3D Printed Surgical Implant Expo Presentation

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Meet the Team

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Agenda

1) Background, Problem, & Objectives
2) Overview & Requirements
3) Uniaxial Tensile Testing Machine
   i. Design & Hardware
   ii. Electronics & Software
4) 3D Printed Implant
   i. Design
   ii. FEA Simulation
5) Conclusion

Background

- Pelvic organ prolapse (POP)
  - ~ 50% parous women, ~ 37% women age 60+

No prolapse | Stage I | Stage II | Stage III | Stage IV

Figure 1: POP progression [1]

- Treatments
  - Pessary
  - Pelvic floor muscle therapy
  - Surgery
    - ~ 5 years

Problem

- Current implant limitations
  - Failure rate is reaching 40%
  - Material
  - Geometry and materials are same for all patients
- Manufacturing (3D printing solution)
  - Medical environment
  - Biomaterial filament
  - Personalized for patient specific needs

Figure 2: 3D Printer *Creality Ender 3* [2]

Objectives

- Design an implant that has the correct anisotropic behavior of human pelvic tissue by:
  1. Researching healthy pelvic tissue properties and obtaining the desire stiffness range.
  2. Research and pick an attainable polymer that is considered biomaterial, safe for implant use.

- Design and build a uniaxial tension testing machine that can:
  1. Provide displacement and force feedback
  2. Test the 3D printed implant for its stiffness ratio

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Anisotropic Properties

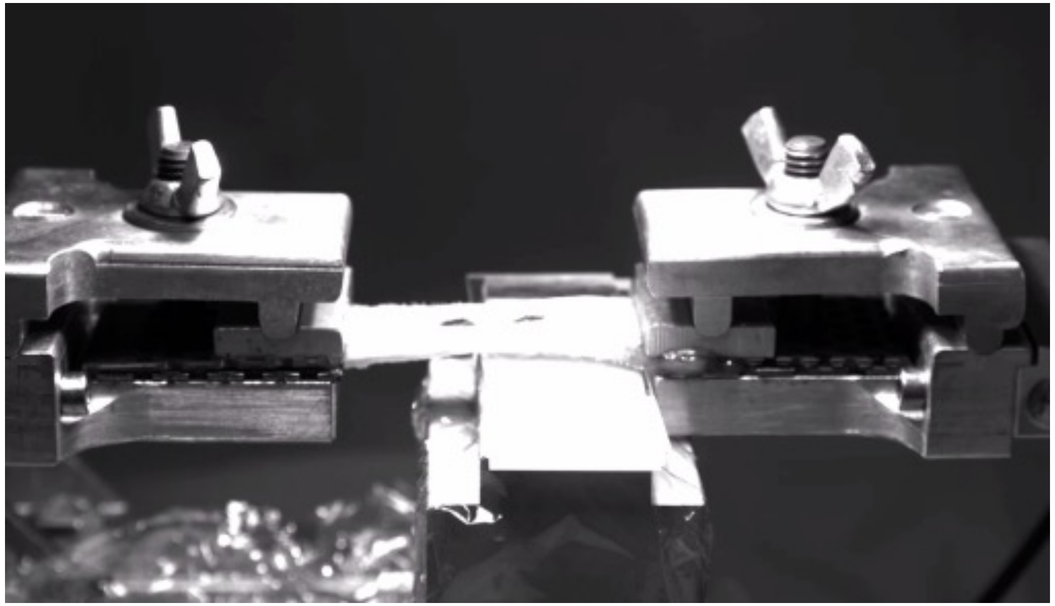

Figure 3: Uniaxial USL Test

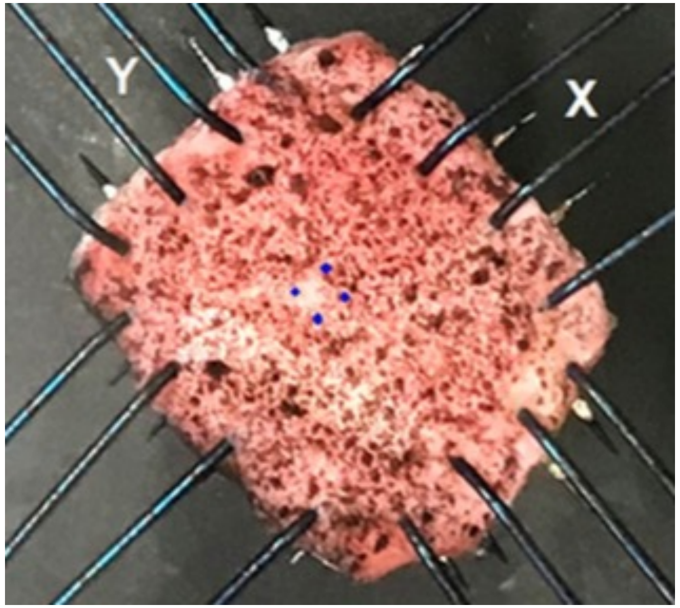

Figure 4: Biaxial USL Test [3]

Anisotropic Properties

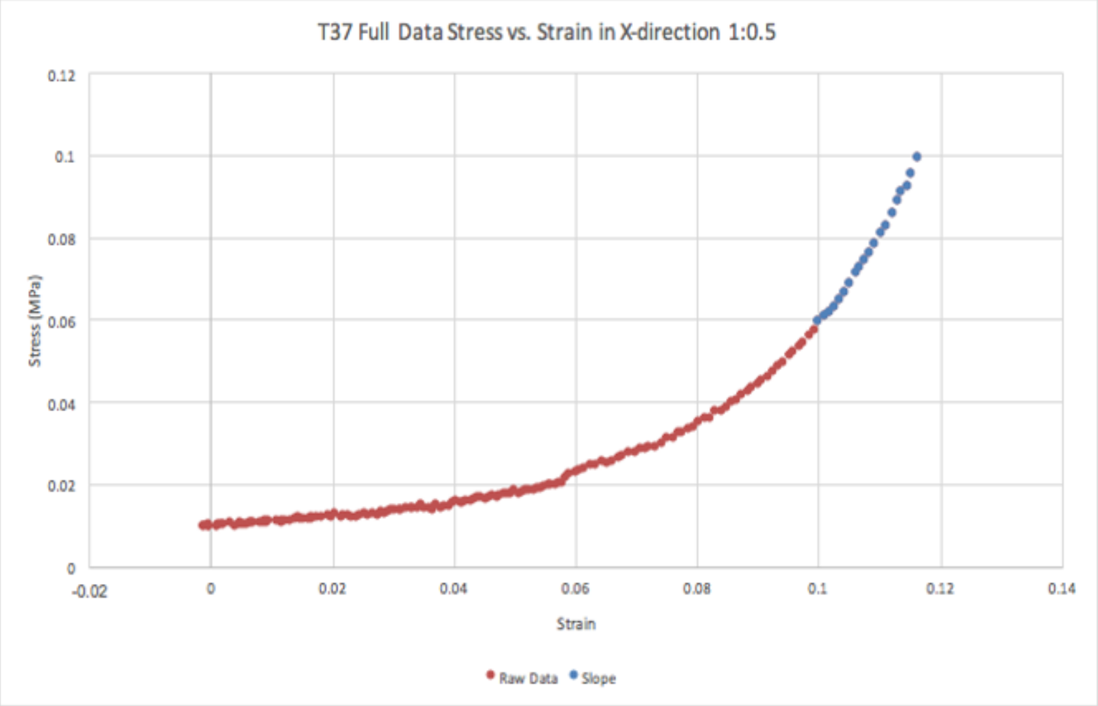

Figure 5: graph of sample T37 data in the x-direction

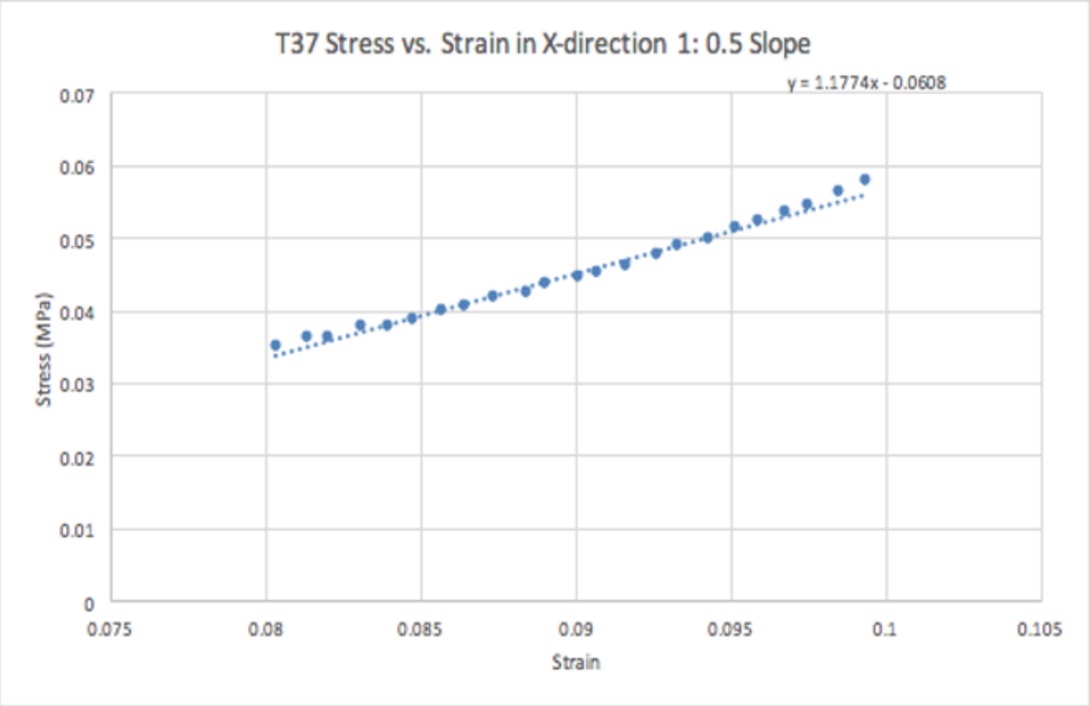

Figure 6: graph of sample T37 data in the x-direction

Pelvic Tissue Properties

Table 1: Comparison of biaxial and uniaxial stiffness

Utero-sacral ligament		
Biaxial Loading		Uniaxial Loading [4]
x-direction (MPa)	y-direction (MPa)	Loading (MPa)
6.3 (± 5.12)	2.96 (± 1.19)	1.9

Project Requirements

Table 2: Requirements & Capability of the project

No.	Title	Requirement	Capability	Method of Verification (A=Analysis, T = Test, D = Design)
1	Implant Material	Biopolymer	Ideal (PLGA) For this Project (PLA)	A
2	Implant Machinability	3D Printable	Creality Ender 3 printer	A
3	Implant Behavior	Anisotropic behavior for healthy pelvic tissue	Stiffness Ratio of 0.467	D, T
4	Testing Machine Design	Minimal manufacturing	Complies, 3D printed parts	D
5	Testing Machine Sensors	Forces and displacement	Complies, with Loadcell and servo motor code	D

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Hardware – Machine Build

Uniaxial Tensile Testing Machine

Machine Goals

- Predict performance: normal and extreme
- Assess requirements being met
- Demonstrate proof of 3D printed concept
- Provide Data
- Provide comparison between printed options

Machine Parts

A. Motor
B. Carriage
C. Rail
D. Ball & Screw device
E. Housing Block
F. 3D Printed Supports/Brackets
G. Grips (pre-design)
H. Extrusion Base
I. Limit Switch
J. Load Cell
K. Lead screw

Preliminary CAD V1

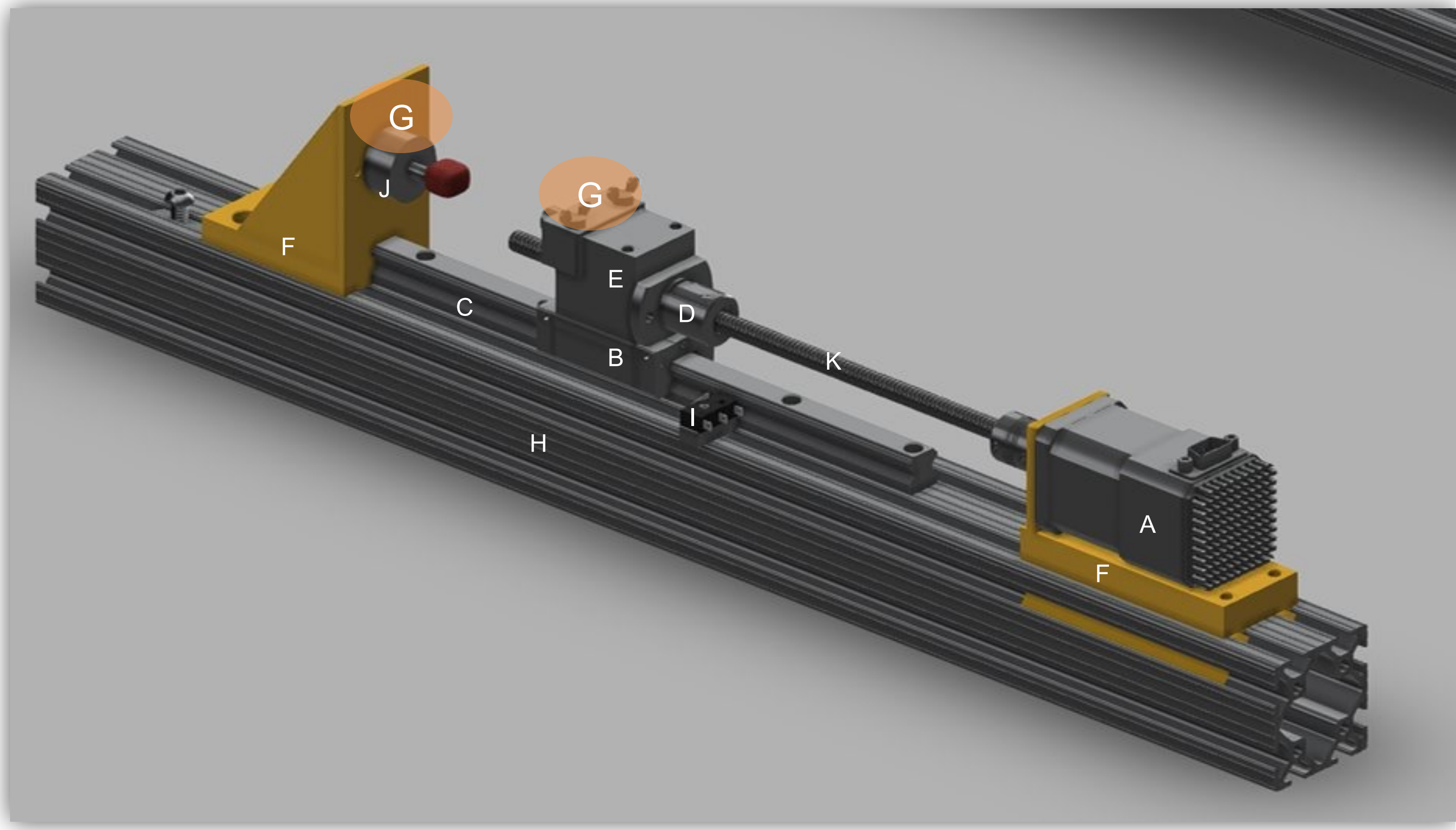


Figure 5: Version 1 concept of the uniaxial tensile testing machine designed in *Fusion 360*

Hardware – Machine Build

Design and Manufacturing Process

Parts Ordered

- 600mm 20x20x20 Al. Profile Extrusion
- 250mm Linear Rail Guide with Carriage
- 550mm Ball Screw Kit with Al. Housing Block
- Float Support & Fixed Support Blocks
- Momentary Micro Switch
- Tension/Compression Load Cell Sensor
- Motor Shaft-to-Screw Coupler
- Miscellaneous Metric Hardware & Fasteners

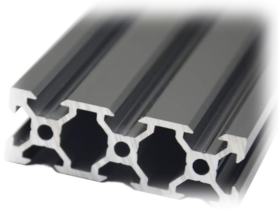


Fig. 6: 2060 Al. triple extrusion from: amazon.com/Iverntech

Fig. 7: Linear rail guide and carriage from: amazon.com/ReliaBot

Fig. 8: Ball Screw kit with both supports, aluminum block, and coupler from: amazon.com/N\C

Fig. 9: Micro limit switch from: amazon.com/URBEST

Fig. 10: Load cell sensor (0-20kg) Ato.com

Hardware – Machine Build

Design and Manufacturing Process

All parts designed in AUTODESK FUSION 360

Parts Designed for 3D Printing

- Float support bracket with load sensor housing (left)
- Fixed support bracket housing (right)
- Aluminum block housing for moving grip attachment
- Fixed grip with compression plate
- Moving grip with compression plate
- Adjustable limit switch holder/slider

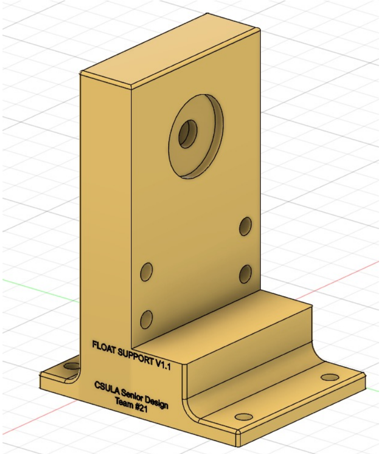


Fig. 11: Float support bracket with load sensor housing

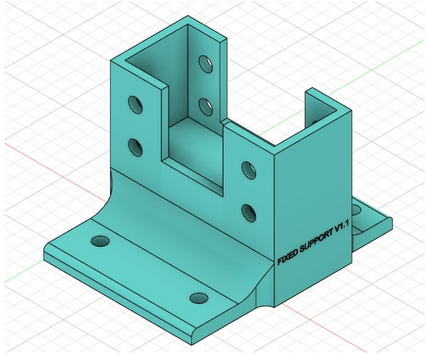


Fig. 12: Fixed support housing

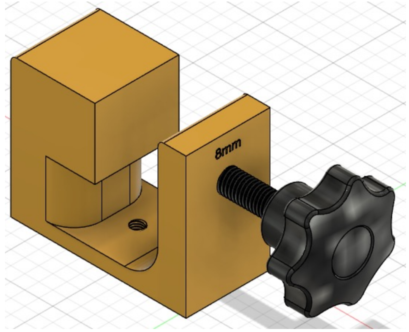


Fig. 13: Fixed grip

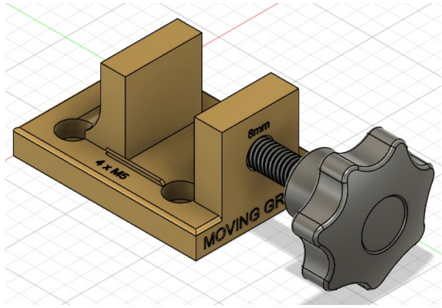


Fig. 14: Moving grip

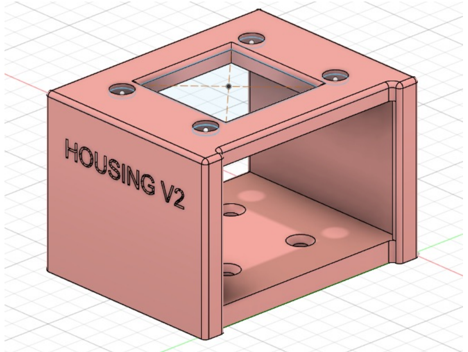


Fig. 15: Aluminum block housing for moving grip

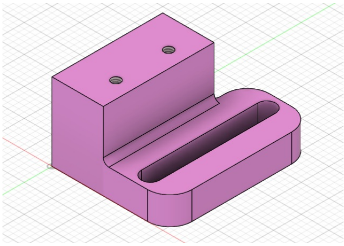
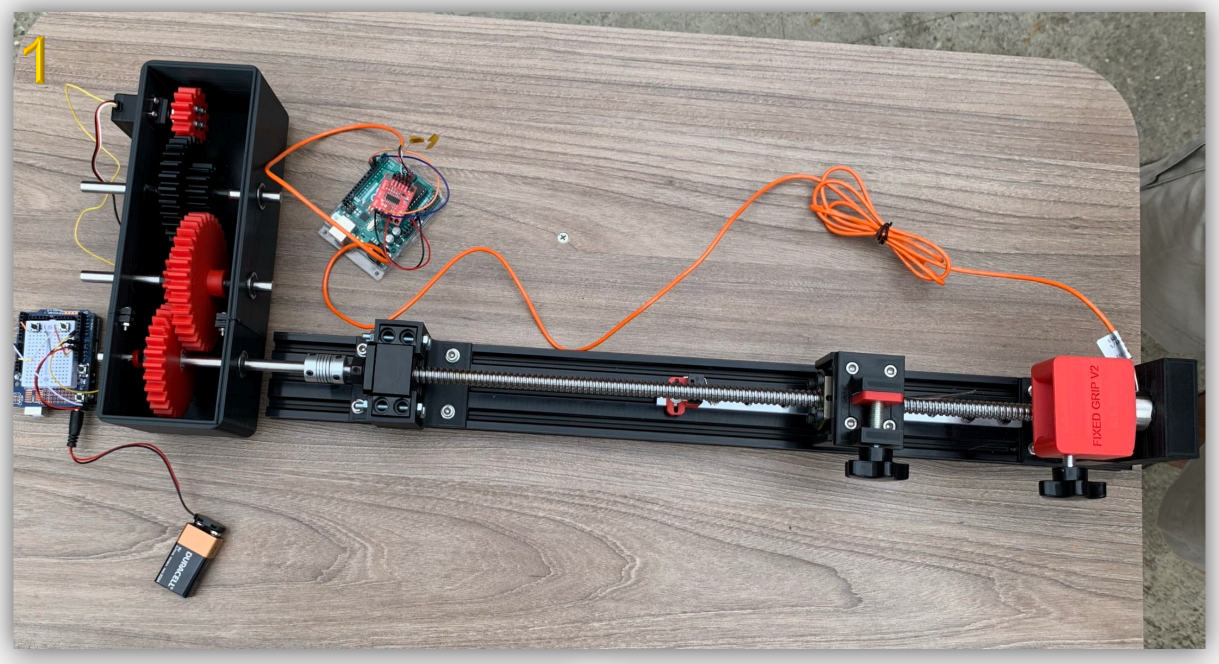


Fig. 16: Limit switch holder/slider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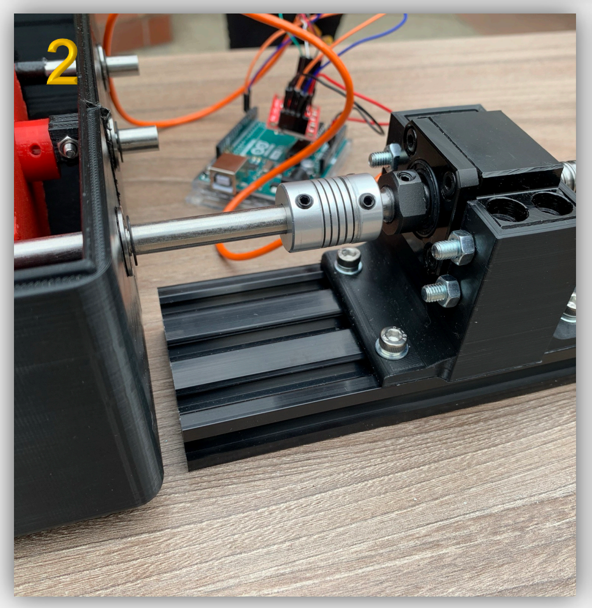
FIXED GRIP V2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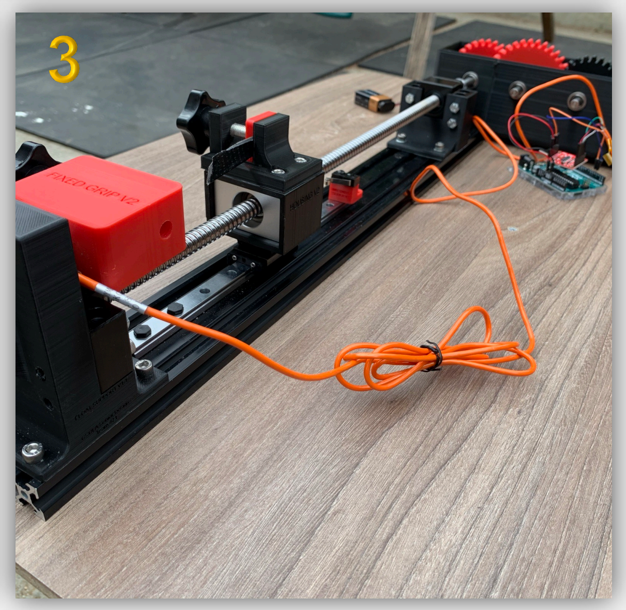
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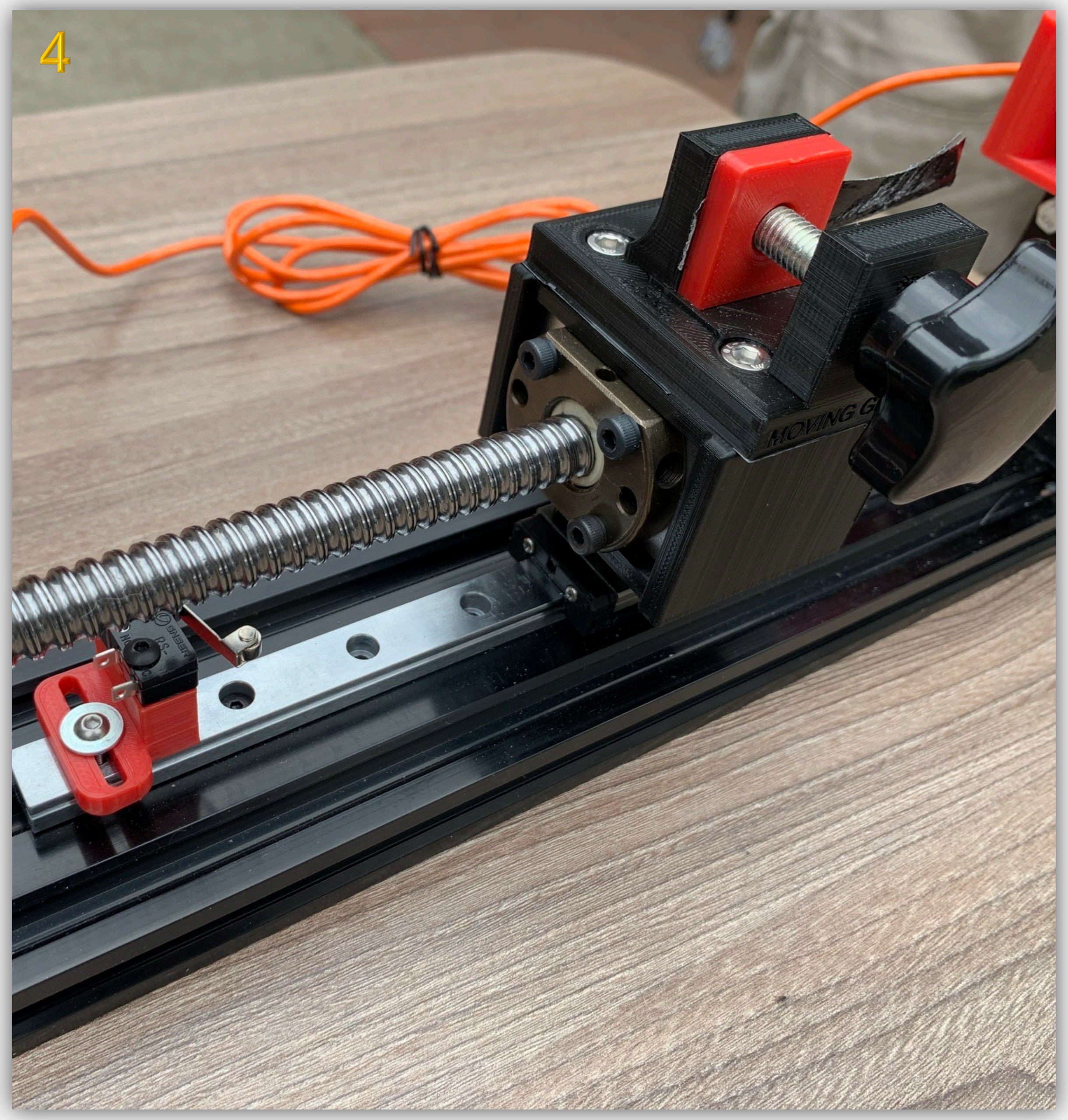

4
MOVING G

Hardware – Motor and Gearbox assembly

Servo Motor Specifications:

- Continuous rotation
- Peak stall torque: 30.5 oz*in
- Angular speed: -120 – 120 rpm with feedback control

Problems:

- Servo Motor directly coupled to lead screw causes unnecessary vibrations
- 50 oz*in torque needed to pull 200 N

Solution:

- Increase torque and decrease speed using a 3D printed gearbox

Servo Motor

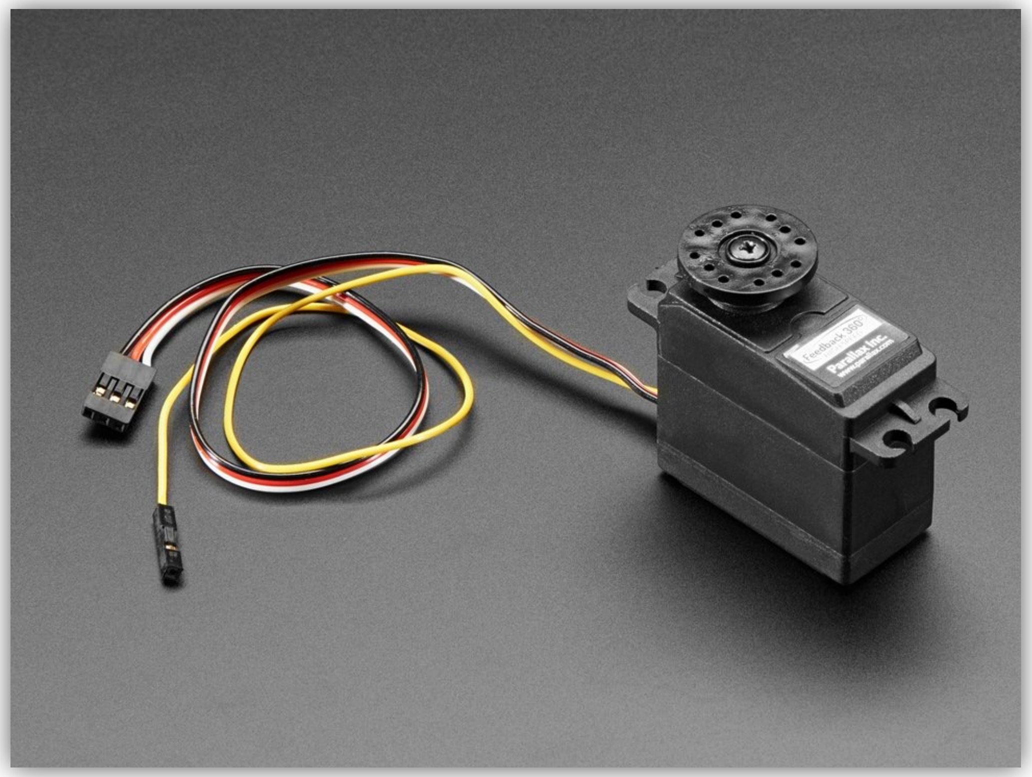


Figure 17: Continuous Rotation Servo Motor

Hardware – Motor and Gearbox Assembly

Constraints, Inputs, and Outputs needed of Gearbox Assembly

- Table shows values needed of gearbox output shaft to satisfy constraints
- Values obtained using principles of kinematics of screw mechanisms

Table 3: Motor and Gearbox requirements

Constraints	
Max Tension force [N]	200
Max displacement [mm]	100
Max speed [mm/min]	20
Duration of test [min]	5
INPUTS	
Pitch diameter [m]	0.0115
Pitch [m]	0.004
Threads/rev [N]	1
Lead [m/rev]	0.004
Coefficient of friction (u)	0.15
Motor input speed [rpm]	50
Motor input torque [oz*in]	30.5
Gear Ratio	10
OUTPUTS	
Output shaft speed [rpm]	5
Output shaft torque (needed) [oz*in]	50
Output shaft torque (actual) [oz*in]	305

Hardware – Motor and Gearbox Assembly

Gearbox and Housing Design

Gearbox Parts

a. 3D printed housing designed using *Fusion 360*
b. 3D printed spur gears designed using *Fusion 360*
c. Servo motor
d. x3 8mm dia. shafts
e. x6 flange bearings
f. M3 bolts to secure parts together
g. 8mm dia. coupler

Why 3D print gearbox?

- can be customized for size and gear ratio

Gear Ratio: 10:1

Designed to obey constraints

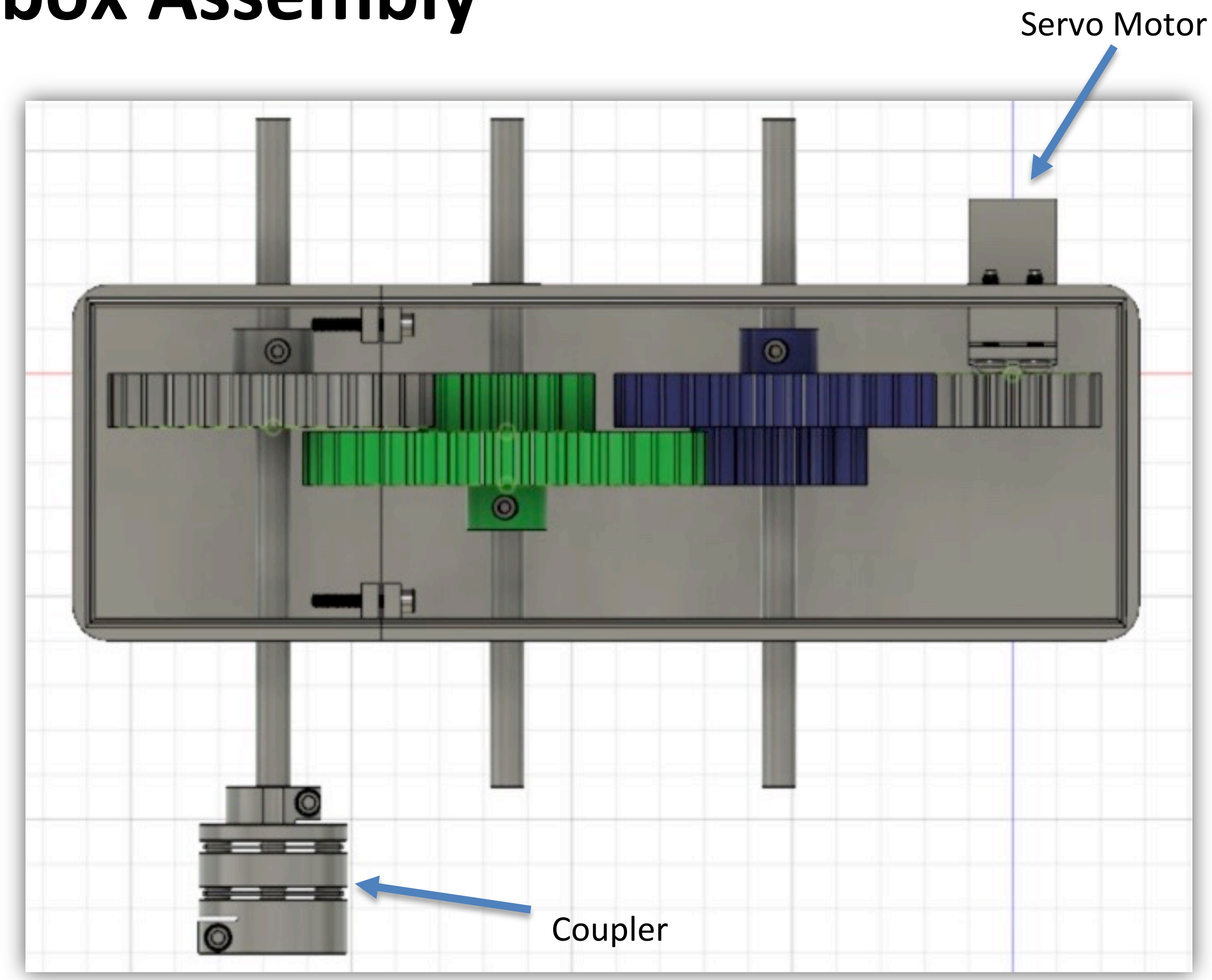
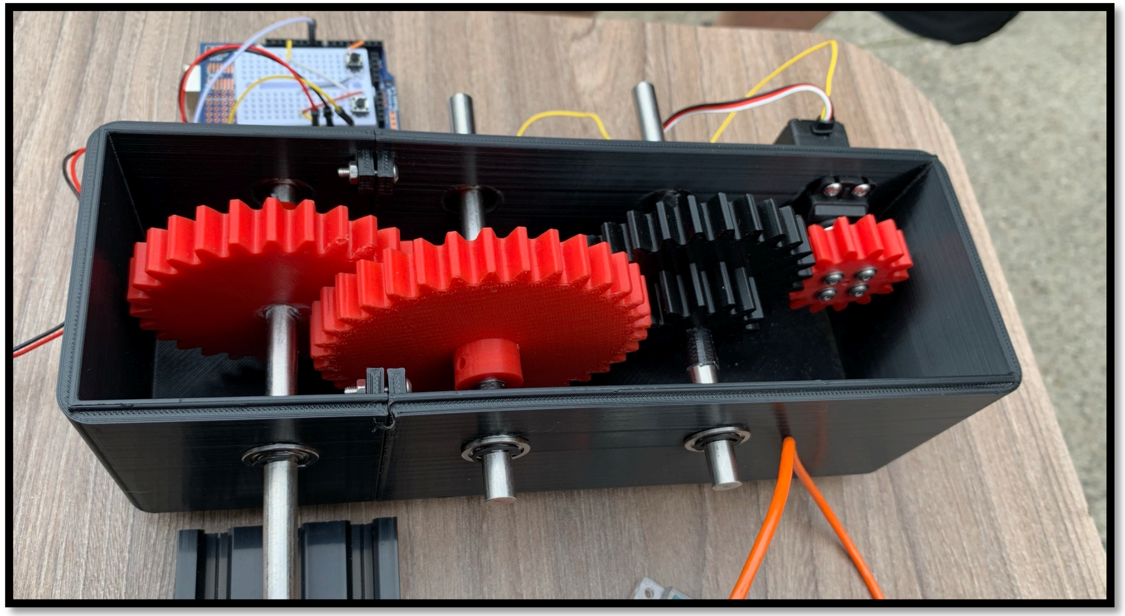
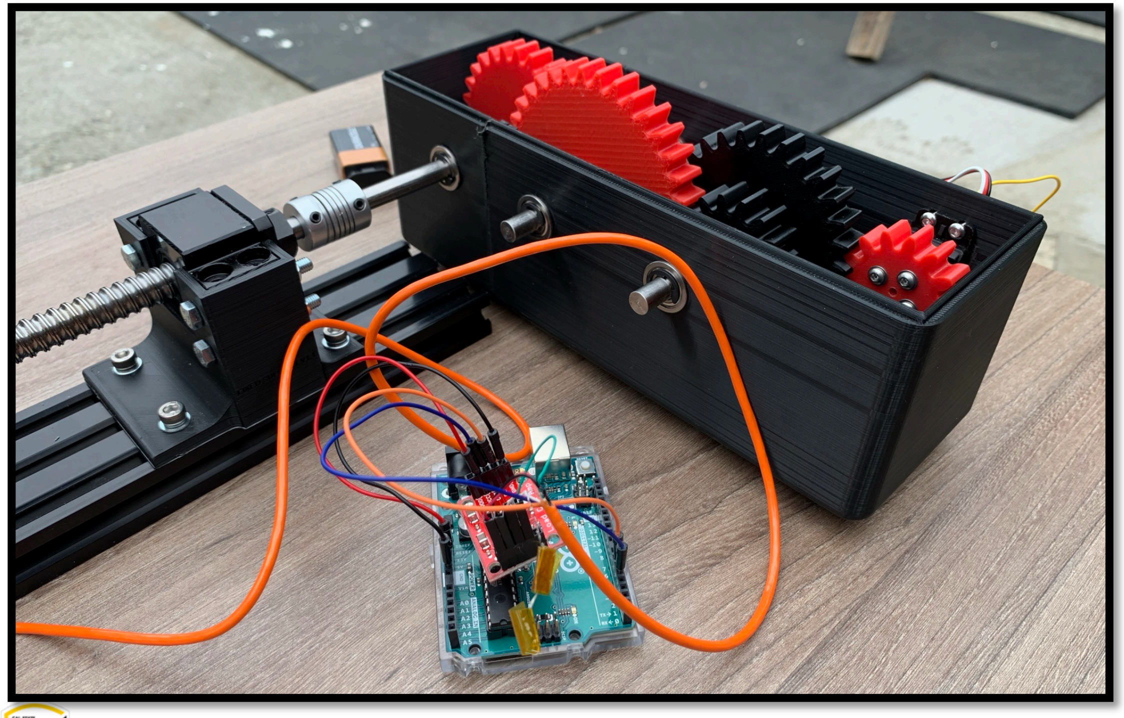
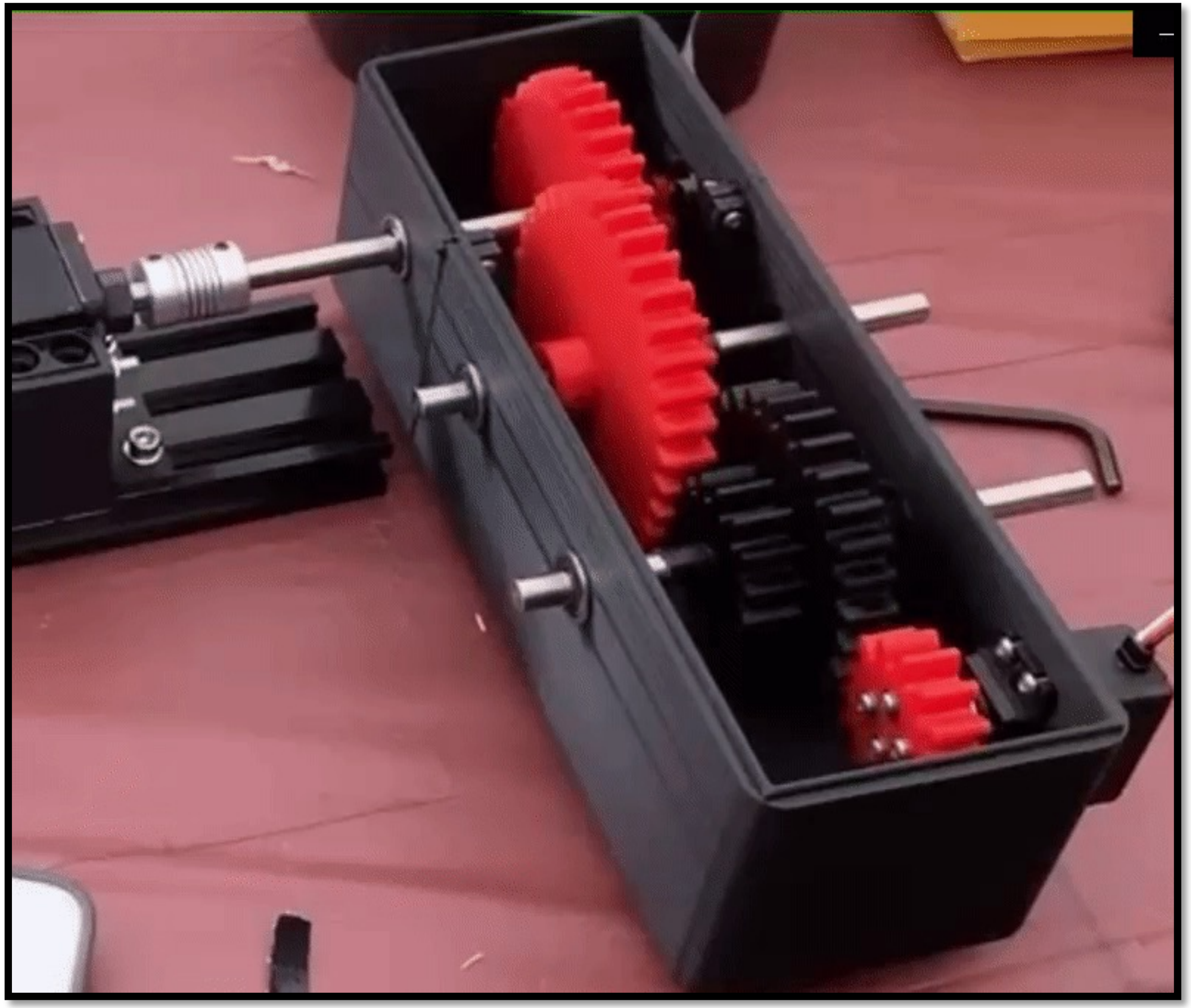


Figure 18: Top View of Gearbox and Housing Assembly







Hardware – Electrical (Motor)

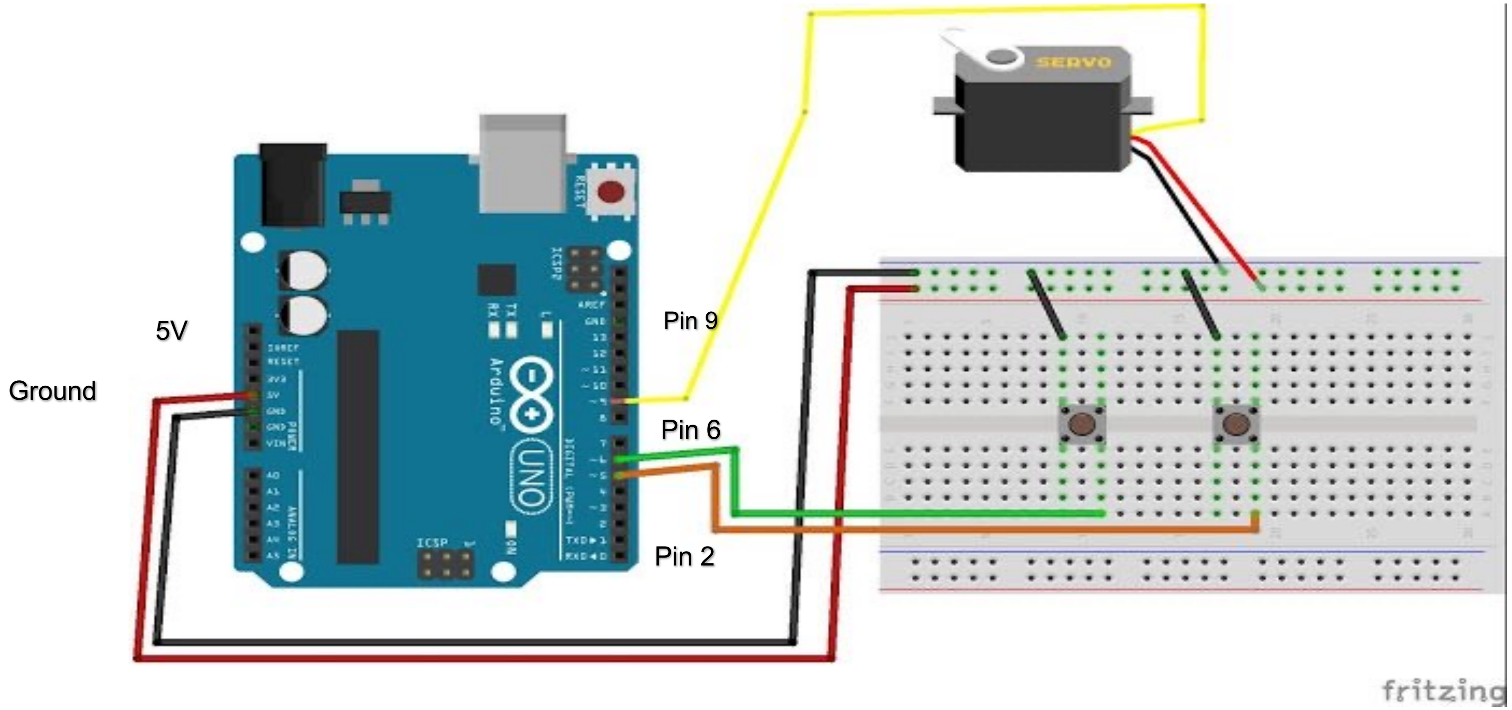


Figure 19: Servo electrical set-up

Hardware – Electrical (Load Cell)

Table 4: Tension-compression load cell specifications

Specifications [5]	
Weight	0.1 kg
Capacity range	0kg-20kg
Accuracy	0.03%F.S (linearity + hysteresis + repeatability)
Sensitivity	1.0 ~ 1.5mV/V
Creep	±0.05%F.S/30min
Zero output	1%F.S
Temperature effect on zero	±0.05%F.S/10˚C
Temperature effect on output	±0.05%F.S/10˚C
Operating temperature	-30˚C ~ +70 ˚C
Input impedance	400 ± 10Ω
Output impedance	350 ± 10Ω
Insulation resistance	≥500MΩ
Safety overload	150%F.S
Overload limit	200%F.S
Bridge voltage (excitation voltage)	DC 5-15V, suggest DC 10V
Material	Stainless steel
Protection class	IP67
Cable length	2m
Wiring	EXC+: Red, EXC-:Black, SIG+:Green, SIG-:White

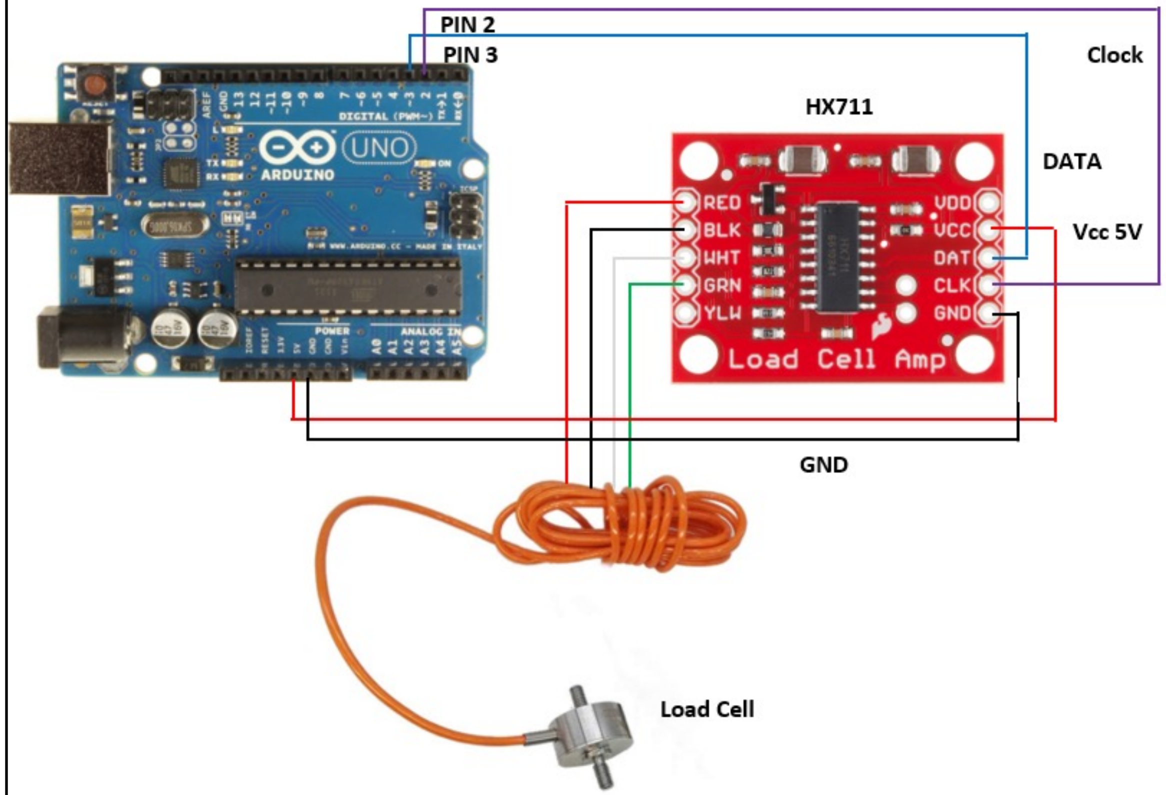


Figure 20: Load cell, Arduino, HX711 schematic

Software

- Open-source Software
- Inexpensive
- Easy to use
- Great for interactive projects

Code → compile → upload → run

Arduino Codes created:

- Button controlled Continuous Servo code.
- HX711 amp Strain load measuring code.

Software

- Button controlled Continuous Servo code.

- Purpose of the code:

Control servo rotation clockwise, or counterclockwise via button switches depending on desired test. Tensile/compression.

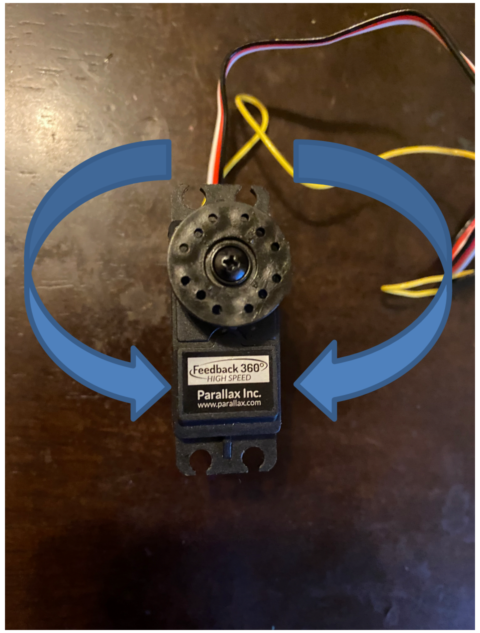


Figure 21: Servo rotation directions

```
#include <Servo.h>
#include <FeedBackServo.h>
Servo myservo;

int servoPin=9;
int angle =0;     // Starting position(degrees)
int angleStep =1;
int feedbackPin = A0;
int feedbackValue;

#define LEFT 12   // pin 12 is connected to left button
#define RIGHT  2  // pin 2 is connected to right button

void setup() {

  Serial.begin(9600);

  myservo.attach(9);  // Servo Pulse width Module connection

  pinMode(LEFT,INPUT_PULLUP); // Left button
  pinMode(RIGHT,INPUT_PULLUP);// right button

  myservo.write(angle);// MOves servoto 90 degrees

  Serial.println("Start test ");
  }
void loop() {
   while(digitalRead(RIGHT) == LOW){

    if (angle > 0 && angle <= 180) {
      angle = angle - angleStep;
       if(angle < 0){
        angle = 0;
       }else{
      myservo.write(angle);
      feedbackValue = analogRead(feedbackPin);
      Serial.print("Moved to: ");
      Serial.print(angle);   // print the angle
      Serial.print(" degree");
      Serial.print("\t");
      Serial.println(feedbackValue);
```

Software

- HX711 amp Strain load measuring code.
- Purpose of code:
  i. Measure and display load applied to load cell.
  ii. Looping code to display new loads as Force keeps getting applied in either direction (tension , compression).

```
#include "HX711.h"

#define DOUT 3
#define CLK 2
float seed=
HX711 scale(DOUT, CLK);

void setup() {
  Serial.begin(9600);

scale.set_scale();//calibrated value

scale.tare();

Serial.println("Put force on Load cell");
while(!Serial.available()){};

float x =scale.get_units(10);
Serial.print("Set scale value is");
Serial.println(x);
}

void loop() {

scale.set_scale(seed);
if (Serial.available()){
  char z =Serialread();
  if(z=='-') seed-=5;
  if(z=='+') seed+=5;
}

Serial.print("Seed value:");
Serial.print(seed);
Serial.print("\tweight:\t");
Serial.println(scale.get_units(10),2);
```

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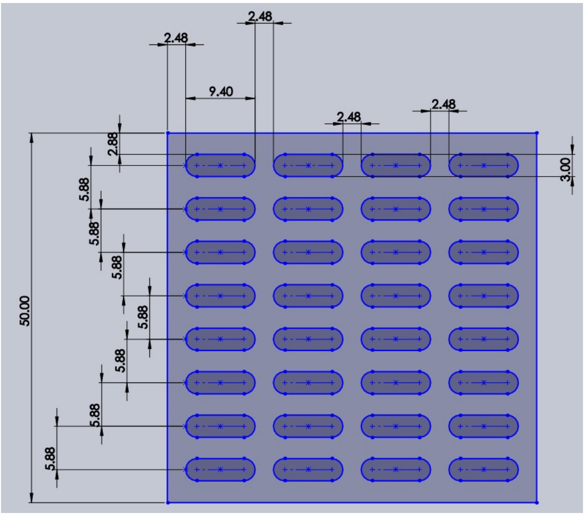
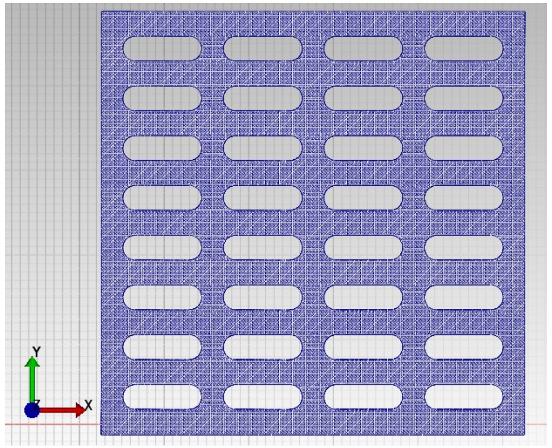
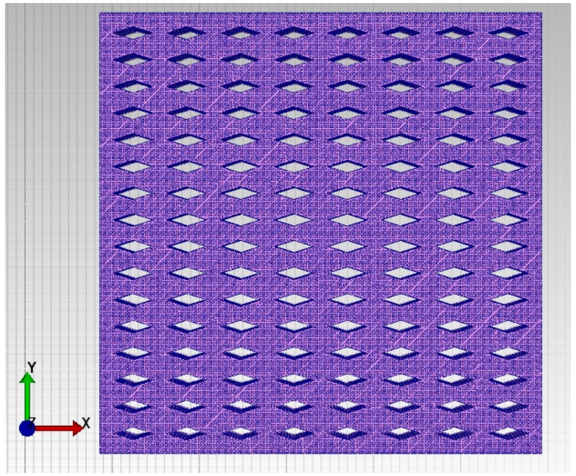
Implant Design

- Prototype
- Pores in the biopolymer reduces stiffness
- Non-symmetric geometric pores changes stiffness direction
- The pores geometry is manipulated to have a stiffness ratio equal to healthy pelvic tissue.



Length x Width x Depth
30mm x 30mm x 1.2mm



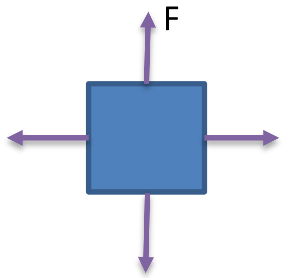


Figures 22: Implant Design Examples

FEA Simulation

Modeled in FEBio Studio

- Neo-Hookean Model
- PLGA material properties
- Biaxial tensile testing simulation



Biaxial Tensile Test

Stress Magnitude   Displacement

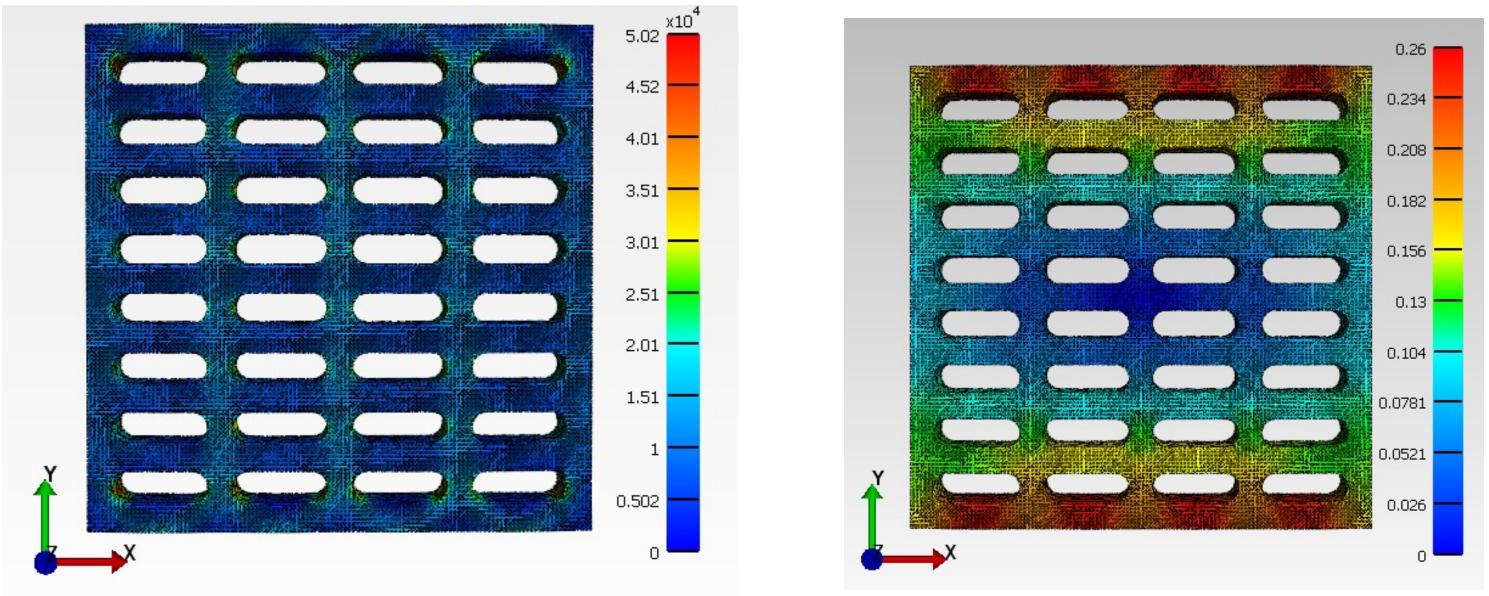


Figure 23: FEA Simulation with colormap

FEA Results

- The simulated biaxial tensile test shows the ideal stiffness ratio was met

Table 5: FEA Results

Youngs Modulus of Elasticity	
Y-axis (MPa)	5.23E+02
X-axis (MPa)	1.12E+03
Stiffness Ratio $\frac{Y}{X}$	
Simulation	0.466964
Ideal	0.469841

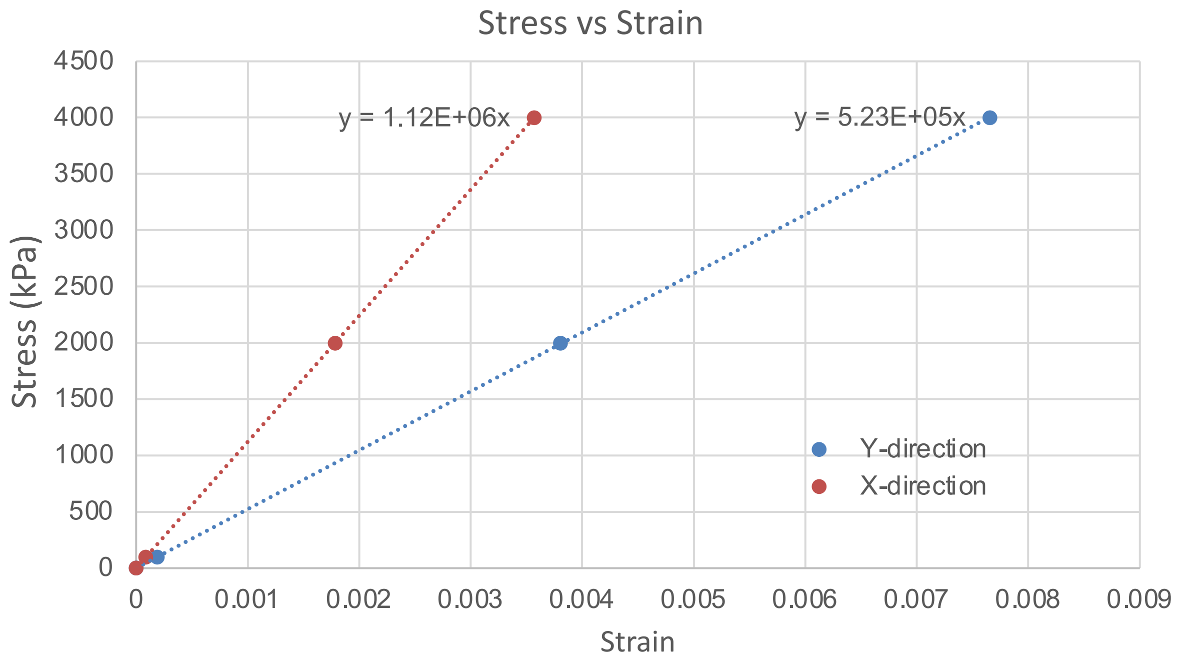


Figure 24: Stress vs Strain results of the oval design

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Conclusion

- Healthy uterosacral ligament stiffness range: 1.9 – 6.3 (+-11.5) MPA
- Implant prototype design satisfies the ideal stiffness ratio (0.467) by FEA simulation analysis
- Designed uniaxial tensile testing machine, with little machinable parts.
- Built the uniaxial testing machine (max tension: 200 N, max displacement 100 mm, max speed: 20mm/min, max time: 5 min)
- Adjustable motor speeds, and directional control
- PLGA material was not attainable for testing

Pending Assignment

- Uniaxial tensile testing an implant prototype replacement material (PLA & PETG) for proof-of-concept experimental stiffness ratio, to compare with FEA simulations

References

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[6] “Learn Arduino” Robojax.com, Inc and Shamshiri 2021