ExoFlex: Mid-term Design Report

BME Design I

Dr. Stephen Arce

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Andrew Baumert

Nick Cadavid

Arianna Escalona

Kyle Giddes

Aaron Gonzalez

Joseph Liberato

Executive Summary

This project focuses on the development of a ~~modular~~ knee exoskeleton aimed at enhancing and accelerating rehabilitation for patients recovering from knee surgeries, particularly total knee replacements (TKR). Rehabilitation after these procedures is crucial but often limited by the shortcomings of current at-home physical therapy methods. Patients frequently encounter uncomfortable, poorly guided exercises and lack access to proper equipment, which slows recovery and reduces motivation. The knee exoskeleton addresses these challenges by integrating mechanical assistance with electrical stimulation (e-stim), specifically neuromuscular electrical stimulation (NMES), offering a comprehensive solution to enhance functional outcomes.

The exoskeleton is being designed to enhance rehabilitation by promoting muscle activation and functional recovery. Through controlled mechanical resistance, it aims to facilitate joint stability and targeted muscle engagement using multiangle isometric and isotonic (concentric and eccentric) exercises. The integration of NMES is intended to support early-stage muscle activation, with the goal of accelerating improvements in quadriceps strength and overall mobility during the recovery process. Additionally, the system is being developed to incorporate sensors capable of tracking torque in real time, providing healthcare providers with actionable data to monitor patient progress and refine therapy regimens. By combining these features, the exoskeleton aims to offer a cost-effective, multifunctional alternative to traditional rehabilitation devices that often require multiple expensive and bulky tools.

The current design includes a simplified knee joint mechanism aligned with the axis of rotation, reducing bulk and manufacturing costs while maintaining biomechanical accuracy. Future plans include mechanical and electrical testing to ensure compliance with FDA guidelines, alongside the development of a control system that allows for adjustable resistance levels based on patient needs. The project will conclude with the integration of e-stim, the final prototype, and the creation of a user-friendly interface. OBJ

One sentence explanation of what is happening: TKR Physical Therapy

What is going on?

After a total knee replacement (TKR), the quadriceps tendon is cut and restitched, disrupting normal nerve pathways and impairing voluntary muscle activation. This surgical trauma can result in significant strength deficits of the quadriceps, further compounded by muscle atrophy. By combining targeted exercises with electrical stimulation, the Exoflex helps restore the mind-muscle connection and enables patients to regain voluntary control of their lower leg.

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Background and Significance

Project Motivation and Introduction

Total knee replacement is one of the most performed surgical procedures in the United States, with over 790,000 surgeries conducted annually [1]. Post-surgery rehabilitation is a critical component of recovery, as it restores joint mobility, reduces pain, and strengthens muscles. However, the current methods for rehabilitation present significant challenges, particularly for TKR patients. In clinical settings, rehabilitation often relies on separate devices, such as isokinetic machines for mechanical assistance and e-stim devices for muscle activation and pain relief [2]. These machines are expensive, bulky, and typically require clinical supervision, limiting their accessibility and practicality for patients.

At-home rehabilitation introduces additional barriers. Many TKR patients face difficulties performing exercises due to a lack of proper equipment, insufficient guidance, or discomfort during therapy. These limitations can lead to slower recovery, reduced motivation, and diminished outcomes. To address these challenges, our project focuses on developing a modular exoskeleton that integrates both mechanical resistance and e-stim into a single, cost-effective, and transportable device. By enhancing early functional mobility and muscle activation simultaneously, this exoskeleton provides significant advantages over existing rehabilitation technologies. The device is designed to support TKR patients by enabling an accessible and holistic recovery process, improving outcomes for both at-home and clinical therapy environments.

Needs Statement

There is a pressing need for a cost-effective, modular knee exoskeleton that combines mechanical assistance and electrical stimulation to optimize rehabilitation outcomes for patients recovering from knee surgeries, particularly those undergoing at-home therapy.

Primary Stakeholders

The key stakeholders involved in this project include patients, healthcare providers, and insurance companies. Firstly, patients recovering from knee surgeries are the primary beneficiaries of this knee exoskeleton. Secondly, physical therapists will be able to implement targeted, customized rehabilitation protocols tailored to each patient's progress. Lastly, third-party entities like insurance companies may find the cost-saving potential appealing, as the exoskeleton could shorten recovery periods and prevent long-term complications, reducing healthcare expenditures.

Knee Anatomy and Physiology

The knee is a hinge joint formed by the femur, tibia, and patella, stabilized by surrounding by ligaments such as the anterior cruciate ligament (ACL), and medial collateral ligament. Cartilage and menisci cushion the joint, while the quadriceps tendon connects the quadriceps muscle group to the patella, enabling knee extension and joint stabilization. This joint endures large amounts of mechanical stress during daily activities and requires precise coordination between surrounding components to function properly. During TKR, damaged cartilage, bone, and sometimes portions of the menisci are removed, disrupting the quadriceps tendon. This disruption results in muscle weakness, joint stiffness, and reduced mobility, causing challenges to rehabilitation. [3]

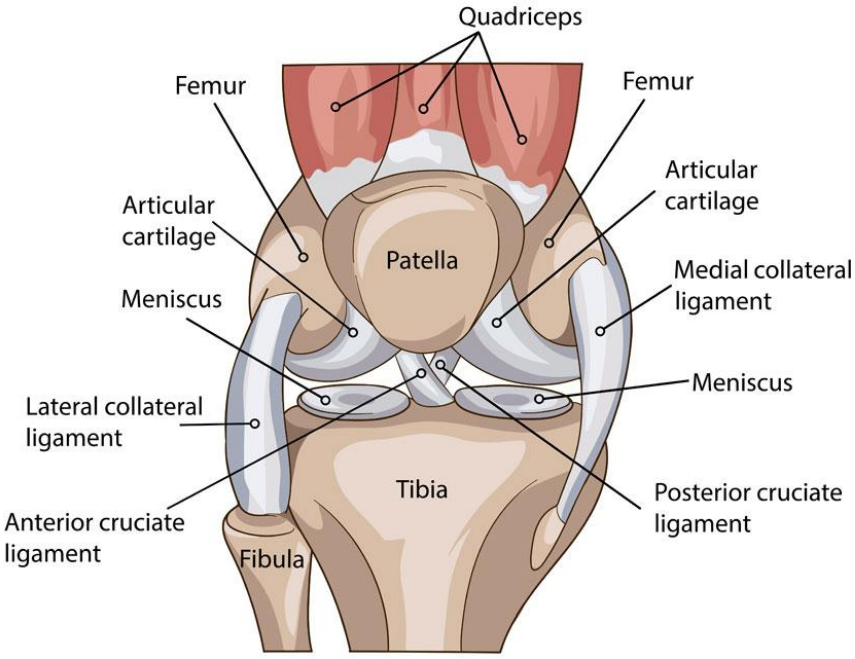


Figure 1. Anatomy of the knee.

Existing Solutions

Market Size

The market potential for our knee exoskeleton is significant, particularly in addressing the rehabilitation needs of patients undergoing TKR. In the United States alone, over 790,000 TKR surgeries are performed annually, with this number expected to grow as the population ages and the prevalence of joint-related conditions increases [1]. Post-surgical rehabilitation is a critical step in recovery, yet the current solutions are often fragmented and inaccessible for many patients. Given the global prevalence of knee replacement surgeries, the demand for effective and accessible rehabilitation solutions is substantial.

The demand for TKR surgeries is expected to rise significantly in the coming years, driven by a combination of demographic and health trends. The aging population is a primary factor, as knee joint degeneration and osteoarthritis are more prevalent among older adults. According to the U.S. Census Bureau, by 2030, over 20% of the U.S. population will be aged 65 or older, contributing to a surge in knee replacement procedures [4]. Additionally, the increasing prevalence of obesity—a key risk factor for knee osteoarthritis—is another critical driver [5]. Recent data from the CDC indicates that over 40% of U.S. adults are classified as obese, a number projected to grow in the coming decades. These alarming trends, coupled with the rise in sedentary lifestyles and the associated strain on knee joints, point to a sharp increase in the number of TKR surgeries performed annually [6].

Opportunity and Competitors

Rehabilitation after knee surgery often relies on a fragmented combination of mechanical devices and electrical stimulation systems, each addressing different aspects of therapy but failing to provide a comprehensive solution. Isokinetic machines, such as the Biodex Multi-Joint System (Figure 2), cost upwards of $60,000 and focus solely on providing controlled resistance for joint mobility. These devices are not only expensive but also bulky, requiring clinical supervision and limiting their practicality for at-home use. Similarly, electrical stimulation devices, such as NMES, are compact and widely used to activate weakened muscles like the quadriceps following surgery. However, these systems operate independently from mechanical devices, forcing patients to alternate between multiple tools, which can be cumbersome, inefficient, and less effective in achieving comprehensive rehabilitation.

Figure 2. The System 4 Quick-Set Knee Rehabilitation Machine by Biodex Medical Systems, Inc. Listed for $63,651.00 on Arrowhead Medical Store's website.

While several devices have been introduced to the market, they typically focus exclusively on either mechanical assistance (such as walking movements) or electrical stimulation, but not both (Table 1). For FDA approval, the ExoFlex is being compared to two devices currently in the market, a powered exoskeleton and an NMES/transcutaneous electrical

nerve stimulation (TENS) unit (Tables 2, 3, and 4). This lack of integration highlights a significant gap in existing solutions, leaving patients and healthcare providers with suboptimal options for recovery. Moreover, the demographics of typical patients undergoing TKR surgeries, many of whom are elderly and live alone, exacerbate the need for accessible and efficient therapy solutions. Transportation challenges and reliance on improvised at-home therapy equipment, such as stairs or chairs, often lead to inconsistent and uncomfortable therapy experiences. Continuous Passive Motion (CPM) devices, for example, attempted to address this issue but failed to provide meaningful functional improvements, further underscoring the unmet need in this space (Figure 3).

Figure 3. Continuous Passive Motion Machine for therapy post-TKR surgery. This device passively exercises the quadricep muscle.

Our knee exoskeleton represents a breakthrough solution by seamlessly integrating mechanical assistance and electrical stimulation into a single device. This integration not only streamlines the rehabilitation process but also makes it more effective by enabling simultaneous therapy for joint mobility and muscle activation. The device's modularity and adjustability allow customization to meet individual patient needs, making it versatile for a wide range of users. In addition, the inclusion of real-time data acquisition empowers physical therapists with actionable insights, enabling remote monitoring and personalized treatment plans. By combining these features into a compact, cost-effective system suitable for both clinical and at-home use, the exoskeleton addresses critical gaps in current rehabilitation practices while enhancing accessibility, efficiency, and patient outcomes.

Table 1. A comprehensive table listing the four main competitors of our exoskeleton.

Features/Functionality	**Competitor 1**: AlterG Anti-Gravity Treadmill	**Competitor 2**: Bioness L300 Go	**Competitor 3**: Ottobock C-Brace	**Competitor 4**: Compex Muscle Stimulator
Mechanical Assistance		No mechanical assistance	Provides real-time	No mechanical assistance

	Supports body weight for easier walking		mechanical support for walking	
Electrical Stimulation (E-stim)	No e-stim	Functional e-stim for foot drop	No e-stim	Delivers NMES/TENS for muscle recovery
Modularity	Adjustable body weight support	Adjustable stimulation settings	Adjustable for different walking conditions	Adjustable intensity for different muscle groups
Data Acquisition	Tracks progress and body weight distribution	Gathers walking data	Provides real-time feedback on movement	No data tracking
Target Use	Gait recovery for various conditions	Foot drop treatment	Walking recovery for mobility issues	Muscle recovery for athletes and patients

Table 2. Summary of the two predicate devices used to compare the ExoFlex.

Device Name	Device Classification Name	Product Code	510(k) Number	Applicant
HAL for Medical Use (Lower Limb Type)	Powered Exoskeleton	PHL - A powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened lower extremity limb(s) for medical purposes.	K171909	Cyberdyne Inc. 2-2-1 Gakuen-Minami Tsukuba, JP 305-0818
Chattanooga Revolution Wireless	Stimulator, Muscle, Powered	IPF – Powered muscle stimulator	K153696	DJO, LLC 1430 Decision Street Vista, CA 92081

Table 3. Predicate comparison table with the Medical HAL Lower Limb Type.

Characteristic	Predicate Device	New Device
Body Coverage	Worn over legs and around hips and lower torso.	Worn from thigh to ankle.
Patient Height	150-190 cm	150-190 cm
Patient Weight	40-100 kg	40-100 kg
Intended Environment	· Flat surface of medical facilities (indoor only) · Must be used in combination with BWS systems.	· Flat surface of medical facilities and at home (indoor only).
Intended Users	Medical professionals that have completed designated training program to use the device	Medical professionals
Hardware and Main Components	The system consists of three major components: · Controller · Main unit · Sensor shoes	· Main unit · Motor
Device Lifetime	5 Years	5 Years
Range of Motion	· Hips: 120° flexion to -20° extension · Knee: 120° flexion to -6° extension	· Knee: 120° flexion to 0° extension
Safety Features	· Limited joint torque and joint velocity · Mechanical stoppers to prevent excessive joint flexion or extension. · System fault for each component throughout operation · Task switching conditions that will not initiate incorrect task changes	· Limited joint torque and joint velocity · Mechanical stoppers to prevent excessive joint flexion or extension.

Table 4. Predicate comparison table with the Chattanooga Revolution Wireless.

Characteristic	Predicate Device	New Device
Prescription/OTC	Prescription	Prescription
Where Used	Physician office, physical therapy Clinic, Hospital, Nursing Home, Post Acute Care, Chiropractic Clinic	Physician office, physical therapy Clinic, Hospital, Nursing Home, Post Acute Care, Chiropractic Clinic
Target Population	Adult Population	Adult Population
Connection of device to electrodes	Stimulation Module is directly connected to the custom male SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) stimulation modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.	Stimulation Module is directly connected to the. User Interface (LCD and buttons) is physically connected through a wire providing two stimulation modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.
Number of Output Modes	Muscle stimulator: Electrodes	Muscle stimulator: Electrodes
Number of Output Channels	4	2
Software Control	Yes	Yes
Automatic Shut Off	Yes, On/Off Switch	Yes, On/Off Switch
Compliance with 21 CFR 898	Yes - 21CFR 898Performance standard for electrode lead wires and patient cables.	Yes - 21CFR 898Performance standard for electrode lead wires and patient cables.
Output Specifications (Waveform)		
Shape	Rectangular	Rectangular
Maximum Output Current (± 10%)	120 mA @ 500 Ω 90 mA @ 2 kΩ 18 mA @ 10 kΩ	40mA – 100mA

Product Definition

Customer Requirements

For the ExoFlex knee exoskeleton, we have identified a total of 11 customer requirements. These requirements are critical in ensuring that the product meets the needs and expectations of its intended users. Below is an in-depth explanation of each requirement:

1. Biomechanically Accurate:

Biomechanical accuracy refers to the exoskeleton's ability to mimic and support the natural movements of the human knee joint. This includes replicating the range of motion and force distribution of the user's leg. Ensuring biomechanical accuracy is crucial for the effectiveness of the exoskeleton in improving physical therapy while preventing injury.

2. Mechanical Rehab:

Mechanical rehabilitation involves the exoskeleton's role in aiding the recovery of knee function through supportive movements and resistance training. This includes features like adjustable resistance levels and programmable exercise routines tailored to the user's rehabilitation needs.

3. Electrical Rehab

Electrical rehabilitation encompasses both uses of electrical stimulation: NMES and TENS. Combined, they can help in activating the quadriceps muscle before exercising and relieving pain afterward. In addition, incorporating electrical rehab capabilities into ExoFlex is what differentiates us from other products in the market, as it provides a holistic approach to rehabilitation.

4. Data Acquisition

Data acquisition involves the collection and analysis of various metrics related to the user's progress with time, such as increased strength and range of motion. Sensors embedded within the exoskeleton capture this data for real-time monitoring and long-term analysis. Accurate data acquisition is essential for personalizing the exoskeleton's performance to each user's specific needs. It enables healthcare providers to track progress and adjust treatment plans.

5. Fitting (Sizing)

Fitting refers to the ability of the exoskeleton to accommodate different knee and leg sizes and shapes. This includes adjustable components that ensure a snug and secure fit for users of varying heights, weights, and anatomical differences. A proper fit is vital for the comfort, effectiveness, and safety of the exoskeleton.

6. Ease of Use

Ease of use pertains to the user-friendliness of the exoskeleton, including intuitive controls, straightforward instructions, and minimal maintenance requirements. Even though the ExoFlex must be used under supervision, a user-friendly design is essential for encouraging consistent use and ensuring that PTs can operate ExoFlex without extensive training or assistance.

7. Comfort/Padding

Comfort involves the physical sensation of wearing the exoskeleton, including factors like weight distribution, cushioning, breathability, and the absence of pressure points. Padding materials should be soft, durable, and designed to prevent skin irritation. Comfort is paramount for user compliance and prolonged use of the exoskeleton. Ensuring high levels of comfort makes ExoFlex more appealing to users.

8. Cost

Cost refers to the overall price of the exoskeleton, including manufacturing, materials, maintenance, and any additional services. It also considers the affordability for both individual users and healthcare providers or institutions. Balancing advanced features with cost-effectiveness is crucial for market competitiveness and accessibility. Keeping ExoFlex affordable ensures that a broader range of users can benefit from the technology.

9. Durability

Durability encompasses the exoskeleton's ability to withstand regular use, environmental factors, and wear and tear over time. It involves selecting materials and engineering designs that ensure longevity and reliability. A durable exoskeleton reduces the need for frequent repairs or replacements, lowering the total cost of ownership and enhancing user trust in the product. Durability is also linked to safety, as a reliable device is less likely to fail during critical moments of use.

10. Togglability

This customer requirement refers to the ability to easily switch the exoskeleton's electrical stimulation feature off when needed. This way, the ExoFlex can still be used by patients with pacemakers or heart conditions without presenting any danger.

11. Bulkiness/Aesthetics

Bulkiness pertains to the size and weight of the exoskeleton, while aesthetics involves the visual design and overall appearance. A sleek, lightweight, and visually appealing design can make the device more attractive to users. Minimizing bulkiness enhances the exoskeleton's portability and ease of movement, making it more convenient for everyday use.

Design Inputs

Table 5 summarizes the prioritized customer requirements for the knee exoskeleton, ranked using a Binary Pairwise Comparison method. This ranking system evaluates the relative importance of each feature to ensure that the device design aligns with user needs and expectations. The criteria are ordered from most important to least important based on their Impact Weight Factor (IWF). Key considerations such as biomechanical accuracy, mechanical rehabilitation, and electrical rehabilitation rank highest, reflecting the primary functional needs of the exoskeleton. Other factors, including data acquisition, ease of use, and fitting (sizing), highlight the importance of accessibility and user comfort. Features such as togglability (e-stim on/off) and bulkiness/aesthetic, while less critical, are still accounted for to ensure the device offers a holistic solution. This systematic prioritization provides a clear framework for guiding the development process toward a customer-centered design.

Table 5. Customer requirements are organized using Binary Pairwise Comparison. Ranked from most important (1) to least important (11).

Ranking:	Customer Requirements	IWF:
1	Biomechanically Acc.	10
2	Mechanical Rehab	9
3	Electrical Rehab	8
4	Data Acquisition	7
5	Fitting (sizing)	6
6	Ease of Use	5
7	Comfort/Padding	4
8	Cost	3
9	Durability	2
10	Togglability (e-stim on/off)	1
11	Bulkiness/Aesthetic	0

House of Quality Table

		Engineering Characteristics									
Improvement Direction		↓	↑	↓	↓	↓	↓	↓	↑	↑	↓
Units		weeks	lbs	° (degrees)	min	min	° (degrees)	kWh	cm	years	$ (USD)
Customer Requirements	Importance Weight Factor	Time to 90% Recovery	Resistive Strength	Prevents excessive flexion	Tracks rehab progress	Time to setup and remove	Resists lateral movement	Enables electrical rehab	Fits large range of heights	System lifecycle	Material Cost
Biomechanically Acc.	**10**	10	5	10	1	1	7	1	7	4	3
Mechanical Rehab	**9**	10	10	10	1	1	1	1	1	8	10
Electrical Rehab	**8**	8	1	1	1	1	1	10	1	4	3
Data Acquisition	**7**	1	7	1	10	1	1	1	1	1	3
Fitting (sizing)	**6**	6	1	5	1	3	5	1	10	3	3
Ease of Use	**5**	1	1	1	1	10	1	1	1	1	1
Comfort/Padding	**4**	1	1	1	1	5	1	1	3	1	4
Cost	**3**	1	5	1	1	1	1	2	3	1	10
Durability	**2**	1	1	1	1	1	1	1	1	10	9
Togglability (estim on/off)	**1**	1	1	1	1	1	1	10	1	1	1
Bulkiness/Aesthetic		1	1	1	1	7	1	5	2	1	5
Raw Score:	1954	312	230	250	118	128	139	139	183	202	253
Relative Weight %:	100.0	16.0	11.8	12.8	6.0	6.6	7.1	7.1	9.4	10.3	12.9
Rank Order:		1	4	3	10	9	7	7	6	5	2

Figure 4. House of Quality table for quantitative targets.

This House of Quality table serves as a tool for translating customer requirements into specific engineering characteristics, providing a structured approach to prioritize design efforts. By linking what customers value most with measurable technical parameters, the table highlights which aspects of the design should receive the most attention during development.

In this particular chart, customer requirements such as having a biomechanically accurate device, facilitating faster recovery, and providing effective resistive strength are weighted based on their relative importance. Among these, biomechanical accuracy was identified as the top priority, reflecting its critical role in ensuring the device aligns with the natural motion of the body. On the engineering side, the reduction in time to recovery emerged as the most impactful characteristic, emphasizing the importance of a device that not only supports rehabilitation but also expedites the process.

This systematic approach ensures that design decisions are data-driven and aligned with customer needs, ultimately guiding the development process to create a device that balances functionality, usability, and efficiency.

Concept Selection

		Concepts						
Engineering Characteristics	Datum	1	2	3	4	5	6	7
Time to 90% Recovery		S	S	S	S	S	S	+
Resistive Strength		+	+	S	-	+	-	+
Prevents excessive flexion		S	S	S	-	S	S	+
Tracks rehab progress		+	+	+	+	+	+	+
Time to setup and remove		-	-	+	+	-	+	-
Resists lateral movement		+	+	-	S	+	-	S
Enables electrical rehab		S	S	S	S	S	S	S
Fits large range of heights		-	-	+	-	-	+	-
System lifecycle		-	-	+	-	-	-	-
Material Cost		-	-	+	S	-	S	-
# of pluses		3	3	5	2	3	3	4
# of minuses		4	4	1	4	4	3	4

1	Gas Springs w/ Dual Legs
2	Servo Motor w/ Dual Legs
3	Servo Motor w/ Single Leg
4	Coiled Spring (Passive)
5	Geartrain w/ Dual Legs
6	Dual Pivot Point Design
7	Hip-to-Ankle Design

Datum: HAL-SJ

Selected Concept

Figure 5. Pugh Chart to aid in concept selection.

This Pugh chart compares the proposed device to the predicate device outlined in the FDA 510(k) documentation. In most categories, the ExoFlex device demonstrates comparable effectiveness to the predicate, as reflected by a similar distribution of strengths and weaknesses. However, one key feature distinguishes the proposed device: the integration of a servo motor in combination with a single-leg design. This innovation not only aligns with the performance of the predicate device but in many cases offers superior functionality, making it a standout feature in the analysis.

Current Design and Change History

The current design of the ExoFlex, shown in Figure 6, is intended to align in parallel with the user's leg, with the actuator positioned to directly align with the axis of rotation of the knee. In knee exoskeletons, the knee joint is often simplified to a single hinge joint because the displacement of the axis of rotation during movement is minimal and does not significantly impact functionality. This simplification allows for a more streamlined and efficient design without compromising biomechanical accuracy. Previous iterations of the ExoFlex featured a longer shank component, but this was shortened to reduce the torque required by the motor, thereby lowering the device's overall manufacturing cost and minimizing bulkiness. These changes enhance both the affordability and usability of the design while maintaining its effectiveness. Technical drawings of each component are provided in Figures 7, 8, and 9, detailing the refined geometry and improved design features.

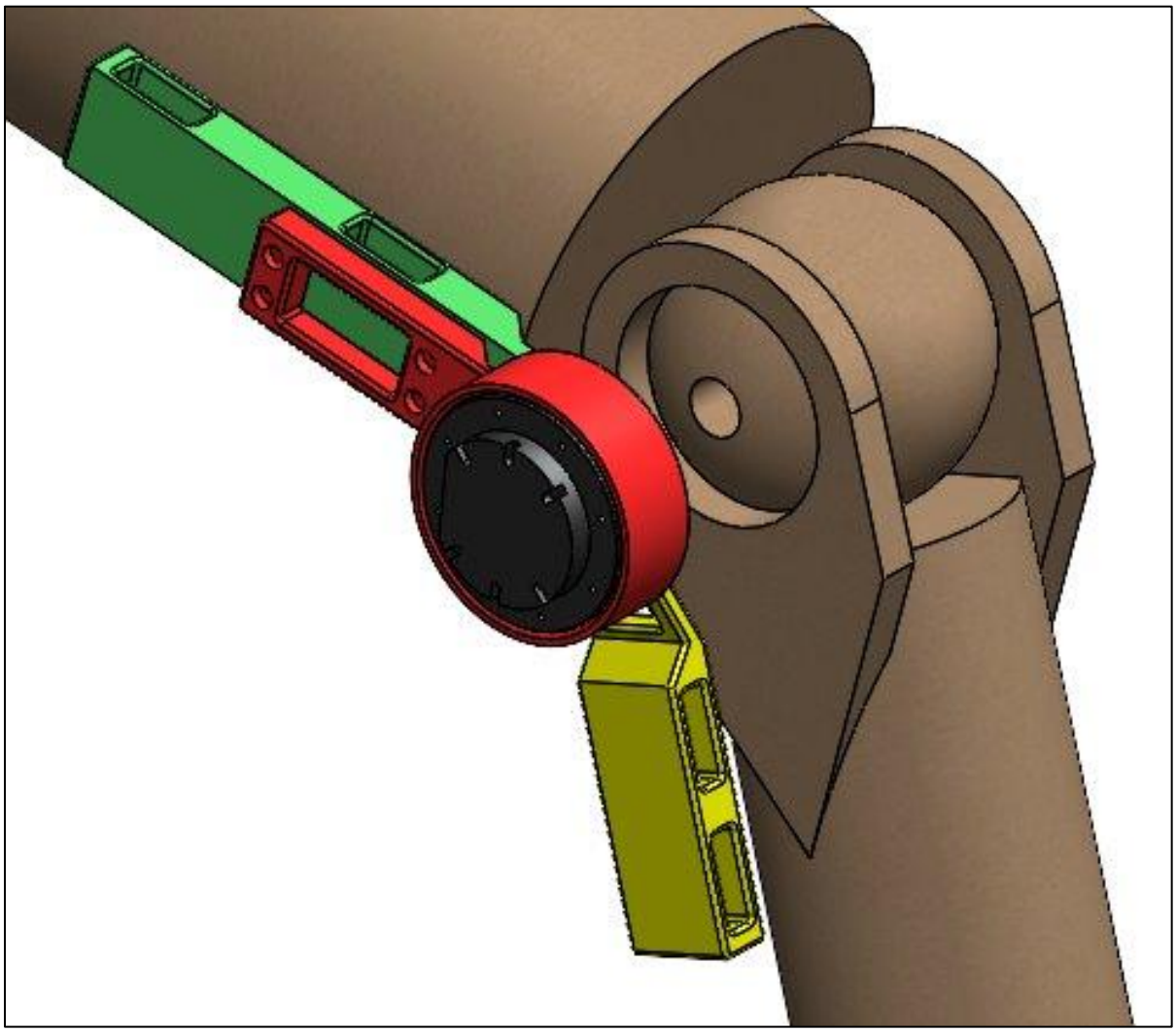


Figure 6. CAD Model showing the side view of the ExoFlex's current prototype. This assembly attaches to the user's leg through Velcro straps. The green part is placed parallel to the user's thigh. The red part is the motor housing. The yellow part is the shank. Made with SolidWorks.

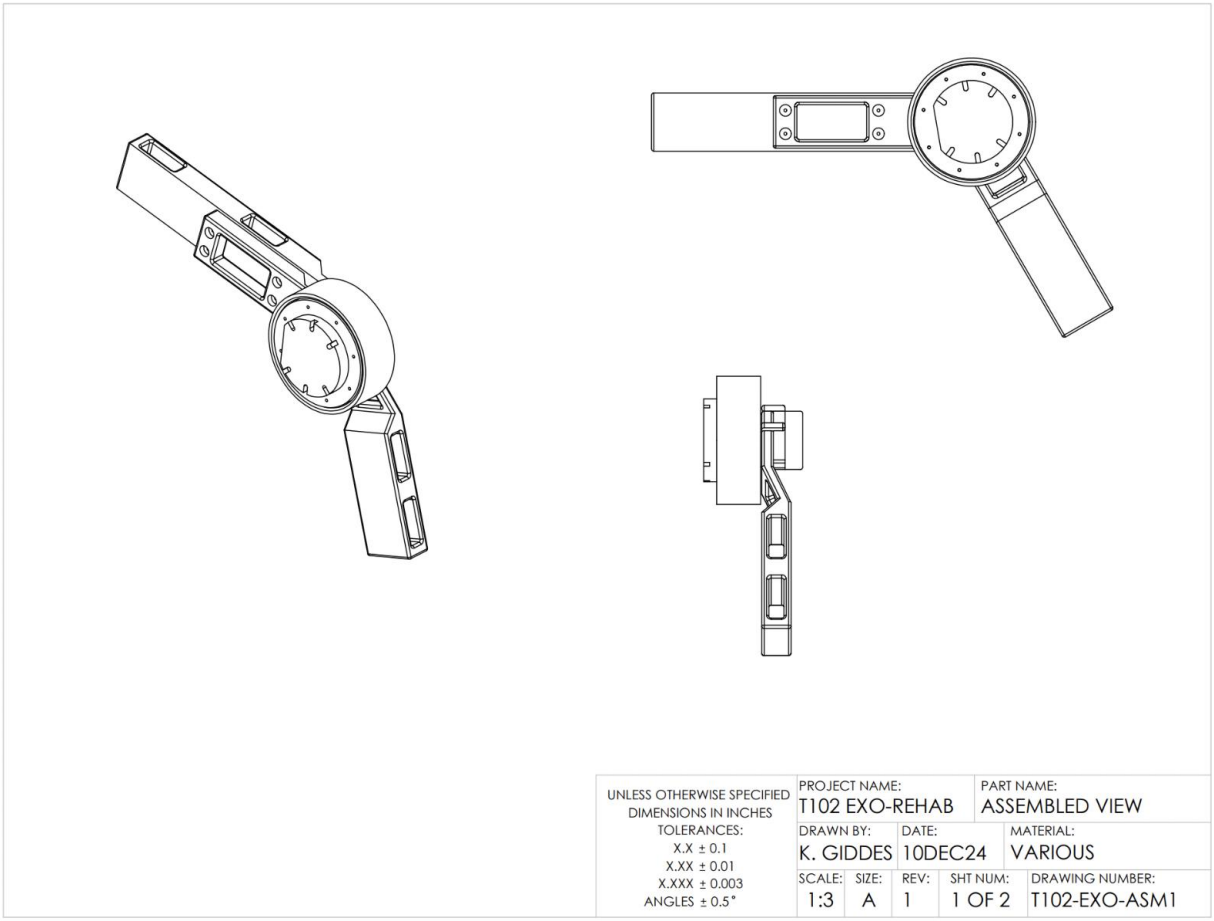


Figure 7. Technical drawing of the current prototype. Made with SolidWorks.

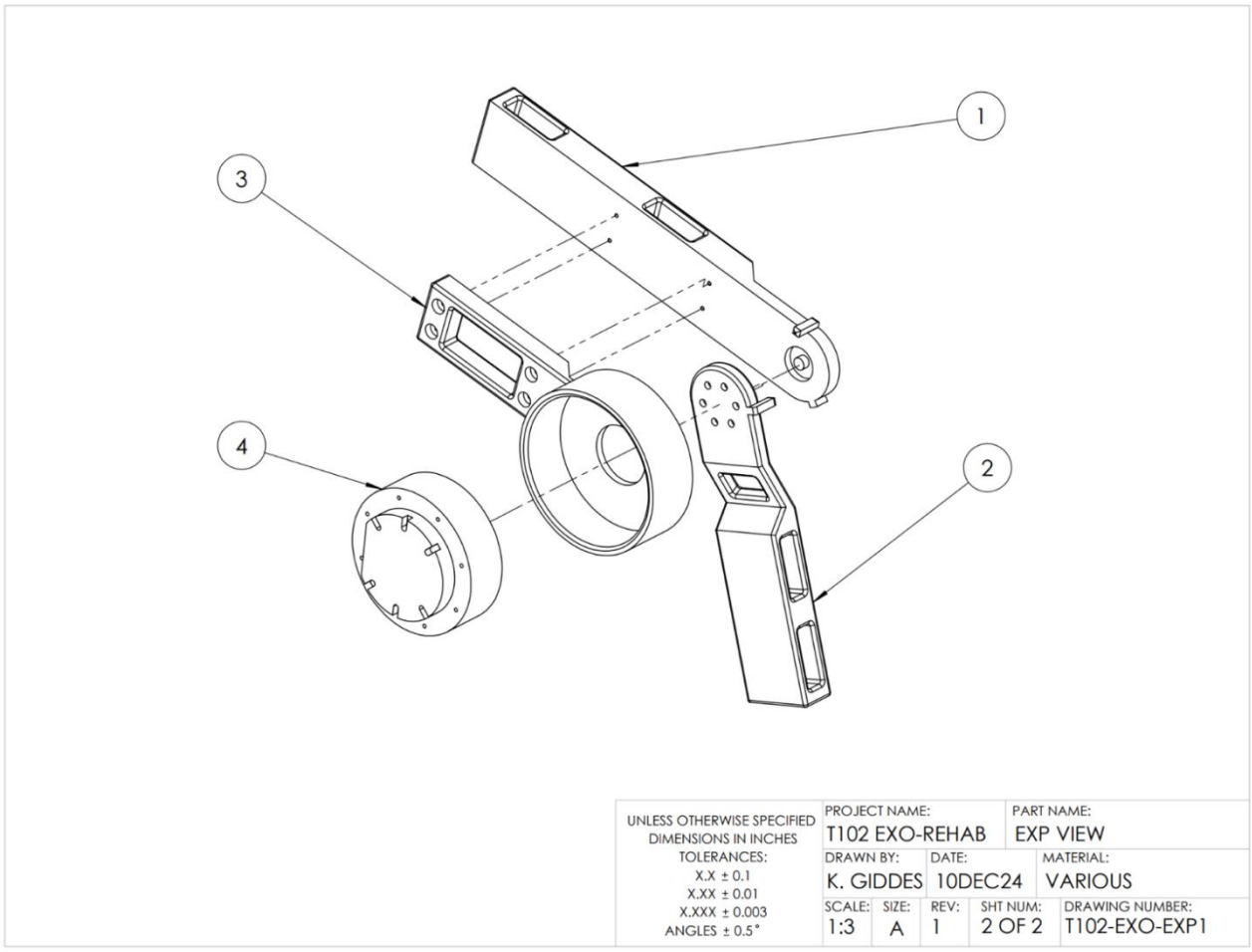


Figure 8. Technical drawing of the motor housing. The motor housing connects the thigh part (1) and the shank part (2). The motor (4) is placed in the exoskeleton (3) to serve as the actuator for the mechanical movements. Made with SolidWorks.

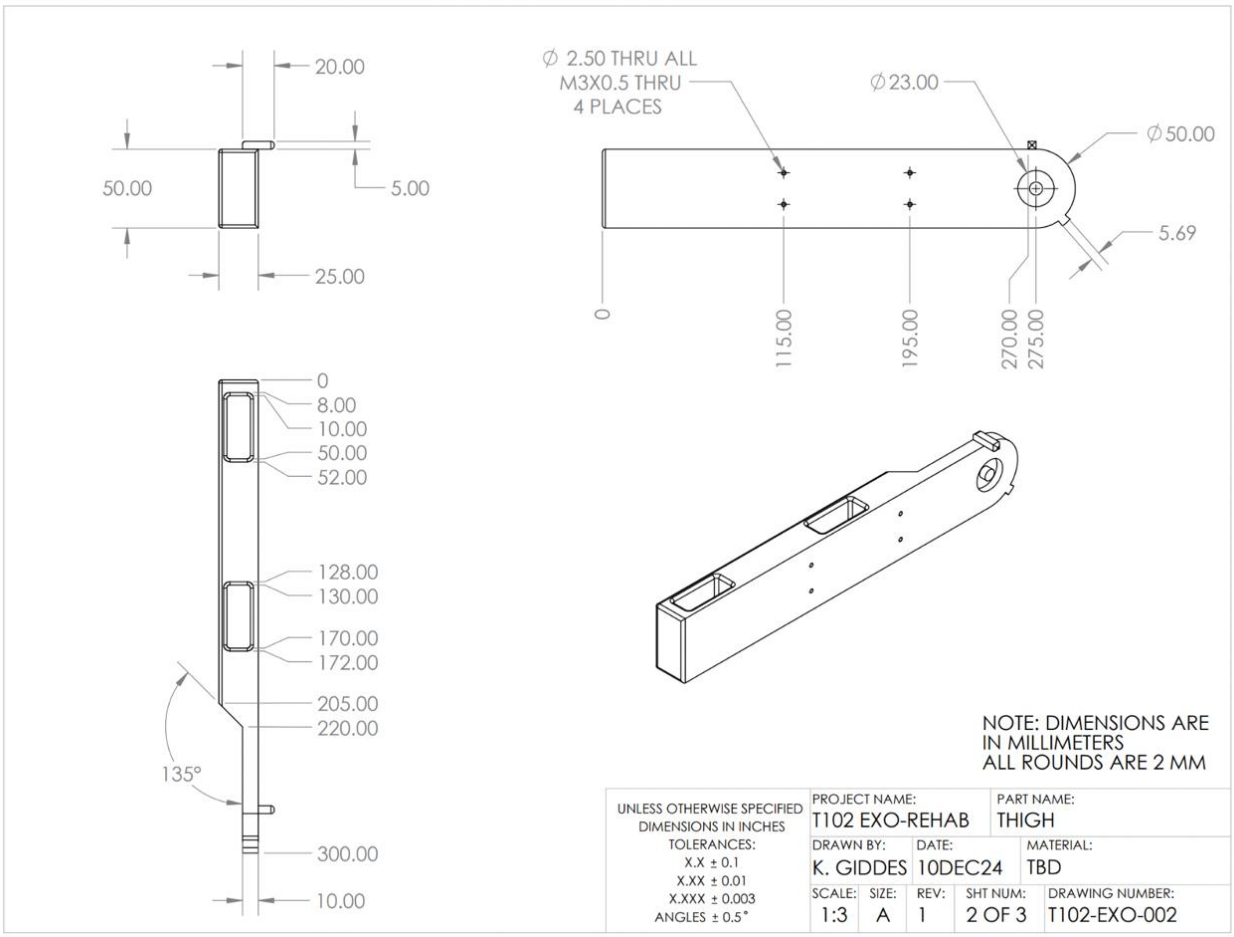


Figure 9. Technical drawing of the thigh part. This part provides stability during mechanical movements. Made using SolidWorks.

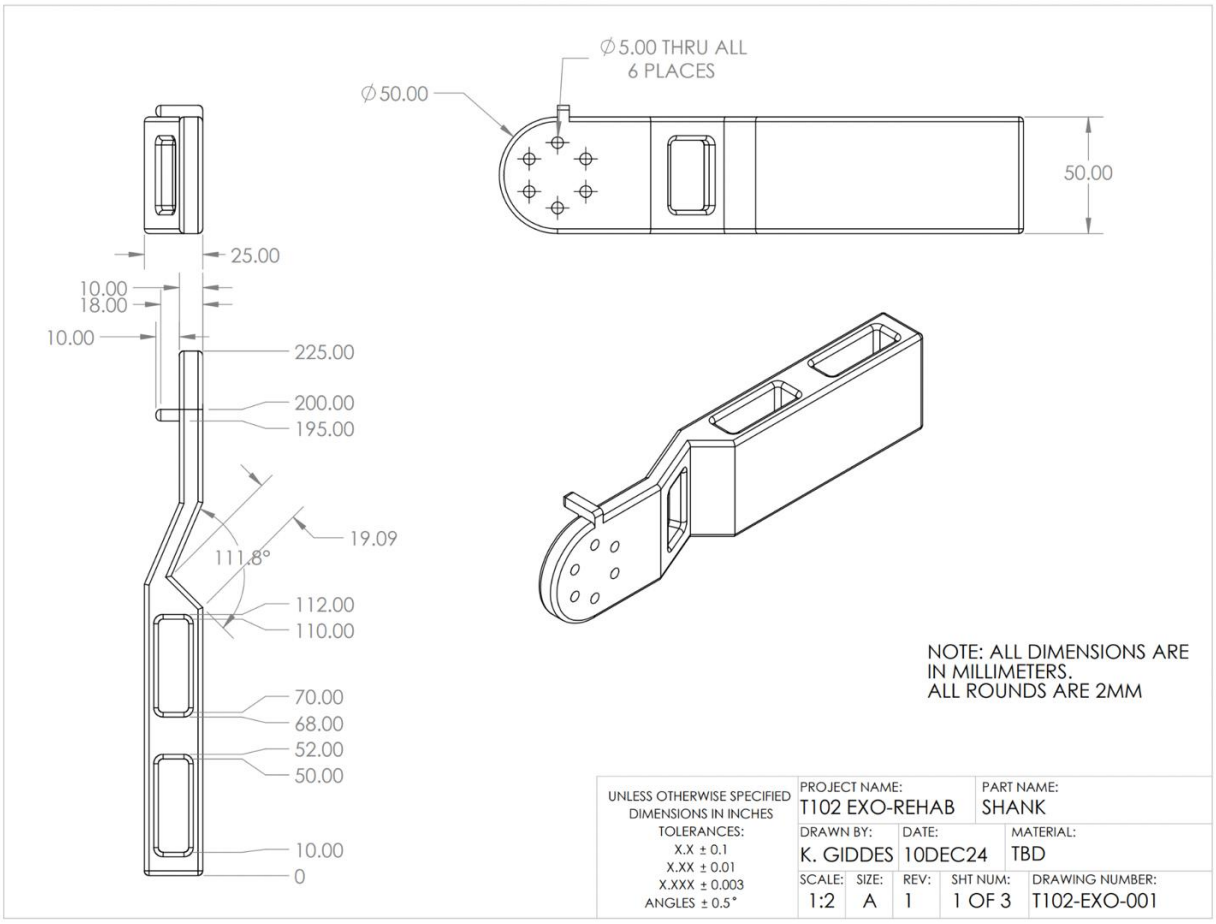


Figure 10. Technical drawing of the shank. The shank attaches to the user's body to transmit the torque from the actuator to the body. Made using SolidWorks.

Prototyping Efforts

Over the course of the past four months, significant effort has been dedicated to refining the mechanical and electrical stimulation components of the device through multiple iterations. These prototypes were developed with a focus on achieving a balance between functionality, safety, and adaptability to meet the diverse needs of rehabilitation therapy. The iterative process involved addressing key challenges, such as ensuring precise biomechanical alignment, integrating advanced features like resistive capabilities, and maintaining patient safety with robust current management. The following figures and descriptions detail this progression, showcasing how each iteration built upon previous designs to enhance both the mechanical framework and electrical systems, ultimately converging toward a comprehensive solution.

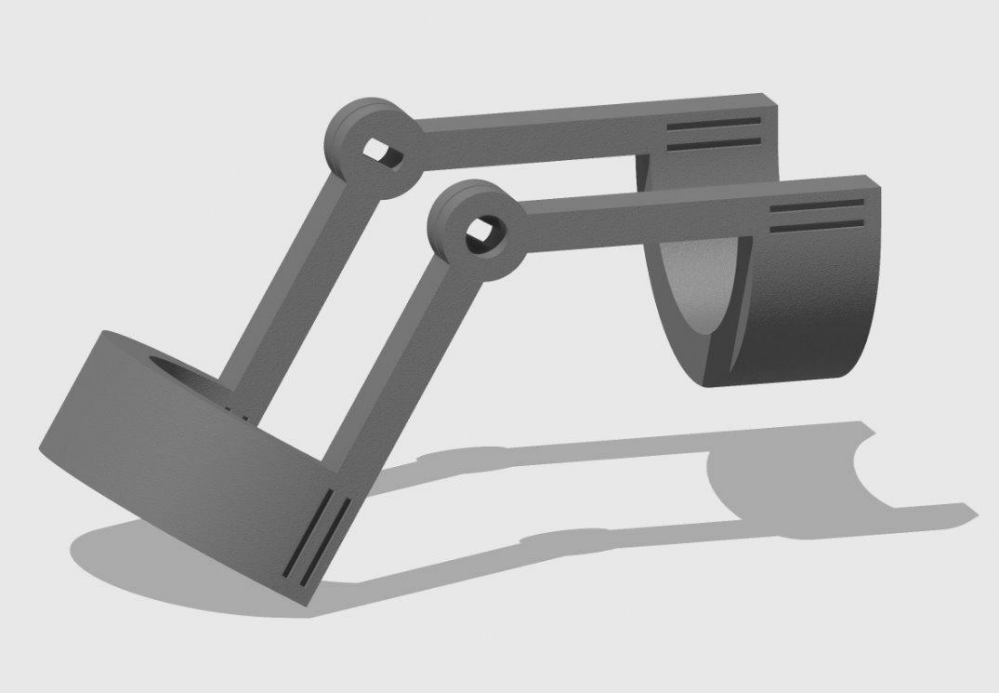


Figure 11. First CAD showing the most basic design features.

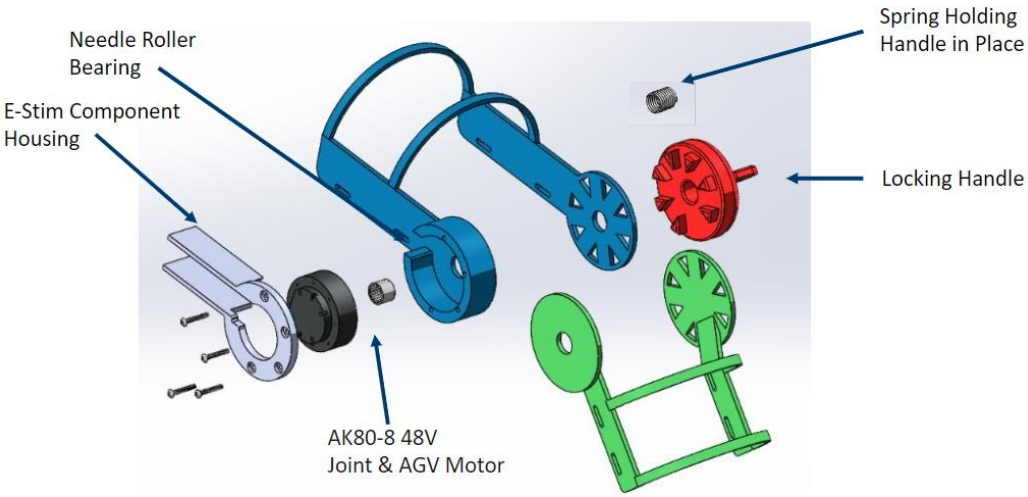


Figure 12. Improved CAD Prototype designed in SolidWorks. This is a more comprehensive view of how the device will work. It displays the motor, bearings, mechanical stops, and overall design shape.

The previous two figures illustrate the progression from the first prototype to the second. The inspiration for the second design, as compared to the first, is evident in several key features. Both designs incorporate top and bottom straps to provide stable support for the leg, ensuring proper alignment during use. The inner circular section, present in both prototypes, is designed to cradle

the knee, facilitating a biomechanically accurate model that mimics the natural motion of the joint.

The second prototype introduces significant advancements. Notably, it includes a motor—specifically, the AK80-8 48V Joint & AGV Motor—integrated to provide resistive capabilities for dynamic exercises. This actuator enables precise control over resistance levels, catering to a variety of rehabilitation needs. Furthermore, this version features a locking handle, allowing the device to be secured in place for isometric exercises, enhancing its versatility. Finally, the addition of an e-stim housing module streamlines the integration of NMES, making the device more efficient and user-friendly for therapeutic applications.

The NMES prototypes were designed with the goal of achieving a rectangular biphasic waveform at a frequency range of 35-80 Hz, which is necessary for effective quadriceps muscle activation. While the ultimate aim is to deliver 80-100 mA through 5x5 cm electrodes, the primary focus of the current prototypes has been to validate the waveform characteristics and ensure the circuit's ability to produce a safe and reliable signal.

In Figure 13, the op-amp section of the circuit is depicted in the bottom-most image. This circuit operates similarly to an H-bridge; however, in this configuration, when one transistor is active, the output generates a positive voltage, and when the other transistor is active, the output produces a negative voltage. The purpose of this design is to ensure zero net current flow into the patient's body. This is achieved because a negative voltage results in a corresponding negative current, allowing current to be sent into and withdrawn from the leg at equal rates. This feature enhances safety. Additionally, for further protection, a transformer can be incorporated at the electrode connections to isolate the patient from the power source in case of a circuit malfunction.

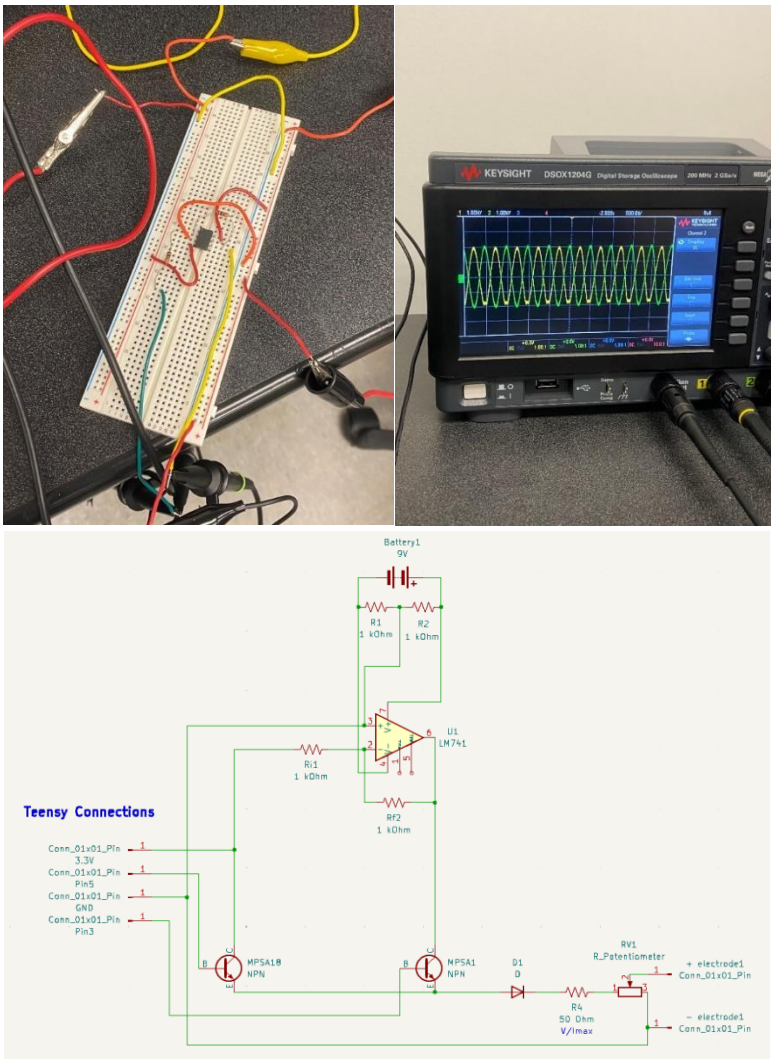


Figure 13. E-stim Model 1 Circuit Prototype (top left), oscilloscope results (top right) and PCB schematic (bottom). The oscilloscope is displaying the results of the inverting op-amp where yellow is the input signal and green is the output signal.

The second NMES prototype, inspired from an online schematic [7] was designed to deliver alternating pulses of electrical stimulation using a 7555-timerr circuit. As shown in figure 13a, the circuit was adapted using LTspice, replacing the 7555 with a NE555 timer, which works as an oscillator, generating the desired frequency based on the resistor and capacitor values:

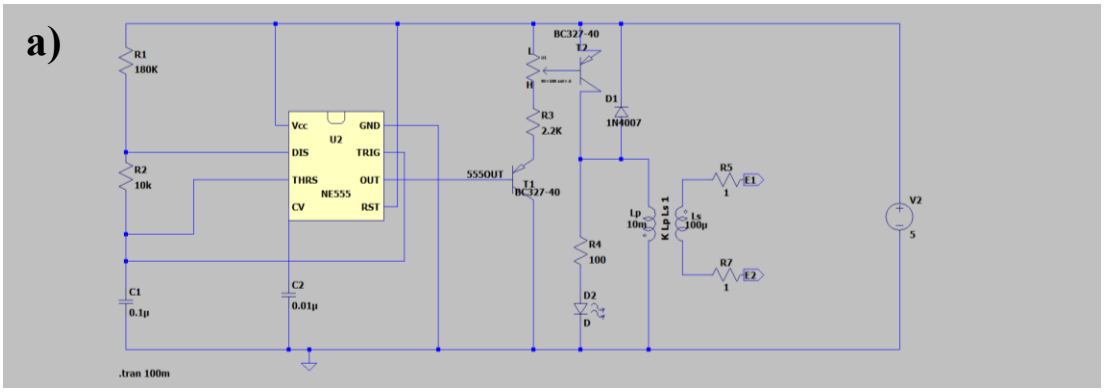
$$R1 = 180k\Omega; R2 = 10k\Omega;\ C1 = 0.1\mu F.$$

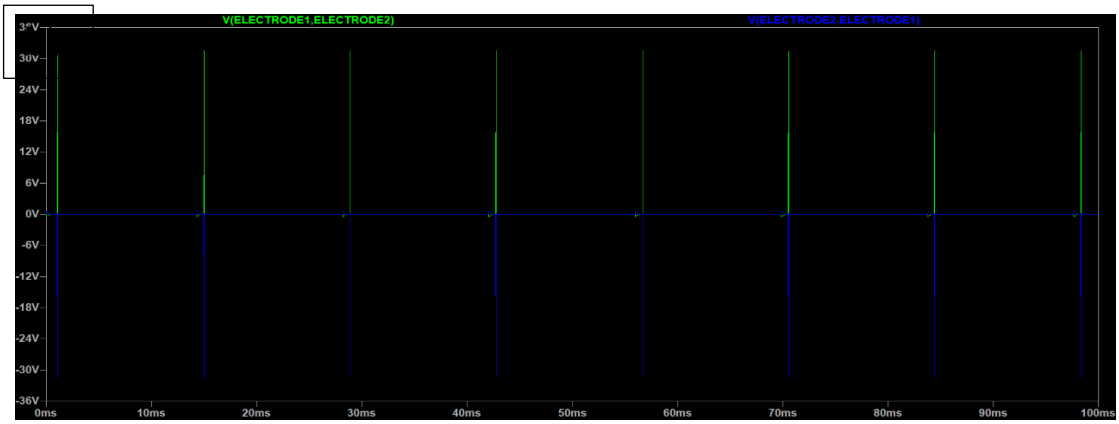
$$f = \frac{1.44}{(R1 + 2R2)C1} = 72Hz$$

Transistors T1 and T2, configured as PNP switches, alternate the current flow through the primary winding of a 1:10 transformer. The transformer steps up the voltage, creating an

alternating output across the secondary winding. Electrode 1 is connected to the top of the secondary winding and Electrode 2 to the bottom, with their polarities alternating at each pulse. This produces an output of approximately ±30 V at each electrode, resulting in a total voltage difference of 60 V, as shown in the oscilloscope simulation (Figure 13b).

The physical prototype, as shown on a breadboard in Figure 14c, was not fully operational due to the unavailability of the required transformer. Additionally, the intensity of the stimulation is regulated by a potentiometer in this design. Future improvements include replacing the 555 timer with a microcontroller for more precise control and exploring software-based solutions to adjust stimulation intensity dynamically, removing the need for a manual potentiometer





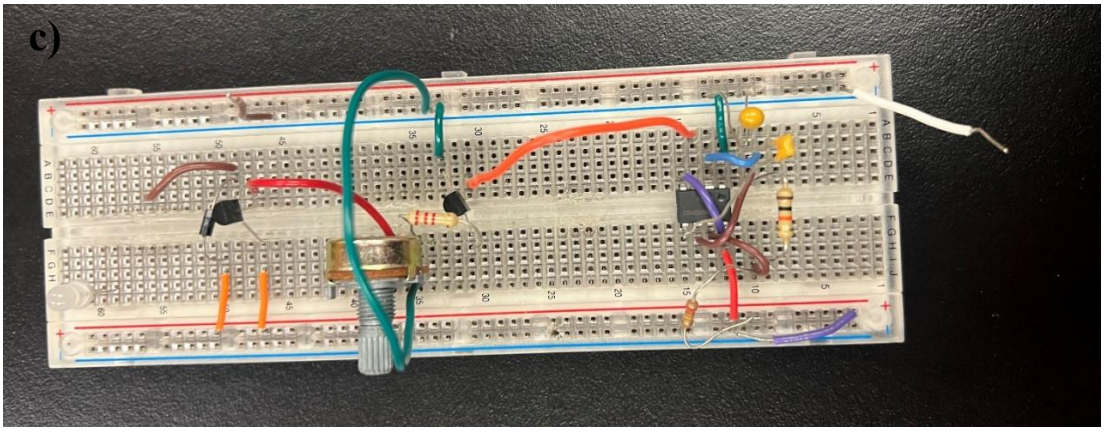


Figure 14. Prototype 2 of the NMES unit. a) LTspice schematic of the prototype. b) LTspice simulation showing the oscilloscope output of the second NMES prototype, with Electrode 1 at +30V and Electrode 2 at -30V, resulting in a total voltage difference of 60V. c) Physical prototype on a breadboard.

Discussion

Spring Prototyping and Testing Plan

	December	January	February	March	April
Finalize Electrical Stimulation Unit					
Complete Circuit Design					
Test Functionality and Safety					
Integrate E-Stim Controls with the User Interface					
Develop Control System for Mechanical Resistance					
Assemble Actuator with the Mechanical Structure					
Design and Implement Motor Control Algorithms					
Test Resistance Adjustment and Performance Under Simulated Conditions					
Integrate E-Stim and Mechanical Systems					
Combine Mechanical and Electrical Components into a Single Prototype					
Ensure Synchronization of E-Stim and Mechanical Assistance during Operation					
Protyping and Refinement					
Conduct Iterative Testing on the Integrated Prototype					
Address Design Flaws or Inefficiencies based on Testing Feedback					
Optimize the Overall Device for Functionality and Usability					
Prepare for Final Presentation					
Develop the Presentation of the ExoFlex's Design, Functionality, and Results					

Figure 15. Gantt Chart outlining the Spring Prototyping and Testing Plan.

Relevant Standards and Guidance

Biocompatibility

The ExoFlex contains components that directly interact with the user's skin, specifically in areas around the thigh, knee, and lower leg. These contact points involve materials such as electrodes and adjustable straps designed to remain in contact with the skin for the duration of rehabilitation sessions. To ensure safety, all materials used in skin-contacting components have been assessed for biocompatibility in accordance with ISO 10993-1 standards for biological evaluation of medical devices within a risk management framework. The primary materials that contact the skin include soft medical-grade silicone for electrodes and synthetic fabrics for straps. These materials have been chosen based on their compatibility with skin contact and history of safe use in medical applications.

Electromagnetic Compatibility and Electrical Safety

The ExoFlex is a Class II medical device that will be tested and verified for compliance with the following applicable standards for electromagnetic compatibility and electrical safety:

- **IEC 60601-1:2005 + A1:2012** - *Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.* This standard ensures the device meets essential safety requirements, minimizing risks associated with electrical hazards.
- **IEC 60601-1-2:2014** - *Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.* This standard confirms that the device operates safely in environments with potential electromagnetic interference without affecting other electronic equipment.
- **IEC 60601-1-11:2015** - *Medical Electrical Equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health care environment.* This standard verifies the device's safety and usability in a home setting.
- **IEC 60601-2-33:2019** - *Medical Electrical Equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.* Ensures the device's safety near common magnetic resonance imaging equipment found in rehabilitation facilities.
- **ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012** - *Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1, MOD).* This U.S.-specific adaptation aligns with general safety performance requirements and is critical for electrical safety compliance in the U.S. market.

Test Objective	Pass/Fail Criteria
Verify that device meets **IEC 60601-1:2005 + A1:2012** requirements (General electrical safety)	See **Exhibit A**. IEC 60601-1 TEST REPORT for Pass/Fail criteria
Verify that device meets **IEC 60601-1-2:2014** requirements (EMC emissions and immunity)	See **Exhibit B**. IEC 60601-1-2 TEST REPORT for Pass/Fail criteria
Verify that device meets **IEC 60601-1-11:2015** standard (Home healthcare environment safety)	See **Exhibit C**. IEC 60601-1-11 TEST REPORT for Pass/Fail criteria
Verify that device meets **IEC 60601-2-33:2019** standard (Safety near MRI equipment)	See **Exhibit D**. IEC 60601-2-33 TEST REPORT for Pass/Fail criteria
Verify that device meets **ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012** (U.S. electrical safety requirements)	See **Exhibit E**. ANSI/AAMI ES60601-1 TEST REPORT for Pass/Fail criteria

Division of Responsibilities

To effectively achieve the objectives for the ExoFlex, the team was divided into two specialized groups: the E-Stim Team and the Mechanical Resistance Team. Each group focuses on distinct aspects of the design while maintaining collaboration through weekly meetings to

share updates, ensure alignment, and address any challenges. Beyond technical tasks, cross-disciplinary collaboration has ensured that the project meets both biomedical engineering (BME) and mechanical engineering (ME) requirements, fostering a cohesive and interdisciplinary approach.

- **E-Stim Team:** Joseph, Andrew, Arianna
  The responsibilities of the E-Stim Team include assessing how an electrical stimulation unit can be integrated with the ExoFlex. During the fall semester, this team explored the feasibility of reverse engineering an existing e-stim unit to interface with a custom user interface. After consulting with several experts, the team determined that designing a custom unit would be more practical and efficient. Consequently, the team has focused on creating a prototype of the e-stim circuit board. This involves designing and testing a unit capable of NMES and transcutaneous electrical nerve stimulation (TENS). In the spring semester, the team will develop a functional e-stim unit controlled by an Arduino, integrating it into the ExoFlex design and ensuring compatibility with the overall system.
- **Mechanical Resistance Team:** Kyle, Nick, Aaron
  The Mechanical Resistance Team's responsibilities involve brainstorming design ideas, concept generation, and evaluating how various rehabilitation exercises can be performed using the ExoFlex. This led to the creation of the CAD design, which underwent several iterations before being finalized and 3D printed into the current prototype. Throughout the fall semester, the team refined the design to minimize bulk and improve functionality. In the spring semester, this team will focus on assembling the prototype with the actuator and developing the control system for the motor, ensuring the ExoFlex can adjust resistance levels based on the user's needs.

In addition to technical tasks, team members have collaborated on interdisciplinary assignments to fulfill both BME and ME program requirements. ME students have worked with BME students to complete Virtual Design Reviews (VDRs), while BME students have collaborated with ME students to develop the Mock 510(k) submission and prepare detailed project reports. This shared effort has fostered a deeper understanding of the regulatory, technical, and practical aspects of the project, ensuring that all deliverables are completed with a comprehensive perspective.

FDA Strategy

The ExoFlex is classified as a Class II medical device due to its intended use in rehabilitation therapy and its moderate risk profile. This classification requires compliance with 510(k) premarket notification requirements, where substantial equivalence to a legally marketed predicate device must be demonstrated. Predicate devices in the same category include knee rehabilitation devices and NMES, providing a framework for demonstrating equivalence.

The FDA strategy for the ExoFlex involves identifying suitable predicate devices (Tables 2, 3, and 4) to benchmark the mechanical assistance and e-stim functionalities. The team prepared a traditional 510(k) submission, including detailed documentation of the device design, functionality, safety, and performance testing results. Bench testing and biocompatibility evaluations will be conducted to ensure compliance with FDA standards, particularly those outlined in ISO 10993-1 for biological evaluation of medical devices. Usability testing with end-users will also be included to verify the device's safety and efficacy under typical operating conditions. Additionally, the integration of e-stim will require adherence to standards specific to NMES and TENS devices, such as IEC 60601-1 for electrical safety and IEC 60601-2-10 for electromedical equipment. The device's modular design and adjustable features will be thoroughly tested to ensure compliance with FDA regulations while maintaining user safety and efficacy.

Reimbursement Strategy

The reimbursement strategy for the ExoFlex focuses on achieving coding, coverage, and payment approvals within the U.S. healthcare system. The device falls under Durable Medical Equipment (DME), allowing for potential reimbursement through public and private insurance plans. To align with reimbursement pathways, the ExoFlex will require an appropriate Healthcare Common Procedure Coding System (HCPCS) code, which will be pursued based on the device's intended use and function. Existing codes for NMES and rehabilitation devices may provide a starting point, but modifications or new code applications may be required to reflect ExoFlex's integrated features.

To demonstrate value and ensure favorable coverage, the team will compile clinical evidence showing the ExoFlex's ability to reduce recovery times, improve functional outcomes, and lower costs compared to traditional rehabilitation methods. This includes cost-effectiveness studies to highlight the device's economic advantages for both patients and healthcare providers. By leveraging real-time data acquisition from the ExoFlex, healthcare providers can monitor patient progress remotely, aligning with the trend toward value-based care.

The reimbursement strategy also includes engaging with key stakeholders, such as private insurers and Medicare/Medicaid, to establish coverage policies. Additionally, partnerships with physical therapy clinics and rehabilitation centers will be explored to demonstrate the device's utility in both clinical and at-home settings. These efforts aim to position the ExoFlex as a cost-effective solution, ensuring accessibility to a wide patient population while fostering adoption across the healthcare system.

Possible Clinical Studies

For the ExoFlex, bench testing is our main approach since it's the easiest and most cost-effective way to check that the device works as intended. This type of testing lets us evaluate things like resistance, range of motion, and e-stim settings in a controlled setup. In addition, cadaver testing could be an option, as it allows us to see how the device performs on human

anatomy, though this would be more for larger-scale projects. Overall, bench testing provides a strong foundation for proving that our device functions safely and as designed. On the other hand, animal testing is not an option, as the ExoFlex is specifically designed for human anatomy and physiology.

Moving forward, our team would start clinical testing after ensuring all components work as expected. To begin clinical trials, approval from an Institutional Review Board (IRB) is required to ensure that the study is ethical and that participants are protected. During clinical testing, the most robust evidence comes from randomized controlled trials, which minimize bias and provide strong, reliable data. Alongside clinical data, we'd also gather economic information to support reimbursement claims, demonstrating that the device is not only effective but also cost-beneficial. Intellectual property considerations and market feasibility also play a role in clinical testing, ensuring that our device can succeed both clinically and commercially if it reaches broader use.

Intellectual Property Considerations

The ExoFlex project requires strategic intellectual property (IP) management to safeguard its unique design and ensure its marketability. A key focus is identifying and protecting novel aspects of the device, including the integration of mechanical resistance and e-stim within a modular framework, as well as its real-time biofeedback capabilities. To accomplish this, the team will conduct a comprehensive prior art search to evaluate existing patents in the fields of knee rehabilitation, exoskeletons, and NMES. This search will help identify areas of innovation and avoid infringement on existing technologies, ensuring that ExoFlex provides a distinct solution within the rehabilitation device market.

To protect these innovations, the team plans to pursue a provisional patent application, which will establish a priority date while allowing flexibility for further design refinement. This application will focus on the ExoFlex's unique technical features, such as its adjustable control system and modular design for personalized therapy. Beyond patents, trade secrets will be leveraged to protect proprietary elements, such as the specific configurations of the e-stim circuitry and any control system used for resistance modulation. Additionally, trademarks will be pursued to secure branding and establish strong market recognition for ExoFlex. These IP protections, developed with the guidance of legal experts, strengthen the project's competitive edge and create a solid foundation for ExoFlex to meet future market demands and achieve successful commercialization.

Safety and Risk Mitigation

The Knee Rehabilitation Exoskeleton incorporates similar safety features as the predicate devices to ensure safe use during rehabilitation:

- **Joint Protection**: Both the Knee Rehabilitation Exoskeleton and the HAL for Medical Use employ mechanical safeguards, including joint torque limits, velocity controls, and mechanical stoppers, to prevent excessive joint movement and reduce the risk of injury.
- **Automatic Shutoff**: Both the Chattanooga Revolution Wireless and the Knee Rehabilitation Exoskeleton include an automatic shutoff feature, which activates in case of system faults or incorrect parameter settings, ensuring patient safety.
- **Compliance with 21 CFR 898 and IEC Standards**: The Knee Rehabilitation Exoskeleton complies with 21 CFR 898 requirements for electrode lead safety and meets IEC 60601-1 and IEC 60601-1-2 standards for electrical safety and electromagnetic compatibility. This is consistent with the safety measures and compliance standards observed in the predicate devices.

Intended Use

Indications for Use Statement (FDA Form 3881): The Knee Rehabilitation Exoskeleton is indicated for prescription use in adult patients undergoing total knee arthroplasty (TKR) and rehabilitation to improve functional outcomes and quadriceps strength. This device is intended to aid in supervised physical therapy by providing controlled mechanical resistance an e-stim to the quadriceps muscle. It is designed to support a structured progression through isometric, isotonic, and eccentric exercises, enhancing muscle recovery and mobility.

The device incorporates NMES to activate and strengthen the quadriceps muscle through targeted high-intensity electrical impulses, promoting muscle re-education and reducing muscle atrophy post-surgery. Additionally, TENS is included to provide pain relief during therapy sessions, enabling a more comfortable recovery experience.

The Knee Rehabilitation Exoskeleton is adjustable to fit a range of adult body sizes and is intended for stationary, indoor environments including hospitals, physical therapy clinics, and supervised at-home therapy settings. It is to be used under the direction and supervision of medical professionals who are trained in the device's setup, safety features, and therapy applications.

Prescription Use (Part 21 CFR 801 Subpart D): Yes

Intended Environment: Hospitals, physical therapy clinics, and supervised at-home therapy environments.

Labeling Information

Proposed Labeling

- **Device Name**: ExoFlex
- **Intended Use**: Prescription device for use in rehabilitation following total knee arthroplasty (TKR) to aid in quadriceps strengthening and functional mobility improvement.
- **Manufacturer**: Arce's Exoskeleton Group
- **Product Code**: PHL

- **Indications for Use**: The Knee Rehabilitation Exoskeleton is intended for prescription use by trained medical personnel in clinical or supervised home settings to support TKR rehabilitation through mechanical resistance and e-stim.

Operation

- Ensure the device is placed on a stable, dry surface.
- Connect to a standard 120V battery power.
- Fit the device securely on the patient, adjusting straps to ensure comfort around the thigh, knee, and ankle.
- **Mechanical Resistance**: Select the appropriate exercise type (isometric, isotonic, eccentric) based on the rehabilitation stage, adjusting resistance settings as needed.
- **Electrical Stimulation**: Place electrodes on the quadriceps, choosing either NMES for muscle activation or TENS for pain relief, and adjust intensity and frequency according to therapeutic goals.
- **Data Acquisition**: Enable real-time data tracking to document progress.
- Once done using the exoskeleton, power off the device, disconnect, and carefully remove from the patient.
- Sanitize electrode contact points as per manufacturer instructions.

Patient Labeling

- **Device Purpose**: The Knee Rehabilitation Exoskeleton is designed to assist in recovery following knee replacement surgery, helping to build strength and manage pain.
- **Patient Instructions**:
    - Use the device only under supervision by medical professionals.
    - Report any discomfort or pain during use to the attending therapist.
    - Refrain from operating the device independently.

Safety Information

    - Avoid contact with water while using the device.
    - If you have any implanted electronic devices, inform your therapist before using the device.

Ethical Considerations

Ethical considerations must also be considered when dealing with medical devices that directly impact patient health. One key ethical factor is ensuring that the device is **safe and comfortable** for all users. This means rigorous testing and validation to make sure the mechanical assistance does not cause injury, and that the e-stim levels are safe and do not cause discomfort or harm to patients. A second ethical factor is considering the **accessibility** of the device. While the exoskeleton is designed for physical therapy clinics, it is important to ensure that its cost does not become a barrier to patient care. The healthcare landscape is marked by disparities in access, and our device is meant to be affordable so that it can benefit as many patients as possible.

Similarly, our project may involve protected personal health information (PHI) due to the collection of real-time biofeedback from patients during rehabilitation, specifically through electromyography (EMG) sensors that monitor muscle activity in the quadriceps. This data, along with information related to the patient's range of motion, strength, and rehabilitation progress, could be considered PHI under the Health Insurance Portability and Accountability Act (HIPAA) since it directly pertains to their medical condition and recovery [7]. To ensure compliance with HIPAA and protect patient privacy, we restricted access to the data to authorized personnel, such as physical therapists and healthcare providers involved in the patient's care.

Conclusion

Reflection and Recommendations

TKR patients often face challenges with post-surgical physical rehabilitation. They typically lack proper exercise equipment, have insufficient guidance, and experience discomfort during therapy. These limitations unfortunately lead to slower recovery, reduced motivation, and diminished outcomes. This device will address these issues by integrating mechanical resistance and e-stim into a single cost-effective, and transportable modular exoskeleton. By enhancing early functional mobility and muscle activation simultaneously, this exoskeleton provides significant advantages over existing rehabilitation technologies. The device is designed to support TKR patients by enabling an accessible and holistic recovery process, improving outcomes for both at-home and clinical therapy environments.

To enhance the development of the device, future efforts should focus on comprehensive testing, rigorous clinical studies, and iterative prototype refinement. Comprehensive testing is crucial to ensure reliability and to identify design flaws, which can then be addressed and retested before commercialization. Clinical studies will provide valuable insights into safety and usability, guiding improvements for a more convenient, comfortable, and user-friendly design. By integrating these enhancements into future iterations, the device can achieve optimal performance, safety, and market appeal. Following these recommendations will pave the way for a highly effective and commercially viable solution.

Contingencies

The device is designed with several contingency features to ensure continued functionality, even in suboptimal conditions. For instance, if the motor becomes inoperable or sustains damage, the resistive isotonic motion feature will be disabled, and the device will automatically switch to a 'safe mode.' In this mode, the e-stim and isometric exercise functionalities will remain operational, while the isotonic features will remain disabled until maintenance is completed. Similarly, if the device's material properties are compromised, such as through cracking or twisting, a previous prototype can be employed temporarily until a new, more robust prototype with enhanced mechanical strength is developed.

Contingency measures are also in place for the e-stim system. If the microcontroller fails or the produced signal becomes unsafe or unreliable, the e-stim functionality can be disabled while preserving other features of the device. Although this would disable the feedback loop and potentially impact motor functionality, isometric exercises would still be fully operational. Additionally, in cases where the device consumes more power than expected, the e-stim feature can be turned off to prioritize motor functionality. If a critical electrical failure prevents power from reaching any component, all electrical functions will be disabled, leaving the isometric

feature as the sole operational mode. These contingency measures are integral to maintaining functionality and ensuring safety under various challenging scenarios.

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