Final Design Report

Elbow Motion Simulator

December 6th, 2024

The University of Western Ontario

Department of Mechanical and Materials Engineering

MME 2259A – “Product Design and Development”

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Final Project Documentation

Executive Summary

Our project addresses the need for total elbow replacement implants due to the increase in elbow replacement surgeries. We did this by designing an elbow implant motion simulator. This simulator is designed to replicate the biomechanical functions of a human elbow and provide a way of testing elbow implants in order to determine their reliability for medical device manufacturers and healthcare professionals.

The simulator uses a cadaveric specimen to assess the performance of an elbow implant. The design focuses on precision, durability and ease of use to ensure that it meets customer needs. Features include actuators mimicking the motion, the load bearing capacity of up to 1kN and chrome stainless steel for corrosion resistance and strength to help with its long-term durability.

Our specification and planning phase included using a Gantt chart, Critical path method, and Quality Function Deployment to ensure efficient use of our time in creating a design that meets the needs of the customer. The concept generation phase allowed us to brainstorm ideas to decide the best way to simulate the natural functions of the elbow. The final design was selected through the Go/No-Go matrix to ensure we picked the best design that met both the customer's needs and functional requirements.

The simulator was designed to create a standardized way of testing elbow implants to ensure patients are receiving the best possible plant that meets their needs. This design ultimately is intended to improve the comfort, functionality and safety of an implant and meet the requirements of a typical medical device.

Introduction

There is an increased number of elbow replacement surgeries, and there are no widely marketed elbow implant testing simulators. As the elbow implant demand increases it is necessary to set a standard of the range of motion, durability and how long each implant would last. The primary purpose of the elbow simulator is to evaluate the biomechanical performance of elbow implants on cadaveric specimens. Testing an elbow implant is necessary to determine its durability, safety and effectiveness. This simulator would benefit medical device manufacturers and medical professionals as it would provide them with a reliable machine for testing elbow implants, ensuring the safety and comfortability of a patient.

Project Plan

Phase 1: Specification and Planning

In this phase we established the problem statement, by identifying gaps in the market. We outlined our constraints to ensure the product effectively meets the needs of the customer. Planning the tasks for the project was important as it ensured each step is built upon the previous one, for the project to be completed efficiently.

Customer Needs

- **Realistic Joint Mechanics -** literature indicates that the elbow's natural range of motion includes flexion, which allows movement between 130 and 154 degrees, and extension, which ranges from –6 to 11 degrees. Additionally, the elbow facilitates pronation, with a range of 75 to 85 degrees, and supination, spanning 80 to 104 degrees so in our elbow simulator we will strive to get the motion as close as possible to these values. [1]
- **Precision and accuracy in motion -** Actuators will deliver smooth and controlled movements that closely mimic human biomechanics
- **Load Testing -** literature shows that a joint load in an elbow implant can induce peak values of about 1kN so our simulator should be capable of withstanding and testing that amount of load. [2]
- **Flexibility in configuration -** the design should have adjustable components that allow for customization by the client however they see fit
- **Ease of Use** - The design must be easy to set up and operate while reducing the time and effort required
- **Safety and regulatory compliance**
- **Long Lasting:**
- **Dynamics Load Response:** The design must be able to accurately detect and show load forces while simulating the natural movement of a forearm
- **Durability:** The simulator must be able to withstand repeated use in realistic conditions (stress and movement). Material must also show little to no wear during and after each testing is done.
- **Compact/reasonable size:** The design must be sturdy and rigid, with little to no wobbling when the cadaveric arm flexes, tenses, supinates and pronates.

Problem Statement

With the increased need for elbow implants, it is important to have standardized testing and performance benchmarks. When patients opt for a total elbow prosthesis, they expect it to restore their original range of motion that allows them to live with little to no pain. Correctly evaluating implant designs ensures that they meet the necessary biomechanical functions, to provide patients with reliable and effective results. Based on this information we set our problem statement as: **Current ex-vivo elbow simulators lack precision and need accuracy to replicate the mechanics and movements of a human elbow.**

Product Design Specification (PDS)

The PDS assisted us in determining the things we need to consider before concept generation, to ensure it meets our customer needs. Extensive research needed to be done to determine the necessary biomechanical functions and safety standards, which is critical for accurately testing a medical device.

Specification Type	Performance	Operating Environment	Standards	Materials
	The elbow simulator must perform the natural functions of a human elbow.	Elbow simulator must withstand pressure ranges of at least 6MPa as contact pressures on cartilage can reach up to 5.5MPa.	ASTM F ASTM E8/E8M ISO 13485 ISO 14708	Not yet determined but should be lightweight and have corrosion resistance and must be able to withstand heavy weight from implant testing procedures.
		In an environment with atmospheric pressure of 101.325 KPa.		
		Must work properly in an environment simulating that of the human body. The human body's average temperature is 36.8 degrees Celsius. To consider different climates and situations our simulator must work between 34 to 38 degrees Celsius		

Specification Type	Ergonomics	Aesthetics, Appearance and Finish	Competition Benchmarking	Quality and Reliability	Testing and Inspection
	Easy to setup and mount the arm with the necessary wires	Simulator must look clean and polished; any wires must not interfere with the view of part inserted in the simulator	Competition can only test implants that slide against each other (i.e. joint implants)	High durability so it can last for thousands of cycles	Regular sanitization of apparatus to get rid of residue from previous cadaveric specimen
			Don't account for the other muscles that act on the joint	Be compatibility with various elbow implants.	Ensure that the simulator is able to handle certain amounts of weight after multiple uses, by testing the machine regularly to avoid accidents
				Be able to do precise motion movements (movements within the range of motion)	

Specification Type	Maintenance and Logistics	Service Life	Market Constraints	Target product Cost	Quantity	Product Life Span
	Clean cadaveric specimen mount before using a new specimen Operation of control system is relatively easy – can be used by someone with basic computer knowledge Comes with a manual	Will last 5-10 years with proper maintenance	Different countries have different medical regulations that to be adhered to	With many medical equipment costing between 2000 to 100 000, the price will likely range from $5000 to $15 000.	Begin with 50-100 units and if there is increasing demand up the quantity to 100-500 units	If the product it consistently updated, it can last about 15+ years. However, new standards or innovative machines may dominate the market by this time

Specification Type	Shelf-life storage	Size	Weight	Shipping	Packaging	In-House Process
	Mechanical Components should last for about 10 years	Should be small enough to fit into a typical medical laboratory	Depending on the material that is chosen the weight may vary, however we aim to have a weight that will ensure the unit will not tip over but still allow for it to be durable and portable.	Allow for the simulator to be disassembled so it can be shipped in smaller pieces, to ensure it does not exceed international skipping sizes	Wrapped in Plastic as a form of weatherproofing	Materials have not been solidified yet, but it is used a sort of metal will be used and therefore a heat treatment will be needed
	Electrical Components should last for about 5 years				Styrofoam inserts to protect the individual pieces	Any sensors or electrical components will need a conformal coating
	With consistent maintenance the machine should last for up to 20 years					

Specification Type	Manufacturing facilities	Patents	Design Schedule	Company Constraints	Social and Political Factors	Safety
	Must be produced in a facility that means the medical device manufacturing standards	Joint simulator testing machine	About 20 days for part modelling and Assembly of the simulator to ensure movement of an elbow is correctly mimicked	The product is niche and maybe be outperformed by competition that simulators different joint implants	Must improve the quality of implants	Wiring should be properly insulated
	Be in a facility that is near were we source some or all the materials to reduce sourcing and shipping cost	Smart Joint Implant Sensors			Must comply with sustainability and environmental regulations and laws	Most have disposable or replaceable components for parts that interact with the cadaveric specimen

Figure 1- Product Design Specification

Work Breakdown Structure

The WBS assisted in dividing the project into manageable components. It was important to divide the tasks into specification and planning, concept generation and the design phase to show how each stage builds on to the next ensuring an efficient workflow with designated responsibilities for each team member. This was used to assist in the preparation of the critical path method and Gantt chart, to ensure every task was accounted for.

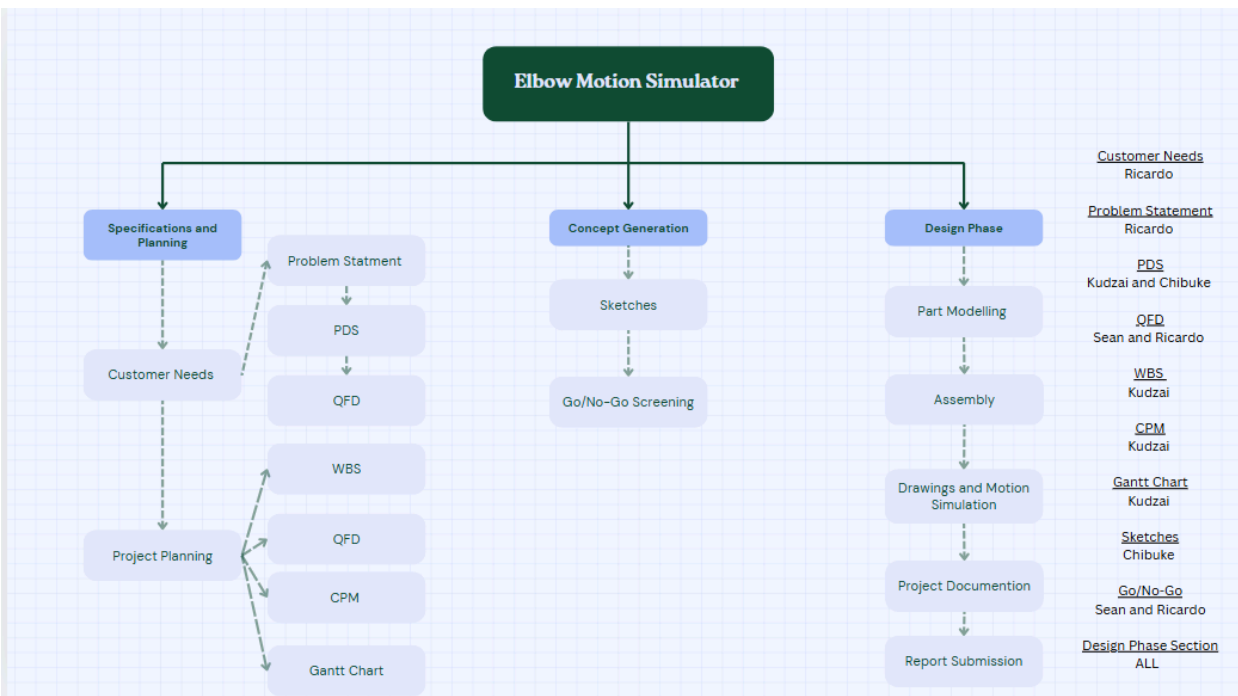


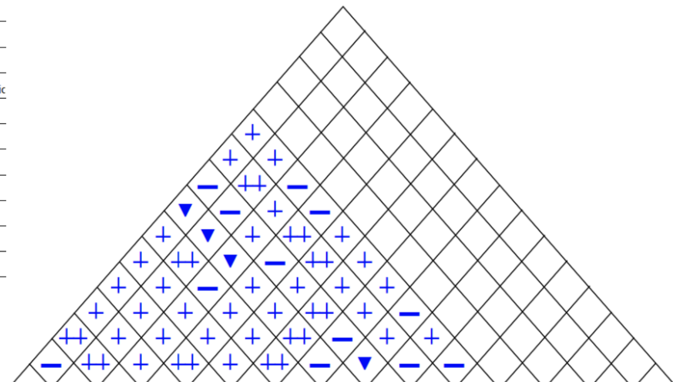
Figure 2 – Work Breakdown Structure

Quality Function Development

The Quality Function Development (QFD) was utilized to translate the identified customer requirements and how it will relate to our technical requirements. This model helped us see how certain solutions or ways we would satisfy those customer needs related to each other and whether certain technical requirements that were needed to satisfy customer needs were doable or out of reach. Additionally, the QFD helped us compare advantages and disadvantages we had over the competition and see how well our design would do against them.

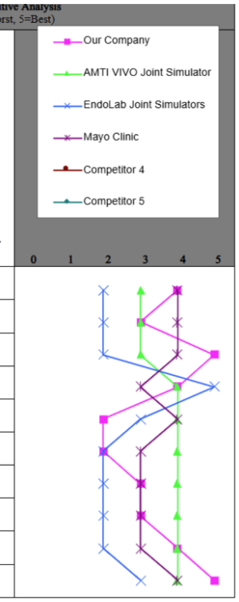
Title:
Author:
Date:
Customer: Primary Custromer: Medical Device Manufacturers and Simulatic
Secondary Customer:Medical Professionals

Legend		
Θ	Strong Relationship	9
O	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
−	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
x	Objective Is To Hit Target	



Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Demanded Quality (a.k.a. "Customer Requirements" or "Whats") \ Quality Characteristics (a.k.a. "Functional Requirements" or "Hows")	1 Control Sensitivity	2 high yield strength of materials used	3 Motion Tracking	4 Wear Resistant	5 Corrosion Resistant	6 User Manual	7 Interchangable Parts	8 Emergency Stop	9 Configurable parameters	10 Minimal maintenance requirement	11 Feedback system	12	13	14	15	Our Company	AMTI VIVO Joint Simulator	EndoLab Joint Simulators	Mayo Clinic	Competitor 4	Competitor 5
				Direction of Improvement: Minimize (▼), Maximize (▲), or Target (x)	▲	▲	▲	▲	▲	x	▲	x	▲	▼	▲										
1	9	13.0	5.0	Precision and accuracy in motion	Θ	▲	Θ	O	O	▲	▲	▲	O	O	Θ					4	3	2	4		
2	9	10.4	4.0	Load Testing	▲	Θ	▲	Θ	Θ	▲	▲	▲	▲	▲	O					3	3	2	4		
3	9	10.4	4.0	Flexibility in Configuration	O	O	O	O	O	O	Θ	▲	Θ	▲	▲					5	3	2	4		
4	9	5.2	2.0	Ease of use	▲	▲	▲	▲	▲	Θ	O	▲	O	O	▲					4	4	5	3		
5	9	13.0	5.0	Safety and regulatory compliance	▲	▲	▲	O	O	O	▲	Θ	▲	▲	▲					2	4	3	4		
6	9	7.8	3.0	Long Lasting	O	O	▲	Θ	Θ	▲	O	▲	▲	Θ	▲					2	4	2	3		
7	9	10.4	4.0	Dynammics Load Response	O	Θ	Θ	O	O	▲	▲	O	Θ	O	Θ					3	4	2	3		
8	9	10.4	4.0	Durability	▲	Θ	▲	Θ	Θ	▲	▲	▲	▲	Θ	▲					3	4	2	3		
9	9	13.0	5.0	Realistic Joint Mechanics	Θ	▲	Θ	▲	▲	▲	▲	▲	▲	▲	O					4	4	2	3		
10	3	6.5	2.5	Compact/reasonable size	▲	O	▲	O	▲	▲	O	▲	▲	O	▲					5	4	3	4		
				Target or Limit Value	Increments or decrements of ±0.1N	Can withstand a maximum stress of 250MPa	Within ±0.1mm in position tracking and ±0.1° in angular measurement	Wear resistance rating of 3000 - 5000 cycles or beyond based on ASTM D4060	degradation after 1000 hours in a simulated bodily fluid	Comprehenseive instructions, readable within 20 minutes	Replceable components can be swapped in under 10 minutes	Response time of <1 seconds	Load, Speed, and direction adjustable with increments of 0.1 units	Once every 6 months	of <60ms with resolution of 0.1N for force and 0.1mm for										
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	4	1	9	5	3	6	9	5	4	4	5										
				Max Relationship Value in Column	9	9	9	9	9	9	9	9	9	9	9										
				Weight / Importance	364.9	398.7	411.7	435.1	422.1	188.3	222.1	224.7	302.6	315.6	333.8										
				Relative Weight	10.1	11.0	11.4	12.0	11.7	5.2	6.1	6.2	8.4	8.7	9.2										

Competitive Analysis (0=Worst, 5=Best)



Powered by QFD Online (http://www.QFDOnline.com)

Figure 3 – Quality Function Development

Gantt Chart

Gantt Chart was used to set deadlines and gave us an indication if we were on track during each task. The durations gave us a basis on how long we should take on each task. The chart was designed in a way to give us flexibility in case of delays. The schedule allowed us to make the entire process more efficient and ensured each team member knew what to do next.

Member	Task Name	Start Date	End Date	Duration (In Days)
ALL	**Specifications and Planning**	11-4-2024	11-8-2024	
ALL	Customer Needs	11-4-2024	11-4-2024	1
Kudzai	Problem Statement	11-4-2024	11-4-2024	1
Kudzai and Chibuke	Design Specification	11-6-2024	11-6-2024	1
Ricardo and Sean	Work Breakdown Structure	11-6-2024	11-6-2024	1
Ricardo and Sean	Quality Function Deveopment	11-8-2024	11-8-2024	1
Kudzai	Critical Path Method	11-8-2024	11-8-2024	1
Kudzai	Gantt Chart	11-8-2024	11-8-2024	1
ALL	**Conceptual Generation and Evaluation**	11-9-2024	11-15-2024	7
Chibuke and Sean	Concept Generation	11-9-2024	11-14-2024	6
Chibuke and Sean	Sketches	11-9-2024	11-14-2024	6
Ricardo and Sean	Go/No-Go Screening	11-14-2024	11-15-2024	2
ALL	**Detail Design Phase**	11-15-2024	12-6-2024	22
	Design Evaluation and Part Modelling	11-15-2024	11-25-2024	11
	Part modelling and Assembly	11-26-2024	11-29-2024	4
	Drawings and Motion Simulation	12-1-2024	12-3-2024	3
	Finalize Project Documentation	12-4-2024	12-5-2024	2
	Final Report Submission	11-8-2024	12-6-2024	29

Figure 4 – Gantt Chart

Critical Path Method

This was used in tandem with the Gantt to ensure we are on the right track and let us determine the maximum and minimum project duration. This allowed us to plan the best course of action, to ensure we had ample time to finish the long components of our project, specifically the design phase. The CPM allowed us to prioritize which task, to ensure we complete everything by the deadline.

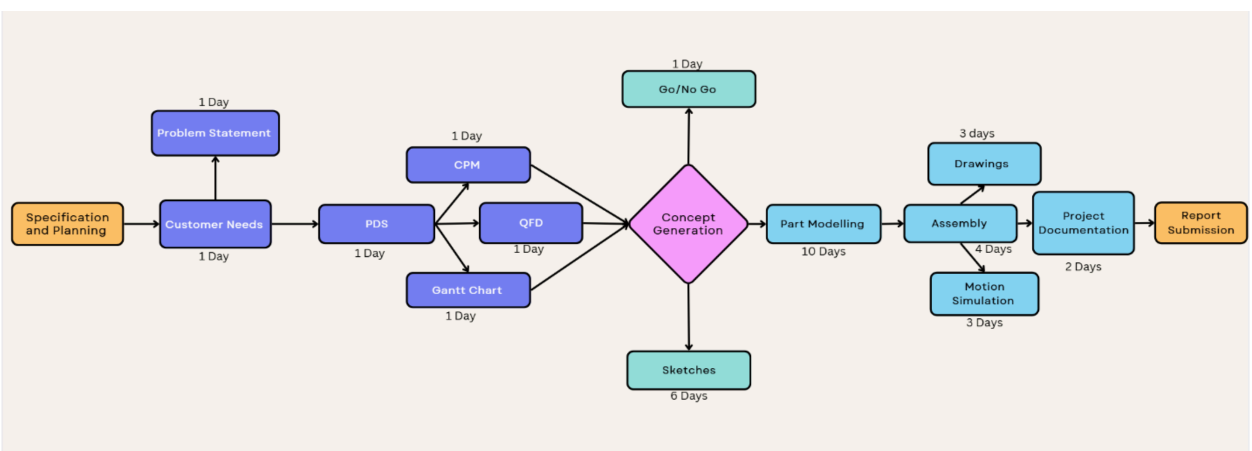


Figure 5- Critical Path Method

Concept Generation

During the initial stages of ideation, we begin with a single concept inspired by our analysis of our competitors. We adapted and improved the original concept which enabled us to brainstorm and design 8 ideas. This strategy allowed us to refine the original idea, creating a design with increased functionality, so we could differentiate ourselves from the competition.

Sketches

To better understand and evaluate our ideas, we created sketches for each concept (see Figures 8-15). These visual representations provided a clearer understanding of how each concept would function and helped identify potential challenges early in the process. Even concepts that we initially believed were not feasible were sketched, to allow us to compare and analyze all the ideas effectively. These sketches played a crucial role in our decision-making process, enabling us to narrow down and select the most promising concept to move forward with.

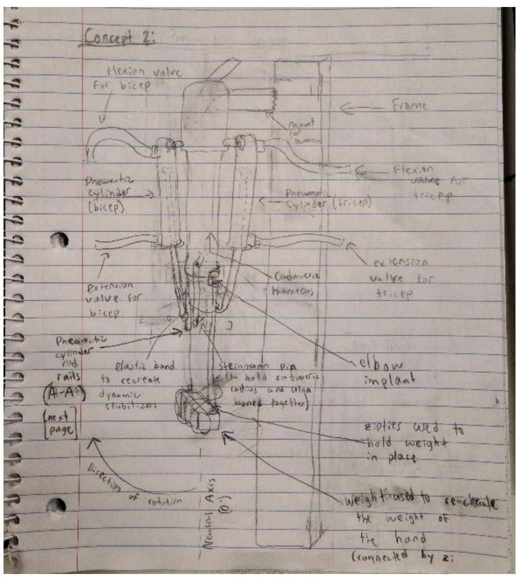


Figure 6 – Guide rails to allow more flexion accuracy + pneumatic actuator connected to ulna and radius to simulate elbow rotation + Clamps to fix humerus in position

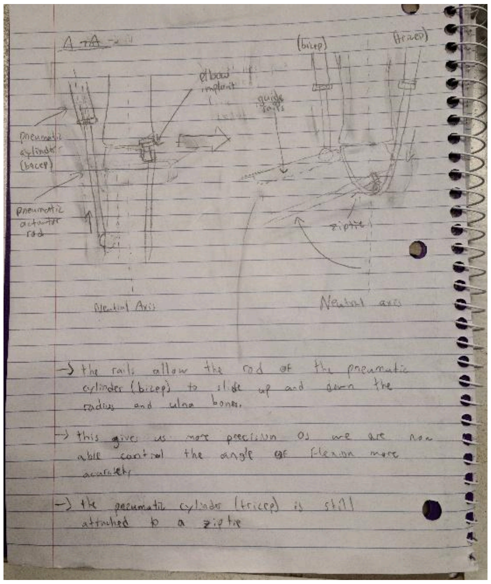


Figure 7 – Explanation of guide rail mechanism

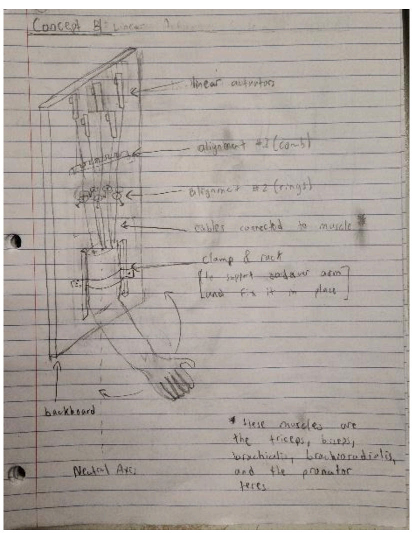


Figure 8 – Add more alignment systems to better align the linear actuators with each other and their respective muscle

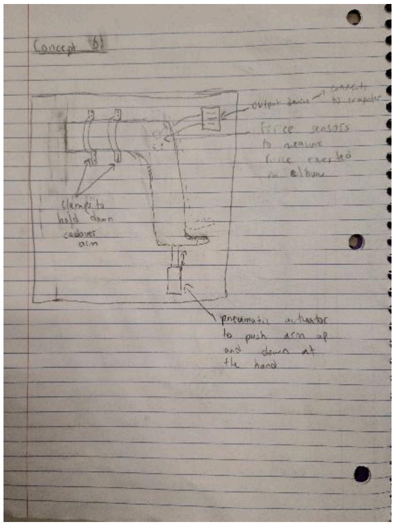


Figure 9 – Actuator pushes the arm up and down at the hand, which exerts a force on the elbow. Force sensors that are surgically added in the elbow measure this force

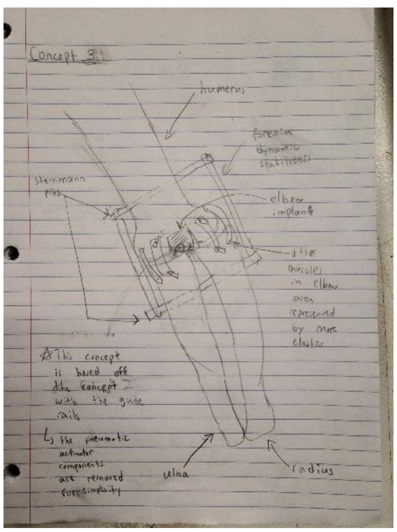


Figure 10 – Add more elastics to give a more realistic representation of the muscles in the elbow area

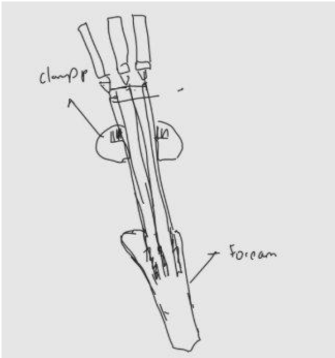


Figure 11 – A clamp to hold down the humerus bone, with movement through pneumatic cylinders

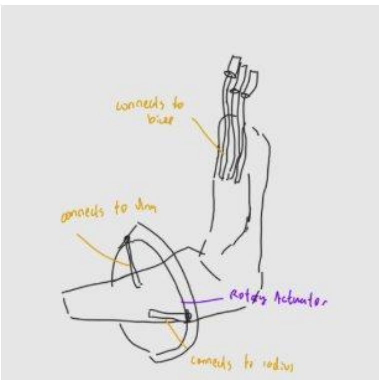


Figure 12 – Movement through pneumatic cylinders and forearm rotation through a rotary actuator around the radius and ulna bones.

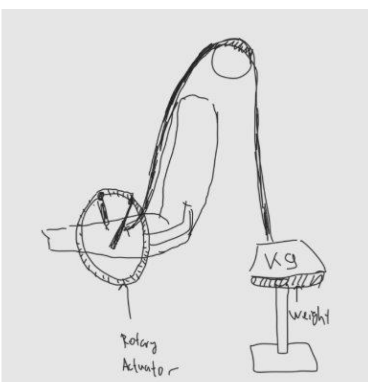


Figure 13 – Flexion and extension through a pulley system with weights at one end and forearm rotation through a rotary actuator around the radius and ulna bone

Functional Decomposition and Morphological Analysis

During our concept generation stage, we employed functional decomposition and morphological analysis to structure our design process. As time went on, our designs became more creative and complex. We focused on the main functions we wanted our simulator to perform and brainstormed methods to achieve them for each concept. For example, in one of our concepts, we wanted to incorporate supination and pronation in the forearm. To do this, we thought to use a rotary actuator to rotate the ulna and radius, the bones in the forearm, at the elbow joint, which is how supination and pronation occur in the human body. The combination of these two design tools allowed us to generate ideas with a more feasible implementation.

Concept Selection – Go/No-Go Screening

To decide on the concept, we used a method called the Go/No-Go Screening. This method compares each concept to a metric, which in our case was the customer needs. The comparisons that met the criteria received a 1, which meant 'go,' the ones that may meet the criteria received a '0,' which meant 'maybe,' and the ones that did not meet the criteria received a –1, which meant 'no-go.' The concept that had the greatest sum, that is, had the greatest net positive comparisons, was the concept we decided to pursue (see Figure 15). (See Appendix A for the final design)

	Precision and Accurray in Motion	Load Testing	Flexibility of Configuration	Ease of use	Safety	Long Lasting	Dynamics Load Response	Durability	Realistic Joint Mechanics	Compact/ reasonable size	Σ
Clamp + mount to hold down humerus bone + movement of muscles through pneumatic system	0	-1	-1	1	1	0	1	1	-1	1	2
Guide rails to allow more flexion accuracy + pneumatic actuator connected in between the ulna and radius through a rope to flex and extend the forearm, simulating the elbow joint movement+ clamps to fix the humerus bone in place	1	1	0	1	1	0	1	1	0	1	7
Add more elastics to give a more realistic represenation of the muscles in the elbow area	1	1	-1	1	-1	-1	1	0	0	1	2
Add more alignment systems to better align the linear actuators with each other and their respective muscle	1	1	-1	1	1	1	1	0	0	1	6
Actuator will connect to the tendon or cable attached to the biceps tendon. when the actuator contract or expand, it pulls on the tendon which simulate the contraction and tension of the bicepts muscle (moving the forearm up and down). + Connection to ulna and radius of rotary actuator to simulate elbow rotation	1	0	-1	1	1	0	1	0	1	1	5
Actuator pushes arm up and down at the hand, which exerts a force in the elbow. Force senors that are surgically added in the elbow measure this force	-1	1	-1	1	1	0	1	-1	-1	1	1
Pulley system where thin and strong cable is connected to forearm and counterweight is at the other end of the cable, moving the forearm up and down. Additionally it has an electric rotary actuator connected in the ulna and radius	-1	1	1	1	0	0	1	1	0	-1	3

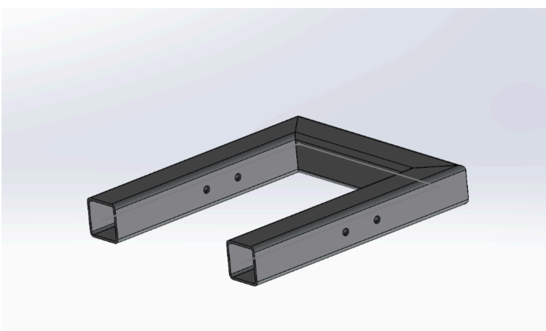
Figure 14 – Go/No-Go Screening

Design Review

Frame Support

This is attached to the frame post as a way for the simulator to have structural stability, by bearing the load of the entire mechanism. The stability it provides allows the user to maintain the safety necessary for using the simulator.

Material: Chrome Stainless Steel
Used for its corrosion-resistant properties, as we mentioned in the PDS. With lubrication and constant sanitation, this material will increase its durability and lifespan.



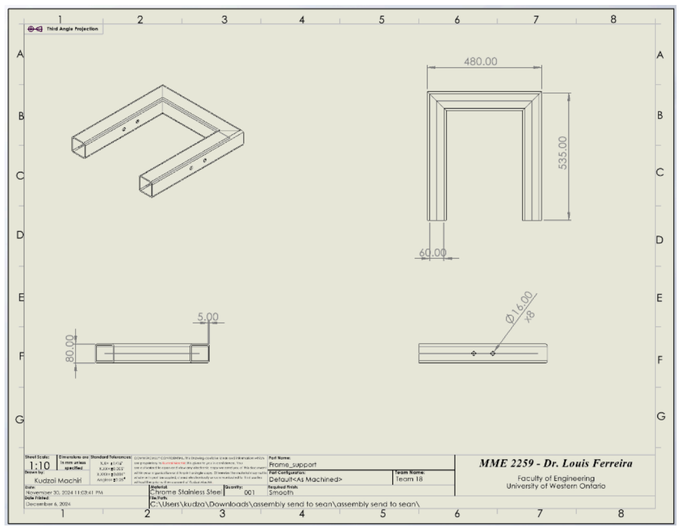


Figure 15 – Frame support CAD and CAD drawing

Frame Post

This is an important part as it assists in the ergonomics of our design as it allows for easy setup of the simulator as it is used to place the rotary actuator, linear actuator, and the cadaveric specimen. The frame post does not have a backboard as it allows for the motion to be clear and visible.

Material: Chrome Stainless Steel
It is used for its corrosion-resistant properties, as well as its low electrical conductivity, therefore increasing the safety if it comes in contact with electrical components.

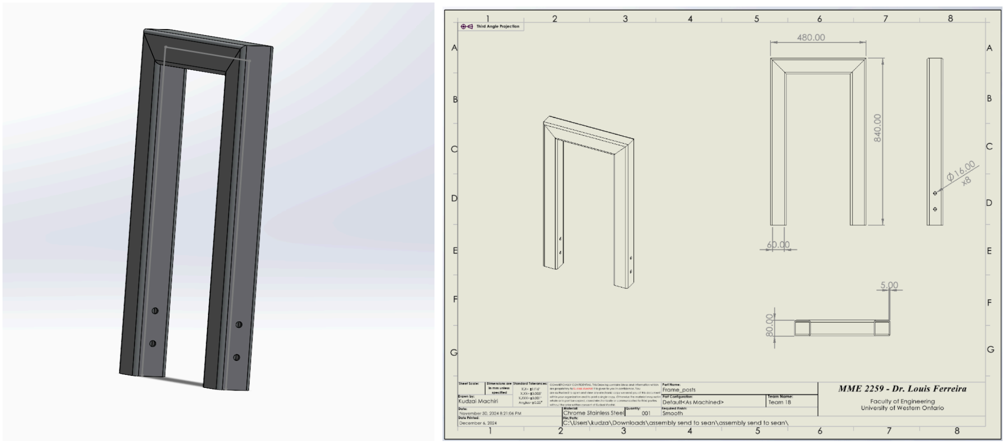


Figure 16 – Frame Post CAD drawing and CAD Drawing

Hinge Mount:

This part is connected to the sheet metal and with the *door hinge* part. The hinge mount, as the name suggests, acts as a mount for the door hinge that will be placed inside this part.

Material: Chrome Stainless Steel is used for its high yield strength and its resistance to corrosion and wear so that it can hold the door hinge part for thousands of cycles and still work perfectly fine.

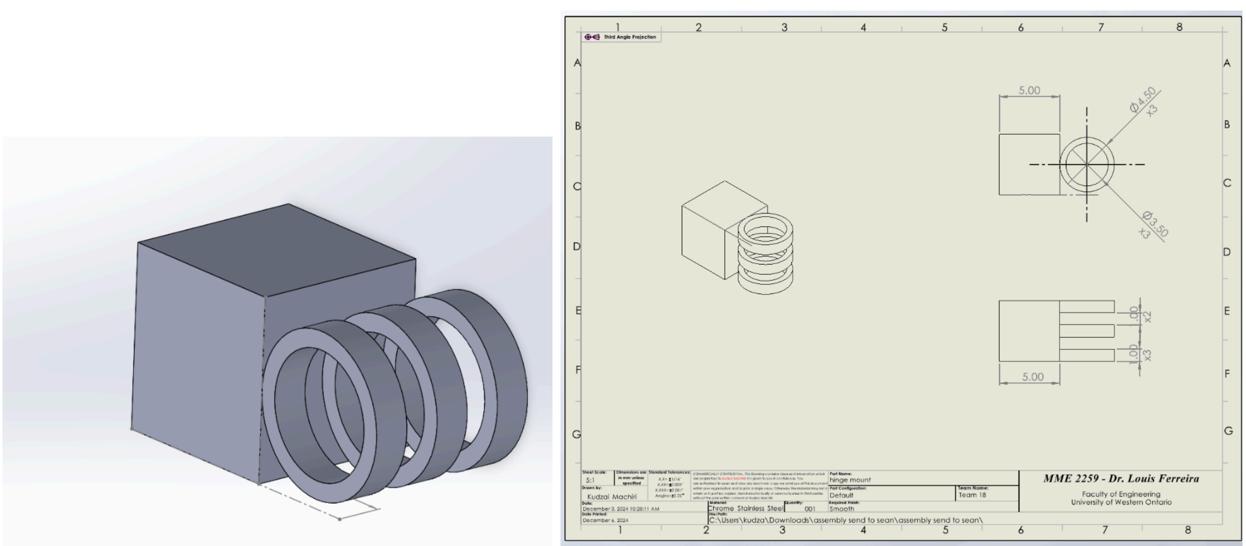


Figure 17- Hinge CAD and CAD Drawing

Door Hinge:

The door hinge allows for an opening of 90 degrees in the clamp to allow for the humerus bone to be placed and then clamped down.

Material: Chrome Stainless Steel is used for its high yield strength and its resistance to corrosion and wear so that it can hold the door hinge part for thousands of cycles and still work perfectly fine.

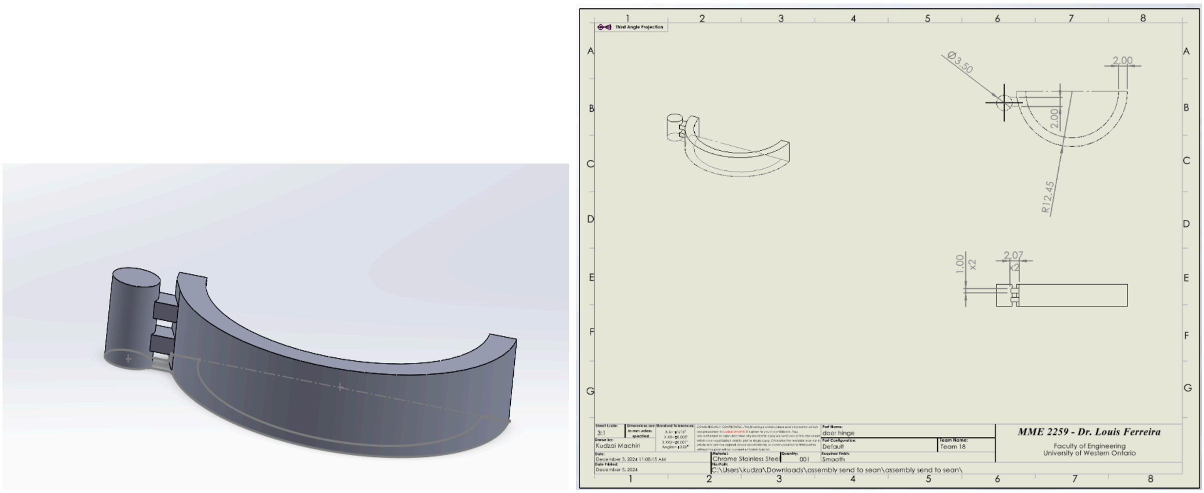


Figure 18- Door Hinge CAD and CAD Drawing

Frame Plates:

This is used to connect the frame supports and frame posts, it assists in increasing the stability of the simulator and therefore its reliability. Which is necessary for the heavy weight of the other components such as the actuators and cadaveric specimen.

Material: AISI 1020 Steel is used for its high corrosion resistance and its high strength.

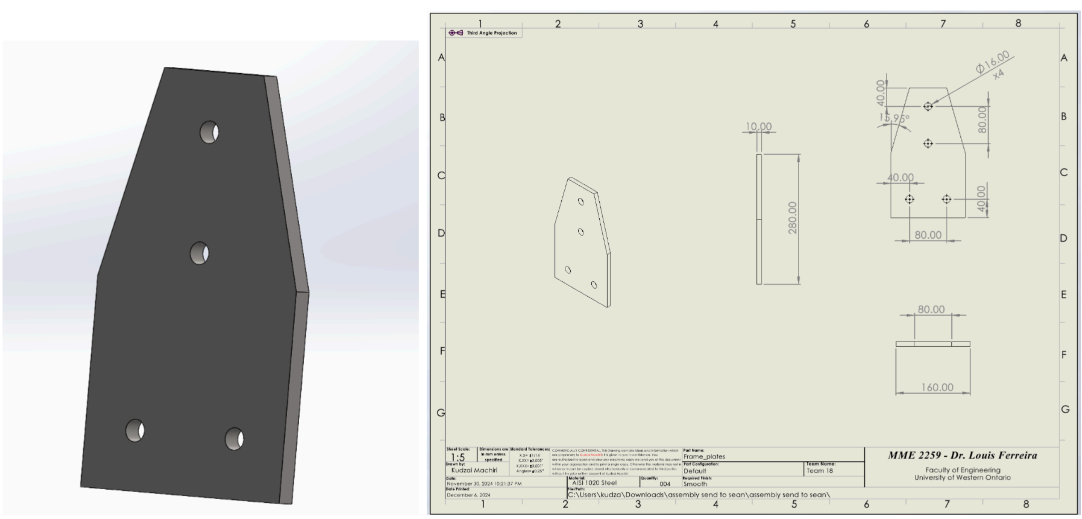


Figure 19 – Frame Plates CAD and CAD Drawing

Cadaver Holder

This is used to hold up the bone and linear actuator, so the bone is visible and clear when performing the necessary testing procedures. It allows for the bone to move without it being moved to unwanted positions.

Materials: Chrome Stainless Steel as it has high strength, to be able to hold the weight of both the entire cadaver and linear actuator.

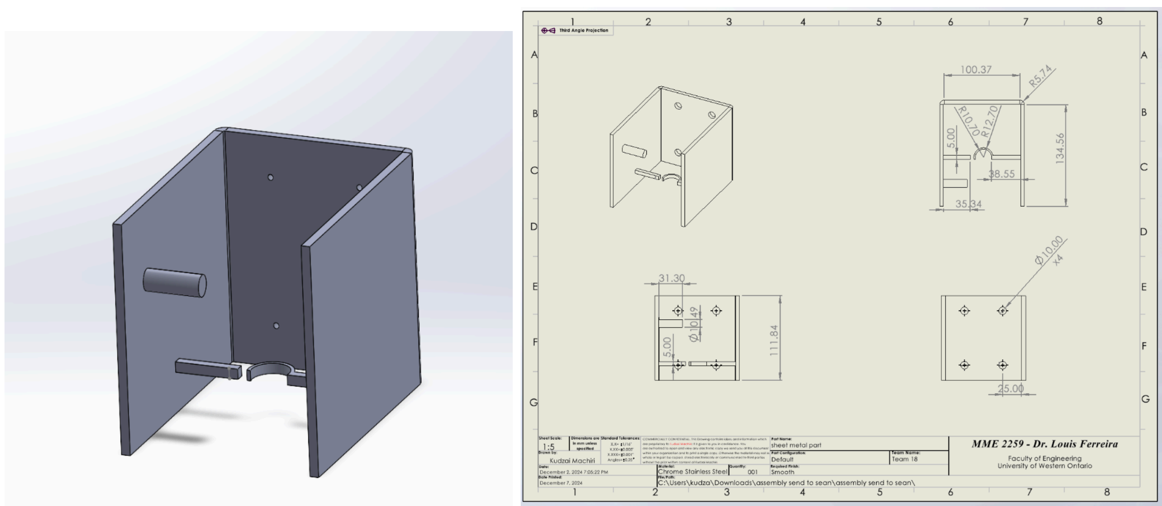


Figure 20 – Cadaver Holder CAD and CAD Drawing

Forearm Dynamics Stabilizers

This is used to stabilize the elbow, so it can flex and extend without the elbow moving side to side. This ensures that during testing procedures, flexion and extension can be accurately measured.

Material: Natural Rubber is used for its elasticity, as it mimics the function of the tendon. So it allows for the controlled movement of the elbow during testing procedures.

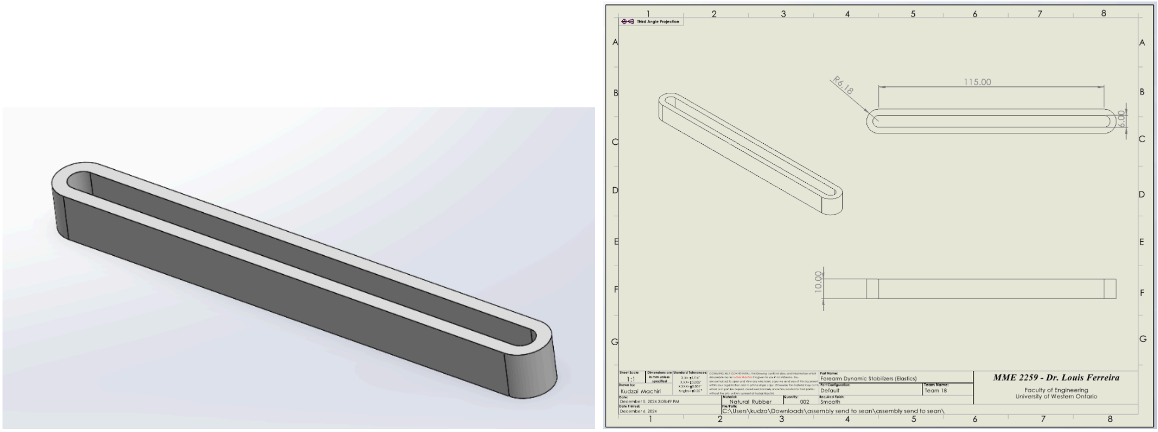


Figure 21- Forearm Dynamic Stabilizers CAD and CAD Drawing

Conclusion

The development of the elbow motion simulator is necessary for advancing the testing procedures of the elbow implants. By assessing all the product design specifications, we were able to determine the necessary precision and durability while maintaining safety, to replicate elbow mechanics of flexion and extension. This simulator sets benchmarks for the testing of implants by inspecting their range of motion, load bearing capacity, and longevity of implants. The simulator ensures that the implant complies with the safety standards of medical devices.

We were guided by the customer needs and used specification and planning methods such as a WBS, Gantt chart and CPM to lead us to comprehensive design. We exhausted design ideas to design a simulator that meets both the customer needs and medical device standards.

Each design component, from the frame support to the rotary actuator mount, was designed to meet the structural needs of the simulator to ensure the stability and reliability of the design to extend its lifespan. The material used also assisted in the reliability of the design by using chrome stainless steel and natural rubber, so the biomechanical functions of the elbow can be replicated with as few problems as possible.

In conclusion, the elbow implant motion simulator is designed to become an essential tool in testing implants. It will contribute to developing safer and more reliable implants, ensuring patients can better their quality of life with better use of their elbow.

Recommendations

-An actuator to simulate the triceps could have been more realistic when simulating the flexion of the forearm, as the current design replaces the flexion done by the triceps with the force of gravity.

-An extra shaft or adding an extra smaller bicep actuator to simulate the tendon that would simulate the supination movement done by the bicep.

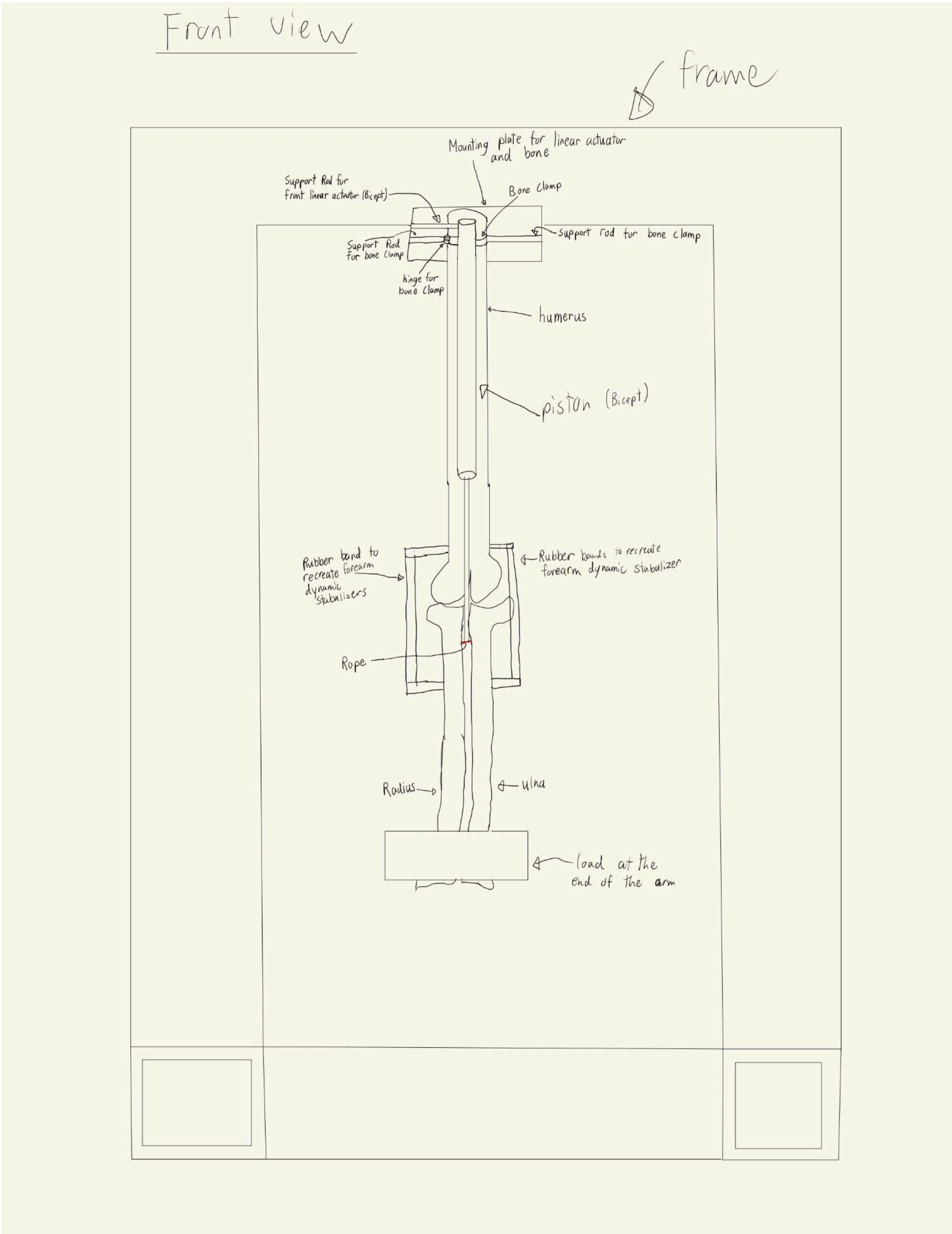
-Adding a replacement for the hand at the end of the forearm so that it can simulate the elbow joint moving when heavily loaded

-Many of the parts are welded which doesn't allow for disassembly

- There is only one clamp on the humerus, which may not be very stable when the arm is heavily loaded. More clamps or ways to hold the humerus in place should be added.

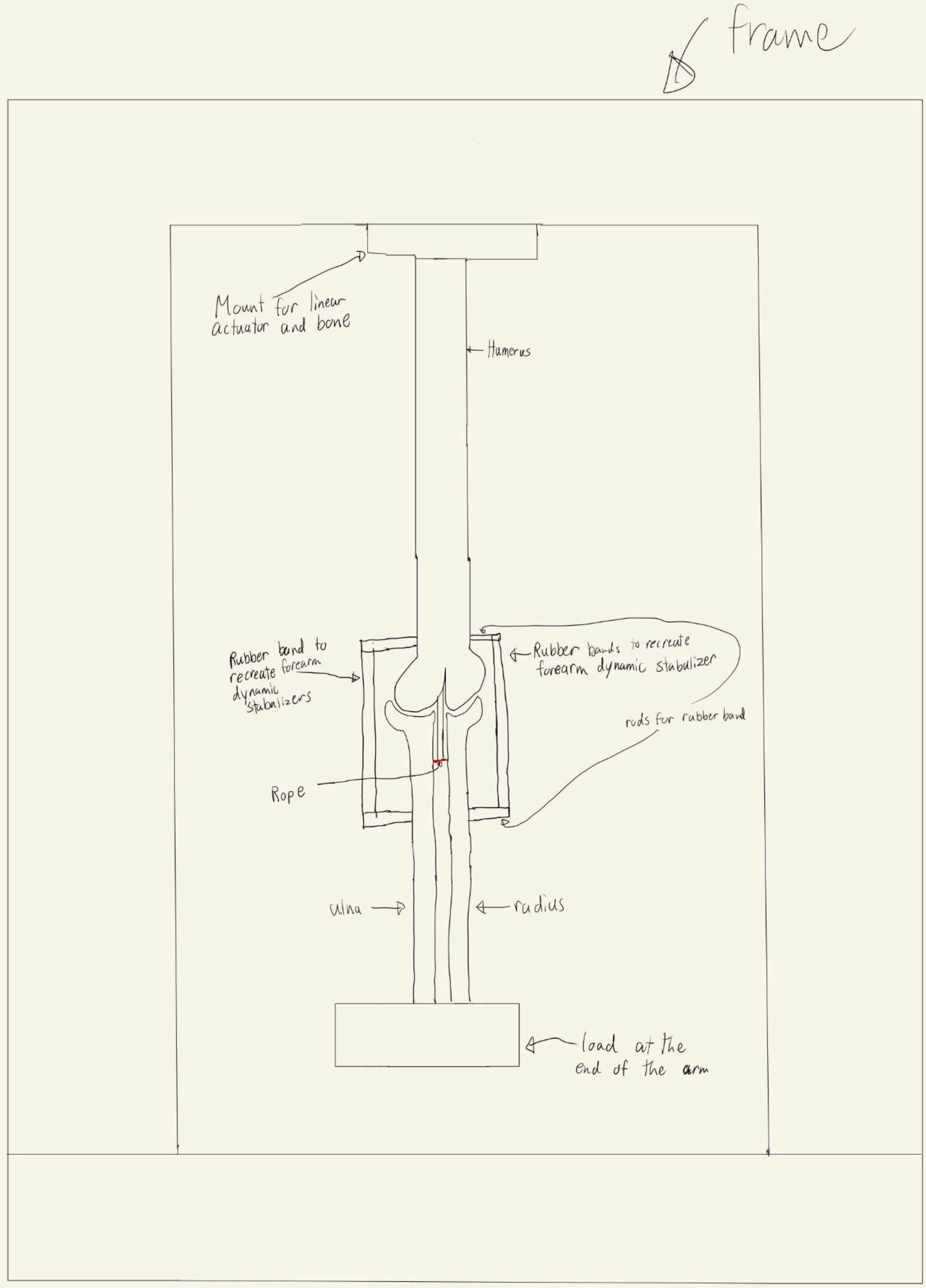
Appendix

[A]



Front view
frame
Mounting plate for linear actuator and bone
Support Rod for front linear actuator (Bicept)
Bone clamp
Support rod for bone clamp
Support Rod for bone clamp
hinge for bone clamp
humerus
piston (Bicept)
Rubber band to recreate forearm dynamic stabalizers
Rubber bands to recreate forearm dynamic stabalizer
Rope
Radius
ulna
load at the end of the arm

Back View


frame
Mount for linear actuator and bone
Humerus
Rubber band to recreate forearm dynamic stabalizers
Rubber bands to recreate forearm dynamic stabalizer
rods for rubber band
Rope
ulna
radius
load at the end of the arm

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