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:

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

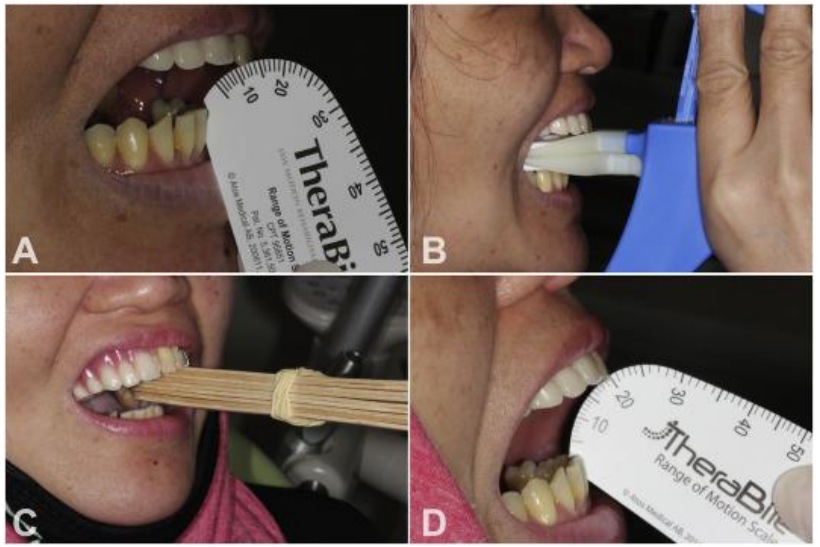


Fig. 1 - Science Direct V16 I1 doi.org

Black Box Model

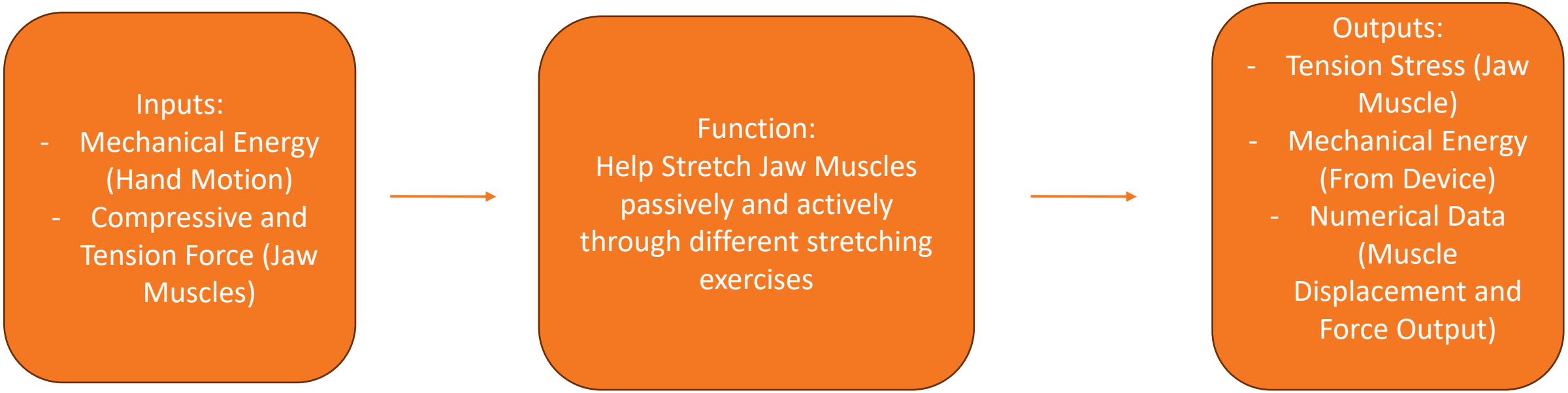


Fig. 2 - Black Box Model

Nathan: 2

Functional Decomposition

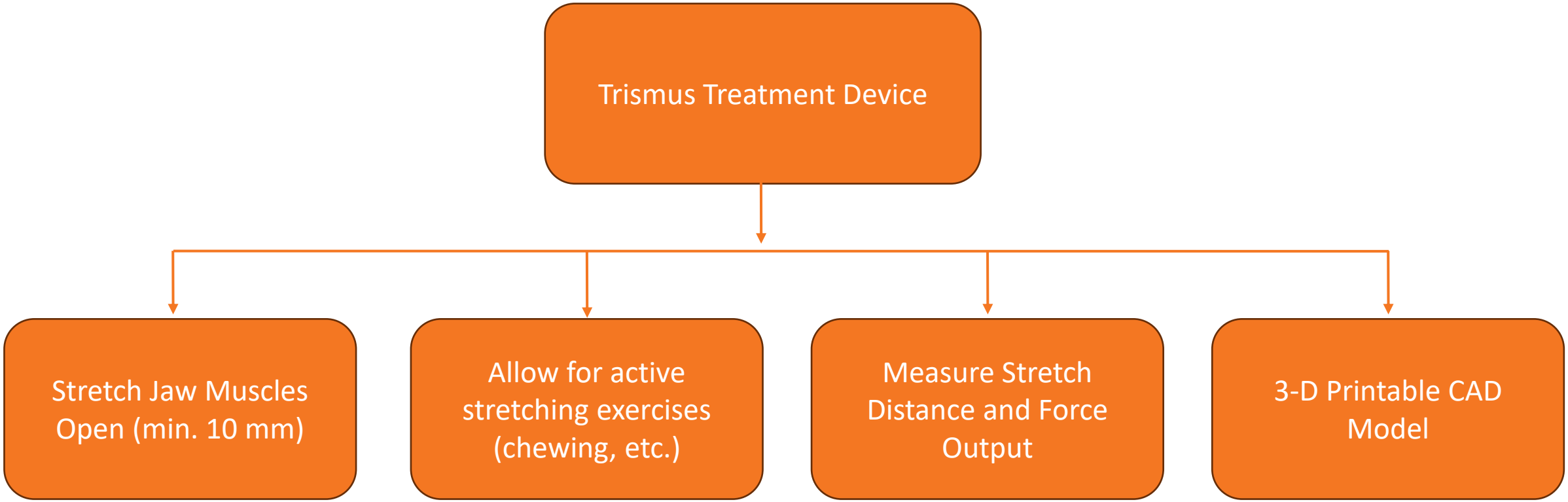


Fig. 3 – Functional Decomposition

Nathan: 3

Concept Generation

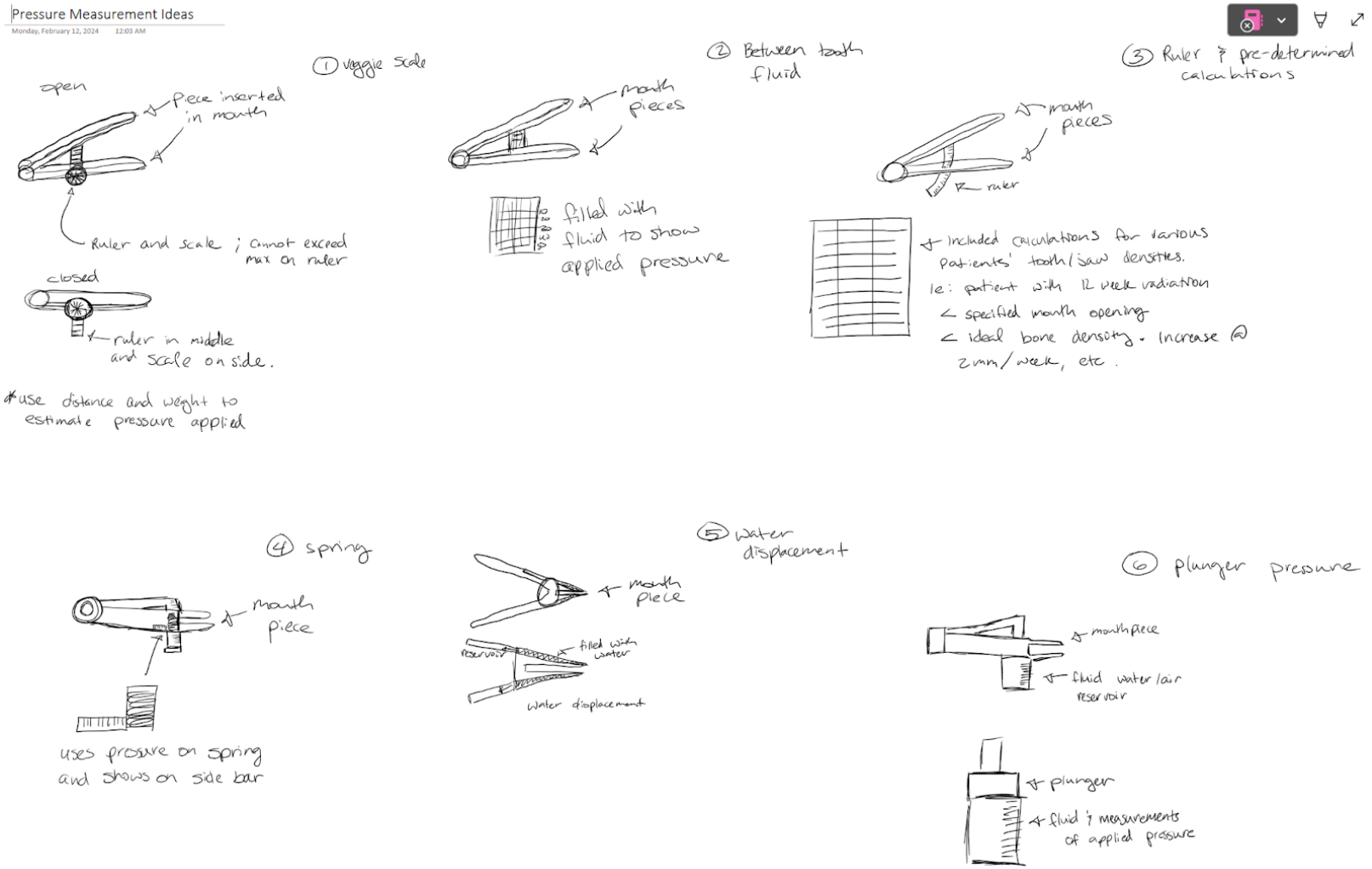


Fig. 4 – Pressure Measurement Systems

Concept Generation

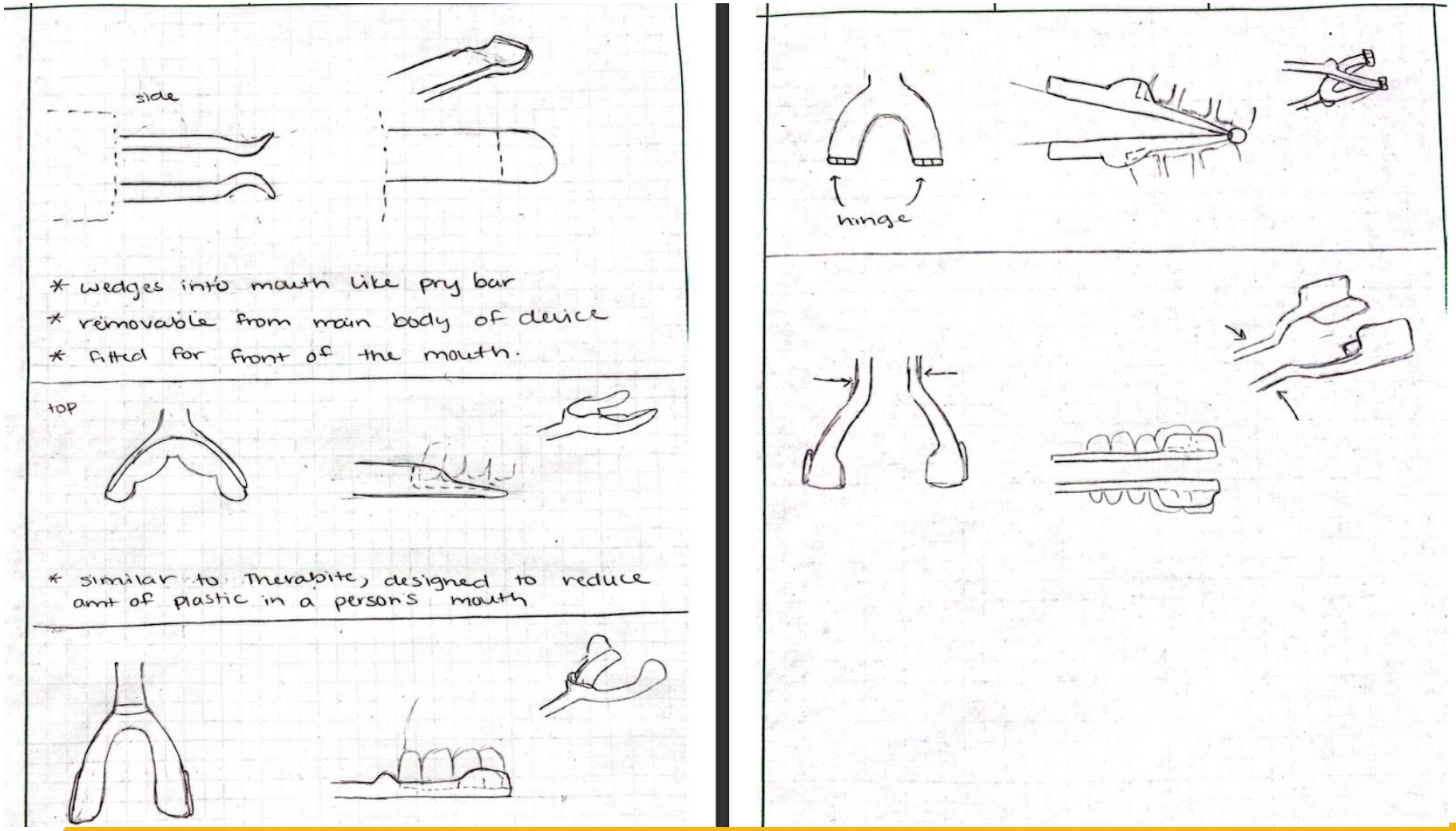


Fig. 5 – Mouthguards Designs

Concept Generation

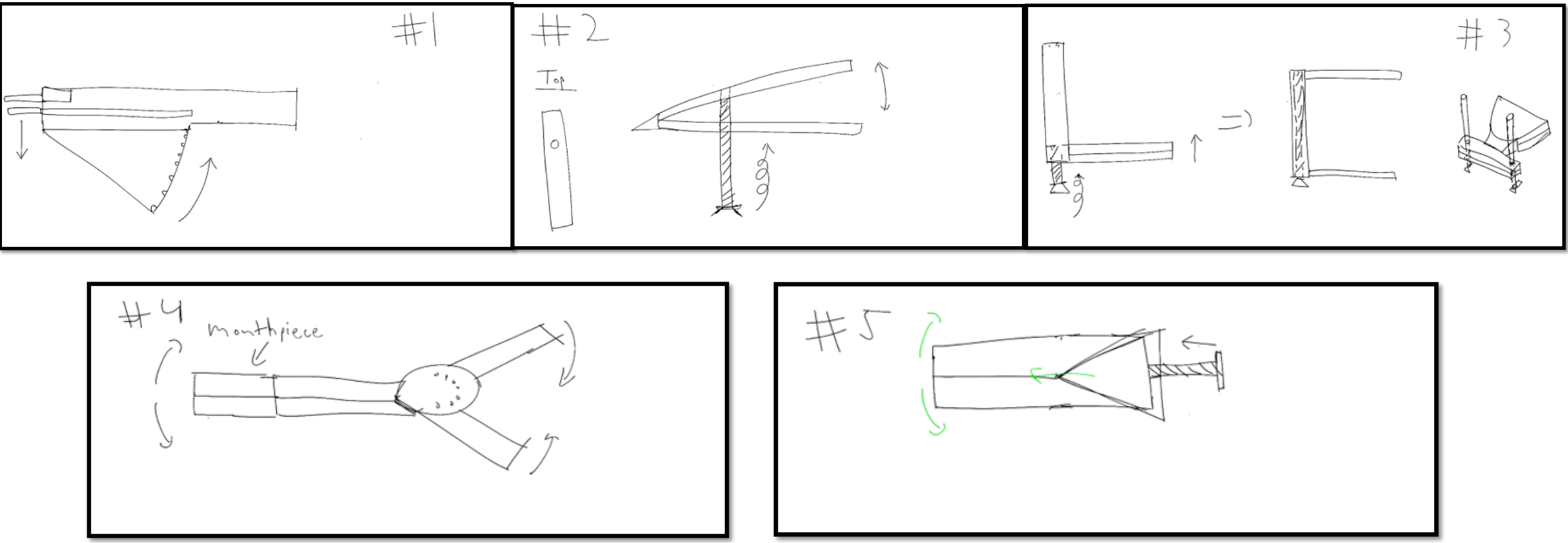


Fig. 6 – Mechanical Systems

Concept Generation

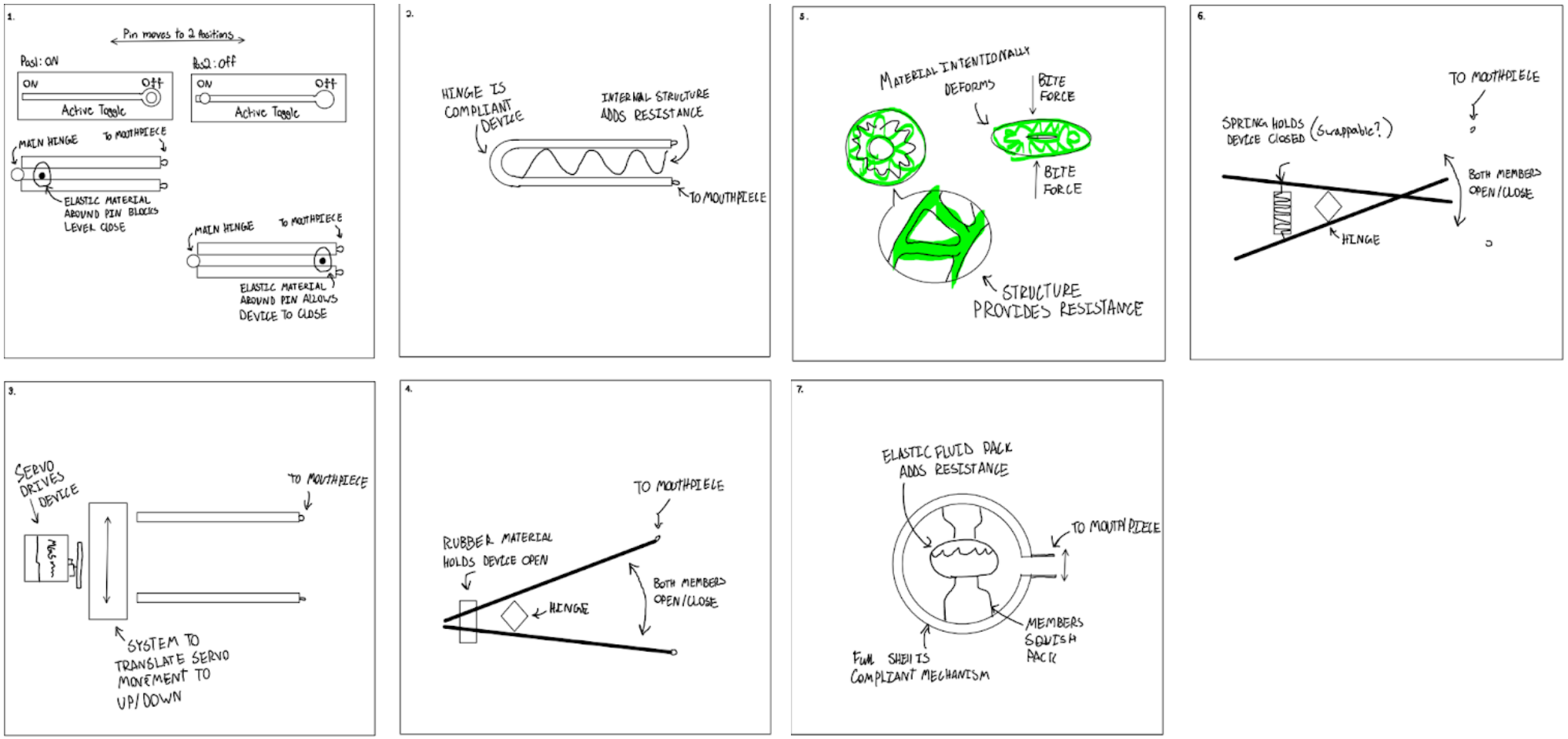


Fig. 7 – Active Resistance Systems

Alternative Designs

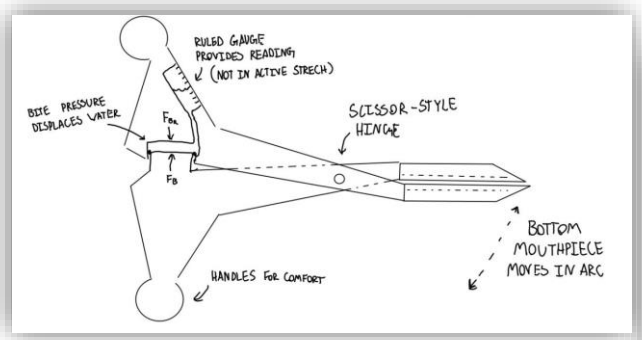


Fig. 11 – Alternative Design 4

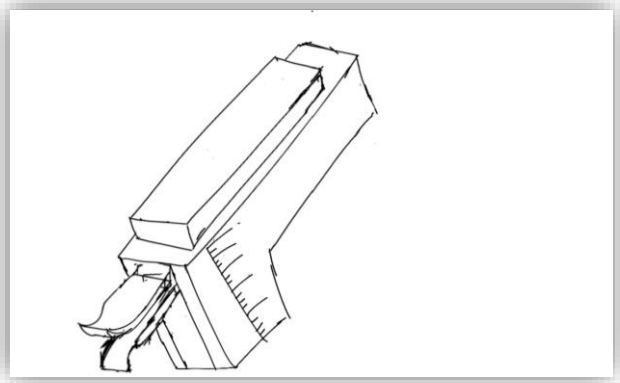


Fig. 8 – Alternative Design 1

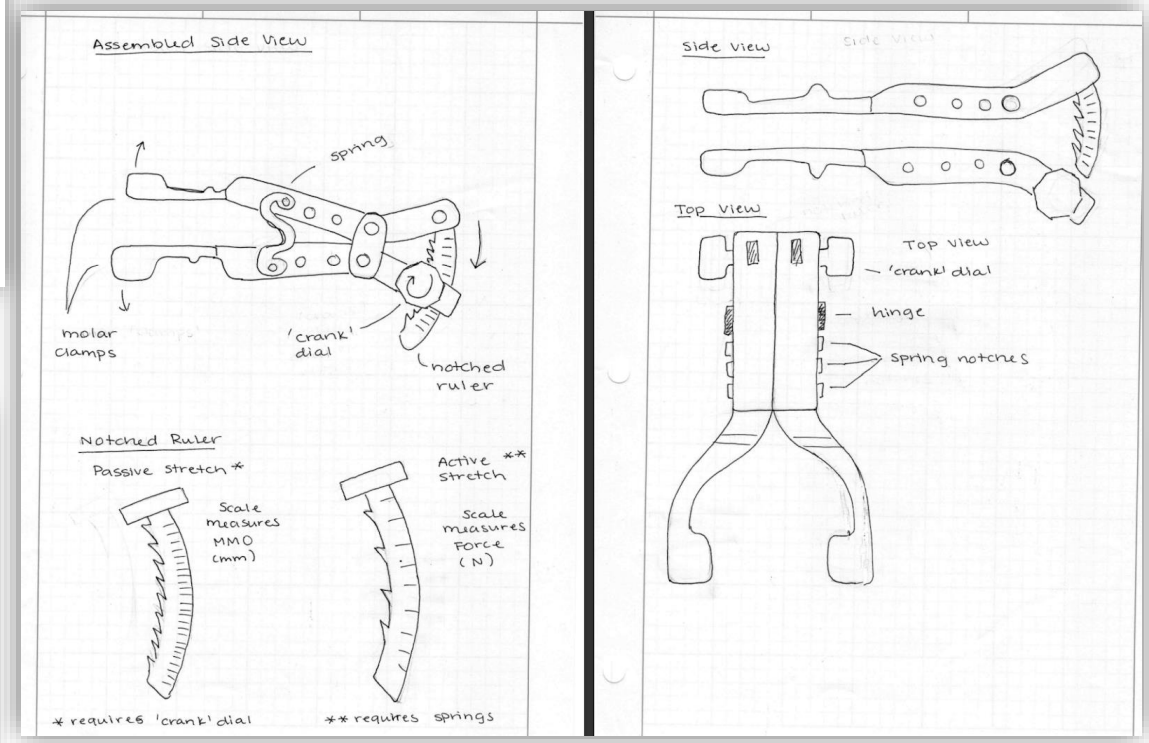


Fig. 10 – Alternative Design 3

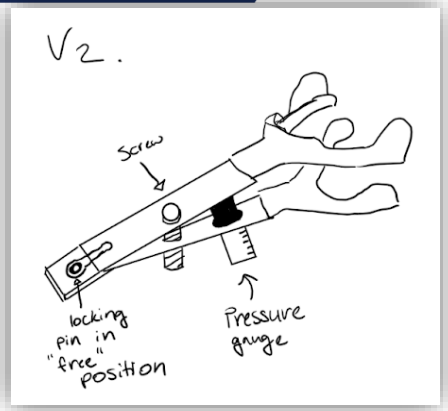


Fig. 9 – Alternative Design 2

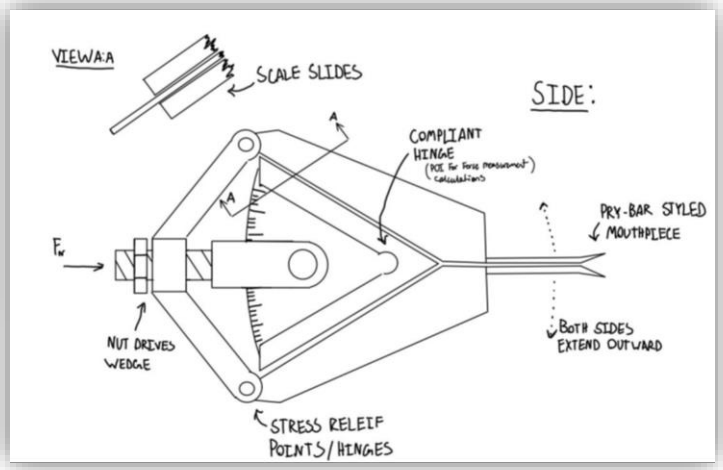


Fig. 12 – Alternative Design 5

CAD - Mechanical:

- Max Depth: ~75mm
- Min Depth: ~5mm
- Compliant Spring Feature
- Plate connects both arms
- Mouthpiece Tabs Fit between gaps in back teeth

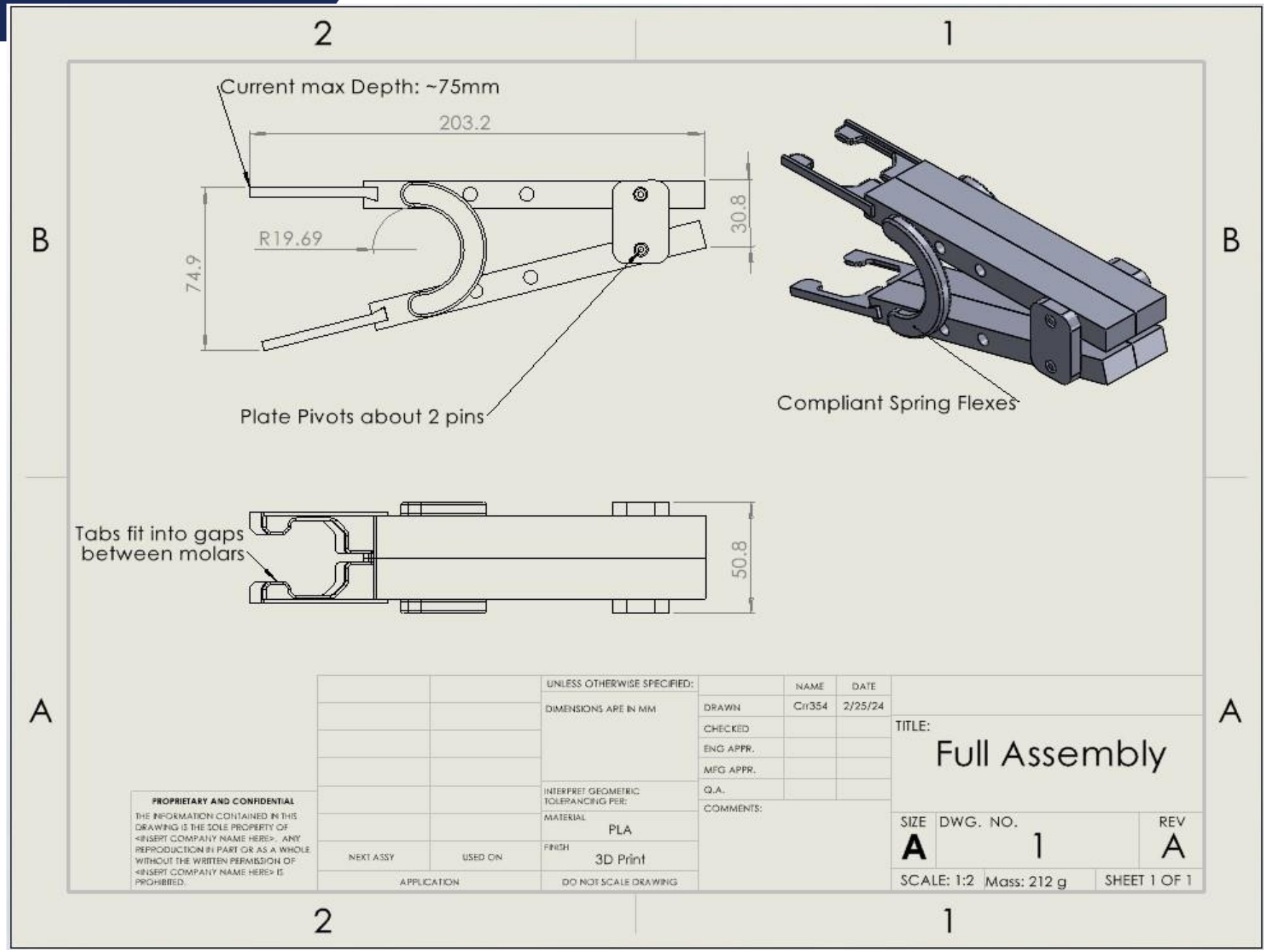


Fig. 13 – CAD Model Drawing

CAD - Measurement:

- Max Measured Depth: ~58mm
- Min Measured Depth: ~0mm
- Dial and Graded surface
- Graded surface calculates force

  based on compliant spring

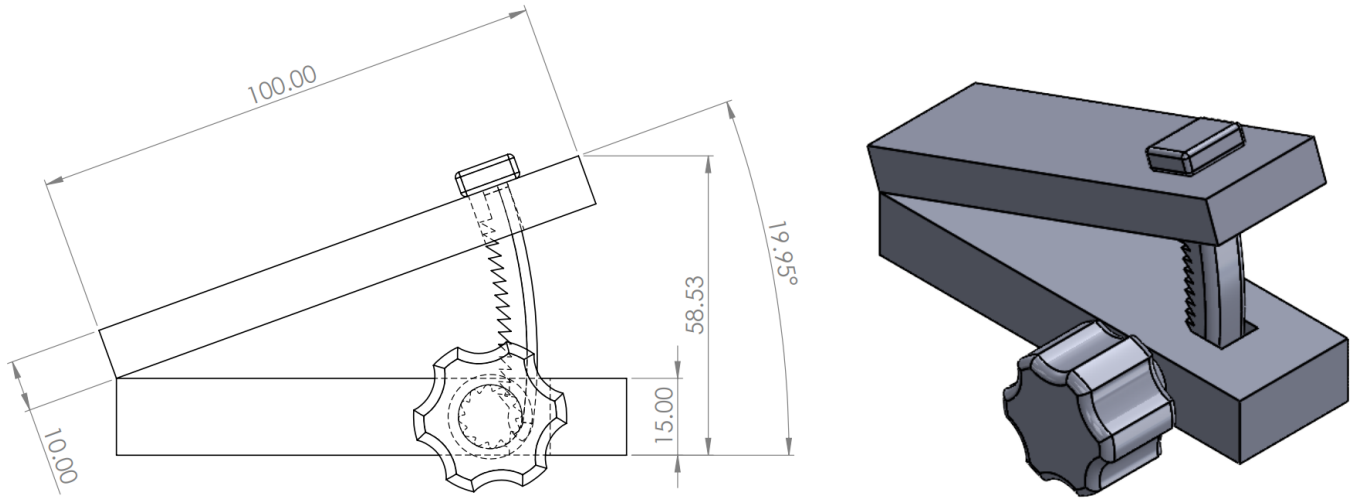
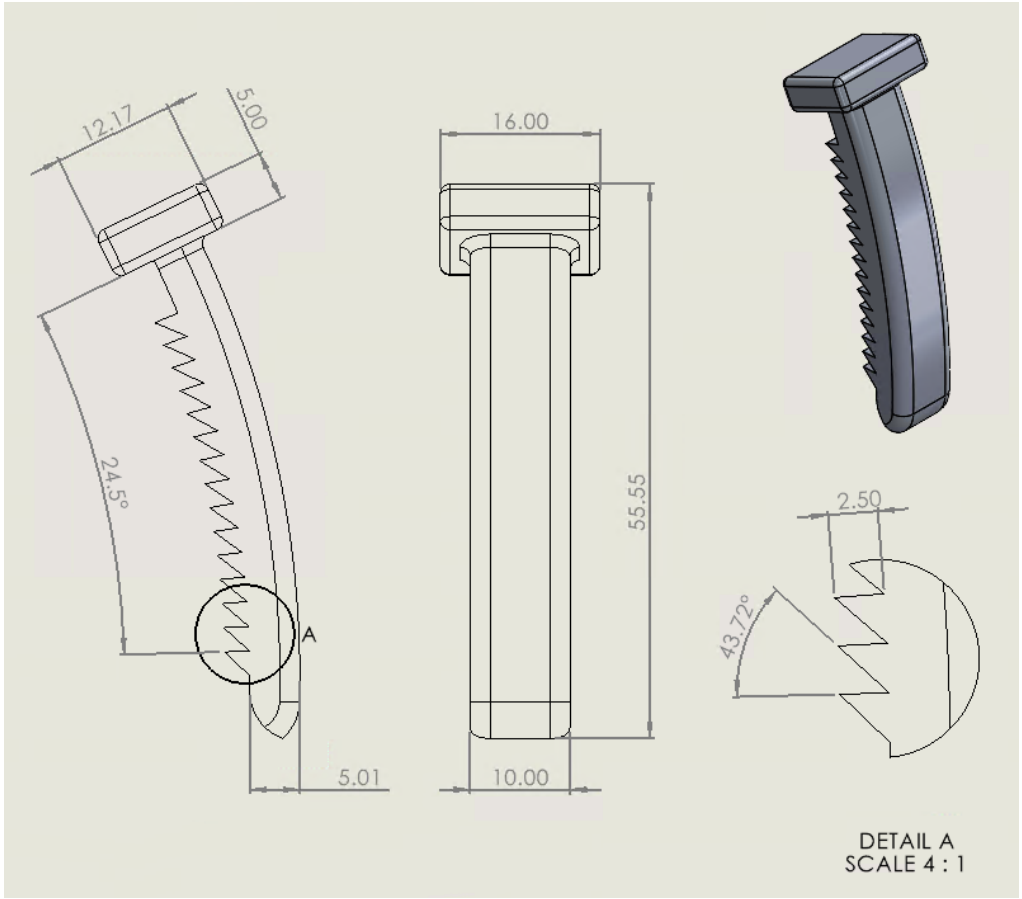


Fig. 14 – CAD Model: Dial-Measurement System



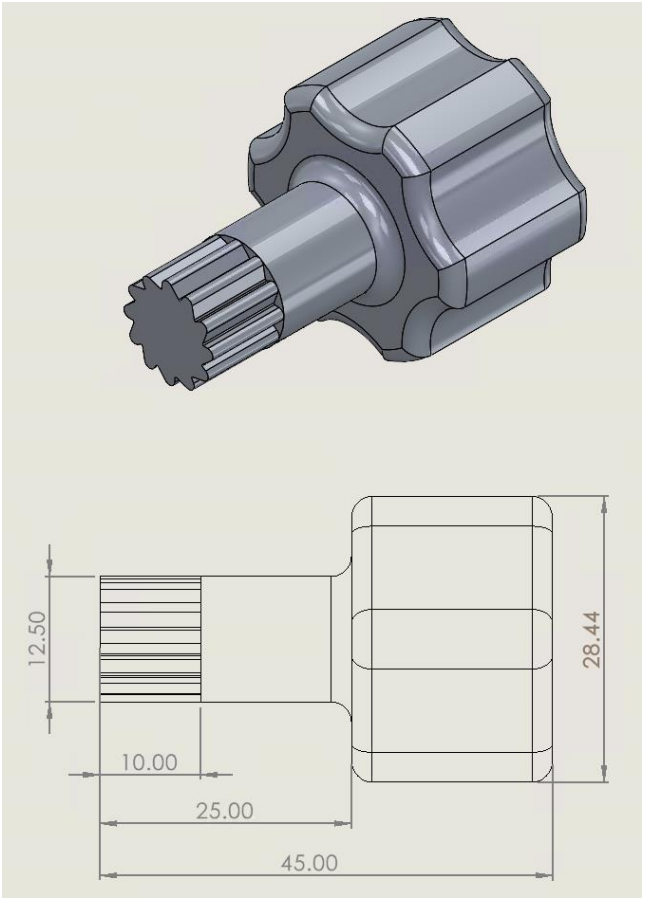


Fig. 15 – CAD Drawing: Dial-Measurement System

Engineering Calculations: Compliant Spring

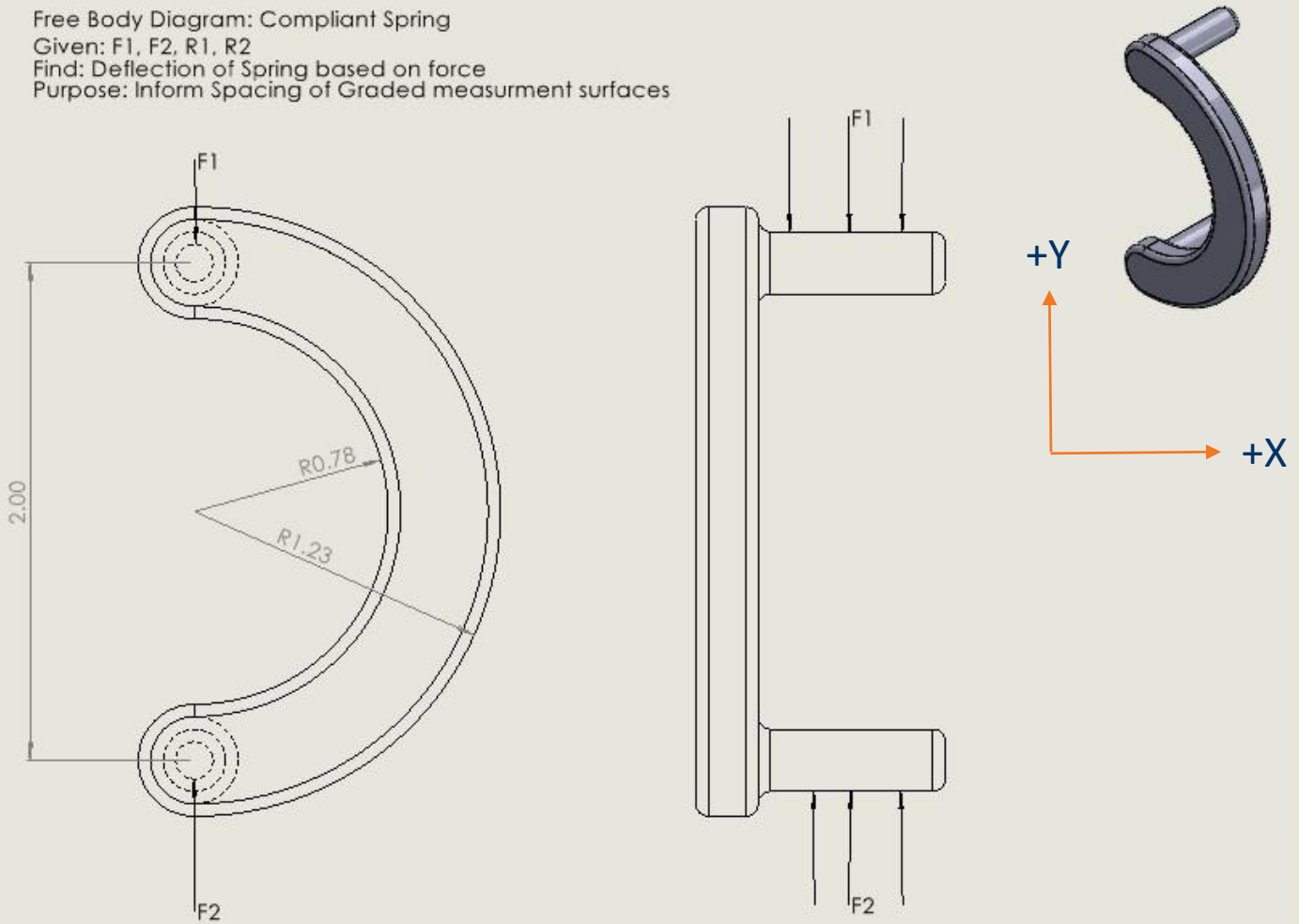


Fig. 16 – CAD Compliant Spring Model

Goals:

- Inform Spacing of Graded force measurement surfaces based on Bite forces
- Identify failure points

Knowns:

- Fr and F2 are evenly distributed across connection pins
- Thickness of Spring

Find:

- Deflection of Spring in Y-Axis based on F1 and F2
- Min Connection Pin Diameter before shear failure
- Max Deflection overall Before Failure

Note: General variables and formulas used for clarity, Calculations apply to all dimensions

Results: Spring Translation Preliminaries

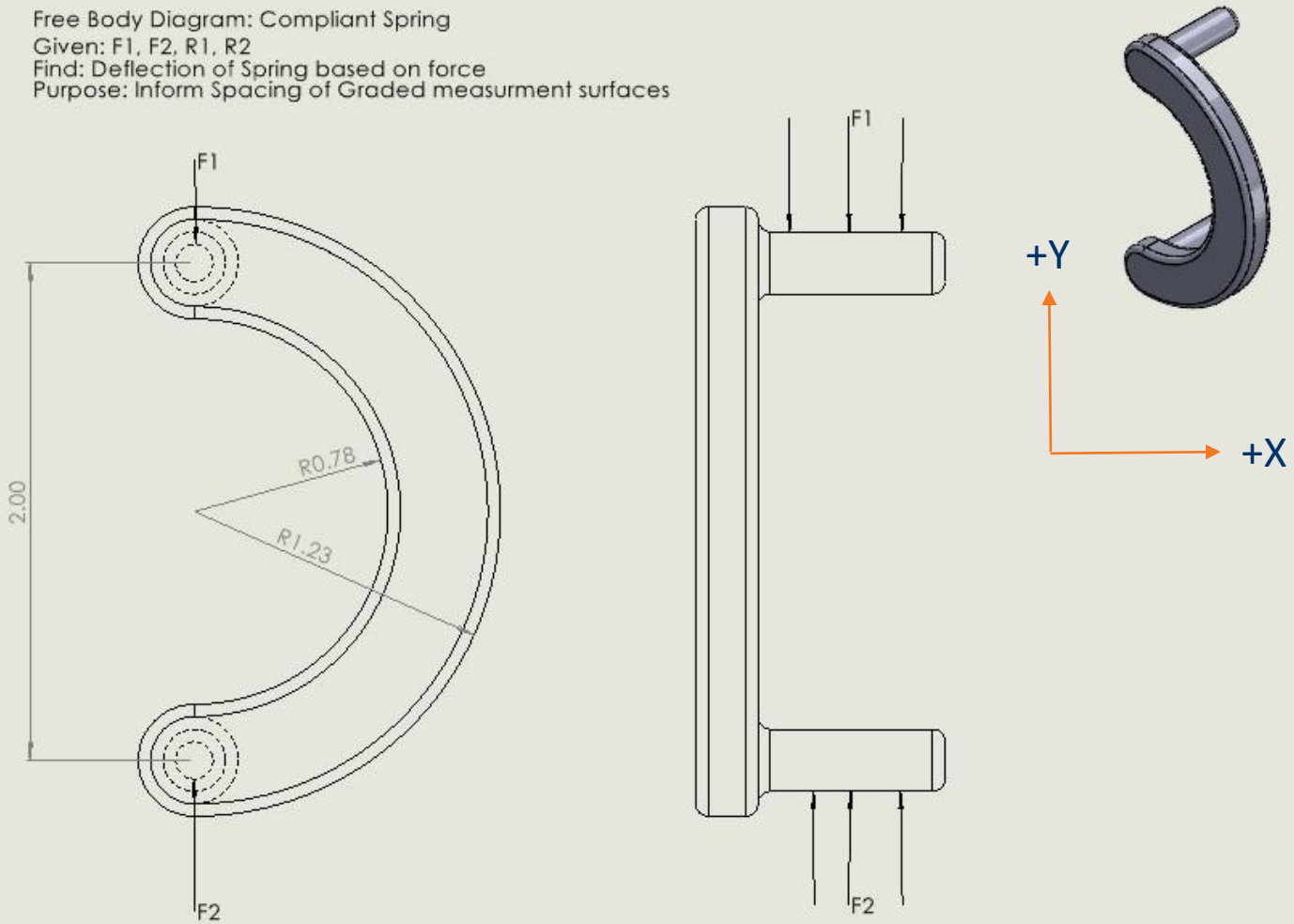


Fig. 16 – CAD Compliant Spring Model

Deflection:

$$PE = \frac{1}{2}kx^2$$

$$x = \sqrt{\frac{2 \cdot PE}{k}}$$

- PE = potential Energy
- K = Spring Constant
- X = Deflection

Max Possible Bite Force:

$$\sigma = \frac{F}{A}$$

$$\varepsilon = \frac{\sigma}{E}$$

$$F_{Max} = \sigma_{Yeild} \cdot A$$

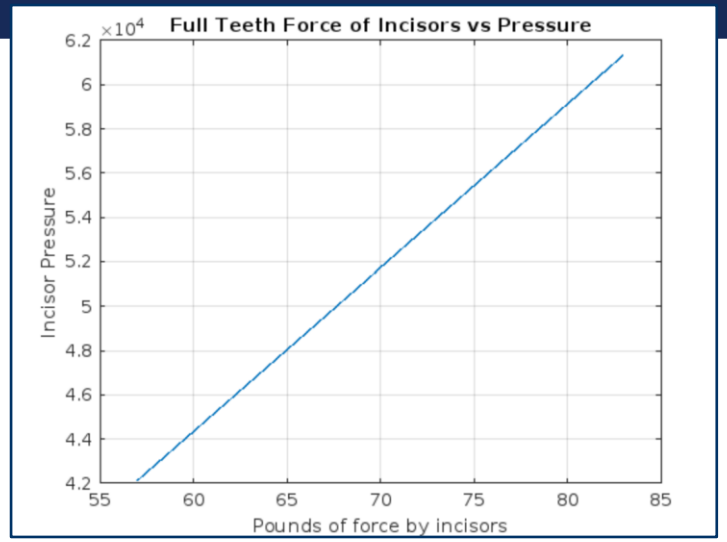
- *σ = Stress*
- *ε = Strain*
- A = Cross section area
- F = Force
- E = Young's Modulus

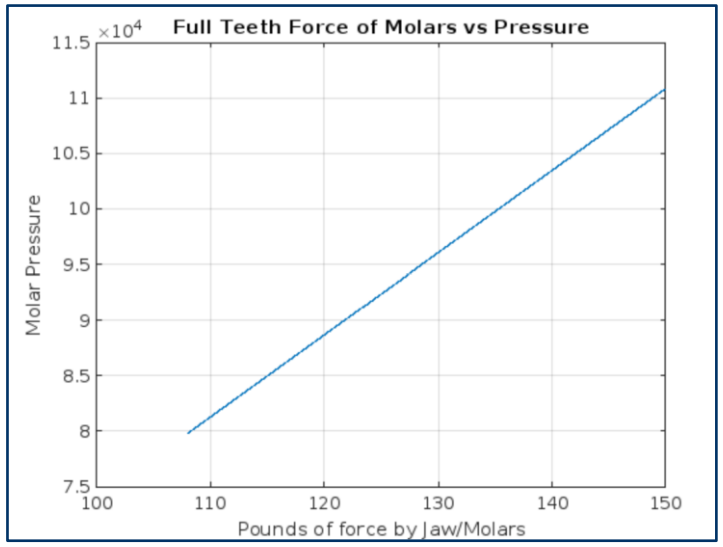
Resistance Force from Spring:

$$F = \sigma \cdot A$$

*This will be iteratively translated to the ruled surface on the back of the device *

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)
```

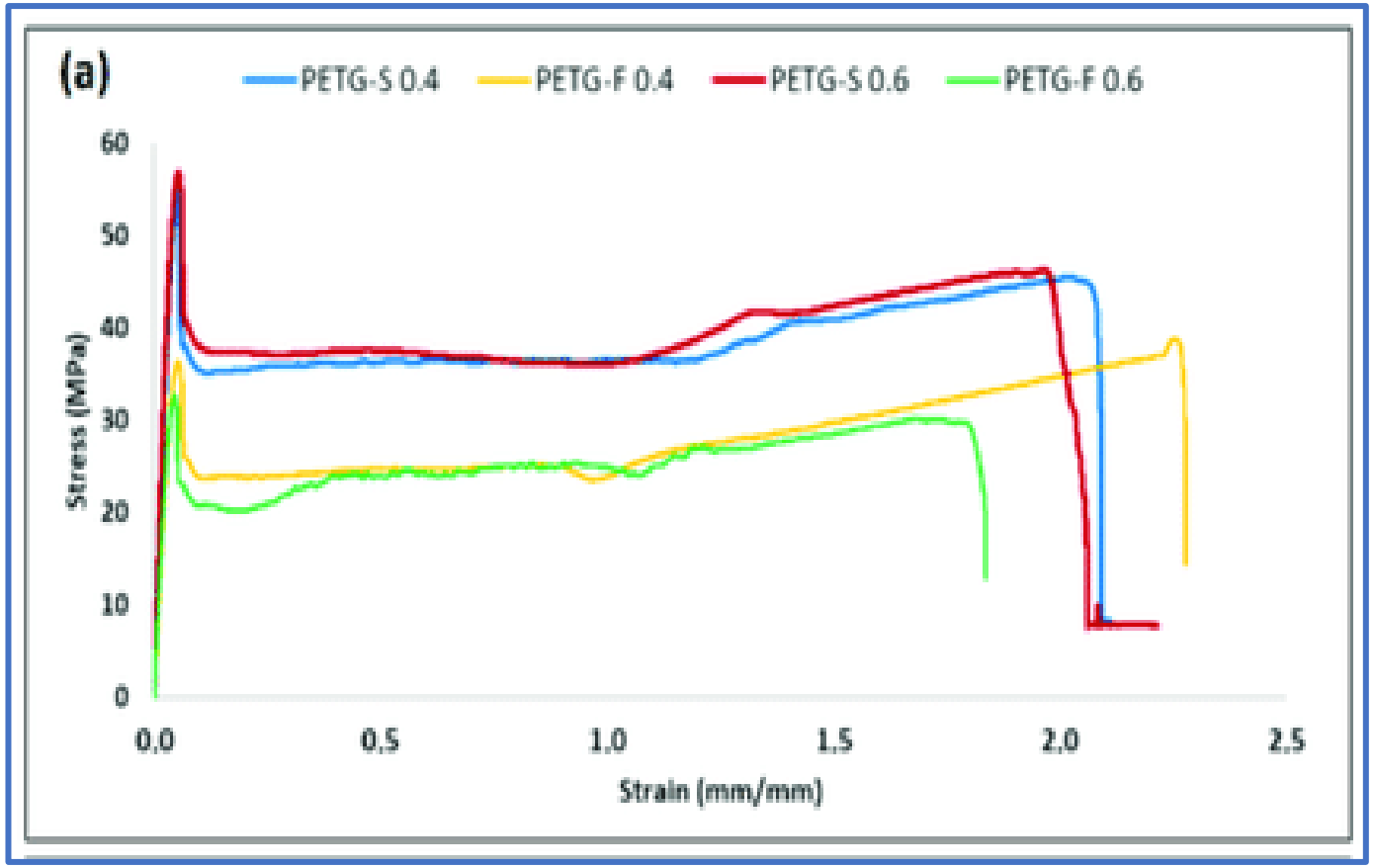
Goals:

- 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. 17 – Full Teeth Incisors and Molars v Pressure

Engineering Calculations: Material Tolerances

- Material: PETG Plastic
- Mechanical Properties:
  - 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



3D Slicer: Ultimaker Cura

Printer: Creality Ender 3 (V2)

Settings:

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

Total Estimated Print Time =
~17 Hours/Assembly

Concept Evaluation: Decision Matrix

Background

Criteria	Weight	Current Solution :TheraBite		Alternate Design 1		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	Rating (0-10)	Weighted Rating	Rating (0-10)	Weighted Rating
Cost (Lower cost scores higher)	30%	1	0.3	7	2.1	6	1.8	7	2.1	4	1.2	9	2.7
Printability	15%	0	0	6	0.9	5	0.75	6	0.9	5	0.75	8	1.2
Print In Place	5%	0	0	8	0.4	3	0.15	2	0.1	2	0.1	7	0.35
Safe	20%	5	1	5	1	5	1	5	1	5	1	5	1
Open Source	5%	0	0	9	0.45	8	0.4	8	0.4	5	0.25	9	0.45
Adaptability	10%	8	0.8	6	0.6	7	0.7	8	0.8	6	0.6	6	0.6
Force Measurement?	15%	3	0.45	7	1.05	6	0.9	8	1.2	3	0.45	8	1.2
Total Percentage:	100%	Total Option A:	2.55	Total Option B:	6.5	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

Note: Safety Rating remains neutral until safety testing is possible

Table I – Decision Matrix

Concept Evaluation

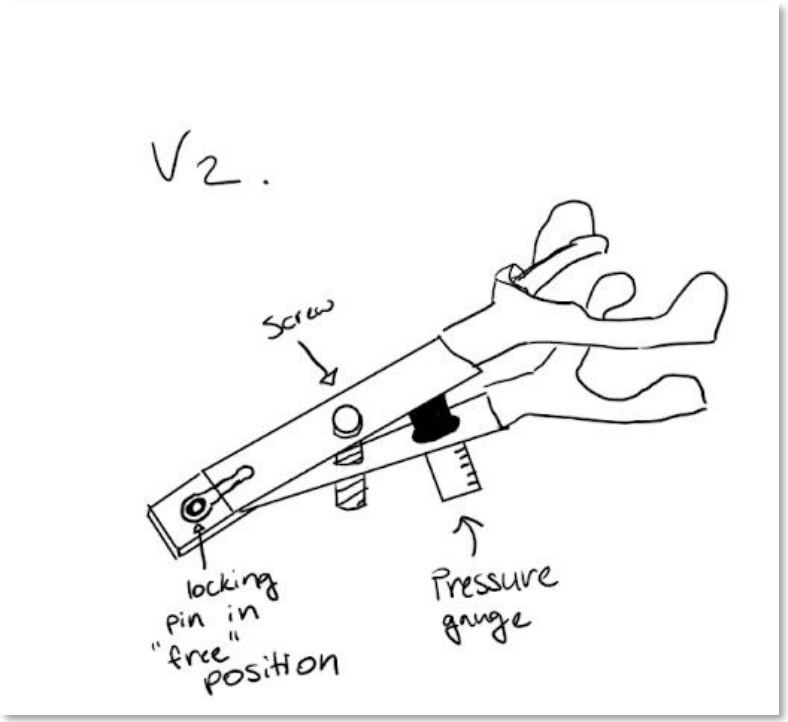


Fig. 9 – Alternative Design 2

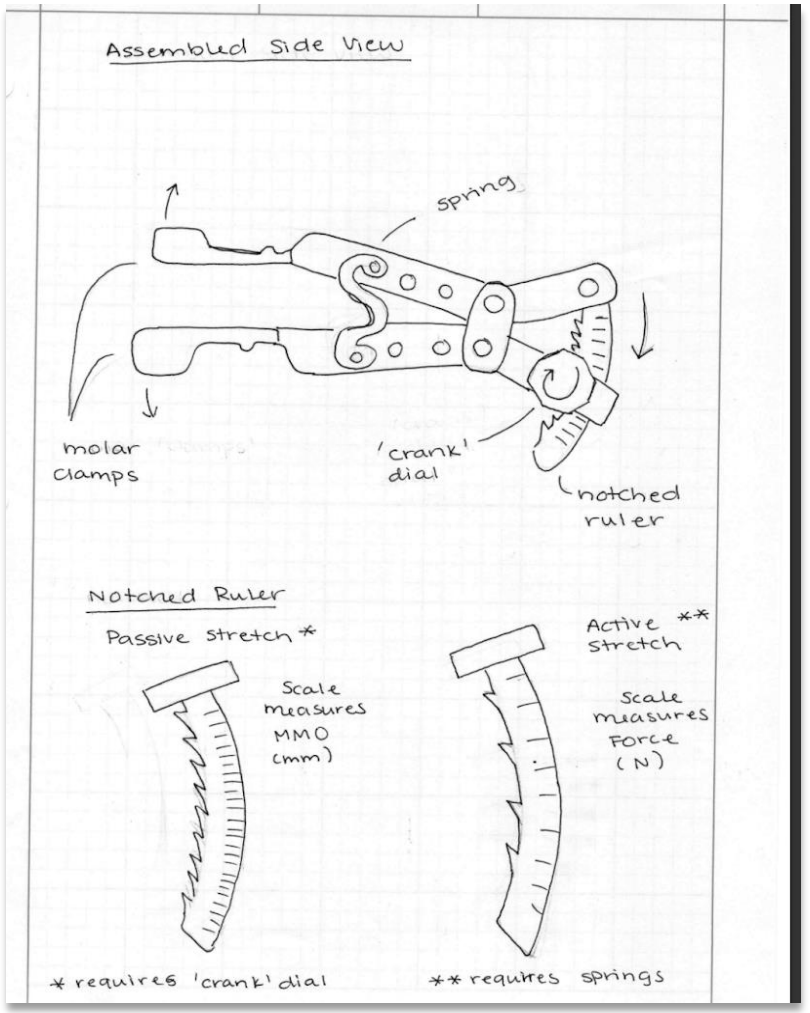


Fig. 10 – Alternative Design 3

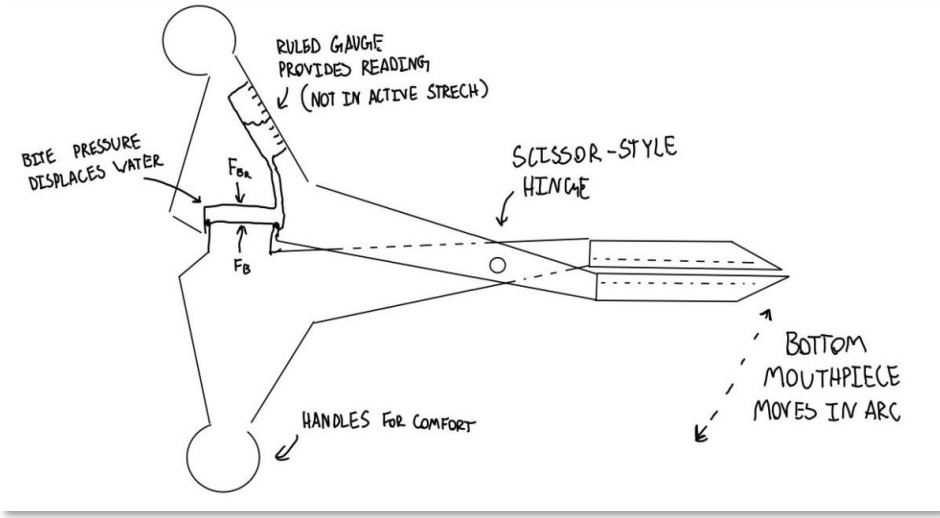


Fig. 11 – Alternative Design 4

Budget

Updates:

- Requested a budget of $200 from the client
  - Approved
- Waiting to receive funds

Fundraising:

- Team donations
  - $100

Next:

- Purchase filament to begin 3D printing

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

Table II – Budget Table

Running Schedule

Main Task:	Team Member(s):	Progress:	Target Completion Date:
Concept Generation	Cassina	Complete	2/26/24
Functional Analysis	Nathan	Complete	2/26/24
Engineering Calculations: "Spring Translation prelims"	Carter	Complete	2/26/24
CAD Mechanical System	Carter	Complete	2/26/24
CAD Measurement System	Shilo	Complete	2/26/24
BOM	Nathan	Complete	2/26/24
Presentation 2	All	Complete	2/26/24
Report #1	All	On Time	3/3/24
Website Update #1	All	On Time	3/15/24

Table III – Scheduling Table

Tentative Bill of Materials

Total Approximate Cost:	$8.58

Item	Part No.	Desc.	Material Use (cm^3)	Appx. Cost/Part ($.05/cm^3)	Qty.
Top Arm	01	Main body of device	33.920	$1.70	4
Pry Bar	02	Mouthpiece side #1	1.875	$0.09	2
Pry Bar Mirror	03	Mouthpiece side #2	1.875	$0.09	2
Compliant Spring	04	Provides active resistance to jaw articulation	7.518	$0.38	2
Connector	05	3D printed dowel to connect all parts	1.019	$0.05	2
Connection Plate	06	3D printed plate to act as a joint for device motion	5.523	$0.28	2

Table IV – Current Bill of Materials

Thank you!

Questions?

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