Trismus Treatment Device

ME 476C

Team Members:

Shilo Bailey, Nathan Bastidas, Cassina Olson, Carter Rhoades

NORTHERN ARIZONA UNIVERSITY

Project Description

The Trismus Treatment Team:

Goals:

-Create more affordable (<$50) devices to open tighter jaws (>6mm) without causing pain.

-Measure applied pressure and strain with only the 3D printed device

Primary Sponsors:

- Dr. Rebecca Bartlett
- Carolyn Abraham from Dignity Health Phoenix

Advisors/Collaborators:

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

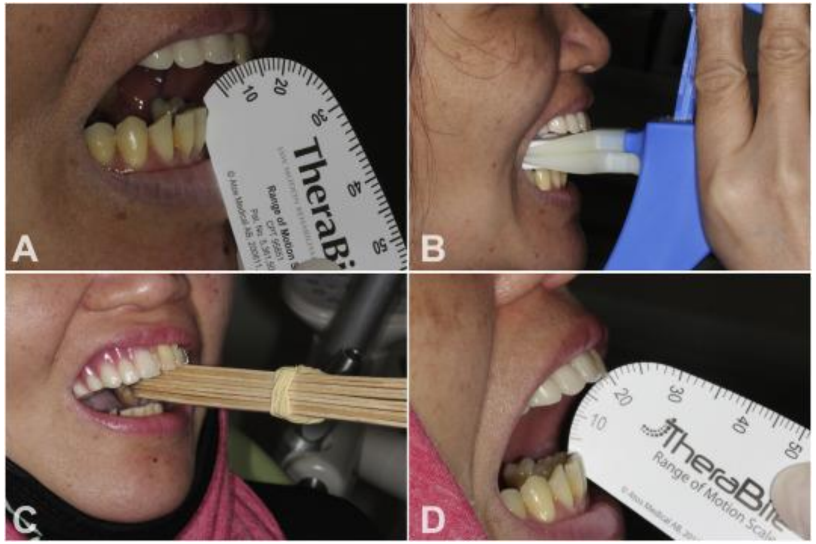


Fig. 1 - Science Direct V16 I1 doi.org

OVERVIEW: Design Description

Top-Level Design Functions:

- Promote jaw motion/function
- Apply active resistance to closing jaw
- Measure Force applied to device
- Measure Overall Jaw Strain

List of Subsystems:

- Device Body/Arms
- Mouthpiece
- Compliant Springs
- Ruled Surface

General Design Updates:

Max Depth: ~45mm

Min Depth: ~6mm

Compliant Spring is now removable

Arms "roll" instead of using hinge

Mouthpieces connect from top and bottom of device instead of front

Part List:

1: Compliant Spring

2: Lower Arm

3: Mouthpiece

4: Ruled Surface

5: Upper Arm

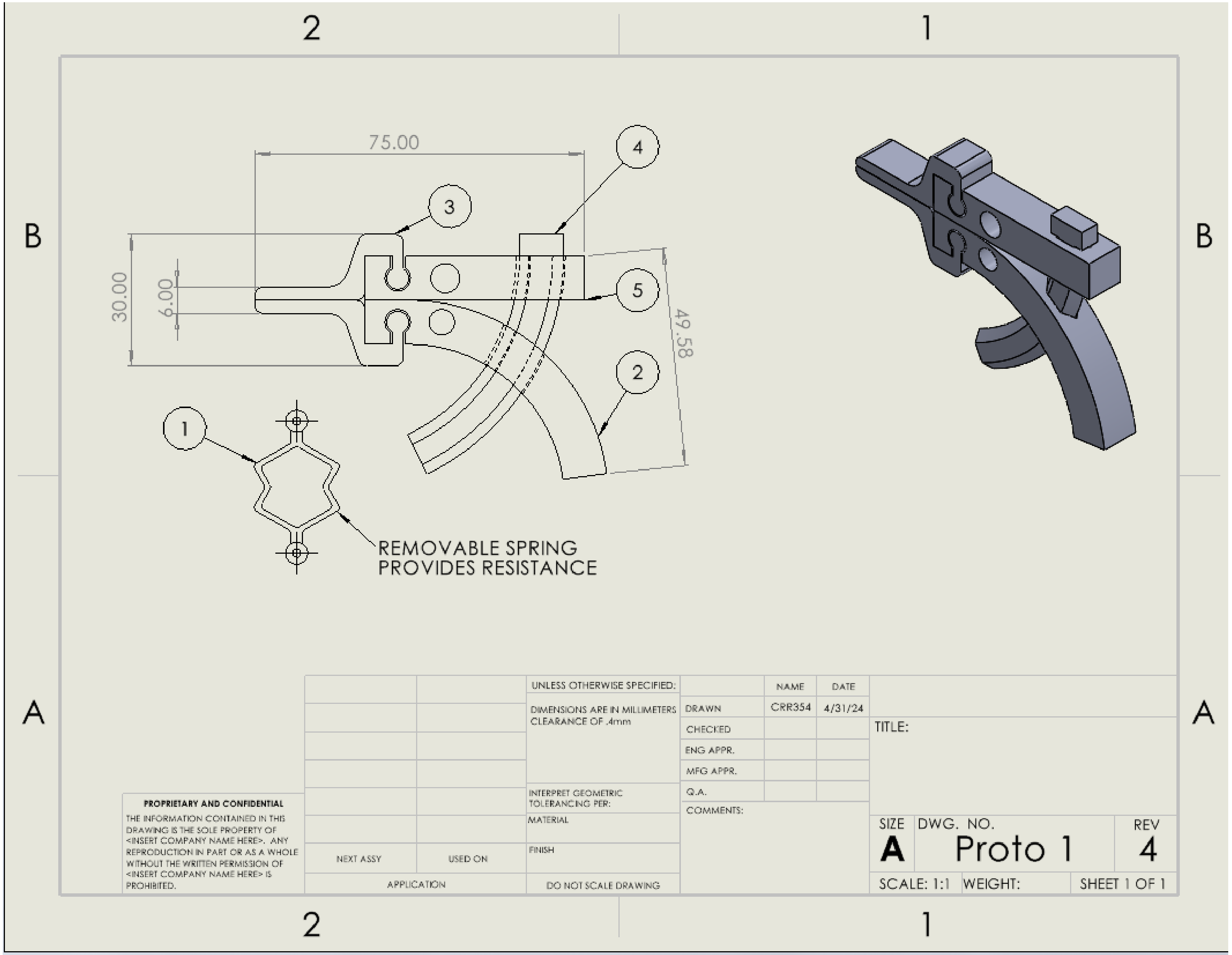


Fig. 2– UPDATED CAD Model Drawing

Design Description:

Updates to: Compliant Spring

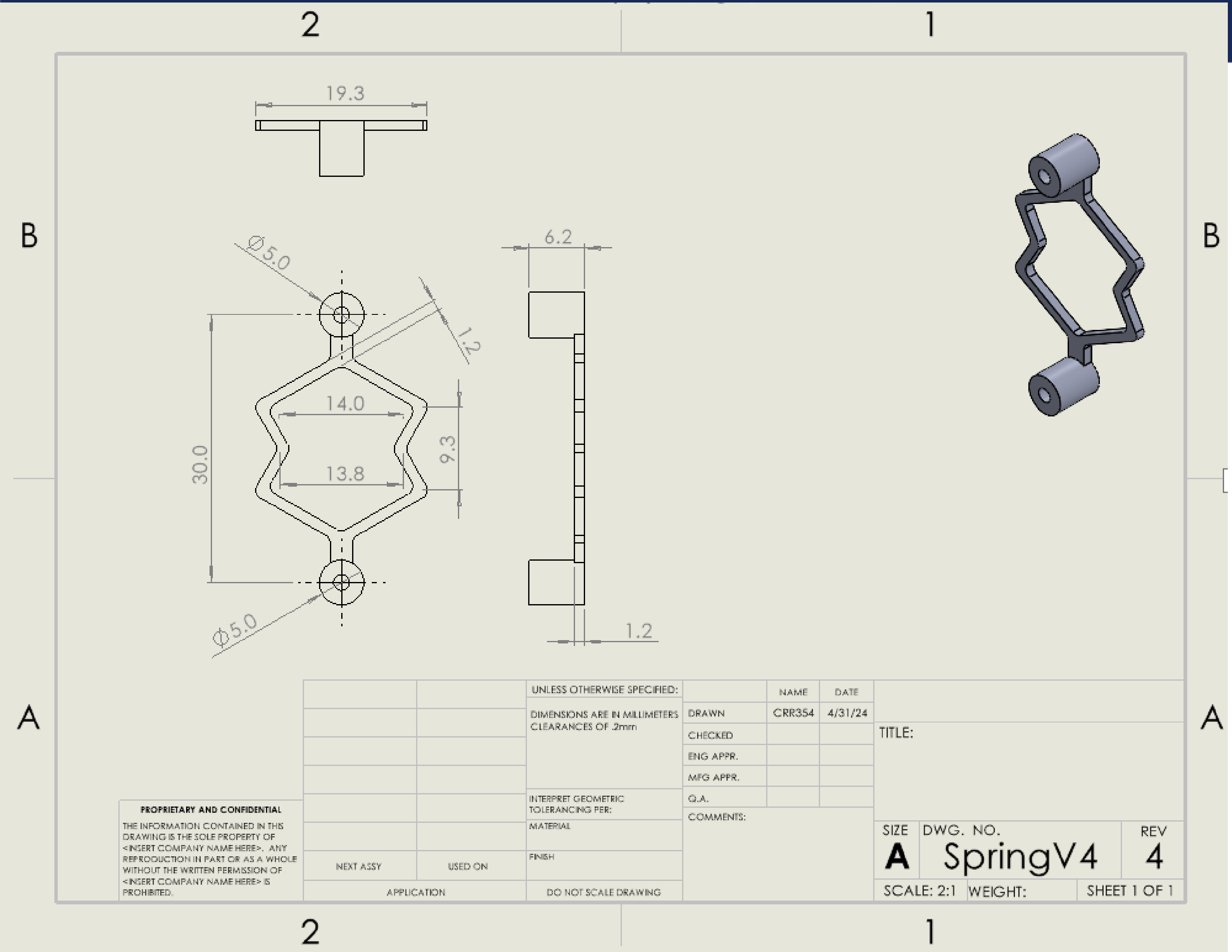


Fig. 3– UPDATED CAD Compliant Spring Model

Goals:

- Provide Active resistance to jaw closing motion
- Removable to provide extra use cases

Outcomes:

- Thinner design can bend properly
- Designed to "crinkle" instead of bend

Design Description:

Updates to: Lower Arm

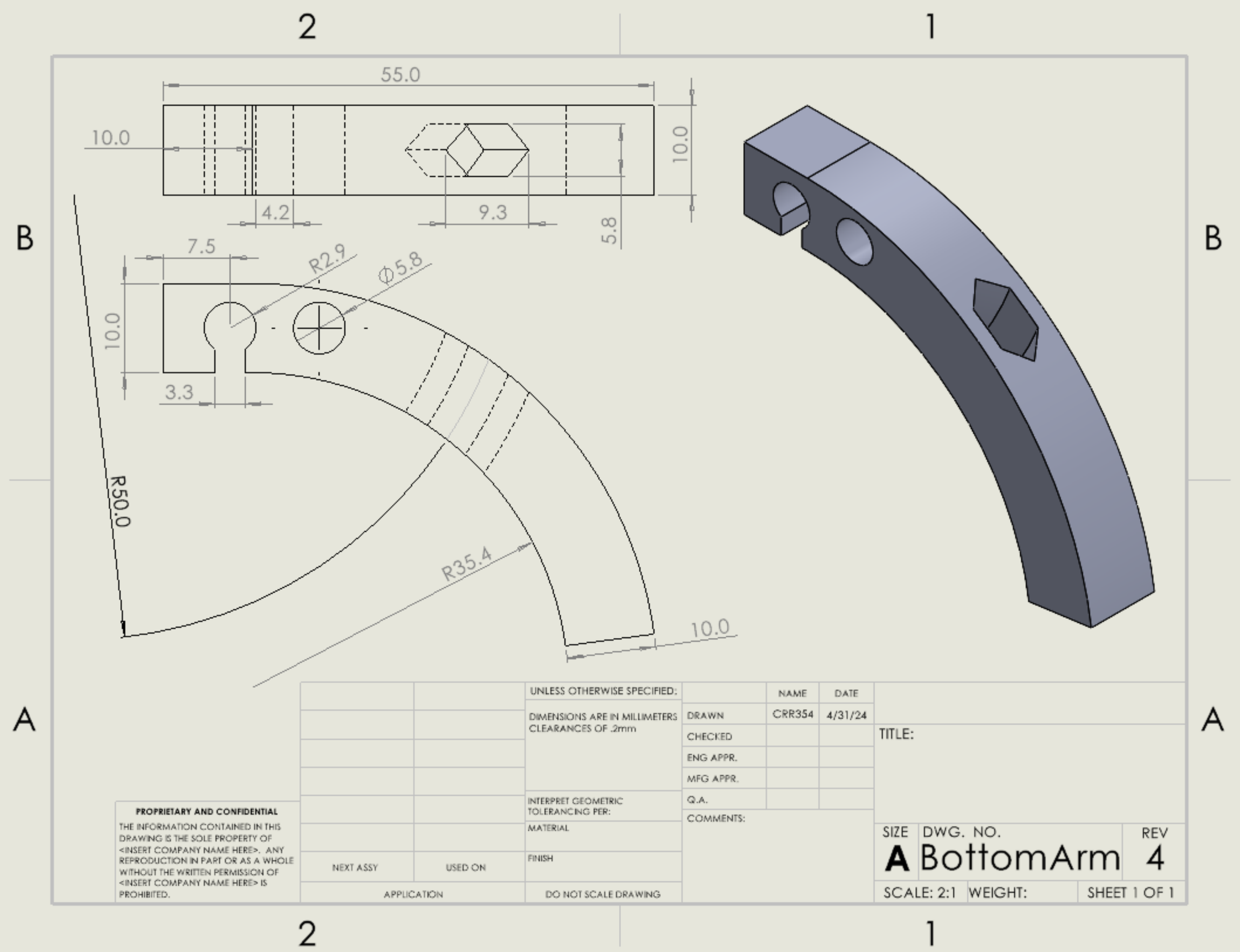


Fig. 4– UPDATED CAD Lower Arm

Goals:

- Change Shape to be curved
- Add channel for ruled measurement surface

Outcomes:

- Lower arm "rolls" against top arm to fit jaw motion more ergonomically
- Reoriented Attachment point to reduce overhangs

Design Description:

Updates to: Mouthpiece

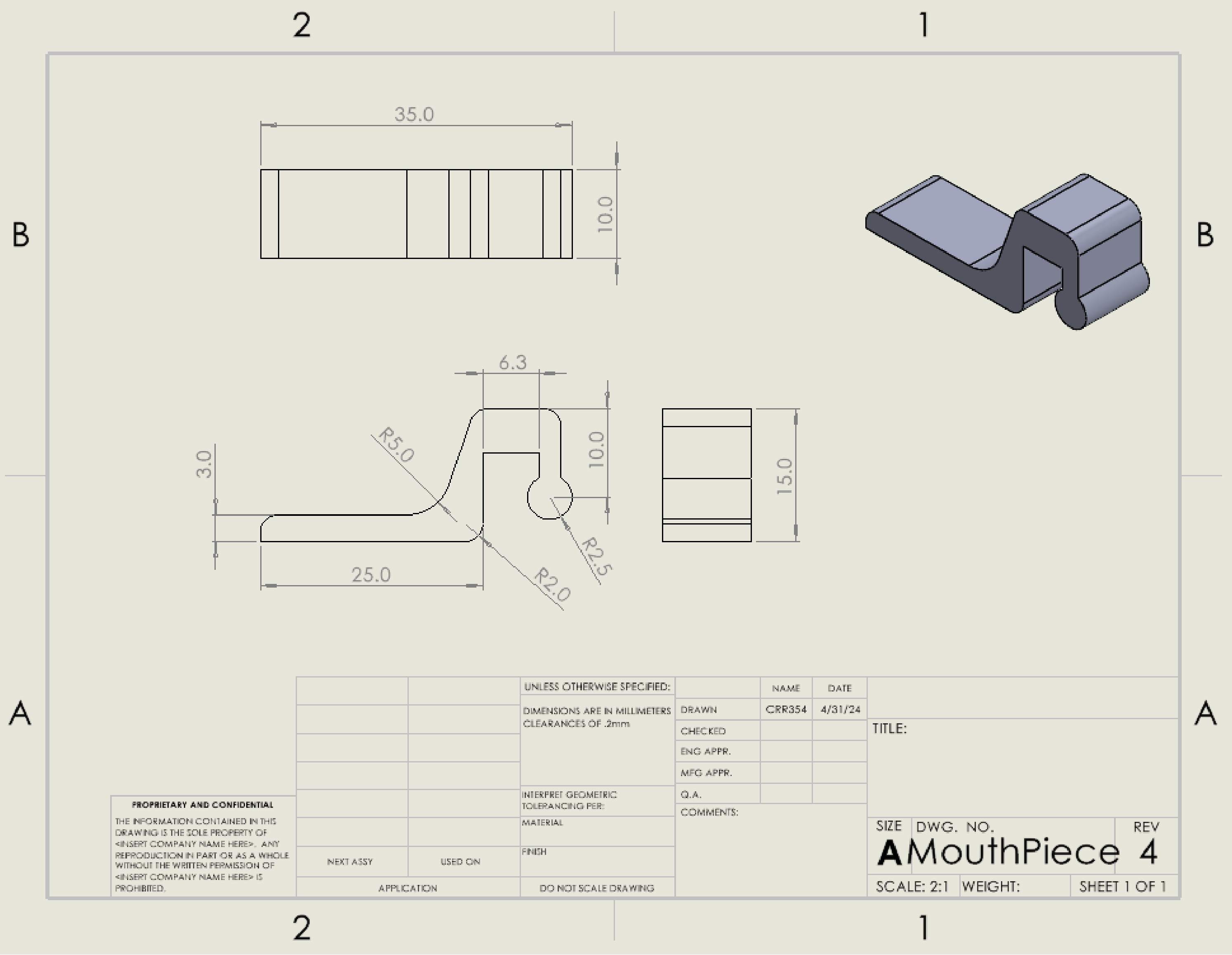


Fig. 5– UPDATED CAD Mouthpiece

Goals:

- Inform Clearances for a better fit on attachment points
- Identify failure points

Outcomes:

- Now attaches to top and bottom of device using a uniform pin
- Device will still hook into back molars

Prototype 1: Goals and Outcomes

Goals:

- Ensure all clearances are properly sized for printed parts
- Test overall motion of the device: does it open the jaw properly?
- Overall quality check for 3D printers

Outcomes:

- Printed parts properly fit together; some adjustments necessary
- The device moved properly overall; improvements needed for ruler
- The overall quality of the printed parts appear to be reliable

Prototype 1

Figure 6: 3D printed prototype

Design Requirements: Customer Requirements

Customer Requirements	Description
Fully 3D Printable and Open Source	Client has requested that the device is able to be fully 3D printed with detailed instructions and clear disclaimers towards what materials and printing tolerances are required for the device.
Medically Safe For User	The device must be made entirely out of FDA / ISO compliant materials that, during normal operation, should not cause any short- or long-term damage to the patient.
<$50 Per Unit	The total cost of printing material required to print the device must be under $50.
Ability to Measure Progress	To aid researchers and clinicians, the device should be able to measure out muscle displacement as well as applied force to the jaw so that progress can be measured over time.

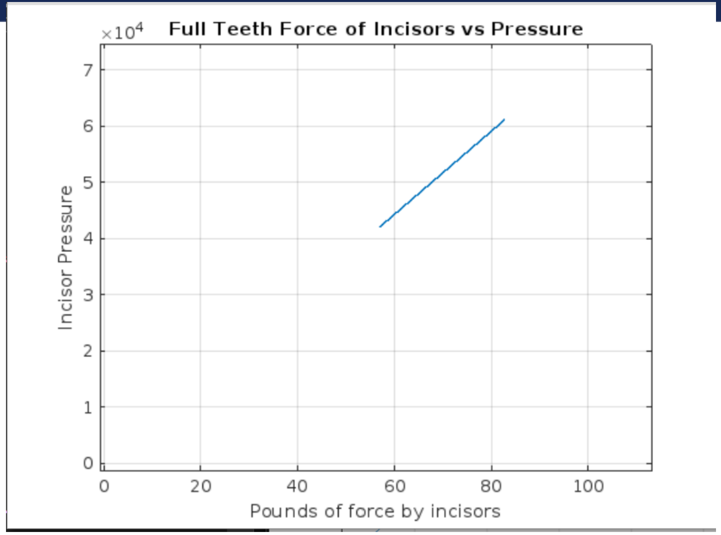
Design Requirements: Engineering Requirements

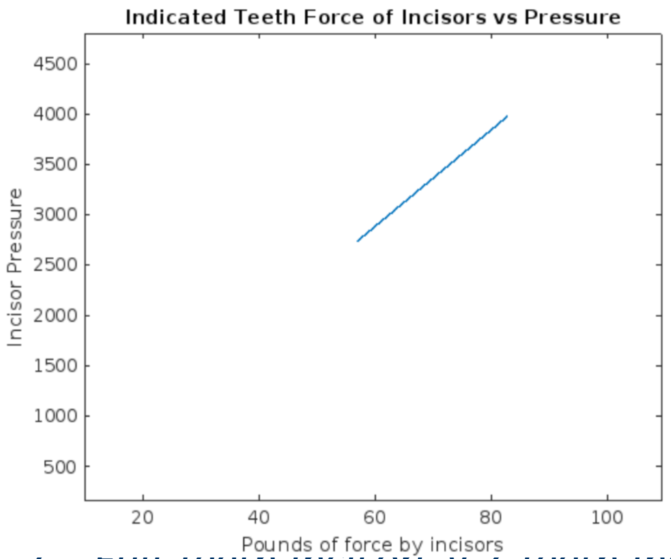
Engineering Requirements	Description	Units
Quick Printing Speed	With a current assembly print time of ~17 hours, the team wishes to reduce this time to allow for faster production.	Hrs
Durable and Flexible	By determining our tolerance range in terms of elastic and tensile strength, we can ensure the device can bend and move without breaking during operation.	MPa
Easily Reproducible	By refining the CAD model, as well as the instruction suite and print settings, the device should be able to be reproducible with limited need for modification of the model or printer being used.	N/A
Measurement System	The device should be able to measure out incisor displacement (in mm/in) and applied force to jaw (in N/lbs)	(mm/in), (N/lbs)

Design Requirements: Correlations

Customer Requirements	Correlation	Engineering Requirements
Fully 3D Printable	To ensure easy and quick replication, both speed and a one-print setup is key to developing an easy access Trismus device.	Quick Printing Speed
Medically Safe For User	By ensuring parts of the device won't break during operation, as well as the general safety of the material, our device will be safer than most homemade solutions.	Durable and Flexible
<$50 Per Unit	By focusing on a low cost per unit, we can ensure that this device is easily producible in mass quantities by clinics and can be afforded by a variety of patients.	Easily Reproducible
Ability to Measure Progress	With a built-in measurement system, clinicians and researchers can track a patient's progress over time and be able to note displacement and applied force.	Measurement System

Engineering Calculations: Applied Pressure






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

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

Goals:

- Use area of teeth/jaw with a range of forces to determine the optimal Pressure Applied.
- Enable full bite, half bite, quad bite, no bite, and special bite calculations.

Fig. 7 – Full Teeth Incisors v 2 Teeth Incisors

Engineering Calculations: Material Tolerances

- Material: PolyLite™ PETG
- Mechanical Properties:
  - 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

3D Slicer: Ultimaker Cura

Printer: Creality Ender 3 (V2)

Settings:

- Quality: Standard (0.2 mm)
- 0.6 mm Nozzle
- Generic PETG
- 20% Infill
- Shell Thickness: 1.6 mm x 0.8 mm

New Total Print Time = ~4 Hours/Assembly

Approximate Prototype Cost = Less than $1

Design Validation

FAILURE MODE AND EFFECTS ANALYSIS

Item:	Trismus Device	Responsibility:	Team Trismus
Model:	Current	Prepared by:	Team Trismus
Core Team:	Team Trismus		

FMEA number:	Unknown
Page :	1 of 1
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

Table II – FMEA

Design Validation

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

Table II – FMEA

Design Validation

Testing Procedures

- Stress / Strain / Shear stress testing on the material
- Cyclic loading to find lifetime use of the device
- Test effectiveness of building instructions / guide
- Customer feedback
- Pressure threshold to snap compliant spring / removable pin on device
- Pressure comparisons to a digital reading over lifetime testing

Design Validation

Equipment, Resources, and Space

- Apparatus to test stress/strain of PETG printed sheet for base calculations and for finished device testing
- Apparatus for full cyclic loading and counter to determine product longevity
- Polling and descriptions for instruction cohesiveness and product comfort
- Pressure test on ease of fracturing device when necessary via pin/spring
- Digital pressure monitor/ sensing equipment

Budget

<u>Updates:</u>

- Filament purchased for $50
- Use team donations for last minute purchases (emergencies)

<u>Fundraising</u>:

- Potentially over Summer break
  - Selling different 'crafts' & projects
  - Goal: $100 total fundraised

Budget Components	Type	Cost
Allocated	Funds from CSD Department	$200
Fundraising	Team Donations	$100
Expenses	Printer Filament (x2)	(- $50)
Total Spent		$50
Remaining		$250

<u>Table II – Budget Table</u>

Running Schedule

Main Task:	Team Member(s):	Progress:	Target Completion Date:
Presentation 3	All	Complete	3/31/24
Prototype #1 Revision	Carter & Shilo	Complete	3/31/24
Report #2	All	On Time	4/23/24
Force and Spring Analysis (HW#4)	Carter	On Time	4/23/24
Material Property & Prototype Testing (HW#4)	Nathan	On Time	4/23/24
Finite Element Analysis via Solidworks	Shilo	On Time	4/23/24
Revised Matlab and Simulink for Jaw Testing (HW#4)	Cassina	On Time	4/23/24
Prototype #2	All	On Time	4/29/24
HW #4	All (Individual)	On Time	5/1/24

Table III – Scheduling Table

Thank you!

Questions?

NAU NORTHERN ARIZONA UNIVERSITY

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.
- [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.
- [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).
- [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).
- [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
- [16] 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.
- [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.
- [20] 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
- [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