (Device Stays Fixed)



Example Shear-Strain:

Shear-strain graphs will be used after forces are calculated to select appropriate materials.

Engineering Tools:

- MatLab analysis Algorithm
- Stress-Strain Measurement Device
- Force Analysis Equipment

Budget

Budget Constraints:

- Budget not provided by client
- Client requirement: Device Cost <$50
- Fundraise at least $100

Fundraising:

- Bake Sale
- Car Wash
- Donations

Budget Components	Type	Cost	Current	Completion
Total Available			$0	
Fundraising		>$100	$0	$100 - $150
Anticipated Expenses	Printer Filament (x2)	$45 - $65	$0	($45 - $65)
	Misc. Components	$0 - $10	$0	($0 - $10)
	Shipping & Handling	$20 - $30	$0	($20 - $30)
Total			$0	$65 - $105
Remaining			$0	$35 - $45

Running Schedule

Trismus Project

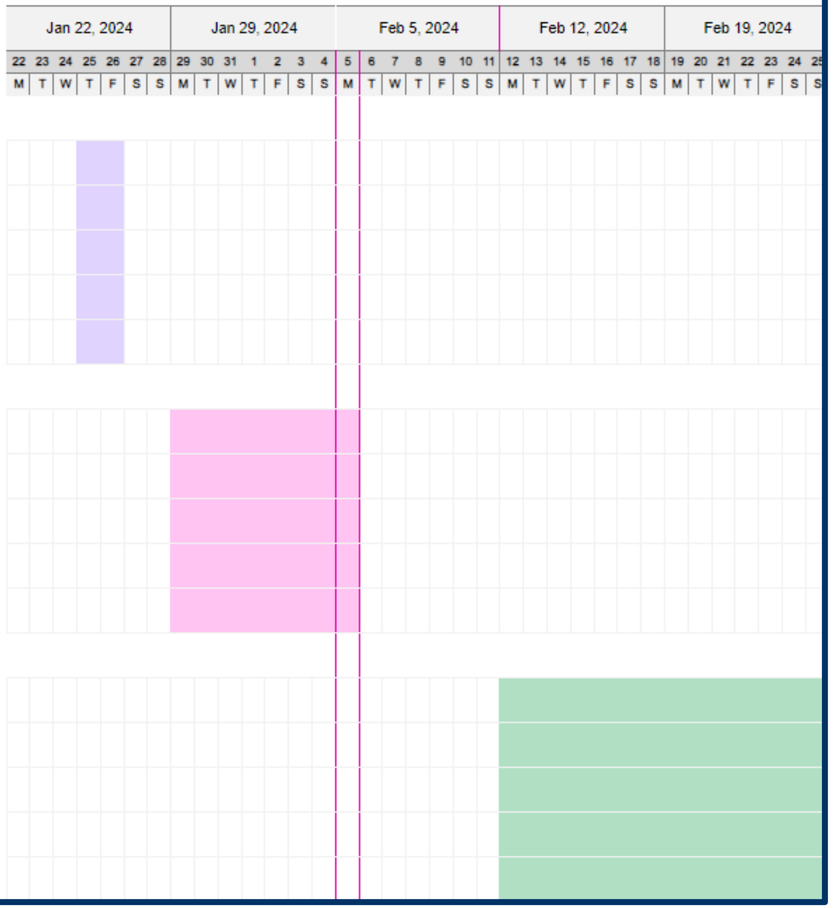
Company — Individual assignments not included

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	0%	2/12/24	2/26/24
BoM/Concept Eval.	Nathan Bastidas	0%	2/12/24	2/26/24
Intro/project desc./concept generation	Cassina Olson	0%	2/12/24	2/26/24
Engineering Calculations	Carter Rhoades	0%	2/12/24	2/26/24
Schedule/Budget	Shilo Bailey	0%	2/12/24	2/26/24



<u>Key Milestones:</u>

- Presentation 1 (Now)
- Suite of Potential Solutions (On Schedule)
- Rough CAD Model (On Schedule
- Presentation 2 (On Schedule)

Thank you!

Questions?

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References:

- [1] Nina Pauli, Ulrika Svensson, Therese Karlsson & Caterina Finizia (2016) “Exercise intervention for the treatment of trismus in head and neck cancer – a prospective two-year follow-up study,” Acta Oncologica, 55:6, 686-692, DOI: 10.3109/0284186X.2015.1133928
- [2] Charters E, Dunn M, Cheng K, Aung V, Mukherjee P, Froggatt C, Dusseldorp JR, Clark JR, “Trismus therapy devices: A systematic review,” Oral Oncology, Volume 126, 2022, 105728, ISSN 1368-8375, https://doi.org/10.1016/j.oraloncology.2022.105728. Accessed February 3, 2024
- [3] Daniel Buchbinder, Robert B. Currivan, Andrew J. Kaplan, Mark L. Urken, “Mobilization regimens for the prevention of jaw hypomobility in the radiated patient: A comparison of three techniques,” Journal of Oral and Maxillofacial Surgery, Volume 51, Issue 8, 1993, Pages 863-867, ISSN 0278-2391, https://doi.org/10.1016/S0278-2391(10)80104-1.
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- [5] W. R. Wagner and B. D. Ratner, *Biomaterials Science: An Introduction to Materials in Medicine*. San Diego, CA: Academic Press, 2020.
- [6] J. B. Park and R. S. Lakes, *Biomaterials: An Introduction*. New York, NY: Springer, 2010.
- [7] D. Dharavath and R. Maddi, “ISO standards of Medical Devices,” World Journal of Current Medical and Pharmaceutical Research, https://wjcmpr.com/index.php/journal/article/view/213 (accessed Feb. 4, 2024).
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- [9] M. Guvendiren, J. Molde, R. Soares, and J. Kohn, “Designing biomaterials for 3D printing - ACS Publications,” ACS Publications, https://pubs.acs.org/doi/abs/10.1021/ACSBIOMATERIALS.6B00121 (accessed Feb. 5, 2024).
- [10] “Biocompatible 3D resins for medical devices,” 3Dresyns, https://www.3dresyns.com/pages/bio-compatible-3dresyns (accessed Feb. 4, 2024).
- [11] “Siraya Tech Blu-tough resin,” Siraya Tech, https://siraya.tech/products/blu-tough-resin-by-siraya (accessed Feb. 4, 2024).
- [12] J. P. Davim, *The design and manufacture of medical devices*. Ch 1. Cambridge: Woodhead Publishing Ltd, 2012.
- [13] D. van Gijn, et al. 'Ch.2: The mandible', Oxford Handbook of Head and Neck Anatomy, Oxford Medical Handbook e-pub, Jan. 2022.
- [14] Y. Ihara et al., “The Device of Ethylene Vinyl Acetate Sheet for Trismus Caused by Bilateral Mandible Fractures,” Case Reports in Dentistry, vol. 2021, pp. 1–6, Aug. 2021, doi: https://doi.org/10.1155/2021/8340485.
- [15] Center for Devices and Radiological Health, “Classify Your Medical Device,” U.S. Food and Drug Administration, Jul. 02, 2020. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
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    - This paper shows the effects of radiation on certain muscle groups and joints in the mandibular area.
- [17] M. Louise Kent et al., “Radiation-Induced trismus in head and neck cancer patients,” Supportive Care in Cancer, vol. 16, no. 3, pp. 305–309, Oct. 2007, doi: https://doi.org/10.1007/s00520-007-0345-5.
- [18] C.-J. Wang, E.-Y. Huang, H.-C. Hsu, H.-C. Chen, F.-M. Fang, and C.-Y. Hsiung, “The Degree and Time-Course Assessment of Radiation-Induced Trismus Occurring After Radiotherapy for Nasopharyngeal Cancer,” The Laryngoscope, vol. 115, no. 8, pp. 1458–1460, Aug. 2005, doi: https://doi.org/10.1097/01.mlg.0000171019.80351.46.
- [19] O. Isman, “Evaluation of jaw bone density and morphology in bruxers using panoramic radiography,” Journal of Dental Sciences, Oct. 2020, doi: https://doi.org/10.1016/j.jds.2020.09.008.
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- [21] C. Guttridge, A. Shannon, A. O’Sullivan, K. J. O’Sullivan, and L. W. O’Sullivan, “Biocompatible 3D printing resins for medical applications: A review of marketed intended use, biocompatibility certification, and post-processing guidance,” *Annals of 3D Printed Medicine*, vol. 5, p. 100044, Mar. 2022. doi:10.1016/j.stlm.2021.100044
- [22] L. Novakova-Marcincinova, J. Novak-Marcincin, J. Barna, and J. Torok, “Special materials used in FDM Rapid Prototyping Technology Application,” *2012 IEEE 16th International Conference on Intelligent Engineering Systems (INES)*, Jun. 2012. doi:10.1109/ines.2012.6249805